Federal Register

8–3–04 Tuesday
Vol. 69 No. 148 Aug. 3, 2004

United States Government Printing Office
SUPERINTENDENT OF DOCUMENTS
Washington, DC 20402

OFFICIAL BUSINESS
Penalty for Private Use, $300

PERIODICALS
Postage and Fees Paid
U.S. Government Printing Office
(ISSN 0097-6326)

Federal Register

8–03–04 Tuesday
Vol. 69 No. 148 August 3, 2004

Pages 46399–46978

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, *www.archives.gov*.

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge as one of the databases on GPO Access, a service of the U.S. Government Printing Office.

The online edition of the **Federal Register** *www.gpoaccess.gov/nara*, available through GPO Access, is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 59, Number 1 (January 2, 1994) forward.

For more information about GPO Access, contact the GPO Access User Support Team, call toll free 1-888-293-6498; DC area 202-512-1530; fax at 202-512-1262; or via email at *gpoaccess@gpo.gov*. The Support Team is available between 7:00 a.m. and 9:00 p.m. Eastern Time, Monday–Friday, except official holidays.

The annual subscription price for the **Federal Register** paper edition is $749 plus postage, or $808, plus postage, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $165, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register**, including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, *bookstore@gpo.gov*.

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 69 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Printing Office, Washington DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Paper or fiche	**202–741–6005**
Assistance with Federal agency subscriptions	**202–741–6005**

Contents

Federal Register

Vol. 69, No. 148

Tuesday, August 3, 2004

Separate Parts In This Issue

Part II
Health and Human Services Department, Centers for Medicare & Medicaid Services, 46631–46863

Part III
Health and Human Services Department, Centers for Medicare & Medicaid Services, 46865–46977

Reader Aids
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents LISTSERV electronic mailing list, go to http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Federal Register
Vol. 69, No. 148
Tuesday, August 3, 2004

Presidential Documents

Title 3—

The President

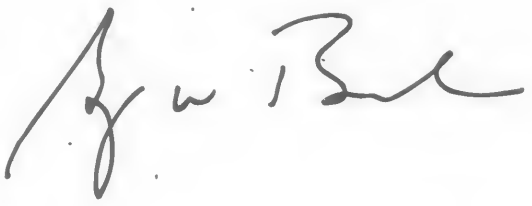
Presidential Determination No. 2004–40 of July 21, 2004

Eligibility of Iraq to Receive Defense Articles and Services Under the Foreign Assistance Act of 1961, as Amended, and the Arms Export Control Act, as Amended

Memorandum for the Secretary of State

Pursuant to the authority vested in me by the Constitution and the laws of the United States, including section 503(a) of the Foreign Assistance Act of 1961, as amended, and section 3(a)(1) of the Arms Export Control Act, as amended, I hereby find that the furnishing of defense articles and services to Iraq will strengthen the security of the United States and promote world peace.

You are authorized and directed to report this finding to the Congress and to publish it in the **Federal Register**.



THE WHITE HOUSE,
Washington, July 21, 2004.

[FR Doc. 04–17783
Filed 8–2–04; 8:45 am]
Billing code 4710–10–P

Rules and Regulations

Federal Register
Vol. 69, No. 148
Tuesday, August 3, 2004

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 14a

[TD 9144]

RIN 1545–BA75

Statutory Options

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to statutory options. These final regulations affect certain taxpayers who participate in the transfer of stock pursuant to the exercise of incentive stock options and the exercise of options granted pursuant to an employee stock purchase plan (statutory options). These regulations provide guidance to assist these taxpayers in complying with the law in addition to clarifying rules regarding statutory options.

DATES: *Effective Date:* These regulations are effective on August 3, 2004. For rules concerning reliance and transition period, see §§ 1.421–1(j)(2), 1.421–2(f)(2), 1.422–5(f)(2), and 1.424–1(g)(2).

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, please contact Erinn Madden at (202) 622–6030 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations (see § 1.6039–1) has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1545–0820. Responses to this collection of information are required to assist taxpayers with the completion of their income tax returns for the taxable year in which a disposition of statutory option stock occurs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by the Office of Management and Budget.

The estimated annual burden per respondent varies from 15 minutes to 25 minutes, depending on individual circumstances, with an estimated average of 20 minutes.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP Washington, DC 20224, and to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Books or records relating to this collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

This document contains amendments to 26 CFR part 1 under sections 421, 422, and, 424 of the Internal Revenue Code (Code). Changes to the applicable tax law concerning section 421 were made by sections 11801 and 11821 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), Pub. L. 101–508 (104 Stat. 1388). Changes to the applicable tax law concerning section 424 were made by section 1003 of the Technical and Miscellaneous Revenue Act of 1988 (TAMRA), Pub. L. 100–647 (102 Stat. 3342), sections 11801 and 11821 of OMBRA 90, which included re-designating section 425 as section 424 of the Code, and section 1702(h) of the Small Business Job Protection Act of 1996, Pub. L. 104–88 (110 Stat. 1755). Changes concerning section 422 were made by section 251 of the Economic Recovery Tax Act of 1981, Pub. L. 97–34 (95 Stat. 172), which added section 422A to the Code. Related changes to section 422A were made by section 102(j) of the Technical Corrections Act of 1982, Pub. L. 97–448 (96 Stat. 2365), section 321(a) of Tax Reform Act of 1986, Pub. L. 99–514 (100 Stat. 2085), section 1003(d) of TAMRA, and sections 11801 and 11821 of OBRA 90, which included re-designating section 422A as section 422 of the Code.

Regulations under section 421 governing the requirements for restricted stock options and qualified stock options, as well as options granted under an employee stock purchase plan, were published in the **Federal Register** on December 9, 1957 (TD 6276), November 26, 1960 (TD 6500), January 19, 1961 (TD 6527), January 20, 1961 (TD 6540), December 12, 1963 (TD 6696), June 24, 1966 (TD 6887), July 24, 1978 (TD 7554), and November 3, 1980 (TD 7728). Temporary regulations under section 422A providing guidance and transitional rules related to incentive stock options were published in the **Federal Register** on December 17, 1981 (TD 7799) and September 18, 1992 (TD 8435). Final regulations under section 422 related to stockholder approval were published in the **Federal Register** on December 1, 1988 (TD 8235) and November 29, 1991 (TD 8374). Regulations under section 425 were published in the **Federal Register** on June 23, 1966 (TD 6887).

Proposed changes to the final regulations under sections 421, 424, and 6039 and proposed regulations under section 422A were previously published in the **Federal Register** at 49 FR 4504 on February 7, 1984 (the 1984 proposed regulations). With the exception of certain stockholder approval rules, the 1984 proposed regulations provided a comprehensive set of rules under section 422 of the Code. The 1984 proposed regulations and the temporary regulations have been withdrawn. See 68 FR 34344.

On June 9, 2003, a notice of proposed rulemaking (REG–122917–02) was published in the **Federal Register** at 68 FR 34344 (the 2003 proposed regulations). No hearing concerning the 2003 proposed regulations was held; however, the IRS received written and electronic comments responding to this notice. After consideration of these comments, the 2003 proposed regulations are adopted as amended by this Treasury decision. The significant revisions are discussed below.

Explanation of Provisions

Overview

In general, the income tax treatment of the grant of an option to purchase stock in connection with the performance of services and of the transfer of stock pursuant to the exercise of such option is determined under section 83 of the Code and the regulations thereunder. However, section 421 of the Code provides special rules for determining the income tax treatment of the transfer of shares of stock pursuant to the exercise of an option if the requirements of section 422(a) or 423(a), as applicable, are met. Section 422 applies to incentive stock options, and section 423 applies to options granted under an employee stock purchase plan (collectively, statutory options).

Under section 421, if a share of stock is transferred to an individual pursuant to the exercise of a statutory option, there is no income at the time of exercise of the option with respect to such transfer, and no deduction under section 162 is allowed to the employer corporation with respect to such transfer. However, pursuant to section 56(b)(3), section 421 does not apply with respect to the exercise of an incentive stock option for purposes of the individual alternative minimum tax.

Section 422(a) of the Code provides that section 421 applies to the transfer of stock to an individual pursuant to the exercise of an incentive stock option if (i) no disposition of the share is made within 2 years from the date of grant of the option or within 1 year from the date of transfer of the share, and (ii) at all times during the period beginning on the date of grant and ending on the day 3 months before the exercise of the option, the individual is an employee of either the corporation granting the option or a parent or subsidiary of such corporation, or a corporation (or a parent or subsidiary of such corporation) issuing or assuming a stock option in a transaction to which section 424(a) applies. Section 422(b) provides several requirements that must be met for an option to qualify as an incentive stock option. Section 422(c) provides special rules applicable to incentive stock options, and section 422(d) provides a $100,000 per year limitation with respect to incentive stock options.

Section 424 of the Code provides special rules applicable to statutory options, including rules concerning the modification of statutory options and the substitution or assumption of an option by reason of a corporate merger, consolidation, acquisition of property or stock, separation, reorganization, or liquidation. Section 424 also contains definitions of certain terms, including *disposition, parent corporation,* and *subsidiary corporation.* Finally, section 424 provides special rules related to attribution of stock ownership and the effect of stockholder approval on the date of grant of a statutory option.

These final regulations provide comprehensive rules governing incentive stock options that, as did the 2003 proposed regulations, incorporate many of the rules contained in the 1984 proposed regulations. However, the 2003 proposed regulations are re-numbered, and these final regulations adopt that reorganization. These final regulations also make changes to the final regulations under sections 421 and 424 to provide additional guidance, as discussed below, in certain areas, to reflect the new organizational structure of the statutory option rules (including the re-designation of § 1.425–1 as § 1.424–1), and to remove obsolete rules and cross-references.

Section 421: General Rules

Sections 422 and 423 provide that a statutory option may be granted to an individual who is an employee of the corporation granting the option, a parent or subsidiary of such corporation, or a corporation or a parent or subsidiary of such corporation issuing or assuming a stock option in a transaction to which section 424(a) applies.

Section 1.421–1(h) of the 2003 proposed regulations further describes the requisite employment relationship for purposes of a statutory option. The 2003 proposed regulations provide that an option is a statutory option only if, at the time the option is granted, the optionee is an employee of the corporation granting the option or a related corporation of such corporation. In the case of an assumption or substitution under § 1.424–1(a), the optionee must, at the time of the assumption or substitution, be an employee of the corporation assuming or substituting the option or a related corporation of such corporation. In response to comments, these final regulations provide that in the case of an assumption or substitution under § 1.424–1(a) an option also will be treated as granted to an employee of the granting corporation if the optionee is an individual who is in the 3-month period following termination of the employment relationship.

Section § 1.421–1(h)(2) of the 2003 proposed regulations also provides that the employment relationship is considered to continue intact while an individual is on military leave, sick leave, or other bona fide leave of absence if the period of leave does not exceed 3 months, or if longer, so long as the individual's right to reemployment with the corporation granting the option (or a related corporation of such corporation) or a corporation assuming or substituting an option under § 1.424–1(a) is guaranteed by statute or contract. Commentors requested clarification in the final regulations concerning whether the right to employment must be absolute and whether the right to reemployment provided by the Family Medical Leave Act or the Uniformed Services Employment and Reemployment Rights Act satisfies the requirements of this section. These final regulations provide that the right to reemployment must be provided by statute or contract. Thus, for example, if an optionee is on leave pursuant to the Family Medical Leave Act, the Uniformed Services Employment and Reemployment Rights Act, or any similar statute providing for continued employment rights for an extended period of time, the employment relationship is considered intact.

Section 422: Incentive Stock Options

1. Special Rules Regarding Disqualifying Dispositions

The general rules concerning disqualifying dispositions are described in § 1.421–2(b) of the 2003 proposed regulations. Under these rules, if there is a disqualifying disposition of a share of stock, the special tax treatment provided by section 421 and § 1.421–2(a) does not apply to the transfer of the share. The effects of a disqualifying disposition are determined under section 83(a). Thus, in the taxable year in which the disqualifying disposition occurs, the individual must recognize compensation income equal to the fair market value of the stock (determined without regard to any lapse restriction and without regard to any reduction for any brokerage fees or other costs paid in connection with the disposition) on the date the stock is substantially vested less the exercise price. (See section 422(c)(2) concerning special rules that are applicable where the amount realized in a disposition is less than this difference.) A deduction is allowable for the taxable year in which such disqualifying disposition occurs to the employer corporation, its parent or subsidiary corporation, or a corporation substituting or assuming an option in a transaction to which § 1.424–1(a) applies. Section 422(c)(2) and § 1.422–1(b) of the 2003 proposed regulations provide special rules concerning disqualifying dispositions.

The application of the disqualifying disposition rules is described in several examples in § 1.422–1(b)(3) of the 2003 proposed regulations. In *Example 1* of § 1.422–1(b)(3) of the 2003 proposed regulations, on exercise of an incentive stock option, the optionee receives vested stock and disposes of the stock before meeting the applicable holding period. In this example, the amount of compensation income is based on the fair market value of the stock on the date of exercise less the exercise price, and the section 422(a)(1) holding period is based on the date of exercise.

However, in *Example 2* of § 1.422–1(b)(3) of the 2003 proposed regulations, the optionee receives nonvested stock on exercise of an incentive stock option. This example retains the same holding period for the receipt of nonvested stock, but computes the amount of compensation income based on the date of vesting of the underlying stock (rather than the date of exercise).

Several commentors suggested that if the option is exercised for nonvested stock the compensation income should not be calculated on the date of vesting because section 83 does not apply to a transaction to which section 421 applies (and section 421(b) applies to a disqualifying disposition). Instead, the compensation income should be computed on the date of exercise. Alternatively, if the proposed rule is retained, commentors suggest that the final regulations and examples provide that an optionee may make a protective section 83(b) election on exercise of the option.

These final regulations retain the rules described in the 2003 proposed regulations, however, the examples in § 1.422–1(b)(3) of the final regulations more fully describe the application of the disqualifying disposition rules. Specifically, *Example 2* indicates that pursuant to section 83(e)(1) of the Code, section 83 does not apply to a transaction to which section 421 applies. Thus, on exercise of a statutory option section 83 does not apply, and an optionee cannot make an effective [illegible] compensation includible is the difference between the fair market value of the stock on the date the substantial risk of forfeiture lapses less the fair market value on the date of exercise. Additionally, *Example 2* demonstrates that there is a transfer (as defined in § 1.421–1(g) of the final regulations) of the stock on the date of exercise for purposes of the holding period requirement of section 422(a)(1). Thus, the holding period for the transfer of the stock for purposes of section 422 and the holding period requirements begins on the date of exercise (rather than the date of vesting). See also, § 1.422–1(b)(3), *Example 3*. However, the amount of capital gain (if any) is computed from the date of vesting.

2. Shareholder Approval

Among other requirements, to qualify as an incentive stock option, the option must be granted pursuant to a plan which is approved by the stockholders of the granting corporation within 12 months before or after the date the plan is adopted. See section 422(b) and § 1.422–2(b)(2)(i) of the 2003 proposed regulations.

These final regulations retain the rules contained in the 2003 proposed regulations concerning shareholder approval. However, an additional example in § 1.422–2(b)(6) illustrates the shareholder approval requirements where an incentive stock option plan is assumed in connection with a corporate transaction. See § 1.422–2(b)(6), *Example 3*.

In *Example 3* of § 1.422–2(b)(6) of these final regulations, Corporation X maintains an incentive stock option plan, but Corporation Y does not maintain such a plan. The companies combine to form one corporation that will be named Y, the plan will be continued by Y, and future grants under the plan will be made by Y (the new combined entity). The consolidation agreement describes the plan, including the maximum aggregate number of shares available for issuance pursuant to incentive stock options under the plan [illegible] agreement is approved. See Rev. Rul. 68–233, 1968–1 C.B. 187.

3. Maximum Aggregate Number of Shares

Section 422(b)(1) provides that an incentive stock option must be granted pursuant to a plan that includes the aggregate number of shares which may be issued under options. Section 1.422–2(b)(3)(i) of the 2003 proposed regulations provides that the plan must designate the maximum aggregate number of shares that may be issued under the plan through incentive stock options, nonstatutory options, and all other stock-based awards to be granted under the plan.

In response to comments, these final regulations provide that the plan must designate the maximum aggregate number of shares that may be issued under the plan through incentive stock options. Thus, for example, if a corporation maintains an omnibus plan under which incentive stock options, nonstatutory options, and other stock-based awards may be made, the plan must contain a maximum number of shares that may be issued as incentive stock options. These final regulations do not require the plan to include the maximum number of shares that may be issued pursuant to nonstatutory options or other stock-based awards.

Commentators also asked whether the maximum aggregate number of shares that may be issued under an incentive stock option plan is affected by the use of outstanding shares used to exercise an option. Under these final regulations, only the net number of shares that are issued pursuant to the exercise of a statutory option are counted against the maximum aggregate number of shares. For example, if the exercise price of an option to purchase 100 shares equals the value of 20 shares, and the corporation permits the employee to use those 20 of the 100 shares to pay the exercise price of the option, and the corporation only issues 80 shares to the optionee, then 80 shares are counted against the maximum aggregate number of shares [illegible]

than the fair market value of the stock on the date of grant.

Section 1.422–2(e)(2)(i) of the 2003 proposed regulations provides that if a share of stock is transferred to an individual pursuant to the exercise of an incentive stock option, which fails to qualify as an incentive stock option because the exercise price is less than the fair market value of the underlying stock on the date of grant, such requirement is still considered to have been met if there was an attempt, made in good faith, to meet the option price requirements of § 1.422–2(e)(1).

For nonpublicly traded stock, § 1.422–2(e)(2)(iii) provides that if it is demonstrated that the fair market value of the stock on the date of grant was based on an average of the fair market values as of such date set forth in the opinions of completely independent and well-qualified experts, such a determination establishes that a good-faith attempt to meet the option price requirements of § 1.422–2(e) was made. Taxpayers are required to retain adequate books and records to demonstrate that the option price requirements are satisfied. See section 6001.

Commentors suggested that the final regulations be revised to provide that a good-faith attempt to meet the option price requirements is demonstrated if the value of the stock is determined by a qualified appraiser (as defined in § 1.170A–13(c)(5)), by an individual (rather than more than one individual) who is not a qualified appraiser, or by the corporation at the date of grant. Because of concerns that the value determined under these approaches may not reliably reflect the fair market value of the stock on the date of grant, these final regulations retain the rules described in the 2003 proposed regulations.

5. $100,000 Limitation

Section 422(d)(1) provides that, to the extent that the aggregate fair market value of stock with respect to which incentive stock options (determined without regard to section 422(d)) are exercisable for the first time by an individual during the calendar year (under all of the plans of the employer corporation and any related corporation) exceeds $100,000, such options are not treated as incentive stock options.

Under section 422(b)(4), the option price of an incentive stock option must not be less than the fair market value of the stock at the time the option is

4. Option Price

(rather than 100).

ater the consolidation and the employees eligible to receive options under the plan. Because there is a change in the granting corporation under § 1.422–2(b)(3)(iii), Y is considered to have adopted a new plan that must satisfy the shareholder

option is not canceled, modified, or transferred prior to the year in which it would first become exercisable, it is treated as outstanding until the end of the year in which it first becomes exercisable. Commentors suggested that the final regulations permit an individual to cancel, modify, or transfer an option at any time prior to the date of exercise (rather than the year it first becomes exercisable). Because of concerns about the administrability of a rule that, for purposes of the $100,000 limitation, would permit an individual to determine the status of an option as statutory or nonstatutory until the date of exercise, these final regulations retain the rule described in the 2003 proposed regulations.

Section 1.422–4(c) of the 2003 proposed regulations provides that the application of the $100,000 limitation may result in an option being treated, in part, as an incentive stock option and, in part, as a nonstatutory option. In response to comments, these final regulations provide additional guidance concerning the treatment of options (and the stock purchasable thereunder) that are bifurcated into an incentive stock option and nonstatutory option as a result of the application of the $100,000 limitation.

These final regulations provide that a corporation may issue a separate certificate for incentive stock option stock or designate such stock as incentive stock option stock in the corporation's transfer records or the plan records. The issuance of separate certificates or designation in plan records is not considered a modification under § 1.424–1(e). However, in the absence of such an issuance or designation, shares are deemed purchased under an incentive stock option first to the extent of the $100,000 limitation, and then the excess shares are deemed purchased under a nonstatutory option.

Section 424: Definitions and Special Rules

1. Substitution, Assumption, and Modification of Options

Section 424(h)(1) provides that if the terms of an option are modified, extended, or renewed, such modification, renewal, or extension is treated as the grant of a new option.

election under section 83(b) for purposes of the income tax consequences on the date of exercise. However, an effective election under section 83(b) may be made for purposes of the alternative minimum tax, which calculates income as if section 83

assumption that meets the requirements of section 424(a) is not a modification of an option.

The 2003 proposed regulations provide that an *eligible corporation* (as defined in § 1.424–1(a)(2)) may, by reason of a *corporate transaction* (as defined in § 1.424–1(a)(3)), substitute a new statutory option (new option) for an outstanding statutory option (old option) or assume an old option without the substitution or assumption being considered a modification of the old option under section 424(h). These final regulations retain most of the rules contained in the 2003 proposed regulations, with certain changes.

Under the 2003 proposed regulations, a *corporate transaction* is (i) A corporate merger, consolidation, acquisition of property or stock, separation, reorganization, or liquidation; (ii) a distribution (excluding ordinary dividends), or change in the terms or number of outstanding shares of such corporation, such as a stock split or stock dividend (a change in capital structure); (iii) a change in the name of a corporation whose stock is purchasable under the old option; and (iv) such other corporate events as may be prescribed by the Commissioner in published guidance.

In response to comments, these final regulations provide that a "distribution" does not include a stock dividend or stock split (including a reverse stock split) that merely changes the number of outstanding shares of a corporation. Thus, an outstanding option is not treated as substituted or assumed under section 424(a) and § 1.424–1(a) in connection with a stock dividend or stock split that merely changes the number of outstanding shares. Instead, the exercise price of an outstanding option may be proportionally adjusted to reflect a stock dividend or stock split that merely changes the number of outstanding shares of a corporation under § 1.424–1(e). This adjustment is not a modification of the option, and because the stock dividend or stock split is not a corporate transaction, the requirements of § 1.424–1(a), including the spread and ratio tests, do not have to be satisfied.

The 2003 proposed regulations also provide that a new or assumed option must otherwise qualify as a statutory option. See § 1.424–1(a)(5)(vi) of the

proposed regulations or 1.423–2, as applicable. Thus, under the 2003 proposed regulations, for example, the new option must be substituted, or the old option must be assumed, under a plan approved by the stockholders of the corporation substituting or assuming the option.

In Rev. Rul. 71–474 (1971–2 C.B. 215) involving qualified stock options, the IRS held that qualified stock options assumed by a corporation in a merger with the granting corporation retained their status as qualified stock options without approval of the assuming corporation's stockholders. In the ruling, the IRS indicated that approval of the persons who owned stock of the granting corporation at the time the plan originally was approved was sufficient to satisfy the stockholder approval requirements.

In response to comments, these final regulations refrain from imposing an additional stockholder approval requirement for statutory options that have been granted and are outstanding at the time of a corporate transaction. Thus, the requirement in § 1.424–1(a)(5)(vi) of the 2003 proposed regulations is removed. Further, the examples in § 1.424–1(a)(10) of these final regulations demonstrate that if the shareholder approval requirements are met on the date of grant, a subsequent substitution or assumption of an outstanding option (old option) by an acquiring corporation does not require additional stockholder approval for the substituted or assumed option (new option) to continue to qualify as a statutory option. See, § 1.424–1(a)(10), *Example 9*. For example, assume Corporation X maintains an incentive stock option plan that meets the requirements of § 1.422–2 on the date of grant. E, an employee of X, holds outstanding incentive stock options to acquire X stock on exercise of the options. If Corporation Y acquires X and substitutes new options to acquire Y stock for the old options to acquire X stock held by E, the substitution of the new Y options does not require new stockholder approval. The result is the same if the options are assumed by Y. However, for future options granted under the plan to qualify as incentive stock options, the plan must be approved by the Y shareholders. (See, § 1.422–2(b)(6) *Example 3*, for guidance concerning future grants under an option plan that is assumed in a corporate transaction.)

Finally, commentors requested guidance concerning the treatment of earn-out payments received by option holders in connection with a corporate transaction. Because of the factual nature of these transactions, these final regulations do not address the issues raised by these transactions. However, this area is currently under study and may be the subject of future guidance of general applicability under § 601.601(d)(2).

2. Modification, Extension, or Renewal of Option

Section 424(h)(3) provides that a modification is any change in the terms of an option which gives the optionee additional benefits under the option, with certain specified exceptions.

Under § 1.424–1(e)(4)(iii) of the 2003 proposed regulations, a change to an option providing that the optionee may receive an additional benefit under the option at the future discretion of the granting corporation is a modification of the option at the time the option is changed to provide the discretion. Additionally, the exercise of such discretion is a modification of the option. Although several commentors suggested that the final regulations provide that the later exercise of the discretion is not a modification of the option, these final regulations retain the rule contained in the 2003 proposed regulations.

However, as under the 2003 proposed regulations, it is not a modification for the granting corporation to exercise discretion specifically reserved under an option related to the payment of a bonus at the time of the exercise of the option, the availability of a loan at exercise, or the right to tender previously-owned stock for the stock purchasable under the option. A change to an option adding such discretion, however, is a modification.

Commentors suggested broadening this rule to include the exercise of any reserved discretion under the option. These final regulations, however, only expand this rule to provide that it is not a modification to exercise discretion specifically reserved under an option with respect to the payment of employment taxes and/or withholding taxes resulting from the exercise of a statutory option.

The 2003 proposed regulations also provide that an option is not modified merely because an optionee is offered a change in the terms of the option if the change is not made. These final regulations retain this rule, but also provide that if an offer to change the terms of the option remains outstanding for less than 30 days, the option is not modified. However, if the offer to change the terms of the option remains outstanding for 30 days or more, the option is treated as modified as of the date the offer to change the terms of the option is made.

Finally, commentors suggested that these final regulations provide an exception to the modification rule for an inadvertent change to a statutory option where the change is promptly reversed. In response, these final regulations provide that any inadvertent modification of an option is not treated as a modification to the extent the modification is reversed by the earlier of the date the option is exercised or the last day of the calendar year during which such change occurred.

Section 6039

Under section 1.6039–1(f) of the 2003 proposed regulations, the issue of furnishing electronic statements was reserved. These final regulations provide that the furnishing of statements in electronic form is permitted, provided the recipient consents to that means of delivery.

Effective Date and Reliance

These final regulations are effective on August 3, 2004. However, these final regulations provide special transitional and reliance rules.

For statutory options granted on or before June 9, 2003, taxpayers may rely on the 1984 proposed regulations LR–279–81 (49 FR 4504), the 2003 proposed regulations REG–122917–02 (68 FR 34344), or these final regulations until the earlier of January 1, 2006, or the first regularly scheduled stockholders meeting of the granting corporation occurring 6 months after August 3, 2004. For statutory options granted after June 9, 2003, and before the earlier of January 1, 2006, or the first regularly scheduled stockholders meeting of the granting corporation occurring 6 months after August 3, 2004, taxpayers may rely on either the REG–122917–02 or the final regulations. Taxpayers may not rely on LR–279–81 or REG–122917–02 after December 31, 2005. Reliance on LR–279–81, REG–122917–02, or the final regulations must be in its entirety, and all statutory options granted during the reliance period must be treated consistently.

Special Analyses

It has been determined that these regulations are not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It is hereby certified that the collection of information in these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the provision of employee

statements provided under these proposed regulations will impose a minimal paperwork burden on most small entities (see the discussion under the heading "Paperwork Reduction Act" earlier in this preamble). Therefore, an analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these final regulations is being submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these proposed regulations is Erinn Madden, Office of the Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Parts 1 and 14a

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

■ Accordingly, 26 CFR parts 1 and 14a are amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

§§ 1.421–1 through 1.421–6 [Removed]

■ **Par. 2.** Sections 1.421–1 through 1.421–6 are removed.

■ **Par. 3.** Section 1.421–7 is re-designated as § 1.421–1 and is amended as follows:

■ 1. In paragraph (a)(1), first sentence, the language "sections 421 through 425" is removed and "this section and §§ 1.421–2 through 1.424–1" is added in its place.

■ 2. In paragraph (a)(1), first sentence, the language "includes" is removed, and "means" is added in its place.

■ 3. In paragraph (a)(1), removing the second sentence.

■ 4. Removing the last sentence of paragraph (a)(1) and adding two sentences in its place.

■ 5. Revising paragraph (a)(3).

■ 6. Revising paragraphs (b)(1) and (b)(2).

■ 7. In paragraph (b)(3)(i), third sentence, removing the language "1.425–1" and inserting "1.424–1" in its place.

■ 8. In the list below, for each section indicated in the left column, remove the language in the middle column and add the language in the right column:

Newly designated section	Remove	Add
1.421–1(b)(3)(ii) *Example 1* first, second, third and fourth sentences.	S–1	X.
1.421–1(b)(3)(ii) *Example 1* second sentence	1964	2004.
1.421–1(b)(3)(ii) *Example 1* third and fourth sentences.	1965	2005.
1.421–1(b)(3)(ii) *Example 2* first and second sentences.	1964	2004.
1.421–1(b)(3)(ii) *Example 2* first, third, and fourth sentences.	S–1	X.
1.421–1(b)(3)(ii) *Example 2* third and fourth sentences.	1965	2005.

■ 9. Revising the last sentence of paragraph (b)(3)(ii) *Example 1*.

■ 10. Removing the last sentence of paragraph (b)(3)(ii) *Example 2*, and adding two sentences in its place.

■ 11. Removing the first sentence of paragraph (c)(1) and adding two new sentences in its place.

■ 12. In paragraph (c)(2), second sentence, the language "425" is removed and "424" is added in its place.

■ 13. In paragraph (c)(3), second and last sentences, the language "1964" is removed and "2004" is added in its place.

■ 14. In paragraph (c)(3), second sentence, the language "1965" is removed wherever it appears and "2005" is added in its place.

■ 15. Revising paragraphs (d) and (e).

■ 16. In paragraph (f), in the first sentence, the language "sections 421 through 425" is removed and "this section and §§ 1.421–2 through 1.424–1" is added in its place.

■ 17. Revising the last sentence of paragraph (f).

■ 18. In paragraph (g), first sentence, the language "sections 421 through 425" is removed and "this section and §§ 1.421–2 through 1.424–1" is added in its place.

■ 19. Adding a new third, fourth, and fifth sentences to paragraph (g).

■ 20. Revising the first, second, and third sentences of paragraph (h)(1).

■ 21. Revising paragraph (h)(2).

■ 22. In paragraph (h)(3), first sentence, the language "425" is removed and "424" is added in its place.

■ 23. In paragraph (h)(3), last sentence, the language "or assuming" is removed and "the option or substituting or assuming the option" is added in its place.

■ 24. In the list below, for each section indicated in the left column, remove the language in the middle column and add the language in the right column:

Newly designated section	Remove	Add
1.421–1(h)(4) *Example 1*, first sentence	1964	2004.
1.421–1(h)(4) *Example 1*, second and last sentences.	1965	2005.
1.421–1(h)(4) *Example 2*, first sentence	425	424.
1.421–1(h)(4) *Example 2*, first sentence	issuing	substituting.
1.424–1(h)(4) *Example 2*, last sentence	1965	2005.

Newly designated section	Remove	Add
1.421–1(h)(4) *Example 2*, last sentence	for A is then employed by a corporation which issued an option under section 425(a).	to the transfer of the M stock because, at all times during the period beginning with the date of grant of the X option and ending with the date of exercise of the M option, A was an employee of the corporation granting the option or substituting or assuming the option under § 1.424–1(a).
1.421–1(h)(4) *Example 3*, second sentence	1964	2004.
1.421–1(h)(4) *Example 3*, third, fourth, and fifth sentences.	1965	2005.
1.421–1(h)(4) *Example 4*, first sentence	425(a)	424(a).
1.421–1(h)(4) *Example 5*, first sentence	qualified stock	statutory.
1.421–1(h)(4) *Example 6*, first sentence	an employment contract with M which provides that upon the termination of any military duty E may be required to serve, E will be entitled to reemployment with M or a parent or subsidiary of M.	a right to reemployment with M or a related corporation on the termination of any military duty E may be required to serve.
1.421–1(h)(4) *Example 6*, third sentence	of M	of M or a related corporation.
1.421–1(h)(4) *Example 6*, last sentence	can apply	applies.
1.421–1(h)(4) *Example 7*, first and last sentences.	a qualified stock	an incentive.
1.421–1(h)(4) *Example 7*, first sentence	parent or subsidiary	related corporation.
1.421–1(h)(4) *Example 7* last sentence	its parent and subsidiary corporation	related corporations.
1.421–1(h)(4) *Example 7*, last sentence	terminated	deemed terminated.

■ 25. Revising paragraph (i).
■ 26. Adding paragraph (j).

The additions and revisions read as follows:

§ 1.421–1 Meaning and use of certain terms.

(a) * * * (1) * * * While no particular form of words is necessary, the option must express, among other things, an offer to sell at the option price, the maximum number of shares purchasable under the option, and the period of time during which the offer remains open. The term *option* includes a warrant that meets the requirements of this paragraph (a)(1).

* * * * *

(3) An option must be in writing (in paper or electronic form), provided that such writing is adequate to establish an option right or privilege that is enforceable under applicable law.

(b) *Statutory options.* (1) The term *statutory option*, for purposes of this section and §§ 1.421–2 through 1.424–1, means an *incentive stock option*, as defined in § 1.422–2(a), or an option granted under an *employee stock purchase plan*, as defined in § 1.423–2.

(2) An option qualifies as a statutory option only if the option is not transferable (other than by will or by the laws of descent and distribution) by the individual to whom the option was granted, and is exercisable, during the lifetime of such individual, only by such individual. See §§ 1.422–2(a)(2)(v) and 1.423–2(j). Accordingly, an option which is transferable or transferred by the individual to whom the option is granted during such individual's lifetime, or is exercisable during such individual's lifetime by another person, is not a statutory option. However, if the option or the plan under which the option was granted contains a provision permitting the individual to designate the person who may exercise the option after such individual's death, neither such provision, nor a designation pursuant to such provision, disqualifies the option as a statutory option. A pledge of the stock purchasable under an option as security for a loan that is used to pay the option price does not cause the option to violate the nontransferability requirements of this paragraph (b). Also, the transfer of an option to a trust does not disqualify the option as a statutory option if, under section 671 and applicable State law, the individual is considered the sole beneficial owner of the option while it is held in the trust. If an option is transferred incident to divorce (within the meaning of section 1041) or pursuant to a domestic relations order, the option does not qualify as a statutory option as of the day of such transfer. For the treatment of nonstatutory options, see § 1.83–7.

(3) * * *

(ii) * * *

Example 1. * * * Because X was a subsidiary of P on the date of the grant of the statutory option, the option does not fail to be a statutory option even though X ceases to be a subsidiary of P.

Example 2. * * * Because X was not a subsidiary of S or P on the date of the grant of the option, the option is not a statutory option even though X later becomes a subsidiary of P. See §§ 1.422–2(a)(2) and 1.423–2(b).

(c) *Time and date of granting option.* (1) For purposes of this section and §§ 1.421–2 through 1.424–1, the language "the date of the granting of the option" and "the time such option is granted," and similar phrases refer to the date or time when the granting corporation completes the corporate action constituting an offer of stock for sale to an individual under the terms and conditions of a statutory option. A corporate action constituting an offer of stock for sale is not considered complete until the date on which the maximum number of shares that can be purchased under the option and the minimum option price are fixed or determinable.

* * *

* * * * *

(d) *Stock and voting stock.* (1) For purposes of this section and §§ 1.421–2 through 1.424–1, the term *stock* means capital stock of any class, including voting or nonvoting common or preferred stock. Except as otherwise provided, the term includes both treasury stock and stock of original issue. Special classes of stock authorized to be issued to and held by employees are within the scope of the term *stock* as used in such sections, provided such stock otherwise possesses the rights and characteristics of capital stock.

(2) For purposes of determining what constitutes voting stock in ascertaining whether a plan has been approved by stockholders under § 1.422–2(b) or 1.423–2(c) or whether the limitations pertaining to voting power contained in §§ 1.422–2(f) and 1.423–2(d) have been met, stock which does not have voting

rights until the happening of an event, such as the default in the payment of dividends on preferred stock, is not voting stock until the happening of the specified event. Generally, stock which does not possess a general voting power, and may vote only on particular questions, is not voting stock. However, if such stock is entitled to vote on whether a stock option plan may be adopted, it is voting stock.

(3) In general, for purposes of this section and §§ 1.421–2 through 1.424–1, ownership interests other than capital stock are considered stock.

(e) *Option price.* (1) For purposes of this section and §§ 1.421–2 through 1.424–1, the term *option price*, *price paid under the option*, or *exercise price* means the consideration in cash or property which, pursuant to the terms of the option, is the price at which the stock subject to the option is purchased. The term *option price* does not include any amounts paid as interest under a deferred payment arrangement or treated as interest.

(2) Any reasonable valuation method may be used to determine whether, at the time the option is granted, the option price satisfies the pricing requirements of sections 422(b)(4), 422(c)(5), 422(c)(7), and 423(b)(6) with respect to the stock subject to the option. Such methods include, for example, the valuation method described in § 20.2031–2 of this chapter (Estate Tax Regulations).

(f) *Exercise.* * * * An agreement or undertaking by the employee to make payments under a stock purchase plan does not constitute the exercise of an option to the extent the payments made remain subject to withdrawal by or refund to the employee.

(g) *Transfer.* * * * For purposes of section 422, a transfer may occur even if a share of stock is subject to a substantial risk of forfeiture or is not otherwise transferable immediately after the date of exercise. See § 1.422–1(b)(3) *Example 3.* A transfer does not fail to occur merely because, under the terms of the arrangement, the individual may not dispose of the share for a specified period of time, or the share is subject to a right of first refusal or a right to reacquire the share at the share's fair market value at the time of sale.

(h) *Employment relationship.* (1) An option is a statutory option only if, at the time the option is granted, the optionee is an employee of the corporation granting the option, or a related corporation of such corporation. If the option has been assumed or a new option has been substituted in its place under § 1.424–1(a), the optionee must, at the time of such substitution or assumption, be an employee (or a former employee within the 3-month period following termination of the employment relationship) of the corporation so substituting or assuming the option, or a related corporation of such corporation. The determination of whether the optionee is an employee at the time the option is granted (or at the time of the substitution or assumption under § 1.424–1(a)) is made in accordance with section 3401(c) and the regulations thereunder. * * *

(2) In addition, § 1.421–2(a) is applicable to the transfer of a share pursuant to the exercise of the statutory option only if the optionee is, at all times during the period beginning with the date of the granting of such option and ending on the day 3 months before the date of such exercise, an employee of either the corporation granting such option, a related corporation of such corporation, or a corporation (or a related corporation of such corporation) substituting or assuming a stock option in a transaction to which § 1.424–1(a) applies. For purposes of the preceding sentence, the employment relationship is treated as continuing intact while the individual is on military leave, sick leave, or other bona fide leave of absence (such as temporary employment by the Government) if the period of such leave does not exceed 3 months, or if longer, so long as the individual's right to reemployment with the corporation granting the option (or a related corporation of such corporation) or a corporation (or a related corporation of such corporation) substituting or assuming a stock option in a transaction to which § 1.424–1(a) applies, is provided either by statute or by contract. If the period of leave exceeds 3 months and the individual's right to reemployment is not provided either by statute or by contract, the employment relationship is deemed to terminate on the first day immediately following such three-month period. Thus, if the option is not exercised before such deemed termination of employment, § 1.421–2(a) applies to the transfer of a share pursuant to an exercise of the option only if the exercise occurs within 3 months from the date the employment relationship is deemed terminated.

* * * * *

(i) *Additional definitions.* (1) *Corporation.* For purposes of this section and §§ 1.421–2 through 1.424–1, the term *corporation* has the meaning prescribed by section 7701(a)(3) and § 301.7701–2(b) of this chapter. For example, a *corporation* for purposes of the preceding sentence includes an S corporation (as defined in section 1361), a foreign corporation (as defined in section 7701(a)(5)), and a limited liability company that is treated as a corporation for all Federal tax purposes.

(2) *Parent corporation and subsidiary corporation.* For the definition of the terms *parent corporation* (and *parent*) and *subsidiary corporation* (and *subsidiary*), for purposes of this section and §§ 1.421–2 through 1.424–1, see § 1.424–1(f)(i) and (ii), respectively. *Related corporation* as used in this section and in §§ 1.421–2 through 1.424–1 means either a parent corporation or subsidiary corporation.

(j) *Effective date*—(1) *In general.* These regulations are effective on August 3, 2004.

(2) *Reliance and transition period.* For statutory options granted on or before June 9, 2003, taxpayers may rely on the 1984 proposed regulations LR–279–81 (49 FR 4504), the 2003 proposed regulations REG–122917–02 (68 FR 34344), or this section until the earlier of January 1, 2006, or the first regularly scheduled stockholders meeting of the granting corporation occurring 6 months after August 3, 2004. For statutory options granted after June 9, 2003, and before the earlier of January 1, 2006, or the first regularly scheduled stockholders meeting of the granting corporation occurring 6 months after August 3, 2004, taxpayers may rely on either the REG–122917–02 or this section. Taxpayers may not rely on LR–279–81 or REG–122917–02 after December 31, 2005. Reliance on LR–279–81, REG–122917–02, or this section must be in its entirety, and all statutory options granted during the reliance period must be treated consistently.

■ **Par. 4.** Section 1.421–8 is redesignated as 1.421–2 and is amended by:

■ 1. Revising paragraphs (a)(1), (b), and (c)(1).

■ 2. In paragraph (c)(2), first sentence, add the phrase "for purposes of section 423(c)" at the end of the first sentence.

■ 3. In the list below, for each section indicated in the left column, remove the language in the middle column and add the language in the right column:

Newly designated section	Remove	Add
1.421–2(c)(2), second sentence	or 424(c)(1).	
1.421–2(c)(2), third sentence	or 424(c)(1).	
1.421–2(c)(3)(i), first, second, and third sentences.	422(c)(1), 423(c), or 424(c)(1)	423(c).
1.421–2(c)(3)(ii) *Example*, first sentence	1964	2004.
1.421–2(c)(3)(ii) *Example*, third, fifth, and sixth sentences.	1966	2006.

■ 4. Removing paragraph (c)(4)(i) and redesignating paragraphs (c)(4)(ii) through (c)(4)(iv) as paragraphs (c)(4)(i) through (c)(4)(iii), respectively.

■ 5. In newly designated paragraph (c)(4)(i)(a), first sentence, removing the phrase "In the case of an employee dying after December 31, 1956" and adding "In the case of the death of an optionee" in its place.

■ 6. Removing *Example (1)* in newly designated paragraph (c)(4)(iii) and redesignating *Examples (2)* through (5) as *Examples (1)* through (4), respectively.

■ 7. In the list below, for each section indicated in the left column, remove the language in the middle column and add the language in the right column:

Newly designated section	Remove	Add
1.421–2(c)(4)(i)(*a*), last sentence	422(c)(1), 423(c), or 424(c)(1)	423(c).
1.421–2(c)(4)(i)(*b*), first, second, and last sentences.	422(c)(1), 423(c), or 424(c)(1)	423(c).
1.421–2(c)(4)(i)(*c*), first sentence	422(c)(1), 423(c), or 424(c)(1)	423(c).
1.421–2(c)(4)(iii) *Example 1*, first sentence	1964	2005.
1.421–2(c)(4)(iii), *Example 1*, eighth sentence	subdivision (ii)(*b*) of this subparagraph	paragraph (c)(4)(i)(*b*) of this section.
1.421–2(c)(4)(iii), *Example 1*, third and fifth sentences.	1966	2006.
1.421–2(c)(4)(iii) *Example 1*, ninth sentence	subdivision (ii)(*c*) of this subparagraph.	paragraph (c)(4)(i)(*c*) of this section.
1.421–2(c)(4)(iii) *Example 2*, second and fifth sentences.	subdivision (ii)(*a*) of this subparagraph	paragraph (c)(4)(i)(*a*) of this section.
1.421–2(c)(4)(iii) *Example 2*, fifth sentence	subdivision (ii)(*b*) of this subparagraph	paragraph (c)(4)(i)(*b*) of this section.
1.421–2(c)(4)(iii) *Example 2*, first sentence	*example (2)*	*Example 1.*
1.421–2(c)(4)(iii) *Example 3*, first sentence	*example (2)*	*Example 1.*
1.421–2(c)(4)(iii), *Example 3*, second and fourth sentences.	subdivision (ii)(*a*) of this subparagraph	paragraph (c)(4)(i)(*a*) of this section.
1.421–2(c)(4)(iii) *Example 3*, fourth sentence	subdivision (ii)(*c*) of this subparagraph	paragraph (c)(4)(i)(*c*) of this section.
1.421–2(c)(4)(iii) *Example 4*, first sentence	*example (2)*	*Example 1.*
1.421–2(c)(4)(iii) *Example 4*, first sentence	1966	2006.
1.421–2(c)(4)(iii) *Example 4*, first and second sentences.	1967	2007.
1.421–2(c)(iii) *Example 4*, third, fifth, and sixth sentences.	subdivision (ii)(*a*) of this subparagraph	paragraph (c)(4)(i)(*a*) of this section.
1.421–2(c)(4)(iii) *Example 4*, fifth and sixth sentences.	subdivision (ii)(*b*) of this subparagraph	paragraph (c)(4)(i)(*b*) of this section.
1.421–2(c)(4)(iii) *Example 4*, sixth sentence	subdivision (ii)(*c*) of this subparagraph	paragraph (c)(4)(i)(*c*) of this section.

■ 8. Revising paragraph (d).

■ 9. Adding paragraph (f).

The revisions read as follows:

§ 1.421–2 General rules.

(a) *Effect of qualifying transfer.* (1) If a share of stock is transferred to an individual pursuant to the individual's exercise of a statutory option, and if the requirements of § 1.422–1(a) (relating to incentive stock options) or § 1.423–1(a) (relating to employee stock purchase plans) whichever is applicable, are met, [illegible] is allowable at any time with respect to the share so transferred; and

(iii) No amount other than the price paid under the option is considered as received by the employer corporation, a related corporation of such corporation, or a corporation substituting or assuming a stock option in a transaction to which § 1.424–1(a) (relating to corporate reorganizations, liquidations, etc.) applies, for the share so transferred.

* * * * *

(b) *Effect of disqualifying disposition.* [illegible] inapplicable to the transfer of such share. See section 83(a) to determine the amount includible on a disqualifying disposition. The income attributable to such transfer (determined without reduction for any brokerage fees or other costs paid in connection with the disposition) is treated by the individual as compensation income received in the taxable year in which such disqualifying disposition occurs. A deduction attributable to such transfer is allowable, to the extent otherwise

[illegible] disposition or the shares. Under paragraph (b)(1)(i) of this section, A made a disqualifying disposition of the stock. Thus, paragraph (a) of this section is inapplicable to the transfer of the shares, and E must include the compensation income attributable to the transfer of the shares in gross income in the year of the disqualifying [illegible] even if the executor, administrator, or such person disposes of the stock so acquired before the expiration of the applicable holding periods as determined under § 1.422–1(a) or 1.423–1(a). This special rule does not affect the applicability of section 423(c), relating [illegible] 1222, relating to what constitutes a short-term and long-term capital gain or loss.

* * * * *

(f) *Effective date*—(1) *In general.* These regulations are effective on August 3, 2004.

allowed as a deduction must be determined as if the requirements of section 83(h) and § 1.83–6(a) apply. No amount is treated as income, and no amount is allowed as a deduction, for any taxable year other than the taxable year in which the disqualifying disposition occurs. If the amount realized on the disposition exceeds (or is less than) the sum of the amount paid for the share and the amount of compensation income recognized as a result of such disposition, the extent to which the difference is treated as gain (or loss) is determined under the rules of section 302 or 1001, as applicable.

(ii) The following examples illustrate the principles of this paragraph (b):

Example 1. On June 1, 2006, X Corporation grants an incentive stock option to A, an employee of X, entitling A to purchase 100 shares of X stock at $10 per share. On August 1, 2006, A exercises the option when the fair market value of X stock is $20 per share, and 100 shares of X stock are transferred to A on that date. On December 15, 2007, A sells the stock for $20 per share. Because A disposed of the stock before June 2, 2008, A did not satisfy the holding period requirements of § 1.422–1(a). Under paragraph (b)(1)(i) of this section, A therefore made a disqualifying disposition of the stock. Thus, paragraph (a) of this section is inapplicable to the transfer of the shares, and A must include the compensation income attributable to the transfer of the shares in gross income in the year of the disqualifying disposition. The amount of compensation income A must include in income is $1,000 ($2,000, the fair market value of X stock on transfer less $1,000, the exercise price per share). If the requirements of § 83(h) and § 1.83–6(a) are satisfied and otherwise allowable under section162, X is allowed a deduction of $1,000 for its taxable year in which the disqualifying disposition occurs.

Example 2. Y Corporation grants an incentive stock option for 100 shares of its stock to E, an employee of Y. The option has an exercise price of $10 per share. E exercises the option and is transferred the shares when the fair market value of a share of Y stock is $30. Before the applicable holding periods are met, Y redeems the shares for $70 per share. Because the holding period requirements of § 1.422–1(a) are not met, the redemption of the shares is a disqualifying disposition of the shares. Under paragraph (b)(1)(i) of this section, E therefore made a disqualifying disposition of the shares, and paragraph (a) of this section is inapplicable to the transfer of the shares. Thus, E must include in income the compensation income attributable to the transfer of the shares. The amount of compensation income E must include in income is $2,000 ($30, the fair market value of Y stock on transfer less $10, the exercise price per share, multiplied by 100 shares). If the requirements of § 83(h) and § 1.83–6(a) are satisfied and otherwise allowable under section 162, Y is allowed a deduction for the taxable year in which the disqualifying disposition occurs for the compensation income of $2,000. Y is not allowed a deduction for the additional gain includible in E's income as a result of the redemption.

(2) If an optionee transfers stock acquired through the optionee's exercise of a statutory option prior to the expiration of the applicable holding periods, paragraph (a) of this section continues to apply to the transfer of the stock pursuant to the exercise of the option if such transfer is not a disposition of the stock as defined in § 1.424–1(c) (for example, a transfer from a decedent to the decedent's estate or a transfer by bequest or inheritance). Similarly, a subsequent transfer by the executor, administrator, heir, or legatee is not a disqualifying disposition by the decedent. If a statutory option is exercised by the estate of the optionee or by a person who acquired the option by bequest or inheritance or by reason of the death of such optionee, see paragraph (c) of this section. If a statutory option is exercised by the individual to whom the option was granted and the individual dies before the expiration of the holding periods, see paragraph (d) of this section.

(3) For special rules relating to the disqualifying disposition of a share of stock acquired by exercise of an incentive stock option, see §§ 1.422–5(b)(2) and 1.424–1(c)(3).

(c) *Exercise by estate.* (1) If a statutory option is exercised by the estate of the individual to whom the option was granted (or by any person who acquired such option by bequest or inheritance or by reason of the death of such individual), paragraph (a) of this section applies to the transfer of stock pursuant to such exercise in the same manner as if the option had been exercised by the deceased optionee. Consequently, neither the estate nor such person is required to include any amount in gross income as a result of a transfer of stock pursuant to the exercise of the option. Paragraph (a) of this section applies [illegible] three months after the death of the individual or is not employed as described in § 1.421–1(h), either when the option is exercised or at any time. However, paragraph (a) of this section does not apply to a transfer of shares pursuant to an exercise of the option by the estate or by such person unless the individual met the employment requirements described in § 1.421–1(h) either at the time of the individual's death or within three months before such time (or, if applicable, within the period described in § 1.422–1(a)(3)). Additionally, paragraph (a) of this section does not apply if the option is exercised by a person other than the executor or administrator, or other than a person who acquired the option by bequest or inheritance or by reason of the death of such deceased individual. For example, if the option is sold by the estate, paragraph (a) of this section does not apply to the transfer of stock pursuant to an exercise of the option by the buyer, but if the option is distributed by the administrator to an heir as part of the estate, paragraph (a) of this section applies to the transfer of stock pursuant to an exercise of the option by such heir.

* * * * *

(d) *Option exercised by the individual to whom the option was granted if the individual dies before expiration of the applicable holding periods.* If a statutory option is exercised by the individual to whom the option was granted and such individual dies before the expiration of the applicable holding periods as determined under § 1.422–1(a) or 1.423–1(a), paragraph (a) of this section does not become inapplicable if the executor or administrator of the estate of such individual, or any person who acquired such stock by bequest or inheritance or by reason of the death of such individual, disposes of such stock before the expiration of such applicable holding periods. This rule does not affect the applicability of section 423(c), relating to the individual's recognition of compensation income, or section [illegible] relating to what constitutes a

scheduled stockholders meeting of the granting corporation occurring 6 months after August 3, 2004. For statutory options granted after June 9, 2003, and before the earlier of January 1, 2006, or the first regularly scheduled stockholders meeting of the granting corporation occurring 6 months after August 3, 2004, taxpayers may rely on either the REG–122917–02 or this section. Taxpayers may not rely on LR–279–81 or REG–122917–02 after December 31, 2005. Reliance on LR–279–81, REG–122917–02, or this section must be in its entirety, and all statutory options granted during the reliance period must be treated consistently.

■ **Par. 5.** Section 1.422–1 is added to read as follows:

§ 1.422–1 Incentive stock options; general rules.

(a) *Applicability of section 421(a).* (1)(i) Section 1.421–2(a) applies to the transfer of a share of stock to an individual pursuant to the individual's exercise of an incentive stock option if the following conditions are satisfied—

(A) The individual makes no disposition of such share before the later of the expiration of the 2-year period from the date of grant of the option pursuant to which such share was transferred, or the expiration of the 1-year period from the date of transfer of such share to the individual; and

(B) At all times during the period beginning on the date of grant of the option and ending on the day 3 months before the date of exercise, the individual was an employee of either the corporation granting the option, a related corporation of such corporation, or a corporation (or a related corporation of such corporation) substituting or assuming a stock option in a transaction to which § 1.424–1(a) applies.

(ii) For rules relating to the disposition of shares of stock acquired pursuant to the exercise of a statutory option, see § 1.424–1(c). For rules relating to the requisite employment relationship, see § 1.421–1(h).

(2)(i) The holding period requirement of section 422(a)(1), described in paragraph (a)(1)(i)(A) of this section, does not apply to the transfer of shares by an insolvent individual described in this paragraph (a)(2). If an insolvent individual holds a share of stock acquired pursuant to the individual's exercise of an incentive stock option, and if such share is transferred to a trustee, receiver, or other similar fiduciary in any proceeding under the Bankruptcy Act or any other similar insolvency proceeding, neither such transfer, nor any other transfer of such share for the benefit of the individual's creditors in such proceeding is a disposition of such share for purposes of this paragraph (a). For purposes of this paragraph (a)(2), an individual is insolvent only if the individual's liabilities exceed the individual's assets or the individual is unable to satisfy the individual's liabilities as they become due. See section 422(c)(3).

(ii) A transfer by the trustee or other fiduciary that is not treated as a disposition for purposes of this paragraph (a) may be a sale or exchange for purposes of recognizing capital gain or loss with respect to the share transferred. For example, if the trustee transfers the share to a creditor in an insolvency proceeding, capital gain or loss must be recognized by the insolvent individual to the extent of the difference between the amount realized from such transfer and the adjusted basis of such share.

(iii) If any transfer by the trustee or other fiduciary (other than a transfer back to the insolvent individual) is not for the exclusive benefit of the creditors in an insolvency proceeding, then whether such transfer is a disposition of the share by the individual for purposes of this paragraph (a) is determined under § 1.424–1(c). Similarly, if the trustee or other fiduciary transfers the share back to the insolvent individual, any subsequent transfer of the share by such individual which is not made in respect of the insolvency proceeding may be a disposition of the share for purposes of this paragraph (a).

(3) If the employee exercising an option ceased employment because of permanent and total disability, within the meaning of section 22(e)(3), 1 year is used instead of 3 months in the employment period requirement of paragraph (a)(1)(i)(B) of this section.

(b) *Failure to satisfy holding period requirements*—(1) *General rule.* For general rules concerning a disqualifying disposition of a share of stock acquired pursuant to the exercise of an incentive stock option, see § 1.421–2(b)(1).

(2)(i) *Special rule.* If an individual makes a disqualifying disposition of a share of stock acquired by the exercise of an incentive stock option, and if such disposition is a sale or exchange with respect to which a loss (if sustained) would be recognized to the individual, then, under this paragraph (b)(2)(i), the amount includible (determined without reduction for brokerage fees or other costs paid in connection with the disposition) in the gross income of such individual, and deductible from the income of the employer corporation (or a related corporation of such corporation, or of a corporation substituting or assuming the option in a transaction to which § 1.424–1(a) applies) as compensation attributable to the exercise of such option, shall not exceed the excess (if any) of the amount realized on such sale or exchange over the adjusted basis of such share. Subject to the special rule provided by this paragraph (b)(2)(i), the amount of compensation attributable to the exercise of the option is determined under section 83(a); see § 1.421–2(b)(1)(i).

(ii) *Limitation to special rule.* The special rule described in paragraph (b)(2)(i) of this section does not apply if the disposition is a sale or exchange with respect to which a loss (if sustained) would not be recognized by the individual. Thus, for example, if a disqualifying disposition is a sale described in section 1091 (relating to loss from wash sales of stock or securities), a gift (or any other transaction which is not at arm's length), or a sale described in section 267(a)(1) (relating to sales between related persons), the special rule described in paragraph (b)(2)(i) of this section does not apply because a loss sustained in any such transaction would not be recognized.

(3) *Examples.* The following examples illustrate the principles of this paragraph (b):

Example 1. Disqualifying disposition of vested stock. On June 1, 2006, X Corporation grants an incentive stock option to A, an employee of X Corporation, entitling A to purchase one share of X Corporation stock. On August 1, 2006, A exercises the option, and the share of X Corporation stock is transferred to A on that date. The option price is $100 (the fair market value of a share of X Corporation stock on June 1, 2006), and the fair market value of a share of X Corporation stock on August 1, 2006 (the date of transfer) is $200. The share transferred to A is transferable and not subject to a substantial risk of forfeiture. A makes a disqualifying disposition by selling the share on June 1, 2007, for $250. The amount of compensation attributable to A's exercise is $100 (the difference between the fair market value of the share at the date of transfer, $200, and the amount paid for the share, $100). Because the amount realized ($250) is greater than the value of the share at transfer ($200), paragraph (b)(2)(i) of this section does not apply and thus does not affect the amount includible as compensation in A's gross income and deductible by X. A must include in gross income for the taxable year in which the sale occurred $100 as compensation and $50 as capital gain ($250, the amount realized from the sale, less A's basis of $200 (the $100 paid for the share plus the $100 increase in basis resulting from the inclusion of that amount in A's gross income as compensation attributable to the exercise of the option)). If the requirements of section 83(h) and § 1.83–6(a) are satisfied

and the deduction is otherwise allowable under section 162, for its taxable year in which the disqualifying disposition occurs, X Corporation is allowed a deduction of $100 for compensation attributable to A's exercise of the incentive stock option.

Example 2. Disqualifying disposition of unvested stock. Assume the same facts as in *Example 1*, except that the share of X Corporation stock received by A is subject to a substantial risk of forfeiture and not transferable for a period of six months after such exercise. Assume further that the fair market value of X Corporation stock is $225 on February 1, 2007, the date on which the six-month restriction lapses. Because section 83 does not apply for ordinary income tax purposes on the date of exercise, A cannot make an effective section 83(b) election at that time (although such an election is permissible for alternative minimum tax purposes). Additionally, at the time of the disposition, section 422 and § 1.422–1(a) no longer apply, and thus, section 83(a) is used to measure the consequences of the disposition. The amount of compensation attributable to A's exercise of the option and disqualifying disposition of the share is $125 (the difference between the fair market value of the share on the date that the restriction lapsed, $225, and the amount paid for the share, $100). Because the amount realized ($225) is greater than the value of the share at transfer ($200), paragraph (b)(2)(i) of this section does not apply and thus does not affect the amount includible as compensation in A's gross income and deductible by X. A must include $125 of compensation income and $25 of capital gain in gross income for the taxable year in which the disposition occurs ($250, the amount realized from the sale, less A's basis of $225 (the $100 paid for the share plus the $125 increase in basis resulting from the inclusion of that amount of compensation in A's gross income)). If the requirements of section 83(h) and § 1.83–6(a) are satisfied and the deduction is otherwise allowable under section 162, for its taxable year in which the disqualifying disposition occurs, X Corporation is allowed a deduction of $125 for the compensation attributable to A's exercise of the option.

Example 3. (i) *Disqualifying disposition and application of special rule.* Assume the same facts as in *Example 1*, except that A sells the share for $150 to M.

(ii) If the sale to M is a disposition that meets the requirements of paragraph (b)(2)(i) of this section, instead of $100 which otherwise would have been includible as compensation under § 1.83–7, under paragraph (b)(2)(i) of this section, A must include only $50 (the excess of the amount realized on such sale, $150, over the adjusted basis of the share, $100) in gross income as compensation attributable to the exercise of the incentive stock option. Because A's basis for the share is $150 (the $100 which A paid for the share, plus the $50 increase in basis resulting from the inclusion of that amount in A's gross income as compensation attributable to the exercise of the option), A realizes no capital gain or loss as a result of the sale. If the requirements of section 83(h) and § 1.83–6(a) are satisfied and the deduction is otherwise allowable under section 162, for its taxable year in which the disqualifying disposition occurs, X Corporation is allowed a deduction of $50 for the compensation attributable to A's exercise of the option and disqualifying disposition of the share.

(iii) Assume the same facts as in paragraph (i) of this *Example 3*, except that 10 days after the sale to M, A purchases substantially identical stock. Because under section 1091(a) a loss (if it were sustained on the sale) would not be recognized on the sale, under paragraph (b)(2)(ii) of this section, the special rule described in paragraph (b)(2)(i) of this section does not apply. A must include $100 (the difference between the fair market value of the share on the date of transfer, $200, and the amount paid for the share, $100) in gross income as compensation attributable to the exercise of the option for the taxable year in which the disqualifying disposition occurred. A recognizes no capital gain or loss on the transaction. If the requirements of section 83(h) and § 1.83–6(a) are satisfied and the deduction is otherwise allowable under section 162, for its taxable year in which the disqualifying disposition occurs X Corporation is allowed a $100 deduction for compensation attributable to A's exercise of the option and disqualifying disposition of the share.

(iv) Assume the same facts as in paragraph (ii) of this *Example 3*, except that A sells the share for $50. Under paragraph (b)(2)(i) of this section, A is not required to include any amount in gross income as compensation attributable to the exercise of the option. A is allowed a capital loss of $50 (the difference between the amount realized on the sale, $50, and the adjusted basis of the share, $100). X Corporation is not allowed any deduction attributable to A's exercise of the option and disqualifying disposition of the share.

(c) *Failure to satisfy employment requirement.* Section 1.421–2(a) does not apply to the transfer of a share of stock pursuant to the exercise of an incentive stock option if the employment requirement, as determined under paragraph (a)(1)(i)(B) of this section, is not met at the time of the exercise of such option. Consequently, the effects of such a transfer are determined under the rules of § 1.83–7. For rules relating to the employment relationship, see § 1.421–1(h).

■ **Par. 6.** Section 1.422–2 is added to read as follows:

§ 1.422–2 Incentive stock options defined.

(a) *Incentive stock option defined*—(1) *In general.* The term *incentive stock option* means an option that meets the requirements of paragraph (a)(2) of this section on the date of grant. An incentive stock option is also subject to the $100,000 limitation described in § 1.422–4. An incentive stock option may contain a number of permissible provisions that do not affect the status of the option as an incentive stock option. See § 1.422–5 for rules relating to permissible provisions of an incentive stock option.

(2) *Option requirements.* To qualify as an incentive stock option under this section, an option must be granted to an individual in connection with the individual's employment by the corporation granting such option (or by a related corporation as defined in § 1.421–1(i)(2)), and granted only for stock of any of such corporations. In addition, the option must meet all of the following requirements—

(i) It must be granted pursuant to a plan that meets the requirements described in paragraph (b) of this section;

(ii) It must be granted within 10 years from the date of the adoption of the plan or the date such plan is approved by the stockholders, whichever is earlier (see paragraph (c) of this section);

(iii) It must not be exercisable after the expiration of 10 years from the date of grant (see paragraph (d) of this section);

(iv) It must provide that the option price per share is not less than the fair market value of the share on the date of grant (see paragraph (e) of this section);

(v) By its terms, it must not be transferrable by the individual to whom the option is granted other than by will or the laws of descent and distribution, and must be exercisable, during such individual's lifetime, only by such individual (see §§ 1.421–1(b)(2) and 1.421–2(c)); and

(vi) Except as provided in paragraph (f) of this section, it must be granted to an individual who, at the time the option is granted, does not own stock possessing more than 10 percent of the total combined voting power of all classes of stock of the corporation employing such individual or of any related corporation of such corporation.

(3) *Amendment of option terms.* Except as otherwise provided in § 1.424–1, the amendment of the terms of an incentive stock option may cause it to cease to be an option described in this section. If the terms of an option that has lost its status as an incentive stock option are subsequently changed with the intent to re-qualify the option as an incentive stock option, such change results in the grant of a new option on the date of the change. See § 1.424–1(e).

(4) *Terms provide option not an incentive stock option.* If the terms of an option, when granted, provide that it will not be treated as an incentive stock option, such option is not treated as an incentive stock option.

(b) *Option plan*—(1) *In general.* An incentive stock option must be granted pursuant to a plan that meets the

requirements of this paragraph (b). The authority to grant other stock options or other stock-based awards pursuant to the plan, where the exercise of such other options or awards does not affect the exercise of incentive stock options granted pursuant to the plan, does not disqualify such incentive stock options. The plan must be in writing or electronic form, provided that such writing or electronic form is adequate to establish the terms of the plan. See § 1.422–5 for rules relating to permissible provisions of an incentive stock option.

(2) *Stockholder approval.* (i) The plan required by this paragraph (b) must be approved by the stockholders of the corporation granting the incentive stock option within 12 months before or after the date such plan is adopted. Ordinarily, a plan is adopted when it is approved by the granting corporation's board of directors, and the date of the board's action is the reference point for determining whether stockholder approval occurs within the applicable 24-month period. However, if the board's action is subject to a condition (such as stockholder approval) or the happening of a particular event, the plan is adopted on the date the condition is met or the event occurs, unless the board's resolution fixes the date of approval as the date of the board's action.

(ii) For purposes of paragraph (b)(2)(i) of this section, the stockholder approval must comply with the rules described in § 1.422–3.

(iii) The provisions relating to the maximum aggregate number of shares to be issued under the plan (described in paragraph (b)(3) of this section) and the employees (or class or classes of employees) eligible to receive options under the plan (described in paragraph (b)(4) of this section) are the only provisions of a stock option plan that, if changed, must be re-approved by stockholders for purposes of section 422(b)(1). Any increase in the maximum aggregate number of shares that may be issued under the plan (other than an increase merely reflecting a change in the number of outstanding shares, such as a stock dividend or stock split), or change in the designation of the employees (or class or classes of employees) eligible to receive options under the plan is considered the adoption of a new plan requiring stockholder approval within the prescribed 24-month period. In addition, a change in the granting corporation or the stock available for purchase or award under the plan is considered the adoption of a new plan requiring new stockholder approval within the prescribed 24-month period. Any other changes in the terms of an incentive stock option plan are not considered the adoption of a new plan and, thus, do not require stockholder approval.

(3) *Maximum aggregate number of shares.* (i) The plan required by this paragraph (b) must designate the maximum aggregate number of shares that may be issued under the plan through incentive stock options. If nonstatutory options or other stock-based awards may be granted, the plan may separately designate terms for each type of option or other stock-based awards and designate the maximum number of shares that may be issued under such option or other stock-based awards. Unless otherwise specified, all terms of the plan apply to all options and other stock-based awards that may be granted under the plan.

(ii) A plan that merely provides that the number of shares that may be issued as incentive stock options under such plan may not exceed a stated percentage of the shares outstanding at the time of each offering or grant under such plan does not satisfy the requirement that the plan state the maximum aggregate number of shares that may be issued under the plan. However, the maximum aggregate number of shares that may be issued under the plan may be stated in terms of a percentage of the authorized, issued, or outstanding shares at the date of the adoption of the plan. The plan may specify that the maximum aggregate number of shares available for grants under the plan may increase annually by a specified percentage of the authorized, issued, or outstanding shares at the date of the adoption of the plan. A plan which provides that the maximum aggregate number of shares that may be issued as incentive stock options under the plan may change based on any other specified circumstances satisfies the requirements of this paragraph (b)(3) only if the stockholders approve an immediately determinable maximum aggregate number of shares that may be issued under the plan in any event.

(iii) It is permissible for the plan to provide that, shares purchasable under the plan may be supplied to the plan through acquisitions of stock on the open market; shares purchased under the plan and forfeited back to the plan; shares surrendered in payment of the exercise price of an option; shares withheld for payment of applicable employment taxes and/or withholding obligations resulting from the exercise of an option.

(iv) If there is more than one plan under which incentive stock options may be granted and stockholders of the granting corporation merely approve a maximum aggregate number of shares that are available for issuance under such plans, the stockholder approval requirements described in paragraph (b)(2) of this section are not satisfied. A separate maximum aggregate number of shares available for issuance pursuant to incentive stock options must be approved for each plan.

(4) *Designation of employees.* The plan described in this paragraph (b), as adopted and approved, must indicate the employees (or class or classes of employees) eligible to receive the options or other stock-based awards to be granted under the plan. This requirement is satisfied by a general designation of the employees (or the class or classes of employees) eligible to receive options or other stock-based awards under the plan. Designations such as "key employees of the grantor corporation"; "all salaried employees of the grantor corporation and its subsidiaries, including subsidiaries which become such after adoption of the plan;" or "all employees of the corporation" meet this requirement. This requirement is considered satisfied even though the board of directors, another group, or an individual is given the authority to select the particular employees who are to receive options or other stock-based awards from a described class and to determine the number of shares to be optioned or granted to each such employee. If individuals other than employees may be granted options or other stock-based awards under the plan, the plan must separately designate the employees or classes of employees eligible to receive incentive stock options.

(5) *Conflicting option terms.* An option on stock available for purchase or grant under the plan is treated as having been granted pursuant to a plan even if the terms of the option conflict with the terms of the plan, unless such option is granted to an employee who is ineligible to receive options under the plan, options have been granted on stock in excess of the aggregate number of shares which may be issued under the plan, or the option provides otherwise.

(6) The following examples illustrate the principles of this paragraph (b):

Example 1. Stockholder approval. (i) S Corporation is a subsidiary of P Corporation, a publicly traded corporation. On January 1, 2006, S adopts a plan under which incentive stock options for S stock are granted to S employees.

(ii) To meet the requirements of paragraph (b)(2) of this section, the plan must be approved by the stockholders of S (in this

case, P) within 12 months before or after January 1, 2006.

(iii) Assume the same facts as in paragraph (i) of this *Example 1*. Assume further that the plan was approved by the stockholders of S (in this case, P) on March 1, 2006. On January 1, 2008, S changes the plan to provide that incentive stock options for P stock will be granted to S employees under the plan. Because there is a change in the stock available for grant under the plan, the change is considered the adoption of a new plan that must be approved by the stockholders of P within 12 months before or after January 1, 2008.

Example 2. Stockholder approval. (i) Assume the same facts as in paragraph (i) of *Example 1*, except that on March 15, 2007, P completely disposes of its interest in S. Thereafter, S continues to grant options for S stock to S employees under the plan.

(ii) The new S options are granted under a plan that meets the stockholder approval requirements of paragraph (b)(2) of this section without regard to whether S seeks approval of the plan from the stockholders of S after P disposes of its interest in S.

(iii) Assume the same facts as in paragraph (i) of this *Example 2*, except that under the plan as adopted on January 1, 2006, only options for P stock are granted to S employees. Assume further that after P disposes of its interest in S, S changes the plan to provide for the grant of options for S stock to S employees. Because there is a change in the stock available for purchase or grant under the plan, under paragraph (b)(2)(iii) of this section, the stockholders of S must approve the plan within 12 months before or after the change to the plan to meet the stockholder approval requirements of paragraph (b) of this section.

Example 3. Stockholder approval. (i) Corporation X maintains a plan under which incentive stock options may be granted to all eligible employees. Corporation Y does not maintain an incentive stock option plan. On May 15, 2006, Corporation X and Corporation Y consolidate under state law to form one corporation. The new corporation will be named Corporation Y. The consolidation agreement describes the Corporation X plan, including the maximum aggregate number of shares available for issuance pursuant to incentive stock options after the consolidation and the employees eligible to receive options under the plan. Additionally, the consolidation agreement states that the plan will be continued by Corporation Y after the consolidation and incentive stock options will be issued by Corporation Y. The consolidation agreement is unanimously approved by the shareholders of Corporations X and Y on May 1, 2006. Corporation Y assumes the plan formerly maintained by Corporation X and continues to grant options under the plan to all eligible employees.

(ii) Because there is a change in the granting corporation (from Corporation X to Corporation Y), under paragraph (b)(2)(iii) of this section, Corporation Y is considered to have adopted a new plan. Because the plan is fully described in the consolidation agreement, including the maximum aggregate number of shares available for issuance pursuant to incentive stock options and employees eligible to receive options under the plan, the approval of the consolidation agreement by the shareholders constitutes approval of the plan. Thus, the shareholder approval of the consolidation agreement satisfies the shareholder approval requirements of paragraph (b)(2) of this section, and the plan is considered to be adopted by Corporation Y and approved by its shareholders on May 1, 2006.

Example 4. Maximum aggregate number of shares. X Corporation maintains a plan under which statutory options and nonstatutory options may be granted. The plan designates the number of shares that may be used for incentive stock options. Because the maximum aggregate number of shares that will be used for incentive stock options is designated in the plan, the requirements of paragraph (b)(3) of this section are satisfied.

Example 5. Maximum aggregate number of shares. Y Corporation adopts an incentive stock option plan on November 1, 2006. On that date, there are two million outstanding shares of Y Corporation stock. The plan provides that the maximum aggregate number of shares that may be issued under the plan may not exceed 15% of the outstanding number of shares of Y Corporation on November 1, 2006. Because the maximum aggregate number of shares that may be issued under the plan is designated in the plan, the requirements of paragraph (b)(3) of this section are met.

Example 6. Maximum aggregate number of shares. (i) B Corporation adopts an incentive stock option plan on March 15, 2005. The plan provides that the maximum aggregate number of shares available for issuance under the plan is 50,000, increased on each anniversary date of the adoption of the plan by 5 percent of the then-outstanding shares.

(ii) Because the maximum aggregate number of shares is not designated under the plan, the requirements of paragraph (b)(3) of this section are not met.

(iii) Assume the same facts as in paragraph (i) of this *Example 6*, except that the plan provides that the maximum aggregate number of shares available under the plan is the lesser of (a) 50,000 shares, increased each anniversary date of the adoption of the plan by 5 percent of the then-outstanding shares, or (b) 200,000 shares. Because the maximum aggregate number of shares that may be issued under the plan is designated as the lesser of one of two numbers, one of which provides an immediately determinable maximum aggregate number of shares that may be issued under the plan in any event, the requirements of paragraph (b)(3) of this section are met.

(c) *Duration of option grants under the plan.* An incentive stock option must be granted within 10 years from the date that the plan under which it is granted is adopted or the date such plan is approved by the stockholders, whichever is earlier. To grant incentive stock options after the expiration of the 10-year period, a new plan must be adopted and approved.

(d) *Period for exercising options.* An incentive stock option, by its terms, must not be exercisable after the expiration of 10 years from the date such option is granted, or 5 years from the date such option is granted to an employee described in paragraph (f) of this section. An option that does not contain such a provision when granted is not an incentive stock option.

(e) *Option price.* (1) Except as provided by paragraph (e)(2) of this section, the option price of an incentive stock option must not be less than the fair market value of the stock subject to the option at the time the option is granted. The option price may be determined in any reasonable manner, including the valuation methods permitted under § 20.2031–2 of this chapter, so long as the minimum price possible under the terms of the option is not less than the fair market value of the stock on the date of grant. For general rules relating to the option price, see § 1.421–1(e). For rules relating to the determination of when an option is granted, see § 1.421–1(c).

(2)(i) If a share of stock is transferred to an individual pursuant to the exercise of an option which fails to qualify as an incentive stock option merely because there was a failure of an attempt, made in good faith, to meet the option price requirements of paragraph (e)(1) of this section, the requirements of such paragraph are considered to have been met. Whether there was a good-faith attempt to set the option price at not less than the fair market value of the stock subject to the option at the time the option was granted depends on the relevant facts and circumstances.

(ii) For publicly held stock that is actively traded on an established market at the time the option is granted, determining the fair market value of such stock by the appropriate method described in § 20.2031–2 of this chapter establishes that a good-faith attempt to meet the option price requirements of this paragraph (e) was made.

(iii) For non-publicly traded stock, if it is demonstrated, for example, that the fair market value of the stock at the date of grant was based upon an average of the fair market values as of such date set forth in the opinions of completely independent and well-qualified experts, such a demonstration generally establishes that there was a good-faith attempt to meet the option price requirements of this paragraph (e). The optionee's status as a majority or minority stockholder may be taken into consideration.

(iv) Regardless of whether the stock offered under an option is publicly traded, a good-faith attempt to meet the option price requirements of this paragraph (e) is not demonstrated unless

the fair market value of the stock on the date of grant is determined with regard to *nonlapse restrictions* (as defined in § 1.83–3(h)) and without regard to *lapse restrictions* (as defined in § 1.83–3(i)).

(v) Amounts treated as interest and amounts paid as interest under a deferred payment arrangement are not includible as part of the option price. See § 1.421–1(e)(1). An attempt to set the option price at not less than fair market value is not regarded as made in good faith where an adjustment of the option price to reflect amounts treated as interest results in the option price being lower than the fair market value on which the option price was based.

(3) Notwithstanding that the option price requirements of paragraphs (e)(1) and (2) of this section are satisfied by an option granted to an employee whose stock ownership exceeds the limitation provided by paragraph (f) of this section, such option is not an incentive stock option when granted unless it also complies with paragraph (f) of this section. If the option, when granted, does not comply with the requirements described in paragraph (f) of this section, such option can never become an incentive stock option, even if the employee's stock ownership does not exceed the limitation of paragraph (f) of this section when such option is exercised.

(f) *Options granted to certain stockholders.* (1) If, immediately before an option is granted, an individual owns (or is treated as owning) stock possessing more than 10 percent of the total combined voting power of all classes of stock of the corporation employing the optionee or of any related corporation of such corporation, then an option granted to such individual cannot qualify as an incentive stock option unless the option price is at least 110 percent of the stock's fair market value on the date of grant and such option by its terms is not exercisable after the expiration of 5 years from the date of grant. For purposes of determining the minimum option price for purposes of this paragraph (f), the rules described in paragraph (e)(2) of this section, relating to the good-faith determination of the option price, do not apply.

(2) For purposes of determining the stock ownership of the optionee, the stock attribution rules of § 1.424–1(d) apply. Stock that the optionee may purchase under outstanding options is not treated as stock owned by the individual. The determination of the percentage of the total combined voting power of all classes of stock of the employer corporation (or of its related corporations) that is owned by the optionee is made with respect to each such corporation in the related group by comparing the voting power of the shares owned (or treated as owned) by the optionee to the aggregate voting power of all shares of each such corporation actually issued and outstanding immediately before the grant of the option to the optionee. The aggregate voting power of all shares actually issued and outstanding immediately before the grant of the option does not include the voting power of treasury shares or shares authorized for issue under outstanding options held by the individual or any other person.

(3) *Examples.* The rules of this paragraph (f) are illustrated by the following examples:

Example 1. (i) E, an employee of M Corporation, owns 15,000 shares of M Corporation common stock, which is the only class of stock outstanding. M has 100,000 shares of its common stock outstanding. On January 1, 2005, when the fair market value of M stock is $100, E is granted an option with an option price of $100 and an exercise period of 10 years from the date of grant.

(ii) Because E owns stock possessing more than 10 percent of the total combined voting power of all classes of M Corporation stock, M cannot grant an incentive stock option to E unless the option is granted at an option price of at least 110 percent of the fair market value of the stock subject to the option and the option, by its terms, expires no later than 5 years from its date of grant. The option granted to E fails to meet the option-price and term requirements described in paragraph (f)(1) of this section and, thus, the option is not an incentive stock option.

(iii) Assume the same facts as in paragraph (i) of this *Example 1*, except that E's father and brother each owns 7,500 shares of M Corporation stock, and E owns no M stock in E's own name. Because under the attribution rules of § 1.424–1(d), E is treated as owning stock held by E's parents and siblings, M cannot grant an incentive stock option to E unless the option price is at least 110 percent of the fair market value of the stock subject to the option, and the option, by its terms, expires no later than 5 years from the date of grant.

Example 2. Assume the same facts as in paragraph (i) of this *Example 1*. Assume further that M is a subsidiary of P Corporation. Regardless of whether E owns any P stock and the number of P shares outstanding, if P Corporation grants an option to E which purports to be an incentive stock option, but which fails to meet the 110-percent-option-price and 5-year-term requirements, the option is not an incentive stock option because E owns more than 10 percent of the total combined voting power of all classes of stock of a related corporation of P Corporation (*i.e.*, M Corporation). An individual who owns (or is treated as owning) stock in excess of the ownership specified in paragraph (f)(1) of this section, in any corporation in a group of corporations consisting of the employer corporation and its related corporations, cannot be granted an incentive stock option by any corporation in the group unless such option meets the 110-percent-option-price and 5-year-term requirements of paragraph (f)(1) of this section.

Example 3. (i) F is an employee of R Corporation. R has only one class of stock, of which 100,000 shares are issued and outstanding. F owns no stock in R Corporation or any related corporation of R Corporation. On January 1, 2005, R grants a 10-year incentive stock option to F to purchase 50,000 shares of R stock at $3 per share, the fair market value of R stock on the date of grant of the option. On April 1, 2005, F exercises half of the January option and receives 25,000 shares of R stock that previously were not outstanding. On July 1, 2005, R grants a second 50,000 share option to F which purports to be an incentive stock option. The terms of the July option are identical to the terms of the January option, except that the option price is $3.25 per share, which is the fair market value of R stock on the date of grant of the July option.

(ii) Because F does not own more than 10% of the total combined voting power of all classes of stock of R Corporation or any related corporation on the date of the grant of the January option and the pricing requirements of paragraph (e) of this section are satisfied on the date of grant of such option, the unexercised portion of the January option remains an incentive stock option regardless of the changes in F's percentage of stock ownership in R after the date of grant. However, the July option is not an incentive stock option because, on the date that it is granted, F owns 20 percent (25,000 shares owned by F divided by 125,000 shares of R stock issued and outstanding) of the total combined voting power of all classes of R Corporation stock and, thus the pricing requirements of paragraph (f)(1) of this section are not met.

(iii) Assume the same facts as in paragraph (i) of this *Example 3* except that the partial exercise of the January incentive stock option on April 1, 2003, is for only 10,000 shares. Under these circumstances, the July option is an incentive stock option, because, on the date of grant of the July option, F does not own more than 10 percent of the total combined voting power (10,000 shares owned by F divided by 110,000 shares of R issued and outstanding) of all classes of R Corporation stock.

§ 1.422–4 [Removed]

■ **Par. 7.** Section 1.422–4 is removed.

§ 1.422–5 [Redesignated as § 1.422–3]

■ **Par. 8.** Section 1.422–5 is redesignated as § 1.422–3.

■ **Par. 9.** New § 1.422–4 is added to read as follows:

§ 1.422–4 $100,000 limitation for incentive stock options.

(a) *$100,000 per year limitation*—(1) *General rule.* An option that otherwise qualifies as an incentive stock option

nevertheless fails to be an incentive stock option to the extent that the $100,000 limitation described in paragraph (a)(2) of this section is exceeded.

(2) *$100,000 per year limitation.* To the extent that the aggregate fair market value of stock with respect to which an incentive stock option (determined without regard to this section) is exercisable for the first time by any individual during any calendar year (under all plans of the employer corporation and related corporations) exceeds $100,000, such option is treated as a nonstatutory option. See § 1.83–7 for rules applicable to nonstatutory options.

(b) *Application.* To determine whether the limitation described in paragraph (a)(2) of this section has been exceeded, the following rules apply:

(1) An option that does not meet the requirements of § 1.422–2 when granted (including an option which, when granted, contains terms providing that it will not be treated as an incentive stock option) is disregarded. See § 1.422–2(a)(4).

(2) The fair market value of stock is determined as of the date of grant of the option for such stock.

(3) Except as otherwise provided in paragraph (b)(4) of this section, options are taken into account in the order in which they are granted.

(4) For purposes of this section, an option is considered to be first exercisable during a calendar year if the option will become exercisable at any time during the year assuming that any condition on the optionee's ability to exercise the option related to the performance of services is satisfied. If the optionee's ability to exercise the option in the year is subject to an acceleration provision, then the option is considered first exercisable in the calendar year in which the acceleration provision is triggered. After an acceleration provision is triggered, the options subject to such provision are then taken into account in accordance with paragraph (b)(3) of this section for purposes of applying the limitation described in paragraph (a)(2) of this section to all options first exercisable during a calendar year. However, because an acceleration provision is not taken into account prior to its triggering, an incentive stock option that becomes exercisable for the first time during a calendar year by operation of such a provision does not affect the application of the $100,000 limitation with respect to any option (or portion thereof) exercised prior to such acceleration. For purposes of this paragraph (b)(4), an acceleration provision includes, for example, a provision that accelerates the exercisability of an option on a change in ownership or control or a provision that conditions exercisability on the attainment of a performance goal. See paragraph (d), *Example 4* of this section.

(5)(i) An option (or portion thereof) is disregarded if, prior to the calendar year during which it would otherwise have become exercisable for the first time, the option (or portion thereof) is modified and thereafter ceases to be an incentive stock option described in § 1.422–2, is canceled, or is transferred in violation of § 1.421–1(b)(2).

(ii) If an option (or portion thereof) is modified, canceled, or transferred at any other time, such option (or portion thereof) is treated as outstanding according to its original terms until the end of the calendar year during which it would otherwise have become exercisable for the first time.

(6) A disqualifying disposition has no effect on the determination of whether an option exceeds the $100,000 limitation.

(c) *Bifurcation*—(1) *Options.* The application of the rules described in paragraph (b) of this section may result in an option being treated, in part, as an incentive stock option and, in part, as a nonstatutory option. *See* § 1.83–7 for the treatment of nonstatutory options.

(2) *Stock.* A corporation may issue a separate certificate for incentive option stock or designate such stock as incentive stock option stock in the corporation's transfer records or plan records. In such a case, the issuance of separate certificates or designation in the corporation's transfer records or plan records is not a modification under § 1.424–1(e). In the absence of such an issuance or designation, shares are treated as first purchased under an incentive stock option to the extent of the $100,000 limitation, and the excess shares are treated as purchased under a nonstatutory option. *See* § 1.83–7 for the treatment of nonstatutory options.

(d) *Examples.* The following examples illustrate the principles of this section. In each of the following examples E is an employee of X Corporation. The examples are as follows:

Example 1. General rule. Effective January 1, 2004, X Corporation adopts a plan under which incentive stock options may be granted to its employees. On January 1, 2004, and each succeeding January 1 through January 1, 2013, E is granted immediately exercisable options for X Corporation stock with a fair market value of $100,000 determined on the date of grant. The options qualify as incentive stock options (determined without regard to this section). On January 1, 2014, E exercises all of the options. Because the $100,000 limitation has not been exceeded during any calendar year, all of the options are treated as incentive stock options.

Example 2. Order of grant. X Corporation is a parent corporation of Y Corporation, which is a parent corporation of Z Corporation. Each corporation has adopted its own separate plan, under which an employee of any member of the corporate group may be granted options for stock of any member of the group. On January 1, 2004, X Corporation grants E an incentive stock option (determined without regard to this section) for stock of Y Corporation with a fair market value of $100,000 on the date of grant. On December 31, 2004, Y Corporation grants E an incentive stock option (determined without regard to this section) for stock of Z Corporation with a fair market value of $75,000 as of the date of grant. Both of the options are immediately exercisable. For purposes of this section, options are taken into account in the order in which granted using the fair market value of stock as of the date on the option is granted. During calendar year 2004, the aggregate fair market value of stock with respect to which E's options are exercisable for the first time exceeds $100,000. Therefore, the option for Y Corporation stock is treated as an incentive stock option, and the option for Z Corporation stock is treated as a nonstatutory option.

Example 3. Acceleration provision. (i) In 2004, X Corporation grants E three incentive stock options (determined without regard to this section) to acquire stock with an aggregate fair market value of $150,000 on the date of grant. The dates of grant, the fair market value of the stock (as of the applicable date of grant) with respect to which the options are exercisable, and the years in which the options are first exercisable (without regard to acceleration provisions) are as follows:

	Date of grant	Fair market value of stock	First exercisable
Option 1	April 1, 2004	$60,000	2004
Option 2	May 1, 2004	50,000	2006
Option 3	June 1, 2004	40,000	2004

(ii) In July of 2004, a change in control of X Corporation occurs, and, under the terms of its option plan, all outstanding options become immediately exercisable. Under the rules of this section, Option 1 is treated as an incentive stock option in its entirety; Option 2 exceeds the $100,000 aggregate fair market value limitation for calendar year 2004 by $10,000 (Option 1's $60,000 + Option 2's $50,000 = $110,000) and is, therefore, bifurcated into an incentive stock option for stock with a fair market value of $40,000 as of the date of grant and a nonstatutory option for stock with a fair market value of $10,000 as of the date of grant. Option 3 is treated as a nonstatutory option in its entirety.

Example 4. Exercise of option and acceleration provision. (i) In 2004, X Corporation grants E three incentive stock options (determined without regard to this section) to acquire stock with an aggregate fair market value of $120,000 on the date of grant. The dates of grant, the fair market value of the stock (as of the applicable date of grant) with respect to which the options are exercisable, and the years in which the options are first exercisable (without regard to acceleration provisions) are as follows:

	Date of grant	Fair market value of stock	First exercisable
Option 1	April 1, 2004	$60,000	2005
Option 2	May 1, 2004	40,000	2006
Option 3	June 1, 2004	20,000	2005

(ii) On June 1, 2005, E exercises Option 3. At the time of exercise of Option 3, the fair market value of X stock (at the time of grant) with respect to which options held by E are first exercisable in 2005 does not exceed $100,000. On September 1, 2005, a change of control of X Corporation occurs, and, under the terms of its option plan, Option 2 becomes immediately exercisable. Under the rules of this section, because E's exercise of Option 3 occurs before the change of control and the effects of an acceleration provision are not taken into account until it is triggered, Option 3 is treated as an incentive stock option in its entirety. Option 1 is treated as an incentive stock option in its entirety. Option 2 is bifurcated into an incentive stock option for stock with a fair market value of $20,000 on the date of grant and a nonstatutory option for stock with a fair market value of $20,000 on the date of grant because it exceeds the $100,000 limitation for 2003 by $20,000 (Option 1 for $60,000 + Option 3 for $20,000 + Option 2 for $40,000 = $120,000).

(iii) Assume the same facts as in paragraph (ii) of this *Example 4*, except that the change of control occurs on May 1, 2005. Because options are taken into account in the order in which they are granted, Option 1 and Option 2 are treated as incentive stock options in their entirety. Because the exercise of Option 3 (on June 1, 2005) takes place after the acceleration provision is triggered, Option 3 is treated as a nonstatutory option in its entirety.

Example 5. Cancellation of option. (i) In 2004, X Corporation grants E three incentive stock options (determined without regard to this section) to acquire stock with an aggregate fair market value of $140,000 as of the date of grant. The dates of grant, the fair market value of the stock (as of the applicable date of grant) with respect to which the options are exercisable, and the years in which the options are first exercisable (without regard to acceleration provisions) are as follows:

	Date of grant	Fair market value of stock	First exercisable
Option 1	April 1, 2004	$60,000	2005
Option 2	May 1, 2004	40,000	2005
Option 3	June 1, 2004	40,000	2005

(ii) On December 31, 2004, Option 2 is canceled. Because Option 2 is canceled before the calendar year during which it would have become exercisable for the first time, it is disregarded. As a result, Option 1 and Option 3 are treated as incentive stock options in their entirety.

(iii) Assume the same facts as in paragraph (ii) of this *Example 5*, except that Option 2 is canceled on January 1, 2005. Because Option 2 is not canceled prior to the calendar year during which it would have become exercisable for the first time (2005), it is treated as an outstanding option for purposes of determining whether the $100,000 limitation for 2005 has been exceeded. Because options are taken into account in the order in which granted, Option 1 is treated as an incentive stock option in its entirety. Because Option 3 exceeds the $100,000

no effect on the determination of whether the underlying option is considered outstanding during the calendar year during which it is first exercisable. Because options are taken into account in the order in which granted, Option 1 is treated as an incentive stock option in its entirety. Because Option 3 exceeds the $100,000 limitation by $40,000 (Option 1 for $60,000 + Option 2 for $40,000 + Option 3 for $40,000 = $140,000), it is treated as a nonstatutory option in its entirety.

Example 6. Designation of stock. On January 1, 2004, X grants E an immediately exercisable incentive stock option (determined without regard to this section) to acquire X stock with a fair market value of $150,000 on that date. Under the rules of this section, the option is bifurcated and treated as an incentive stock option for X stock with

in its transfer records. In the absence of such a designation (or a designation in the corporation's transfer records or the plan records) shares with a fair market value of $100,000 are deemed purchased first under an incentive stock option, and shares with a fair market value of $50,000 are deemed purchased under a nonstatutory option.

■ **Par. 10.** Section 1.422–5 is added to read as follows:

§ 1.422–5 Permissible provisions.

(a) *General rule.* An option that otherwise qualifies as an incentive stock option does not fail to be an incentive stock option merely because such option contains one or more of the provisions described in paragraphs (b), (c), and (d) of this section.

special rules relating to the use of statutory option stock to pay the option price of an incentive stock option, see § 1.424–1(c)(3).

(2) All shares acquired through the exercise of an incentive stock option are individually subject to the holding period requirements described in § 1.422–1(a) and the disqualifying disposition rules of § 1.422–1(b), regardless of whether the option is exercised with previously acquired stock of the corporation that granted the option or stock of the corporation whose stock is being offered for purchase under the option. If an incentive stock option is exercised with such shares, and the exercise results in the basis allocation described in paragraph (b)(3) of this section, the optionee's disqualifying disposition of any of the stock acquired through such exercise is treated as a disqualifying disposition of the shares with the lowest basis.

(3) If the exercise of an incentive stock option with previously acquired shares is comprised in part of an exchange to which section 1036 (and so much of section 1031 as relates to section 1036) applies, then:

(i) The optionee's basis in the incentive stock option shares received in the section 1036 exchange is the same as the optionee's basis in the shares surrendered in the exchange, increased, if applicable, by any amount included in gross income as compensation pursuant to sections 421 through 424 or section 83. Except for purposes of § 1.422–1(a), the holding period of the shares is determined under section 1223. For purposes of § 1.422–1 and sections 421(b) and 83 and the regulations thereunder, the amount paid for the shares purchased under the option is the fair market value of the shares surrendered on the date of the exchange.

(ii) The optionee's basis in the incentive stock option shares not received pursuant to the section 1036 exchange is zero. For all purposes, the holding period of such shares begins as of the date that such shares are transferred to the optionee. For determined in any manner, including by reference to the fair market value of the stock at the time of exercise or to the option price.

(d) *Option subject to a condition.* (1) An option does not fail to be an incentive stock option merely because the option is subject to a condition, or grants a right, that is not inconsistent with the requirements of §§ 1.422–2 and 1.422–4.

(2) An option that includes an alternative right is not an incentive stock option if the requirements of § 1.422–2 are effectively avoided by the exercise of the alternative right. For example, an alternative right extending the option term beyond ten years, setting an option price below fair market value, or permitting transferability prevents an option from qualifying as an incentive stock option. If either of two options can be exercised, but not both, each such option is a disqualifying alternative right with respect to the other, even though one or both options would individually satisfy the requirements of §§ 1.422–2, 1.422–4, and this section.

(3) An alternative right to receive a taxable payment of cash and/or property in exchange for the cancellation or surrender of the option does not disqualify the option as an incentive stock option if the right is exercisable only when the then fair market value of the stock exceeds the exercise price of the option and the option is otherwise exercisable, the right is transferable only when the option is otherwise transferable, and the exercise of the right has economic and tax consequences no more favorable than the exercise of the option followed by an immediate sale of the stock. For this purpose, the exercise of the alternative right does not have the same economic and tax consequences if the payment exceeds the difference between the then fair market value of the stock and the exercise price of the option.

(e) *Examples.* The principles of this section are illustrated by the following examples:

the open market on June 1, 2002, for $5 per share, to pay the full option price. After exercising the option, A owns 100 shares of incentive stock option stock. Under section 1036 (and so much of section 1031 as relates to section 1036), 40 of the shares have a $200 aggregate carryover basis (the $5 purchase price x 40 shares) and a three-year holding period for purposes of determining capital gain, and 60 of the shares have a zero basis and a holding period beginning on June 1, 2005, for purposes of determining capital gain. All 100 shares have a holding period beginning on June 1, 2005, for purposes of determining whether the holding period requirements of § 1.422–1(a) are met.

Example 2. Assume the same facts as in *Example 1.* Assume further that, on September 1, 2005, A sells 75 of the shares that A acquired through exercise of the incentive stock option for $30 per share. Because the holding period requirements were not satisfied, A made a disqualifying disposition of the 75 shares on September 1, 2005. Under the rules of paragraph (b)(3) of this section, A has sold all 60 of the non-section-1036 shares and 15 of the 40 section-1036 shares. Therefore, under paragraph (b)(3) of this section and section 83(a), the amount of compensation attributable to A's exercise of the option and subsequent disqualifying disposition of 75 shares is $1,500 (the difference between the fair market value of the stock on the date of transfer, $1,875 (75 shares at $25 per share), and the amount paid for the stock, $375 (60 shares at $0 per share plus 15 shares at $25 per share)). In addition, A must recognize a capital gain of $675, which consists of $375 ($450, the amount realized from the sale of 15 shares, less A's basis of $75) plus $300 ($1,800, the amount realized from the sale of 60 shares, less A's basis of $1,500 resulting from the inclusion of that amount in income as compensation). Accordingly, A must include in gross income for the taxable year in which the sale occurs $1,500 as compensation and $675 as capital gain. For its taxable year in which the disqualifying disposition occurs, if otherwise allowable under section 162 and if the requirements of § 1.83–6(a) are met, X Corporation is allowed a deduction of $1,500 for the compensation paid to A.

Example 3. Assume the same facts as in *Example 2,* except that, instead of selling the 75 shares of incentive stock option stock on September 1, 2005, A uses those shares to exercise a second incentive stock option. The second option was granted to A by X

share), and the amount paid for the stock, $375 (60 shares at $0 per share plus 15 shares at $25 per share)). Unlike *Example 2*, A does not recognize any capital gain as a result of exercising the second option because, for all purposes other than the determination of whether the exercise is a disposition pursuant to section 424(c), the exercise is considered an exchange to which section 1036 applies. Accordingly, A must include in gross income for the taxable year in which the disqualifying disposition occurs $1,500 as compensation. If the requirements of § 83(h) and § 1.83–6(a) are satisfied and the deduction is otherwise allowable under section 162, for its taxable year in which the disqualifying disposition occurs, X Corporation is allowed a deduction of $1,500 for the compensation paid to A. After exercising the second option, A owns a total of 125 shares of incentive stock option stock. Under section 1036 (and so much of section 1031 as relates to section 1036), the 100 "new" shares of incentive stock option stock have the following bases and holding periods: 15 shares have a $75 carryover basis and a three-year-and-three-month holding period for purposes of determining capital gain, 60 shares have a $1,500 basis resulting from the inclusion of that amount in income as compensation and a three-month holding period for purposes of determining capital gain, and 25 shares have a zero basis and a holding period beginning on September 1, 2005, for purposes of determining capital gain. All 100 shares have a holding period beginning on September 1, 2005, for purposes of determining whether the holding period requirements of § 1.422–1(a) are met.

Example 4. Assume the same facts as in *Example 2*, except that, instead of selling the 75 shares of incentive stock option stock on September 1, 2005, A uses those shares to exercise a nonstatutory option. The nonstatutory option was granted to A by X Corporation on January 1, 2005, entitling A to purchase 100 shares of X Corporation common stock at $22.50 per share. Unlike *Example 3*, A has not made a disqualifying disposition of the 75 shares of stock. After exercising the nonstatutory option, A owns a total of 100 shares of incentive stock option stock and 25 shares of nonstatutory stock option stock. Under section 1036 (and so much of section 1031 as relates to section 1036), the 75 new shares of incentive stock option stock have the same basis and holding period as the 75 old shares used to exercise the nonstatutory option. The additional 25 shares of stock received upon exercise of the nonstatutory option are taxed under the rules of section 83(a). Accordingly, A must include in gross income for the taxable year in which the transfer of such shares occurs $750 (25 shares at $30 per share) as compensation. A's basis in such shares is the same as the amount included in gross income. For its taxable year in which the transfer occurs, X Corporation is allowed a deduction of $750 for the compensation paid to A to the extent the requirements of section 83(h) and § 1.83–6(a) are satisfied and the deduction is otherwise allowable under section 162.

Example 5. Assume the same facts in *Example 1*, except that the shares transferred pursuant to the exercise of the incentive stock option are subject to a substantial risk of forfeiture and not transferable (substantially nonvested) for a period of six months after such transfer. Assume further that the shares that A uses to exercise the incentive stock option are similarly restricted. Such shares were transferred to A on January 1, 2005, through A's exercise of a nonstatutory stock option which was granted to A on January 1, 2004. A paid $5 per share for the stock when its fair market value was $22.50 per share. A did not file a section 83(b) election to include the $700 spread (the difference between the option price and the fair market value of the stock on date of exercise of the nonstatutory option) in gross income as compensation. After exercising the incentive stock option with the 40 substantially-nonvested shares, A owns 100 shares of substantially-nonvested incentive stock option stock. Section 1036 (and so much of section 1031 as relates to section 1036) applies to the 40 shares exchanged in exercise of the incentive stock option. However, pursuant to section 83(g), the stock received in such exchange, because it is incentive stock option stock, is not subject to restrictions and conditions substantially similar to those to which the stock given in such exchange was subject. For purposes of section 83(a) and § 1.83–1(b)(1), therefore, A has disposed of the 40 shares of substantially-nonvested stock on June 1, 2005, and must include in gross income as compensation $800 (the difference between the amount realized upon such disposition, $1,000, and the amount paid for the stock, $200). Accordingly, 40 shares of the incentive stock option stock have a $1,000 basis (the $200 original basis plus the $800 included in income as compensation) and 60 shares of the incentive stock option stock have a zero basis. For its taxable year in which the disposition of the substantially-nonvested stock occurs, X Corporation is allowed a deduction of $800 for the compensation paid to A, provided the requirements of section 83(h) and § 1.83–6(a) are satisfied and the deduction is otherwise allowable under section 162.

(f) *Effective date*—(1) *In general.* These regulations are effective on August 3, 2004.

(2) *Reliance and transition period.* For statutory options granted on or before June 9, 2003, taxpayers may rely on the 1984 proposed regulations LR–279–81 (49 FR 4504), the 2003 proposed regulations REG–122917–02 (68 FR 34344), or this section until the earlier of January 1, 2006, or the first regularly scheduled stockholders meeting of the granting corporation occurring 6 months after August 3, 2004. For statutory options granted after June 9, 2003, and before the earlier of January 1, 2006, or the first regularly scheduled stockholders meeting of the granting corporation occurring 6 months after August 3, 2004, taxpayers may rely on either the REG–122917–02 or this section. Taxpayers may not rely on LR–279–81 or REG–122917–02 after December 31, 2005. Reliance on LR–279–81, REG–122917–02, or this section must be in its entirety, and all statutory options granted during the reliance period must be treated consistently.

§ 1.423–1 [Amended]

■ **Par. 11.** Section 1.423–1 is amended as follows:

■ 1. In paragraph (a)(2), the language "425(a)" is removed and "424(a)" is added in its place.

■ 2. In paragraph (b), first sentence, the language "§ 1.421–7" is removed and "§ 1.421–1" is added in its place.

■ 3. In paragraph (b), second sentence, the language "§ 1.421–8" is removed and § 1.421–2" is added in its place.

■ 4. In paragraph (b), last sentence, the language "425(c)" is removed and "424(c)" is added in its place.

■ 5. In paragraph (b), last sentence, the language "§ 1.425–1" is removed and "§ 1.424–1" is added in its place.

§ 1.423–2 [Amended]

■ **Par. 12.** Section 1.423–2 is amended by:

■ 1. In paragraph (b), last sentence, the language "§ 1.421–7" is removed and "§ 1.421–1" is added in its place.

■ 2. In paragraph (d)(1), second sentence, the language "425(d)" is removed and "424(d)" is added in its place.

■ 3. In paragraph (d)(3), *Example 1*, fourth sentence, the language "425(d)" is removed and "424(d)" is added in its place.

■ 4. In paragraph (e)(2), the language "§ 1.421–7" is removed and "§ 1.421–1" is added in its place.

■ 5. In paragraph (g)(1), the first sentence of the concluding text, the language "§ 1.421–7" is removed and "§ 1.421–1" is added in its place.

■ 6. In paragraph (g)(1), the second sentence of the concluding text, the language "§ 1.421–7" is removed and "§ 1.421–1" is added in its place.

■ 7. In paragraph (j), second sentence, the language "§ 1.421–7" is removed and "§ 1.421–1" is added in its place.

■ 8. In paragraph (j), last sentence, the language "425" is removed and "424" is added in its place.

■ 9. In paragraph (k)(2), second sentence, the language "§ 1.421–8" is removed and "§ 1.421–2" is added in its place.

§ 1.425–1 [Redesignated as § 1.424–1]

■ **Par. 13.** Section 1.425–1 is redesignated as § 1.424–1 and is amended by:

■ 1. Revising paragraphs (a)(1) through (a)(6).

■ 2. Redesignating paragraph (a)(7) as paragraph (a)(9).

■ 3. Adding a new paragraph (a)(7).

■ 4. Revising paragraph (a)(8).

■ 5. Adding paragraph (a)(10).
■ 6. In paragraph (b)(1), first, second, and last sentences, the language "425" is removed wherever it appears, and "424" is added in their places.
■ 7. In paragraph (c)(1), first sentence, the language "425" is removed and "424" is added in its place.
■ 8. In paragraph (c)(1), first sentence, the language "*disposition*" is removed and "*disposition of stock*" is added in its place.
■ 9. Adding paragraph (c)(1)(iv).
■ 10. Redesignating paragraph (c)(3) as (c)(4).
■ 11. Adding new paragraph (c)(3).
■ 12. Adding newly designated paragraph (c)(4) *Examples 7* through *9*.
■ 13. In the list below, for each section indicated in the left column, remove the language in the middle column and add the language in the right column:

Newly designated section	Remove	Add
1.424–1(c)(4) *Example 1*, first sentence	1964	2004.
1.424–1(c)(4) *Example 1*, first sentence	qualified stock option	statutory option.
1.424–1(c)(4) *Example 1*, second and fourth sentences.	1965	2005.
1.424–1(c)(4) *Example 1*, third sentence	1968	2006.
1.424–1(c)(4) *Example 2*, first sentence	1968	2006.
1.424–1(c)(4) *Example 2*, last sentence	long-term	
1.424–1(c)(4) *Example 3*, first sentence	1968	2006.
1.424–1(c)(4) *Example 4*, first sentence	1968, two years and 11 months after the transfer of shares to him.	2006.
1.424–1(c)(4) *Example 4*, last sentence	three years from the date	two years from the date the options were granted and within one year of the date that.
1.424–1(c)(4) *Example 5*, first sentence	1965	2005.
1.424–1(c)(4) *Example 5*, first sentence	qualified stock option	statutory option.
1.424–1(c)(4) *Example 6*, first sentence	1965	2005.
1.424–1(c)(4) *Example 6*, third sentence	three years	2 years.
1.424–1(c)(4) *Example 6*, third sentence	income	compensation income.
1.424–1(c)(4) *Example 6*, third sentence	a qualified stock option	the option.
1.424–1(c)(4) *Example 6*, last sentence	paragraph (b)(2) of § 1.421–8	§ 1.421–2(b)(2).

■ 14. Revising paragraph (d).
■ 15. Revising paragraphs (e)(1) and (e)(2).
■ 16. In paragraph (e)(3), first sentence, remove the phrase "Except as otherwise provided in subparagraph (4) of this paragraph" and add "If section 423(c) applies to an option then,".
■ 17. In paragraph (e)(3), first sentence, remove the language ", and 424(b)(1)."
■ 18. Removing paragraph (e)(4).
■ 19. Redesignating paragraph (e)(5) as paragraph (e)(4).
■ 20. Revising newly designated paragraph (e)(4).
■ 21. Redesignating paragraph (e)(6) as paragraph (e)(5) and removing the second and third sentences.
■ 22. Adding and reserving a new paragraph (e)(6).
■ 23. In list below, for each section indicated in the left column, remove the language in the middle column and add the language in the right column:

Section	Remove	Add
1.424–1(e)(7) *Example 1*, first and sixth sentences.	1964	2004
1.424–1(e)(7) *Example 1*, first sentence	1966	2006
1.424–1(e)(7) *Example 1*, third, fourth, fifth, sixth and last sentences.	1965	2005
1.424–1(e)(7) *Example 1*, fifth sentence	425(h)	424(h)
1.424–1(e)(7) *Example 1*, last sentence	The exercise of such	Because the requirements of § 1.424–1(e)(3) and § 1:423–2(g) have not been met, the exercise of such
1.424–1(e)(7) *Example 2*, first, second, and fifth sentences.	1964	2004
1.424–1(e)(7) *Example 2*, first, third, fourth, and fifth sentences, wherever it appears.	1965	2005
1.424–1(e)(7) *Example 2*, first and third sentences.	1966	2006
1.424–1(e)(7) *Example 2*, fifth sentence	425(h)	424(h)
1.424–1(e)(7) *Example 2*, last sentence	The exercise of such	Because the requirements of § 1.424–1(e)(3) and § 1.423–2(g) have not been met, the exercise of such
1.424–1(e)(7) *Example 3*, first, second, and last sentences.	1965	2005

■ 24. In paragraph (e)(7), remove *Example 4*.
■ 25. Adding paragraphs (f) and (g).

The additions and revisions are as follows:

§ 1.424–1 Definitions and special rules applicable to statutory options.

(a) *Substitutions and assumptions of options*—(1) *In general.* (i) This paragraph (a) provides rules under which an *eligible corporation* (as defined in paragraph (a)(2) of this section) may, by reason of a *corporate transaction* (as defined in paragraph (a)(3) of this section), substitute a new statutory option (new option) for an outstanding statutory option (old option) or assume an old option without such substitution or assumption being considered a modification of the old option. For the definition of *modification*, see paragraph (e) of this section.

(ii) For purposes of §§ 1.421–1 through 1.424–1, the phrase "substituting or assuming a stock option in a transaction to which section 424 applies," "substituting or assuming a stock option in a transaction to which § 1.424–1(a) applies," and similar phrases means a substitution of a new option for an old option or an assumption of an old option that meets the requirements of this paragraph (a). For a substitution or assumption to qualify under this paragraph (a), the substitution or assumption must meet all of the requirements described in paragraphs (a)(4) and (a)(5) of this section.

(2) *Eligible corporation.* For purposes of this paragraph (a), the term *eligible corporation* means a corporation that is the employer of the optionee or a related corporation of such corporation. For purposes of this paragraph (a), the determination of whether a corporation is the employer of the optionee or a related corporation of such corporation is based upon all of the relevant facts and circumstances existing immediately after the corporate transaction. See § 1.421–1(h) for rules concerning the employment relationship.

(3) *Corporate transaction.* For purposes of this paragraph (a), the term *corporate transaction* includes—

(i) A corporate merger, consolidation, acquisition of property or stock, separation, reorganization, or liquidation;

(ii) A distribution (excluding an ordinary dividend or a stock split or stock dividend described in § 1.424–1(e)(v)) or change in the terms or number of outstanding shares of such corporation; and

(iii) Such other corporate events prescribed by the Commissioner in published guidance.

(4) *By reason of.* (i) For a change in an option or issuance of a new option to qualify as a substitution or assumption under this paragraph (a), the change must be made by an *eligible corporation* (as defined in paragraph (a)(2) of this section) and occur by reason of a *corporate transaction* (as defined in paragraph (a)(3) of this section).

(ii) Generally, a change in an option or issuance of a new option is considered to be by reason of a corporate transaction, unless the relevant facts and circumstances demonstrate that such change or issuance is made for reasons unrelated to such corporate transaction. For example, a change in an option or issuance of a new option will be considered to be made for reasons unrelated to a corporate transaction if there is an unreasonable delay between the corporate transaction and such change in the option or issuance of a new option, or if the corporate transaction serves no substantial corporate business purpose independent of the change in options. Similarly, a change in the number or price of shares purchasable under an option merely to reflect market fluctuations in the price of the stock purchasable under an option is not by reason of a corporate transaction.

(iii) A change in an option or issuance of a new option is by reason of a distribution or change in the terms or number of the outstanding shares of a corporation (as described in paragraph (a)(3)(ii) of this section) only if the option as changed, or the new option issued, is an option on the same stock as under the old option (or if such class of stock is eliminated in the change in capital structure, on other stock of the same corporation).

(5) *Other requirements.* For a change in an option or issuance of a new option to qualify as a substitution or assumption under this paragraph (a), all of the requirements described in this paragraph (a)(5) must be met.

(i) In the case of an issuance of a new option (or a portion thereof) in exchange for an old option (or portion thereof), the optionee's rights under the old option (or portion thereof) must be canceled, and the optionee must lose all rights under the old option (or portion thereof). There cannot be a substitution of a new option for an old option within the meaning of this paragraph (a) if the optionee may exercise both the old option and the new option. It is not necessary to have a complete substitution of a new option for the old option. However, any portion of such option which is not substituted or assumed in a transaction to which this paragraph (a) applies is an outstanding option to purchase stock or, to the extent paragraph (e) of this section applies, a modified option.

(ii) The excess of the aggregate fair market value of the shares subject to the new or assumed option immediately after the change in the option or issuance of a new option over the aggregate option price of such shares must not exceed the excess of the aggregate fair market value of all shares subject to the old option (or portion thereof) immediately before the change in the option or issuance of a new option over the aggregate option price of such shares.

(iii) On a share by share comparison, the ratio of the option price to the fair market value of the shares subject to the option immediately after the change in the option or issuance of a new option must not be more favorable to the optionee than the ratio of the option price to the fair market value of the stock subject to the old option (or portion thereof) immediately before the change in the option or issuance of a new option. The number of shares subject to the new or assumed option may be adjusted to compensate for any change in the aggregate spread between the aggregate option price and the aggregate fair market value of the shares subject to the option immediately after the change in the option or issuance of the new option as compared to the aggregate spread between the option price and the aggregate fair market value of the shares subject to the option immediately before the change in the option or issuance of the new option.

(iv) The new or assumed option must contain all terms of the old option, except to the extent such terms are rendered inoperative by reason of the corporate transaction.

(v) The new option or assumed option must not give the optionee additional benefits that the optionee did not have under the old option.

(6) *Obligation to substitute or assume not necessary.* For a change in the option or issuance of a new option to meet the requirements of this paragraph (a), it is not necessary to show that the corporation changing an option or issuing a new option is under any obligation to do so. In fact, this paragraph (a) may apply even when the option that is being replaced or assumed expressly provides that it will terminate upon the occurrence of certain corporate transactions. However, this paragraph (a) cannot be applied to revive a statutory option which, for reasons not related to the corporate transaction, expires before it can properly be replaced or assumed under this paragraph (a).

(7) *Issuance of stock without meeting the requirements of this paragraph (a).* A change in the terms of an option resulting in a modification of such option occurs if an optionee's new employer (or a related corporation of the new employer) issues its stock (or stock of a related corporation) upon exercise of such option without satisfying all of the requirements described in paragraphs (a)(4) and (5) of this section.

(8) *Date of grant.* For purposes of applying the rules of this paragraph (a), a substitution or assumption is considered to occur on the date that the optionee would, but for this paragraph (a), be considered to have been granted the option that the eligible corporation is substituting or assuming. A substitution or an assumption that occurs by reason of a corporate transaction may occur before or after the corporate transaction.

* * * * *

(10) *Examples.* The principles of this paragraph (a) are illustrated by the following examples:

Example 1. Eligible corporation. X Corporation acquires a new subsidiary, Y Corporation, and transfers some of its employees to Y. Y Corporation wishes to grant to its new employees and to the employees of X Corporation new options for Y shares in exchange for old options for X shares that were previously granted by X Corporation. Because Y Corporation is an employer with respect to its own employees and a related corporation of X Corporation, Y Corporation is an eligible corporation under paragraph (a)(2) of this section with respect to both the employees of X and Y Corporations.

Example 2. Corporate transaction. (i) On January 1, 2004, Z Corporation grants E, an employee of Z, an option to acquire 100 shares of Z common stock. At the time of grant, the fair market value of Z common stock is $200 per share. E's option price is $200 per share. On July 1, 2005, when the fair market value of Z common stock is $400, Z declares a stock dividend of preferred stock distributed on common stock that causes the fair market value of Z common stock to decrease to $200 per share. On the same day, Z grants to E a new option to acquire 200 shares of Z common stock in exchange for E's old option. The new option has an exercise price of $100 per share.

(ii) A stock dividend other than that described in § 1.424–1(e)(4)(v) is a corporate transaction under paragraph (a)(3)(ii) of this section. Generally, the issuance of a new option is considered to be by reason of a corporate transaction. None of the facts in this *Example 2* indicate that the new option is not issued by reason of the stock dividend. In addition, the new option is issued on the same stock as the old option. Thus, the substitution occurs by reason of the corporate transaction. Assuming the other requirements of this section are met, the issuance of the new option is a substitution that meets the requirements of this paragraph (a) and is not a modification of the option.

(iii) Assume the same facts as in paragraph (i) of this *Example 2.* Assume further that on December 1, 2005, Z declares an ordinary cash dividend. On the same day, Z grants E a new option to acquire Z stock in substitution for E's old option. Under paragraph (a)(3)(ii) of this section, an ordinary cash dividend is not a corporate transaction. Thus, the exchange of the new option for the old option does not meet the requirements of this paragraph (a) and is a modification of the option.

Example 3. Corporate transaction. On March 15, 2004, A Corporation grants E, an employee of A, an option to acquire 100 shares of A stock at $50 per share, the fair market value of A stock on the date of grant. On May 2, 2005, A Corporation transfers several employees, including E, to B Corporation, a related corporation. B Corporation arranges to purchase some assets from A on the same day as E's transfer to B. Such purchase is without a substantial business purpose independent of making the exchange of E's old options for the new options appear to be by reason of a corporate transaction. The following day, B Corporation grants to E, one of its new employees, an option to acquire shares of B stock in exchange for the old option held by E to acquire A stock. Under paragraph (a)(3)(i) of this section, the purchase of assets is a corporate transaction. Generally, the substitution of an option is considered to occur by reason of a corporate transaction. However, in this case, the relevant facts and circumstances demonstrate that the issuance of the new option in exchange for the old option occurred by reason of the change in E's employer rather than a corporate transaction and that the sale of assets is without a substantial corporate business purpose independent of the change in the options. Thus, the exchange of the new option for the old option is not by reason of a corporate transaction that meets the requirements of this paragraph (a) and is a modification of the old option.

Example 4. Corporate transaction. (i) E, an employee of Corporation A, holds an option to acquire 100 shares of Corporation A stock. On September 1, 2006, Corporation A has one class of stock outstanding and declares a stock dividend of one share of common stock for each outstanding share of common stock. The rights associated with the common stock issued as a dividend are the same as the rights under existing shares of stock. In connection with the stock dividend, E's option is exchanged for an option to acquire 200 shares of Corporation A stock. The per-share exercise price is equal to one half of the per-share exercise price of the original option. The stock dividend merely changes the number of shares of Corporation A outstanding and effects no other change to the stock of Corporation A. The option is proportionally adjusted and the aggregate exercise price remains the same and therefore satisfies the requirements described in § 1.424–1(e)(4)(v).

(ii) The stock dividend is not a corporate transaction under paragraph (a)(3) of this section, and the declaration of the stock dividend is not a modification of the old option under paragraph (a) of this section. Pursuant to § 1.424–1(e)(4)(v), the exercise price of the old option may be adjusted proportionally with the change in the number of outstanding shares of Corporation A such that the ratio of the aggregate exercise price of the option to the number of shares covered by the option is the same both before and after the stock dividend. The adjustment of E's option is not treated as a modification of the option.

Example 5. Additional benefit. On June 1, 2004, P Corporation acquires 100 percent of the shares of S Corporation and issues a new option to purchase P shares in exchange for an old option to purchase S shares that is held by E, an employee of S. On the date of the exchange, E's old option is exercisable for 3 more years, and, after the exchange, E's new option is exercisable for 5 years. Because the new option is exercisable for an additional period of time beyond the time allowed under the old option, the effect of the exchange of the new option for the old option is to give E an additional benefit that E did not enjoy under the old option. Thus, the requirements of paragraph (a)(5) of this section are not met, and this paragraph (a) does not apply to the exchange of the new option for the old option. Therefore, the exchange is a modification of the old options.

Example 6. Spread and ratio tests. E is an employee of S Corporation. E holds an old option that was granted to E by S to purchase 60 shares of S at $12 per share. On June 1, 2005, S Corporation is merged into P Corporation, and on such date P issues a new option to purchase P shares in exchange for E's old option to purchase S shares. Immediately before the exchange, the fair market value of an S share is $32; immediately after the exchange, the fair market value of a P share is $24. The new option entitles E to buy P shares at $9 per share. Because, on a share-by-share comparison, the ratio of the new option price ($9 per share) to the fair market value of a P share immediately after the exchange ($24 per share) is not more favorable to E than the ratio of the old option price ($12 per share) to the fair market value of an S share immediately before the exchange ($32 per share) ($9/24 = 12/32$), the requirements of paragraph (a)(5)(iii) of this section are met. The number of shares subject to E's option to purchase P stock is set at 80. Because the excess of the aggregate fair market value over the aggregate option price of the shares subject to E's new option to purchase P stock, $1,200 ($80 \times \$24$ minus $80 \times \$9$), is not greater than the excess of the aggregate fair market value over the aggregate option price of the shares subject to E's old option to purchase S stock, $1,200 ($60 \times \$32$ minus $60 \times \$12$), the requirements of paragraph (a)(5)(ii) of this section are met.

Example 7. Ratio test and partial substitution. Assume the same facts as in *Example 6*, except that the fair market value of an S share immediately before the exchange of the new option for the old option is $8, that the option price is $10 per share, and that the fair market value of a P share immediately after the exchange is $12. P sets the new option price at $15 per share. Because, on a share-by-share comparison, the ratio of the new option price ($15 per share)

to the fair market value of a P share immediately after the exchange ($12) is not more favorable to E than the ratio of the old option price ($10 per share) to the fair market value of an S share immediately before the substitution ($8 per share) (15/12= 10/8), the requirements of paragraph (a)(5)(iii) of this section are met. Assume further that the number of shares subject to E's P option is set at 20, as compared to 60 shares under E's old option to buy S stock. Immediately after the exchange, 2 shares of P are worth $24, which is what 3 shares of S were worth immediately before the exchange (2 × $12 = 3 × $8). Thus, to achieve a complete substitution of a new option for E's old option, E would need to receive a new option to purchase 40 shares of P (*i.e.*, 2 shares of P for each 3 shares of S that E could have purchased under the old option (2/3= 40/60)). Because E's new option is for only 20 shares of P, P has replaced only ½ of E's old option, and the other ½ is still outstanding.

Example 8. Partial substitution. X Corporation forms a new corporation, Y Corporation, by a transfer of certain assets and, in a spin-off, distributes the shares of Y Corporation to the stockholders of X Corporation. E, an employee of X Corporation, is thereafter an employee of Y. Y wishes to substitute a new option to purchase some of its stock for E's old option to purchase 100 shares of X. E's old option to purchase shares of X, at $50 a share, was granted when the fair market value of an X share was $50, and an X share was worth $100 just before the distribution of the Y shares to X's stockholders. Immediately after the spin-off, which is also the time of the substitution, each share of X and each share of Y is worth $50. Based on these facts, a new option to purchase 200 shares of Y at an option price of $25 per share could be granted to E in complete substitution of E's old option. It would also be permissible to grant E a new option to purchase 100 shares of Y, at an option price of $25 per share, in substitution for E's right to purchase 50 of the shares under the old option.

Example 9. Stockholder approval requirements. (i) X Corporation, a publicly traded corporation, adopts an incentive stock option plan that meets the requirements of § 1.422–2. Under the plan, options to acquire X stock are granted to X employees. X Corporation is acquired by Y Corporation and becomes a subsidiary corporation of Y Corporation. After the acquisition, X employees remain employees of X. In connection with the acquisition, Y Corporation substitutes new options to acquire Y stock for the old options to acquire X stock previously granted to the employees of X. As a result of this substitution, on exercise of the new options, X employees receive Y Corporation stock.

(ii) Because the requirements of § 1.422–2 were met on the date of grant, the substitution of the new Y options for the old X options does not require new stockholder approval. If the other requirements of paragraphs (a)(4) and (5) of this section are met, the issuance of new options for Y stock in exchange for the old options for X stock meets the requirements of this paragraph (a) and is not a modification of the old options.

(iii) Assume the same facts as in paragraphs (i) and (ii) of this *Example 9*. Assume further that as part of the acquisition, X amends its plan to allow future grants under the plan to be grants to acquire Y stock. Because the amendment of the plan to allow options on a different stock is considered the adoption of a new plan under § 1.422–2(b)(2)(iii), the stockholders of X must approve the plan within 12 months before or after the date of the amendment of the plan. If the stockholders of X timely approve the plan, the future grants to acquire Y stock will be incentive stock options (assuming the other requirements of § 1.422–2 have been met).

Example 10. Modification. X Corporation merges into Y Corporation. Y Corporation retains employees of X who hold old options to acquire X Corporation stock. When the former employees of X exercise the old options, Y Corporation issues Y stock to the former employees of X. Under paragraph (a)(7) of this section, because Y issues its stock on exercise of the old options for X stock, there is a change in the terms of the old options for X stock. Thus, the issuance of Y stock on exercise of the old options is a modification of the old options.

Example 11. Eligible corporation. (i) D Corporation grants an option to acquire 100 shares of D Corporation stock to E, an employee of D Corporation. S Corporation is a subsidiary of D Corporation. On March 1, 2005, D Corporation spins off S Corporation. E remains an employee of D Corporation. In connection with the spin off, D Corporation substitutes a new option to acquire D Corporation stock and a new option to acquire S Corporation stock for the old option in a manner that meets the requirements of paragraph (a) of this section.

(ii) The substitution of the new option to acquire S and D stock for the old option to acquire D stock is not a modification of the old option. However, because S is no longer a related corporation with respect to D Corporation, E must exercise the option for S stock within three months from March 1, 2005, for the option to be treated as a statutory option. See § 1.421–1(h).

(iii) Assume the same facts as in paragraph (i) of this *Example 11* except that E's employment with D Corporation is terminated on February 20, 2005. The substitution of the new option to acquire S and D stock for the old option to acquire D stock is not a modification of the old option. However, because the employment relationship between E and D Corporation terminated on February 20, 2005, E must exercise the option for the D and S stock within three months from February 20, 2005, for the option to be treated as a statutory option. See § 1.421–1(h).

* * * * *

(c) * * * (1) * * *

(iv) A transfer between spouses or incident to divorce (described in section 1041(a)). The special tax treatment of § 1.421–2(a) with respect to the transferred stock applies to the transferee. However, see § 1.421–1(b)(2) for the treatment of the transfer of a statutory option incident to divorce.

* * * * *

(3) If an optionee exercises an incentive stock option with statutory option stock and the applicable holding period requirements (under § 1.422–1(a) or § 1.423–1(a)) with respect to such statutory option stock are not met before such transfer, then sections 354, 355, 356, or 1036 (or so much of 1031 as relates to 1036) do not apply to determine whether there is a disposition of those shares. Therefore, there is a disposition of the statutory option stock, and the special tax treatment of § 1.421–2(a) does not apply to such stock.

(4) * * *

Example 7. On January 1, 2004, X Corporation grants to E, an employee of X Corporation, an incentive stock option to purchase 100 shares of X Corporation stock at $100 per share (the fair market value of an X Corporation share on that date). On January 1, 2005, when the fair market value of a share of X Corporation stock is $200, E exercises half of the option, pays X Corporation $5,000 in cash, and is transferred 50 shares of X Corporation stock with an aggregate fair market value of $10,000. E makes no disposition of the shares before January 2, 2006. Under § 1.421–2(a), no income is recognized by E on the transfer of shares pursuant to the exercise of the incentive stock option, and X Corporation is not entitled to any deduction at any time with respect to its transfer of the shares to E. E's basis in the shares is $5,000.

Example 8. Assume the same facts as in *Example 7*, except that on December 1, 2005, one year and 11 months after the grant of the option and 11 months after the transfer of the 50 shares to E, E uses 25 of those shares, with a fair market value of $5,000, to pay for the remaining 50 shares purchasable under the option. On that day, X Corporation transfers 50 of its shares, with an aggregate fair market value of $10,000, to E. Because E disposed of the 25 shares before the expiration of the applicable holding periods, § 1.421–2(a) does not apply to the January 1, 2005, transfer of the 25 shares used by E to exercise the remainder of the option. As a result of the disqualifying disposition of the 25 shares, E recognizes compensation income under the rules of § 1.421–2(b).

Example 9. On January 1, 2005, X Corporation grants an incentive stock option to E, an employee of X Corporation. The exercise price of the option is $10 per share. On June 1, 2005, when the fair market value of an X Corporation share is $20, E exercises the option and purchases 5 shares with an aggregate fair market value of $100. On January 1, 2006, when the fair market value of an X Corporation share is $50, X Corporation is acquired by Y Corporation in a section 368(a)(1)(A) reorganization. As part of the acquisition, all X Corporation shares are converted into Y Corporation shares. After the conversion, if an optionee holds a fractional share of Y Corporation stock, Y Corporation will purchase the fractional share for cash equal to its fair market value.

After applying the conversion formula to the shares held by E, E has 10 ½ Y Corporation shares. Y Corporation purchases E's one-half share for $25, the fair market value of one-half of a Y Corporation share on the conversion date. Because E sells the one-half share prior to expiration of the holding periods described in § 1.422–1(a), the sale is a disqualifying disposition of the one-half share. Thus, in 2006, E must recognize compensation income of $5 (one-half of the fair market value of an X Corporation share on the date of exercise of the option, or $10, less one-half of the exercise price per share, or $5). For purposes of computing any additional gain, E's basis in the one-half share increases to $10 (reflecting the $5 included in income as compensation). E recognizes an additional gain of $15 ($25, the fair market value of the one-half share, less $10, the basis in such share). The extent to which the additional $15 of gain is treated as a redemption of Y Corporation stock is determined under section 302.

(d) *Attribution of stock ownership.* To determine the amount of stock owned by an individual for purposes of applying the percentage limitations relating to certain stockholders described in §§ 1.422–2(f) and 1.423–2(d), shares of the employer corporation or of a related corporation that are owned (directly or indirectly) by or for the individual's brothers and sisters (whether by the whole or half blood), spouse, ancestors, and lineal descendants, are considered to be owned by the individual. Also, for such purposes, if a domestic or foreign corporation, partnership, estate, or trust owns (directly or indirectly) shares of the employer corporation or of a related corporation, the shares are considered to be owned proportionately by or for the stockholders, partners, or beneficiaries of the corporation, partnership, estate, or trust. The extent to which stock held by the optionee as a trustee of a voting trust is considered owned by the optionee is determined under all of the facts and circumstances.

(e) *Modification, extension, or renewal of option.* (1) This paragraph (e) provides rules for determining whether a share of stock transferred to an individual upon the individual's exercise of an option after the terms of the option have been changed is transferred pursuant to the exercise of a statutory option.

(2) Any modification, extension, or renewal of the terms of an option to purchase shares is considered the granting of a new option. The new option may or may not be a statutory option. To determine the date of grant of the new option for purposes of section 422 or 423, see § 1.421–1(c).

* * * * *

(4)(i) For purposes of §§ 1.421–1 through 1.424–1 the term *modification* means any change in the terms of the option (or change in the terms of the plan pursuant to which the option was granted or in the terms of any other agreement governing the arrangement) that gives the optionee additional benefits under the option regardless of whether the optionee in fact benefits from the change in terms. In contrast, for example, a change in the terms of the option shortening the period during which the option is exercisable is not a modification. However, a change providing an extension of the period during which an option may be exercised (such as after termination of employment) or a change providing an alternative to the exercise of the option (such as a stock appreciation right) is a modification regardless of whether the optionee in fact benefits from such extension or alternative right. Similarly, a change providing an additional benefit upon exercise of the option (such as the payment of a cash bonus) or a change providing more favorable terms for payment for the stock purchased under the option (such as the right to tender previously acquired stock) is a modification.

(ii) If an option is not immediately exercisable in full, a change in the terms of the option to accelerate the time at which the option (or any portion thereof) may be exercised is not a modification for purposes of this section. Additionally, no modification occurs if a provision accelerating the time when an option may first be exercised is removed prior to the year in which it would otherwise be triggered. For example, if an acceleration provision is timely removed to avoid exceeding the $100,000 limitation described in § 1.422–4, a modification of the option does not occur.

(iii) A change to an option which provides, either by its terms or in substance, that the optionee may receive an additional benefit under the option at the future discretion of the grantor, is a modification at the time that the option is changed to provide such discretion. In addition, the exercise of discretion to provide an additional benefit is a modification of the option. However, it is not a modification for the grantor to exercise discretion specifically reserved under an option with respect to the payment of a cash bonus at the time of exercise, the availability of a loan at exercise, the right to tender previously acquired stock for the stock purchasable under the option, or the payment of employment taxes and/or required withholding taxes resulting from the exercise of a statutory option. An option is not modified merely because an optionee is offered a change in the terms of an option if the change to the option is not made. An offer to change the terms of an option that remains open less than 30 days is not a modification of the option. However, if an offer to change the terms of an option remains outstanding for 30 days or more, there is a modification of the option as of the date the offer to change the option is made.

(iv) A change in the terms of the stock purchasable under the option that increases the value of the stock is a modification of such option, except to the extent that a new option is substituted for such option by reason of the change in the terms of the stock in accordance with paragraph (a) of this section.

(v) If an option is amended solely to increase the number of shares subject to the option, the increase is not considered a modification of the option but is treated as the grant of a new option for the additional shares. Notwithstanding the previous sentence, if the exercise price and number of shares subject to an option are proportionally adjusted to reflect a stock split (including a reverse stock split) or stock dividend, and the only effect of the stock split or stock dividend is to increase (or decrease) on a pro rata basis the number of shares owned by each shareholder of the class of stock subject to the option, then the option is not modified if it is proportionally adjusted to reflect the stock split or stock dividend and the aggregate exercise price of the option is not less than the aggregate exercise price before the stock split or stock dividend.

(vi) Any change in the terms of an option made in an attempt to qualify the option as a statutory option grants additional benefits to the optionee and is, therefore, a modification. However, if the terms of an option are changed to provide that the optionee cannot transfer the option except by will or by the laws of descent and distribution in order to meet the requirements of section 422(b)(5) or 423(b)(9) such change is not a modification.

(vii) An extension of an option refers to the granting by the corporation to the optionee of an additional period of time within which to exercise the option beyond the time originally prescribed. A renewal of an option is the granting by the corporation of the same rights or privileges contained in the original option on the same terms and conditions. The rules of this paragraph apply as well to successive modifications, extensions, and renewals.

(viii) Any inadvertent change to the terms of an option (or change in the

terms of the plan pursuant to which the option was granted or in the terms of any other agreement governing the arrangement) that is treated as a modification under this paragraph (e) is not considered a modification of the option to the extent the change in the terms of the option is removed by the earlier of the date the option is exercised or the last day of the calendar year during which such change occurred. Thus, for example, if the terms of an option are inadvertently changed on March 1 to extend the exercise period and the change is removed on November, then if the option is not exercised prior to November 1, the option is not considered modified under this paragraph (e).

* * * * *

(6) [Reserved.]

* * * * *

(f) *Definitions.* The following definitions apply for purposes of §§ 1.421–1 through 1.424–1:

(1) *Parent corporation.* The term *parent corporation*, or *parent*, means any corporation (other than the employer corporation) in an unbroken chain of corporations ending with the employer corporation if, at the time of the granting of the option, each of the corporations other than the employer corporation owns stock possessing 50 percent or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

(2) *Subsidiary corporation.* The term *subsidiary corporation*, or *subsidiary*, means any corporation (other than the employer corporation) in an unbroken chain of corporations beginning with the employer corporation if, at the time of the granting of the option, each of the corporations other than the last corporation in an unbroken chain owns stock possessing 50 percent or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

(g) *Effective date*—(1) *In general.* These regulations are effective on August 3, 2004.

(2) *Reliance and transition period.* For statutory options granted on or before June 9, 2003, taxpayers may rely on the 1984 proposed regulations LR–279–81 (49 FR 4504), the 2003 proposed regulations REG–122917–02 (68 FR 34344), or this section until the earlier of January 1, 2006, or the first regularly scheduled stockholders meeting of the granting corporation occurring 6 months after August 3, 2004. For statutory options granted after June 9, 2003, and before the earlier of January 1, 2006, or the first regularly scheduled stockholders meeting of the granting corporation occurring 6 months after August 3, 2004, taxpayers may rely on either the REG–122917–02 or this section. Taxpayers may not rely on LR–279–81 or REG–122917–02 after December 31, 2005. Reliance on LR–279–81, REG–122917–02, or this section must be in its entirety, and all statutory options granted during the reliance period must be treated consistently.

§ 1.6039–1 and 1.6039–2 · [Removed]

■ **Par. 14.** Section 1.6039–1 and 1.6039–2 are removed.

■ **Par. 15.** A new § 1.6039–1 is added to read as follows:

§ 1.6039–1 Statements to persons with respect to whom information is furnished.

(a) *Requirement of statement with respect to incentive stock options under section 6039(a)(1).* Every corporation which transfers stock to any person pursuant to such person's exercise of an incentive stock option described in section 422(b) must furnish to such transferee, for each calendar year in which such a transfer occurs, a written statement with respect to the transfer or transfers made during such year. This statement must include the following information—

(1) The name, address, and employer identification number of the corporation transferring the stock;

(2) The name, address, and identifying number of the person to whom the share or shares of stock were transferred;

(3) The name and address of the corporation the stock of which is the subject of the option (if other than the corporation transferring the stock);

(4) The date the option was granted;

(5) The date the shares were transferred to the person exercising the option;

(6) The fair market value of the stock at the time the option was exercised;

(7) The number of shares of stock transferred pursuant to the option;

(8) The type of option under which the transferred shares were acquired; and

(9) The total cost of all the shares.

(b) *Requirement of statement with respect to stock purchased under an employee stock purchase plan under section 6039(a)(2).* (1) Every corporation which records, or has by its agent recorded, a transfer of the title to stock acquired by the transferor pursuant to the transferor's exercise on or after January 1, 1964, of an option granted under an employee stock purchase plan which meets the requirements of section 423(b), and with respect to which the special rule of section 423(c) applied, must furnish to such transferor, for each calendar year in which such a recorded transfer of title to such stock occurs, a written statement with respect to the transfer or transfers containing the information required by paragraph (b)(2) of this section.

(2) The statement required by paragraph (b)(1) of this section must contain the following information—

(i) The name and address of the corporation whose stock is being transferred;

(ii) The name, address, and identifying number of the transferor;

(iii) The date such stock was transferred to the transferor;

(iv) The number of shares to which title is being transferred; and

(v) The type of option under which the transferred shares were acquired.

(3) If the statement required by this paragraph is made by the authorized transfer agent of the corporation, it is deemed to have been made by the corporation. The term *transfer agent*, as used in this section, means any designee authorized to keep the stock ownership records of a corporation and to record a transfer of title of the stock of such corporation on behalf of such corporation.

(4) A statement is required by reason of a transfer described in section 6039(a)(2) of a share only with respect to the first transfer of such share by the person who exercised the option. Thus, for example, if the owner has record title to a share or shares of stock transferred to a recognized broker or financial institution and the stock is subsequently sold by such broker or institution (on behalf of the owner), the corporation is only required to furnish a written statement to the owner relating to the transfer of record title to the broker or financial institution. Similarly, a written statement is required when a share of stock is transferred by the optionee to himself and another person (or persons) as joint tenants, tenants by the entirety or tenants in common. However, when stock is originally issued to the optionee and another person (or persons) as joint tenants, or as tenants by the entirety, the written statement required by this paragraph shall be furnished (at such time and in such manner as is provided by this section) with respect to the first transfer of the title to such stock by the optionee.

(5) Every corporation which transfers any share of stock pursuant to the exercise of an option described in this paragraph shall identify such stock in a manner sufficient to enable the accurate reporting of the transfer of record title

to such shares. Such identification may be accomplished by assigning to the certificates of stock issued pursuant to the exercise of such options a special serial number or color.

(c) *Time for furnishing statements*—(1) *In general.* Each statement required by this section to be furnished to any person for a calendar year must be furnished to such person on or before January 31 of the year following the year for which the statement is required.

(2) *Extension of time.* For good cause shown upon written application of the corporation required to furnish statements under this section, the Director, Martinsburg Computing Center, may grant an extension of time not exceeding 30 days in which to furnish such statements. The application must contain a full recital of the reasons for requesting an extension to aid the Director in determining the period of the extension, if any, which will be granted and must be sent to the Martinsburg Computing Center (Attn: Extension of Time Coordinator). Such a request in the form of a letter to the Martinsburg Computing Center, 250 Murall Drive, Kearneysville, West Virginia 25430, signed by the applicant (or its agent) will suffice as an application. The application must be filed on or before the date prescribed in paragraph (c)(1) of this section for furnishing the statements required by this section, and must contain the employer identification number of the corporation required to furnish statements under this section.

(3) *Last day for furnishing statement.* For provisions relating to the time for performance of an act when the last day prescribed for performance falls on Saturday, Sunday, or a legal holiday, *see* § 301.7503–1 of this chapter (Regulations on Procedure and Administration).

(d) *Statements furnished by mail.* For purposes of this section, a statement is considered to be furnished to a person if it is mailed to such person's last known address.

(e) *Penalty.* For provisions relating to the penalty provided for failure to furnish a statement under this section, see section 6722.

(f) *Electronic furnishing of statements.* The statements required to be furnished pursuant to this section may be provided in an electronic format in lieu of a paper format, with the consent of the recipient. *See* § 31.6051–1(j) of the Regulations on Employment Taxes and Collection of Income Tax at the Source for further guidance regarding the manner in which such electronic statements must be furnished.

(g) *Effective date*— (1) *In general.* These regulations are effective on August 3, 2004.

(2) *Reliance and transition period.* For statutory options transferred on or before June 9, 2003, taxpayers may rely on the 1984 proposed regulations LR–279–81 (49 FR 4504), the 2003 proposed regulations REG–122917–02 (68 FR 34344), or this section until the earlier of January 1, 2006, or the first regularly scheduled stockholders meeting of the granting corporation occurring 6 months after August 3, 2004. For statutory options transferred after June 9, 2003, and before the earlier of January 1, 2006, or the first regularly scheduled stockholders meeting of the granting corporation occurring 6 months after August 3, 2004, taxpayers may rely on either the REG–122917–02 or this section. Taxpayers may not rely on LR–279–81 or REG–122917–02 after December 31, 2005. Reliance on LR–279–81, REG–122917–02, or this section must be in its entirety, and all statutory options granted during the reliance period must be treated consistently.

PART 14a—TEMPORARY INCOME TAX REGULATIONS RELATING TO INCENTIVE STOCK OPTIONS

PART 14A [REMOVED]

■ **Par. 16.** Part 14a is removed.

Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

Approved: July 20, 2004.

Gregory Jenner,

Acting Assistant Secretary of Treasury.

[FR Doc. 04–17448 Filed 8–2–04; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AK77

Additional Disability or Death Due to Hospital Care, Medical or Surgical Treatment, Examination, Training and Rehabilitation Services, or Compensated Work Therapy Program

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) adjudication regulations concerning awards of compensation or dependency and indemnity compensation for additional disability or death caused by VA hospital care, medical or surgical treatment, examination, training and rehabilitation services, or compensated work therapy (CWT) program. Under this amendment, benefits are payable for additional disability or death caused by VA hospital care, medical or surgical treatment, or examination only if VA fault or "an event not reasonably foreseeable" proximately caused the disability or death. Benefits also are payable for additional disability or death proximately caused by VA's provision of training and rehabilitation services or CWT program. This amendment reflects amendments to 38 U.S.C. 1151, the statutory authority for such benefits.

DATES: *Effective Date:* September 2, 2004.

FOR FURTHER INFORMATION CONTACT: Beth McCoy, Consultant, Regulations Staff, Compensation and Pension Service (211A), Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, telephone (202) 273–7211.

SUPPLEMENTARY INFORMATION: In a document published in the **Federal Register** on December 12, 2002 (67 FR 76322), we proposed to amend the VA adjudication regulations concerning awards of compensation or dependency and indemnity compensation (DIC) for additional disability or death caused by VA hospital care, medical or surgical treatment, examination, training and rehabilitation services, or compensated work therapy (CWT) program to comply with changes to the governing statute, section 1151 of Title 38, United States Code. Based on the rationale described in this document and in the notice of proposed rule making, VA adopts the proposed rules as revised in this document.

Effective for claims filed on or after October 1, 1997, section 422(a) of Public Law 104–204, 110 Stat. 2874, 2926 (1996), amended 38 U.S.C. 1151 to authorize an award of compensation or DIC for a veteran's "qualifying additional disability" or "qualifying death." Under 38 U.S.C. 1151, as amended, an additional disability or death qualifies for compensation or DIC if it (1) was not the result of the veteran's willful misconduct; (2) was caused by hospital care, medical or surgical treatment, or examination furnished the veteran under any law administered by VA, either by a VA employee or in a VA facility; and (3) was proximately caused by carelessness, negligence, lack of proper skill, error in judgment, or similar instance of fault on VA's part in furnishing the care, treatment, or examination, or by an

event not reasonably foreseeable. An additional disability or death also qualifies for benefits if it was not the result of the veteran's willful misconduct and was proximately caused by VA's provision of training and rehabilitation services as part of an approved rehabilitation program under 38 U.S.C. chapter 31.

Section 303 of Public Law 106–419, 114 Stat. 1853, effective November 1, 2000, amended 38 U.S.C. 1151(a)(2) to further expand the circumstances under which benefits are payable. For claims received on or after November 1, 2000, additional disability or death qualifies for entitlement to compensation and DIC if it was not the result of the veteran's willful misconduct and was proximately caused by participation in a CWT program under 38 U.S.C. 1718. We asked interested people to submit comments on or before February 10, 2003. We received two comments on our proposed rule: one from a veteran's service organization and one from another interested individual. We made several changes in the final rule based on these comments.

Section 3.154

We proposed to revise 38 CFR 3.154 to state that VA may accept as a claim any communication in writing indicating an intent to file a claim with the Veterans Benefits Administration for disability or death benefits under 38 CFR 3.358 or 3.361, whether such communication is contained in a formal claim for pension, compensation, DIC, or in any other document.

One commenter suggested deleting the reference to claims indicating an intent to request benefits under § 3.358 because all claims received on or after October 1, 1997, seeking benefits for injuries covered by these rules would necessarily be claims under § 3.361 rather than § 3.358. We agree. Section 3.358 applies only to claims that were received by VA prior to October 1, 1997. Any claims received in the future will be governed by § 3.361. We will therefore delete the reference to § 3.358 from this provision. In the event we receive a claim requesting benefits under § 3.358, we would construe it as indicating an intent to seek benefits under § 3.361.

One commenter asserted that the proposed rule should not require claimants to identify the specific regulation under which they seek benefits or to specify that they seek benefits from the Veterans Benefits Administration rather than simply from VA. We believe this commenter misunderstands the requirements of the proposed rule. The rule would not require claimants to cite the governing regulation, but would require only that the claimant's communication indicate "an intent" to seek benefits provided by 38 CFR 3.361. In this respect, the rule is similar to the general rule in 38 CFR 3.155(a) governing informal claims, which provides that any communication indicating "an intent" to apply for VA benefits may be considered an informal claim. It is well established that this regulation does not require the claimant to cite the specific governing regulations. *See Servello* v. *Derwinski*, 3 Vet. App. 196, 199 (1992). A written communication indicating that the claimant seeks compensation or DIC for disability or death due to VA hospital care, medical or surgical treatment, or examination, VA-authorized training and rehabilitation services, or participation in a compensated work therapy program, would satisfy the requirements of the rule regardless of whether the communication specifically cited § 3.361.

The rule also would not require claimants to specifically state that they sought benefits from the Veterans Benefits Administration, but would require only that their communication indicate an intent to claim such benefits. The Veterans Benefits Administration is responsible for administering the compensation benefits provided by the statutes and regulations governing veterans' benefits, including the benefits provided by 38 U.S.C. 1151 and 38 CFR 3.361. *See* 38 U.S.C. 7703. A communication indicating an intent to seek compensation or DIC, under the statutes and regulations governing veterans' benefits, for disability or death due to VA hospital care, medical or surgical treatment, examination, training and rehabilitation services, or compensated work therapy program, would satisfy the requirements of the rule regardless of whether the communication specifically references the Veterans Benefits Administration by name.

We believe it is necessary to distinguish between claims that seek benefits from the Veterans Benefits Administration under the statutes and regulations governing veterans' benefits from claims seeking other types of payment for disability or death allegedly due to VA hospital care, medical or surgical treatment, examination, training and rehabilitation services, or compensated work therapy program. A person who believes he or she was injured by one of those causes has a choice of remedies. The claimant may seek compensation under the statutes and regulations governing veterans' benefits as provided in 38 U.S.C. 1151 and 38 CFR 3.361. Such claims are decided by the Veterans Benefits Administration and are governed by the non-adversarial procedures applicable to claims for veterans' benefits. Alternatively, a claimant may elect to file a claim against the United States under the Federal Tort Claims Act, 28 U.S.C. 2671 *et seq*. Such claims are decided by VA Regional Counsels or by Federal courts, and are not governed by the non-adversarial procedures applicable to claims for veterans' benefits. A claimant may elect to pursue one or the other of those remedies, or may pursue both, although any benefits awarded under section 1151 would be offset by the amount of any tort recovery. Because a claimant has the option of pursuing a tort claim without simultaneously pursuing a section 1151 claim, we do not believe that a claim submitted to VA seeking damages under the Federal Tort Claims Act should routinely be construed by VA as a claim for benefits under 38 U.S.C. 1151 and 38 CFR 3.361. Accordingly, we believe it is appropriate to provide that a claim will be construed as a claim for benefits under 38 U.S.C. 1151 and 38 CFR 3.361 only if the veteran intended to seek those benefits as distinguished from monetary damages under the Federal Tort Claims Act.

Although we disagree with the commenter's characterization of the proposed rule, we recognize that the language of the proposed rule may be confusing and that the standards governing claims for benefits under 38 U.S.C. 1151 and 38 CFR 3.361 may be stated more simply. Accordingly, we are revising 38 CFR 3.154 to state that VA may accept as a claim "any communication in writing indicating an intent to file a claim for disability compensation or DIC under the laws governing entitlement to veterans' benefits for a disability or death due to VA hospital care, medical or surgical treatment, examination, training and rehabilitation services, or compensated work therapy program." This language is consistent with the proposed rule, but more clearly indicates that a claimant need not cite the governing regulation or reference the Veterans Benefits Administration. The requirement that the communication indicate an intent to apply for benefits "under the laws governing entitlement to veterans" benefits' is intended to make clear that claims under the Federal Tort Claims Act are not routinely construed as claims under 38 U.S.C. 1151 or 38 CFR 3.361, because the Federal Tort Claims Act is not a law governing veterans' benefits.

The commenter also asserts that 38 CFR 3.154 should not require a claimant to indicate that he or she believes the claimed injury was caused by VA hospital care, medical or surgical treatment, examination, training and rehabilitation services, or compensated work therapy program. The commenter states that claimants should not be required to submit anything more than an application reflecting an intent to seek compensation or DIC. The commenter is correct that any communication indicating an intent to claim compensation or DIC may be accepted by VA as an informal claim for that benefit. This rule is expressly stated in 38 CFR 3.155(a). Our revision of § 3.154 would not alter that rule, nor would it preclude VA from accepting a claim for compensation or DIC meeting the requirements of § 3.155(a) and subsequently awarding benefits under 38 U.S.C. 1151 and 38 CFR 3.361 if development establishes that the claimant is entitled to benefits under those provisions. Section 3.154 would, however, make clear, as current § 3.154 does, that not all claims for compensation or DIC must be treated as claims for benefits under 38 U.S.C. 1151 and 38 CFR 3.361. As explained below, this distinction is both reasonable and necessary.

When VA receives a claim for benefits, it is required to inform the claimant of the information and evidence necessary to substantiate the claim, and to assist the claimant in obtaining such evidence. *See* 38 U.S.C. 5103, 5103A. Only a small percentage of claims received for compensation or DIC are claims for the benefits authorized by 38 U.S.C. 1151. The majority of claims received for compensation and DIC ordinarily require a determination concerning whether the claimed disability results from a disease or injury incurred in or aggravated by military service. *See* 38 U.S.C. 1110, 1310. Absent any indication to the contrary, VA will ordinarily inform the claimants of the need to submit information and evidence relevant to those factual issues and will focus its attention on those issues in developing and deciding the claim. Claims under section 1151 involve distinct factual determinations concerning whether the claimed disability was proximately caused by training and rehabilitation services or compensated work therapy or was proximately caused by VA fault in administering hospital care, medical or surgical treatment, or examination. If a claimant provides no indication that the claimed disability resulted from VA hospital care, medical or surgical treatment, examination, training and rehabilitation services, or compensated work therapy program, VA would have no reason to infer that the claimant seeks the benefits provided by 38 U.S.C. 1151 and would have no reason to develop or decide that issue or to notify the claimant of the need to submit information or evidence relating to that issue. For these reasons, we believe it is reasonable to require claimants to indicate that they are seeking benefits for disability due to one of the factors covered by 38 U.S.C. 1151 and 38 CFR 3.361 before VA incurs the duty to develop and decide the issues relevant to such claims.

As stated above, this rule does not preclude VA from accepting a non-specific claim for compensation or DIC under 38 CFR 3.155 or from later granting benefits on that claim under 38 U.S.C. 1151 and 3.361 if circumstances warrant. It merely clarifies that a claim will not routinely be construed as a claim under 38 U.S.C. 1151 or 38 CFR 3.361 unless it indicates an intent to apply for the benefits authorized by those provisions. To further clarify this narrow purpose, we will revise the introductory clause of § 3.154 as proposed from "VA may accept as a claim" to "VA may accept as a claim for benefits under 38 U.S.C. 1151 and § 3.361 of this part". We believe this will make clearer that § 3.154 merely explains when a claim for compensation or DIC will be considered a claim under section 1151 and § 3.361 and does not limit VA's authority under § 3.155 to accept non-specific claims for compensation or DIC.

We have made one further change to § 3.154 that was not raised by the commenters. As proposed, § 3.154 stated that VA would accept as a claim any written communication indicating an intent to seek benefits under section 1151, regardless of "whether such communication is contained in a formal claim for pension, compensation, dependency and indemnity compensation or in any other document." We have added "or" between "compensation" and "dependency and indemnity compensation." We believe this change merely improves the grammatical structure of the rule without altering its meaning.

Section 3.361(c)(2)

Section 1151 authorizes compensation for disability that was caused by VA hospital care, medical or surgical treatment, or examination. Proposed § 3.361(c)(2) states that "[h]ospital care, medical or surgical treatment, or examination cannot cause the continuance or natural progress of a disease or injury for which the care, treatment, or examination was furnished unless VA's failure to timely diagnose and properly treat the disease or injury proximately caused the continuance or natural progress." One commenter suggested that the term "proximately caused" should be changed to "proximately worsened." We disagree. Proposed § 3.361(c)(2) reflects principles stated in a precedent opinion of VA's General Counsel, designated as VAOPGCPREC 5–2001, dated February 5, 2001. The General Counsel stated that VA medical care ordinarily could not be viewed as "causing" disability that results from the ordinary course and progression of a preexisting disease. However, the General Counsel also noted that under longstanding principles of causation in the context of tort law, medical treatment could be considered to have caused the natural progress of a preexisting disease in the limited circumstance where the physician negligently fails to properly diagnose and treat a disease. In such cases, the finding of causation is not based on a determination that the treatment made the disease worse than it would have been without treatment, but on the premise that the physician's negligence "caused" the natural progress of the disease by failing to prevent it in circumstances where a physician exercising due skill and care would have prevented such natural progress from occurring. We believe the commenter's suggestion would create the misleading impression that the physician's actions must have made the progress of the disease worse than it would have been in the absence of any treatment. Accordingly, we make no change based on this comment. Circumstances where VA negligence worsens a preexisting disease are clearly covered by 38 U.S.C. 1151 and proposed 38 CFR 3.361(b), which provide for compensation where a veteran incurs "additional disability" as a result of such negligence. Proposed § 3.361(c)(2) is intended to address the narrower circumstance where a claimant seeks compensation under section 1151 for the natural progress of the preexisting disease.

Section 3.361(d)(1)

Section 1151 authorizes benefits for disability or death resulting from VA hospital care, medical or surgical treatment, or examination if the proximate cause of the disability or death was "carelessness, negligence, lack of proper skill, error in judgment, or similar instance of fault" on the part of VA, or "an event not reasonably

foreseeable." Proposed § 3.361(d)(1) states that, to establish carelessness, negligence, lack of proper skill, error in judgment, or similar instance of fault on the part of VA, a claimant must show that "VA failed to exercise the degree of care that would be expected of a reasonable health care provider" or that "VA furnished the hospital care, medical or surgical treatment, or examination without the veteran's or, in appropriate cases, the veteran's representative's informed consent." In the notice of proposed rule making, we explained that VA interprets the reference in section 1151 to "carelessness, negligence, lack of proper skill, error in judgment, or similar instance of fault" as reflecting ordinary common-law principles of negligence and that the provisions of proposed § 3.361(d)(1) are intended merely to restate, more simply and clearly, the standards governing determinations of negligence.

One commenter disagreed with our interpretation of the statutory language "carelessness, negligence, lack of proper skill, error in judgment, or similar instance of fault" as reflecting general principles of common-law negligence. The commenter asserted that the statutory reference to "fault" simply implies a cause-and-effect relationship between VA action and the resulting disability or death. We disagree. The term "fault" is commonly understood to refer to negligence or other deviation from a legal duty. Black's Law Dictionary, 608 (6th ed. 1990). As explained in the notice of proposed rule making, the language in section 1151 referring to "carelessness, negligence, lack of proper skill, error in judgment, or similar instance of fault" reflects terms and concepts commonly associated with common-law negligence, and thus supports the conclusion that the statutory reference to "similar instance of fault" is intended to refer to circumstances that would likewise support a finding of negligence. The history of section 1151 makes clear that the term "fault" is not intended merely to connote a cause-and-effect relationship. Section 1151 was enacted in response to the Supreme Court's decision in *Brown* v. *Gardner*, 513 U.S. 115 (1994), which construed an earlier version of that statute to require only a cause-and-effect relationship between VA treatment and resulting disability or death, and rejected the Government's claim that the statute required a showing of VA fault. In response to that decision, Congress revised section 1151 in 1996 to expressly require a showing of VA "carelessness, negligence, lack of proper skill, error in judgment, or similar instance of fault." Pub. L. 104–204, § 422(a), 110 Stat. 2874, 2926 (1996). To conclude that the term "fault" connotes only a cause-and-effect relationship would improperly deprive the 1996 amendment of any effect. The legislative history makes clear that the purpose of the amendment was to add a requirement for a showing of fault or negligence in addition to the causation requirement in the statute. *See* H.R. Rep. 812, 104th Cong., 2nd Sess. 84 (1996) (characterizing the statute as "requiring that there be an element of fault as a precondition for entitlement to compensation"); 142 Cong. Rec. H10182, 10183 (Sept. 11, 1996) (statement of Rep. Stokes) (indicating that the statute was intended to overturn the *Gardner* decision and allow payment only if there is evidence that VA was at fault); 142 Cong. Rec. S9875, 9879 (Sept. 5, 1996) (statement of Sen. Daschle) (stating that the statute "requires that veterans wishing to file liability claims against the VA show negligence, as is done in the private sector, to be entitled to benefits").

The commenter also points to the fact that section 1151 authorizes compensation for the results of "an event not reasonably foreseeable" as evidence that Congress did not intend to impose a fault requirement. We believe the language of section 1151 makes clear that Congress intended to authorize compensation for disability proximately caused either by VA fault or by an event not reasonably foreseeable. The fact that the statutory provisions relating to events not reasonably foreseeable contain no fault requirement does not suggest that the distinct provisions expressly referencing VA fault may be construed to contain no fault requirement. Accordingly, we will make no change based on this comment.

One commenter suggested that we add a provision explaining that compensation is payable for negligent errors in judgment but is not payable for "non-negligent" errors in judgment. The same commenter also suggested that we explain what constitutes a "non-negligent error in judgment." This comment refers to our discussion of the proposed rules in the **Federal Register** of December 12, 2002 (67 FR 76323). We explained that we construed the statutory phrase "carelessness, negligence, lack of proper skill, error in judgment, or similar instances of fault on the part of the Department" to refer to the standards used to establish liability for negligence under the common law of torts. We noted that courts applying tort law have sometimes used the phrase "error in judgment" to refer to non-negligent actions, such as a choice among diagnoses or treatment options that accorded with professional standards of care when made, but which in hindsight may have been less accurate or favorable than other reasonable alternatives. At other times, courts use that phrase to refer to decisions by health care providers regarding diagnosis or treatment that are negligent because they are not based on the exercise of due skill and care. We explained that we interpreted the phrase "error in judgment" as used in section 1151 to refer to decisions that are based on the lack of due skill and care and that, therefore, meet the common law definition of negligence.

We believe it is unnecessary to include a provision in the rules distinguishing negligent errors in judgment from non-negligent errors in judgment. As noted above, the operative distinction between those two types of actions depends upon whether the health care provider's decision was based on the exercise of due skill and care. This principle is reflected in § 3.361(d)(1)(i) of the proposed rules, which refers to circumstances where "VA failed to exercise the degree of care that would be expected of a reasonable health care provider." We believe this general standard provides a sufficient basis for VA adjudicators to determine whether the alleged error, whether an error of judgment or some other type of error, establishes a basis for compensation under section 1151. A specific discussion of the distinction between negligent and non-negligent errors or decisions relating to diagnosis and treatment would be merely duplicative of the general standard and would thus be unnecessary. Further, although the discussion of negligent and non-negligent errors of judgment in our notice of proposed rule making was necessary to explain the seemingly inconsistent judicial usage of the phrase "error in judgment," we believe that inserting references to "negligent errors of judgment" and "non-negligent errors of judgment" into these rules would be unnecessarily confusing to readers and may detract attention from the operative standard in § 3.361(d)(1)(i).

A number of courts and legal commentators have noted that the judicial use of the phrase "error in judgment" to describe non-negligent choices among reasonable alternative diagnoses or treatment options is confusing and inaccurate. *See* Joseph H. King, Jr., *Reconciling the Exercise of Judgment and the Objective Standard of Care in Medical Malpractice*, 52 Okla. L. Rev. 49, 60–62 (1999); *Francouer* v. *Piper*, 776 A.2d 1270, 1274–75 (N.H.

2001); *Rogers* v. *Meridian Park Hospital*, 772 P.2d 929, 932–33 (Or. 1989). As an initial matter, a decision among diagnoses or treatment options that accords with established standards of care would not constitute an "error in judgment" within the ordinary meaning of that term, even if the choice may ultimately lead to an unfavorable result. The term "error" is commonly defined to mean "an act or condition of often ignorant or imprudent deviation from a code of behavior." Webster's Third New International Dictionary 772 (unabridged 1976). Accordingly, as some courts have noted, if a physician's decision does not breach the accepted standards of care, "he or she by definition has committed no error of judgment." *Rogers*, 772 P.2d at 933. Courts have also noted that the term "error in judgment" is confusing because decisions that were reasonable and therefore not erroneous when made may nevertheless appear erroneous in hindsight simply because they did not have the anticipated outcome. *See Hirahara* v. *Tanaka*, 959 P.2d 830, 834 (Haw. 1998). These ambiguities have led numerous courts in the past two decades to conclude that the phrase "error in judgment" should not be used in jury instructions in malpractice cases and that juries should be instructed that the determinative issue is whether the physician used due skill and care in making determinations and rendering treatment. *See, e.g., Hirahara,*, 959 P.2d at 463 n.2 (citing cases from several courts); *Day* v. *Morrison*, 657 So.2d 808, 812 (Miss. 1995) (same).

In view of the ambiguity and potential for confusion inherent in the phrase "error of judgment," we do not believe it would be helpful to reference or explain that term in these rules. We believe it is clearer to explain that the determinative issue is whether the health care provider exercised the degree of skill and care expected of a reasonable health care provider, and we believe this standard provides a sufficient basis for deciding claims under 38 U.S.C. 1151 in all cases, including those based on alleged errors in judgment. Accordingly, we will make no change based on this comment.

Section 3.361(d)(2)

Section 1151 authorizes compensation for disability or death due to VA hospital care, medical or surgical treatment, or examination in cases where the proximate cause of the injury is either VA fault or "an event not reasonably foreseeable." Proposed 38 CFR 3.361(d)(2) would state that whether the proximate cause of a disability or death is "an event not reasonably foreseeable" will be determined in each claim based upon what a reasonable health care provider would have foreseen.

One commenter suggested that VA clarify what constitutes an event not reasonably foreseeable. The commenter referenced a 1990 opinion by VA's General Counsel discussing the term "accident," as previously used in 38 U.S.C. 1151, and equating that term with an event that is not reasonably foreseeable. The commenter suggested that we incorporate principles stated in that opinion (designated as VAOPGCPREC 99–90) into this rule. Among other things, the opinion stated that almost no medical event is totally unforeseeable and suggested that VA determinations should not turn solely upon whether a risk is foreseeable in any measure, but on whether the result is one that is truly unexpected or not "reasonably" foreseeable in relation to the treatment provided, as distinguished from a clearly recognized risk of such procedure.

Terms such as "clearly recognized risk" and "truly unexpected results" are themselves ambiguous and subject to varying interpretations. It is not possible in our view, to state a comprehensive definition of "an event not reasonably foreseeable," and we do not believe the clarity of this rule would be improved by introducing additional qualitative but ambiguous terms. We believe it may be helpful, however, to explain that the risk need not be completely unforeseeable or unimaginable. Accordingly, we are adding a sentence stating that the event need not be completely unforeseeable or unimaginable but must be one that a reasonable health care provider would not have considered an ordinary risk of the treatment provided.

We also believe it may be helpful to state that, in determining whether an event was reasonably foreseeable, VA will consider whether it was the type of risk that a reasonable health care provider would have disclosed in connection with the informed consent procedures of 38 CFR 17.32. Section 17.32 provides that, before rendering treatment, VA must disclose "reasonably foreseeable associated risks, complications, or side effects" of the treatment. Because the requirements of informed consent require VA health care providers to assess reasonably foreseeable risks, we believe reference to the informed consent requirements will provide a helpful framework for adjudicators in seeking medical opinions and considering the issue of what constitutes an event not reasonably foreseeable. Accordingly, we will add a sentence to § 3.361(d)(2) stating that, in determining whether an event was reasonably foreseeable, VA will consider whether the risk of that event was the type of risk that a reasonable health care provider would have disclosed in connection with the informed consent procedures of 38 CFR 17.32.

One commenter suggested that we state that compensation is not payable for the results of "high-risk" medical treatment, but may be payable for adverse outcomes in "low-risk" procedures. The commenter further suggested that we establish a baseline risk threshold by stating, for example, that, if a medical procedure has a 5 percent or greater known risk of complications and such complications result, they will be deemed foreseeable. We do not believe such standards would be helpful. The risk of an event may be reasonably foreseeable by medical standards even if the event occurs in only a small percentage of cases. At the same time, an event that is not reasonably foreseeable may occur even in a high-risk procedure. We therefore make no change based on this comment.

The commenter also suggested that we add a statement, based on VAOPGCPREC 99–90, dated December 24, 1990, explaining that, if the only treatment that can possibly arrest a life-threatening condition involves a high risk of additional injury, such additional injury should be considered to result from the disease itself, rather than being classified as an event not reasonably foreseeable. We believe it is unnecessary to include this statement. We believe the statute and the proposed rule make it sufficiently clear that well-known risks of necessary treatment, if they materialize, would not constitute reasonably unforeseeable events. This rule is intended to state general rules governing a wide variety of possible factual scenarios, and we see no need to explain the application of the general rule to a specific and limited set of facts, such as those involving necessary treatment for life-threatening injuries. Insofar as the referenced statement from VAOPGCPREC 99–90 suggests that the results of well-known risks of necessary treatment should be considered results of the condition for which the treatment was sought, that suggestion is not directly relevant to these rules. An existing VA regulation at 38 CFR 3.310 provides for service connection of disability that is proximately due to a service-connected disease or injury. We therefore make no change based on this comment.

Section 3.361(f)

Section 1151 authorizes benefits for disability or death due to hospital care, medical or surgical treatment, or examination that, among other things, was administered "either by a Department employee or in a Department facility." Proposed 38 CFR 3.361(e)(2) defines the term "Department facility" to mean a facility over which the Secretary of Veterans Affairs has direct jurisdiction. Proposed § 3.361(f) identifies activities that would not constitute services furnished by a Department employee or in a Department facility, including "[h]ospital care or medical services furnished under a contract made under 38 U.S.C. 1703," and "[h]ospital care or medical services, including examination, provided under 38 U.S.C. 8153 in a facility over which the Secretary does not have direct jurisdiction."

One commenter asserted that the proposed rules are ambiguous as to whether hospital care or medical services that are provided in a facility over which the Secretary has direct jurisdiction but are administered by non-VA personnel pursuant to a contract would be covered by section 1151. We do not agree that the regulations are ambiguous in this regard. Section 1151 itself provides that the disability or death must result from hospital care or medical services administered "either by a Department employee or in a Department facility" may be covered. The terms "either" and "or" unambiguously provide that hospital care or medical services provided in a Department facility may be covered regardless of whether they are also administered by a Department employee. Nothing in the proposed rules suggests otherwise. Proposed § 3.361(f)(1) provides that hospital care or medical services provided pursuant to a contract under 38 U.S.C. 1703 are not services furnished by a Department employee or in a Department facility. Section 1703 refers to "[c]ontracts for hospital care and medical services in non-Department facilities." Because proposed § 3.361(f)(1) applies only to services in non-VA facilities, it cannot be construed to exclude services rendered in VA facilities by non-VA employees. Proposed § 3.361(f)(3) provides that hospital care or medical services provided pursuant to a contract under 38 U.S.C. 8153 "in a facility over which the Secretary does not have direct jurisdiction" are not services furnished by a Department employee or in a Department facility. Because proposed § 3.361(f)(3) excludes only services provided in non-VA facilities, it cannot be construed to exclude services rendered in VA facilities by non-VA employees. Accordingly, we make no change based on this comment.

One commenter suggested that the rules clarify that an injury to a patient due to accidents or errors caused by non-health care workers, such as janitors, police, engineers, or administrators, is not compensable under 38 U.S.C. 1151. Proposed § 3.361(e)(1) defines a "Department employee" for purposes of section 1151 as a person who is, among other things "engaged in furnishing hospital care, medical or surgical treatment, or examinations under authority of law." The terms "hospital care," "medical or surgical treatment," and "examinations," refer to activities of a medical nature. Because non-health care workers generally would not be engaged in furnishing such medical services under authority of law, we believe the proposed rules sufficiently provide that injuries due to the actions of non-health care workers generally are not within the scope of the rules. We believe it is more consistent with the language of section 1151 to refer to the types of medical activities the VA employees were engaged in, rather than the employees' occupational classifications. Accordingly, we will make no change based on this comment.

Additional Changes to Proposed Rules

In addition to the changes made in response to public comments, we have made certain other changes in these final rules for the reasons set forth below.

Section 3.361(a) and (d)(3)

We have revised § 3.361(a) and (d)(3) to clarify that the provisions of § 3.361 apply to claims alleging disability or death due to compensated work therapy if such claims were either pending before VA on November 1, 2000, or were received by VA after that date. This change reflects VA's interpretation of existing statutory requirements and therefore does not require additional notice and comment procedures under 5 U.S.C. 553 prior to adoption. Moreover, this change is a relatively minor departure from the proposed rules and will be beneficial to claimants.

Proposed § 3.361(a) stated that § 3.361 would apply to claims received by VA on or after October 1, 1997. Our notice of proposed rule making, however, stated that the rule would apply to claims based on disability or death due to CWT only if such claims were received by VA on or after November 1, 2000. Further, in proposed § 3.361(d)(3), we stated that benefits for injury or death due to training, rehabilitation services, or CWT could be paid only if the veteran had participated in such activity as part of a program authorized under 38 U.S.C. chapter 31 (pertaining to training and rehabilitation services), or "for claims received on or after November 1, 2000, as part of a CWT program under 38 U.S.C. 1718."

The referenced dates of October 1, 1997, and November 1, 2000, correspond to two distinct statutes that amended 38 U.S.C. 1151. The first statute, Public Law 104–204, revised section 1151, effective October 1, 1997, to require a showing of VA fault in order to establish entitlement to benefits under that statute. Neither the preexisting statute, nor the amendments made by Public Law 104–204, applied to claims involving disability or death allegedly due to CWT. Section 303 of Public Law 106–419, however, revised section 1151, effective November 1, 2000, to authorize benefits for disability or death due to participation in a CWT program. The proposed rules reflect the view that the restrictive changes made by Public Law 104–204 apply to all claims filed on or after October 1, 1997, but that the liberalizing changes made by Public Law 106–419 apply only to claims filed on or after November 1, 2000. We believe the significance of those two dates should be stated more clearly, however, by referencing both dates in § 3.361(a), rather than in the separate provisions of § 3.361(a) and (d)(3).

We have also determined that the proposed rule was too restrictive insofar as it would have authorized benefits based on CWT only in claims filed on or after November 1, 2000. We have determined that the provisions of Public Law 106–419 authorizing benefits for disability or death due to CWT are applicable not only to claims that were filed on or after November 1, 2000, but also to claims that were filed prior to that date but had not yet been finally decided by VA as of that date. This determination is based on VA's interpretation of Public Law 106–419 and the statutes and judicial rules governing the retroactive effect of new statutes.

Pursuant to 38 U.S.C. 5110(g) and 38 CFR 3.114(a), VA may not pay benefits for any period prior to the effective date of a new statute authorizing the benefit in question. Accordingly, the provisions of Public Law 106–419 authorizing VA to pay benefits for disability or death due to CWT must be construed to permit benefit payments only for periods beginning on or after the date of its enactment on November 1, 2000.

However, the prohibition on payment for periods prior to November 1, 2000, does not compel a prohibition on considering claims that were filed before that date. VA could consider claims filed before November 1, 2000, and award benefits to the claimant for periods after that date, if warranted.

Under established rules of statutory construction, new statutes are presumed not to operate retroactively unless their language requires that result. *See Landgraf* v. *USI Film Products,* 511 U.S. 244 (1994). However, a statute does not operate retroactively merely because it is applied to a claim filed before the statute was enacted. *Id.* at 269. Rather, a statute would have a disfavored retroactive effect only if it impairs previously established rights, imposes new duties with respect to transactions already completed, or imposes some similar alteration with respect to past events. *Id.* at 280. A new provision that merely authorizes prospective benefits is not retroactive simply because it is applied to a claim filed before the statute was enacted. *Id.* at 273. Accordingly, because section 303 of Public Law 106–419 affects only entitlement to prospective benefits for periods after the date of its enactment, we conclude that it may be applied to claims that were filed before the date that statute was enacted and which remained pending before VA on that date.

For the foregoing reasons we are revising proposed § 3.361(a) to state that the provisions of that rule apply generally to claims that were received by VA on or after October 1, 1997, subject to the exception that, in claims based on disability or death allegedly caused by participation in a CWT program, the provisions of § 3.361 will apply only to claims that were pending before VA on November 1, 2000, or were received by VA after that date. We are also including a sentence noting that the effective date of any benefits awarded under that provision will be subject to 38 CFR 3.114(a) and 3.400(i), but may not be earlier than November 1, 2000. Further, we are removing the reference in proposed § 3.361(d)(3) to "claims received on or after November 1, 2000," because that limitation, as modified, will now be stated in the paragraph (a) of § 3.361. Because this change merely reflects VA's interpretation of the governing statutes and judicial rules, it is an interpretive rule and is not subject to the notice-and-comment requirements under 5 U.S.C. 553.

Section 3.361(d)(1)(ii)

The proposed rule stated that a patient's informed consent may be "expressed (*i.e.*, given orally or in writing) or implied." We believe the language of the proposed rule makes clear that the term "expressed" was intended as an adjective referring to clearly-conveyed communications of consent, as distinguished from the implied communications of consent referenced later in the same sentence. However, the commonly-used adjectival form of that word is "express" rather than "expressed." Accordingly, we have changed that word to "express" in the final rule in order to eliminate confusion. This grammatical change does not alter the meaning of the proposed rule.

Section 3.807

Section 3.807(c) discusses the types of "service-connected" disability that will establish entitlement to dependents' educational assistance under chapter 35 of title 38, United States Code. The last sentence of current § 3.807(c) states that chapter 35 benefits are not payable in "[c]ases where eligibility for the service-connected benefits is established under § 3.800." Section 3.800 is one of two VA regulations—the other being § 3.358—that implemented the provisions of section 1151 as it existed prior to October 1, 1997.

We proposed to revise the last sentence of § 3.807(c) to refer to "[c]ases where eligibility for the service-connected benefits is established under §§ 3.358, 3.361." We are now revising that sentence to refer to "[c]ases where eligibility for the service-connected benefits is established under § 3.358, 3.361, or 3.800." This would fix the obvious grammatical defect in the proposed rule and would also result in retaining the reference in the current regulation to § 3.800. Although reference to that provision may be unnecessary because § 3.800 merely authorizes the same benefit authorized by § 3.358, we believe it is preferable to refer to both of those provisions to eliminate any ambiguity. In view of the proximity of § 3.800 and § 3.807 in the Code of Federal Regulations, we believe it may be helpful to retain the reference to § 3.800. This change would not alter the meaning of the proposed rules because § 3.800 authorizes the same benefit as § 3.358. Because the retention of the reference to § 3.800 is consistent with the current regulation as well as the proposed regulation, there is no requirement for an additional notice and comment period with respect to this change.

Executive Order 12866

This document has been reviewed by the Office of Management and Budget under Executive Order 12866.

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3521).

Unfunded Mandates

The Unfunded Mandates Reform Act requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of $100 million or more in any given year. This rule will have no such effect on State, local, or tribal governments, or the public sector.

Regulatory Flexibility Act

The Secretary hereby certifies that this regulatory amendment will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This amendment will not directly affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

The Catalog of Federal Domestic Assistance numbers are 64.104 and 64.109.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Veterans.

Approved: May 20, 2004.

Anthony J. Principi,

Secretary of Veterans Affairs.

■ For the reasons set forth in the preamble, 38 CFR part 3 is amended as follows:

PART 3—ADJUDICATION

■ 1. The authority citation for Part 3 continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation

■ 2. Section 3.154 and the Cross References at the end of the section are revised to read as follows:

§ 3.154 Injury due to hospital treatment, etc.

VA may accept as a claim for benefits under 38 U.S.C. 1151 and § 3.361 any communication in writing indicating an intent to file a claim for disability compensation or dependency and indemnity compensation under the laws governing entitlement to veterans' benefits for disability or death due to VA hospital care, medical or surgical treatment, examination, training and rehabilitation services, or compensated work therapy program, whether such communication is contained in a formal claim for pension, compensation, or dependency and indemnity compensation or in any other document.

(Authority: 38 U.S.C. 1151)

Cross references: Effective dates. See § 3.400(i). Disability or death due to hospitalization, *etc.* See §§ 3.358, 3.361 and 3.800.

■ 3. In § 3.358, the authority citation at the end of paragraph (a) is removed, and paragraphs (a) and (b)(2) are revised to read as follows:

§ 3.358 Compensation for disability or death from hospitalization, medical or surgical treatment, examination or vocational rehabilitation training (§ 3.800).

(a) *General.* This section applies to claims received by VA before October 1, 1997. If it is determined that there is additional disability resulting from a disease or injury or aggravation of an existing disease or injury suffered as a result of hospitalization, medical or surgical treatment, examination, or vocational rehabilitation training, compensation will be payable for such additional disability. For claims received by VA on or after October 1, 1997, see § 3.361.

(b) * * *

(2) Compensation will not be payable under this section for the continuance or natural progress of a disease or injury for which the hospitalization, medical or surgical treatment, or examination was furnished, unless VA's failure to exercise reasonable skill and care in the diagnosis or treatment of the disease or injury caused additional disability or death that probably would have been prevented by proper diagnosis or treatment. Compensation will not be payable under this section for the continuance or natural progress of a disease or injury for which vocational rehabilitation training was provided.

* * * * *

■ 4. Section 3.361 is added to read as follows:

§ 3.361 Benefits under 38 U.S.C. 1151(a) for additional disability or death due to hospital care, medical or surgical treatment, examination, training and rehabilitation services, or compensated work therapy program.

(a) *Claims subject to this section*—(1) *General.* Except as provided in paragraph (2), this section applies to claims received by VA on or after October 1, 1997. This includes original claims and claims to reopen or otherwise readjudicate a previous claim for benefits under 38 U.S.C. 1151 or its predecessors. The effective date of benefits is subject to the provisions of § 3,400(i). For claims received by VA before October 1, 1997, see § 3.358.

(2) *Compensated Work Therapy.* With respect to claims alleging disability or death due to compensated work therapy, this section applies to claims that were pending before VA on November 1, 2000, or that were received by VA after that date. The effective date of benefits is subject to the provisions of §§ 3.114(a) and 3.400(i), and shall not be earlier than November 1, 2000.

(b) *Determining whether a veteran has an additional disability.* To determine whether a veteran has an additional disability, VA compares the veteran's condition immediately before the beginning of the hospital care, medical or surgical treatment, examination, training and rehabilitation services, or compensated work therapy (CWT) program upon which the claim is based to the veteran's condition after such care, treatment, examination, services, or program has stopped. VA considers each involved body part or system separately.

(c) *Establishing the cause of additional disability or death.* Claims based on additional disability or death due to hospital care, medical or surgical treatment, or examination must meet the causation requirements of this paragraph and paragraph (d)(1) or (d)(2) of this section. Claims based on additional disability or death due to training and rehabilitation services or compensated work therapy program must meet the causation requirements of paragraph (d)(3) of this section.

(1) *Actual causation required.* To establish causation, the evidence must show that the hospital care, medical or surgical treatment, or examination resulted in the veteran's additional disability or death. Merely showing that a veteran received care, treatment, or examination and that the veteran has an additional disability or died does not establish cause.

(2) *Continuance or natural progress of a disease or injury.* Hospital care, medical or surgical treatment, or examination cannot cause the continuance or natural progress of a disease or injury for which the care, treatment, or examination was furnished unless VA's failure to timely diagnose and properly treat the disease or injury proximately caused the continuance or natural progress. The provision of training and rehabilitation services or CWT program cannot cause the continuance or natural progress of a disease or injury for which the services were provided.

(3) *Veteran's failure to follow medical instructions.* Additional disability or death caused by a veteran's failure to follow properly given medical instructions is not caused by hospital care, medical or surgical treatment, or examination.

(d) *Establishing the proximate cause of additional disability or death.* The proximate cause of disability or death is the action or event that directly caused the disability or death, as distinguished from a remote contributing cause.

(1) *Care, treatment, or examination.* To establish that carelessness, negligence, lack of proper skill, error in judgment, or similar instance of fault on VA's part in furnishing hospital care, medical or surgical treatment, or examination proximately caused a veteran's additional disability or death, it must be shown that the hospital care, medical or surgical treatment, or examination caused the veteran's additional disability or death (as explained in paragraph (c) of this section); and

(i) VA failed to exercise the degree of care that would be expected of a reasonable health care provider; or

(ii) VA furnished the hospital care, medical or surgical treatment, or examination without the veteran's or, in appropriate cases, the veteran's representative's informed consent. To determine whether there was informed consent, VA will consider whether the health care providers substantially complied with the requirements of § 17.32 of this chapter. Minor deviations from the requirements of § 17.32 of this chapter that are immaterial under the circumstances of a case will not defeat a finding of informed consent. Consent may be express (*i.e.*, given orally or in writing) or implied under the circumstances specified in § 17.32(b) of this chapter, as in emergency situations.

(2) *Events not reasonably foreseeable.* Whether the proximate cause of a veteran's additional disability or death was an event not reasonably foreseeable is in each claim to be determined based on what a reasonable health care provider would have foreseen. The event need not be completely

unforeseeable or unimaginable but must be one that a reasonable health care provider would not have considered to be an ordinary risk of the treatment provided. In determining whether an event was reasonably foreseeable, VA will consider whether the risk of that event was the type of risk that a reasonable health care provider would have disclosed in connection with the informed consent procedures of § 17.32 of this chapter.

(3) *Training and rehabilitation services or compensated work therapy program.* To establish that the provision of training and rehabilitation services or a CWT program proximately caused a veteran's additional disability or death, it must be shown that the veteran's participation in an essential activity or function of the training, services, or CWT program provided or authorized by VA proximately caused the disability or death. The veteran must have been participating in such training, services, or CWT program provided or authorized by VA as part of an approved rehabilitation program under 38 U.S.C. chapter 31 or as part of a CWT program under 38 U.S.C. 1718. It need not be shown that VA approved that specific activity or function, as long as the activity or function is generally accepted as being a necessary component of the training, services, or CWT program that VA provided or authorized.

(e) *Department employees and facilities.* (1) A *Department employee is an individual*—

(i) Who is appointed by the Department in the civil service under title 38, United States Code, or title 5, United States Code, as an employee as defined in 5 U.S.C. 2105;

(ii) Who is engaged in furnishing hospital care, medical or surgical treatment, or examinations under authority of law; and

(iii) Whose day-to-day activities are subject to supervision by the Secretary of Veterans Affairs.

(2) A *Department facility* is a facility over which the Secretary of Veterans Affairs has direct jurisdiction.

(f) *Activities that are not hospital care, medical or surgical treatment, or examination furnished by a Department employee or in a Department facility.* The following are not hospital care, medical or surgical treatment, or examination furnished by a Department employee or in a Department facility within the meaning of 38 U.S.C. 1151(a):

(1) Hospital care or medical services furnished under a contract made under 38 U.S.C. 1703.

(2) Nursing home care furnished under 38 U.S.C. 1720.

(3) Hospital care or medical services, including examination, provided under 38 U.S.C. 8153 in a facility over which the Secretary does not have direct jurisdiction.

(g) *Benefits payable under 38 U.S.C. 1151 for a veteran's death. (1) Death before January 1, 1957.* The benefit payable under 38 U.S.C. 1151(a) to an eligible survivor for a veteran's death occurring before January 1, 1957, is death compensation. See §§ 3.5(b)(2) and 3.702 for the right to elect dependency and indemnity compensation.

(2) *Death after December 31, 1956.* The benefit payable under 38 U.S.C. 1151(a) to an eligible survivor for a veteran's death occurring after December 31, 1956, is dependency and indemnity compensation.

(Authority: 38 U.S.C. 1151)

■ 5. Section 3.362 is added to read as follows:

§ 3.362 Offsets under 38 U.S.C. 1151(b) of benefits awarded under 38 U.S.C. 1151(a).

(a) *Claims subject to this section.* This section applies to claims received by VA on or after October 1, 1997. This includes original claims and claims to reopen or otherwise readjudicate a previous claim for benefits under 38 U.S.C. 1151 or its predecessors.

(b) *Offset of veterans' awards of compensation.* If a veteran's disability is the basis of a judgment under 28 U.S.C. 1346(b) awarded, or a settlement or compromise under 28 U.S.C. 2672 or 2677 entered, on or after December 1, 1962, the amount to be offset under 38 U.S.C. 1151(b) from any compensation awarded under 38 U.S.C. 1151(a) is the entire amount of the veteran's share of the judgment, settlement, or compromise, including the veteran's proportional share of attorney fees.

(c) *Offset of survivors' awards of dependency and indemnity compensation.* If a veteran's death is the basis of a judgment under 28 U.S.C. 1346(b) awarded, or a settlement or compromise under 28 U.S.C. 2672 or 2677 entered, on or after December 1, 1962, the amount to be offset under 38 U.S.C. 1151(b) from any dependency and indemnity compensation awarded under 38 U.S.C. 1151(a) to a survivor is only the amount of the judgment, settlement, or compromise representing damages for the veteran's death the survivor receives in an individual capacity or as distribution from the decedent veteran's estate of sums included in the judgment, settlement, or compromise to compensate for harm suffered by the survivor, plus the survivor's proportional share of attorney fees.

(d) *Offset of structured settlements.* This paragraph applies if a veteran's disability or death is the basis of a structured settlement or structured compromise under 28 U.S.C. 2672 or 2677 entered on or after December 1, 1962.

(1) *The amount to be offset.* The amount to be offset under 38 U.S.C. 1151(b) from benefits awarded under 38 U.S.C. 1151(a) is the veteran's or survivor's proportional share of the cost to the United States of the settlement or compromise, including the veteran's or survivor's proportional share of attorney fees.

(2) *When the offset begins.* The offset of benefits awarded under 38 U.S.C. 1151(a) begins the first month after the structured settlement or structured compromise has become final that such benefits would otherwise be paid.

(Authority: 38 U.S.C. 1151)

■ 6. Section 3.363 is added to read as follows:

§ 3.363 Bar to benefits under 38 U.S.C. 1151.

(a) *Claims subject to this section.* This section applies to claims received by VA on or after October 1, 1997. This includes original claims and claims to reopen or otherwise readjudicate a previous claim for benefits under 38 U.S.C. 1151 or its predecessors.

(b) *Administrative award, compromises, or settlements, or judgments that bar benefits under 38 U.S.C. 1151.* If a veteran's disability or death was the basis of an administrative award under 28 U.S.C. 1346(b) made, or a settlement or compromise under 28 U.S.C. 2672 or 2677 finalized, before December 1, 1962, VA may not award benefits under 38 U.S.C. 1151 for any period after such award, settlement, or compromise was made or became final. If a veteran's disability or death was the basis of a judgment that became final before December 1, 1962, VA may award benefits under 38 U.S.C. 1151 for the disability or death unless the terms of the judgment provide otherwise.

(Authority: 38 U.S.C. 1151)

■ 7. In § 3.400, the section heading of paragraph (i) is revised to read as follows:

§ 3.400 General.

* * * * *

(i) *Disability or death due to hospitalization, etc.* (38 U.S.C. 5110(c), (d); Public Law 87–825; §§ 3.358, 3.361, and 3.800.) * * *

* * * * *

§ 3.708 [Amended]

■ 8. In § 3.708, paragraph (a)(4) is amended by removing "or training." and adding, in its place, "or hospital care, training, or compensated work therapy program. See §§ 3.358 and 3.361."

■ 9. Section 3.800 is amended by adding introductory text to read as follows:

§ 3.800 Disability or death due to hospitalization, *etc.*

This section applies to claims received by VA before October 1, 1997. For claims received by VA on or after October 1, 1997, see §§ 3.362 and 3.363.

* * * * *

■ 10. In § 3.807, the last sentence of paragraph (c) is revised to read as follows:

§ 3.807 Dependents' educational assistance; certification.

* * * * *

(c) * * * Cases where eligibility for service-connected benefits is established under § 3.358, 3.361, or 3.800 are not included.

* * * * *

[FR Doc. 04–17597 Filed 8–2–04; 8:45 am]
BILLING CODE 8320–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket No. FEMA–7839]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are suspended on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will be withdrawn by publication in the **Federal Register**.

EFFECTIVE DATES: The effective date of each community's suspension is the third date ("Susp.") listed in the third column of the following tables.

ADDRESSES: If you wish to determine whether a particular community was suspended on the suspension date, contact the appropriate FEMA Regional Office or the NFIP servicing contractor.

FOR FURTHER INFORMATION CONTACT: Mike Grimm, Mitigation Division, 500 C Street, SW.; Room 412, Washington, DC 20472, (202) 646–2878.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the National Flood Insurance Program, 42 U.S.C. 4001 *et seq.*; unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59 *et seq.* Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register**.

In addition, the Federal Emergency Management Agency has identified the special flood hazard areas in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of the FIRM if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may legally be provided for construction or acquisition of buildings in the identified special flood hazard area of communities not participating in the NFIP and identified for more than a year, on the Federal Emergency Management Agency's initial flood insurance map of the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment under 5 U.S.C. 553(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives a 6-month, 90-day, and 30-day notification addressed to the Chief Executive Officer that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications have been made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Considerations. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless they take remedial action.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, October 26, 1987, 3 CFR, 1987 Comp.; p. 252.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778, October 25, 1991, 56 FR 55195, 3 CFR, 1991 Comp.; p. 309.

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

■ Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in special flood hazard areas
Region VII				
Nebraska:				
Dunbar, Village of, Otoe County	310163	April 28, 1975, Emerg; August 19, 1985, Reg; August 4, 2004, Susp.	Aug. 4, 2004	Aug. 4, 2004.
Otoe County, Unincorporated Areas.	310462	July 2, 1993, Emerg; March 2, 1998, Reg; August 4, 2004, Susp.	.....do	do.

*-do- =Ditto
Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

Dated: July 28, 2004.

David I. Maurstad,

Acting Mitigation Division Director, Emergency Preparedness and Response Directorate.

[FR Doc. 04–17631 Filed 8–2–04; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: Base (1% annual-chance) Flood Elevations and modified Base Flood Elevations (BFEs) are made final for the communities listed below. The BFEs and modified BFEs are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The date of issuance of the Flood Insurance Rate Map (FIRM) showing BFEs and modified BFEs for each community. This date may be obtained by contacting the office where the FIRM is available for inspection as indicated in the table below.

ADDRESSES: The final base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency makes the final determinations listed below of BFEs and modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Mitigation Division Director of the Emergency Preparedness and Response Directorate has resolved any appeals resulting from this notification.

This final rule is issued in accordance with Section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and 44 CFR Part 67.

The Federal Emergency Management Agency has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR Part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community.

The BFEs and modified BFEs are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to establish and maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of Section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and record keeping requirements.

■ Accordingly, 44 CFR Part 67 is amended to read as follows:

PART 67—[AMENDED]

■ 1. The authority citation for Part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.11 [Amended]

■ 2. The tables published under the authority of § 67.11 are amended as follows:

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD) Modified ♦Elevation in feet (NAVD) Modified
Ohio	Bentleyville (Village), Cuyahoga County (FEMA Docket No. P7637).	Aurora Branch	Approximately 1,500 feet upstream of the mouth.	*833
			At the corporate limits, approximately 1,700 feet upstream of the Norfolk Southern Railroad bridge.	*893
		Chagrin River	At the corporate limits, approximately 700 feet downstream of Miles Road.	*823
			At the corporate limits, approximately 4,550 feet upstream of the confluence of Aurora Branch.	*838
		Tributary 2	At the mouth	*889
			Approximately 140 feet downstream of Liberty Road.	*889

Maps are available for inspection at the Bentleyville Village Hall, 6253 Chagrin River Road, Bentleyville, Ohio.

(Catalog of Federal Domestic Assistance No. 83.100, "Flood Insurance.")

Dated: July 28, 2004.

David I. Maurstad,

Acting Director, Mitigation Division, Emergency Preparedness and Response Directorate.

[FR Doc. 04–17632 Filed 8–2–04; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: Base (1% annual-chance) Flood Elevations and modified Base Flood Elevations (BFEs) are made final for the communities listed below. The BFEs and modified BFEs are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

EFFECTIVE DATE: The date of issuance of the Flood Insurance Rate Map (FIRM) showing BFEs and modified BFEs for each community. This date may be obtained by contacting the office where the FIRM is available for inspection as indicated in the table below.

ADDRESSES: The final base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency makes the final determinations listed below of BFEs and modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Mitigation Division Director of the Emergency Preparedness and Response Directorate has resolved any appeals resulting from this notification.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and 44 CFR part 67.

The Federal Emergency Management Agency has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community.

The BFEs and modified BFEs are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to establish and maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of Section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and record keeping requirements.

■ Accordingly, 44 CFR Part 67 is amended to read as follows:

PART 67—[AMENDED]

■ 1. The authority citation for Part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.11 [Amended]

■ 2. The tables published under the authority of § 67.11 are amended as follows:

Source of flooding and location of referenced elevation	*Elevation in feet (NGVD) modified	Communities affected
FEMA Docket No. P7645:		
Muskingum River	669	Village of Malta.
Muskingum River	669	Village of McConnelsville.

ADDRESSES:
Village of Malta, Morgan County, Ohio: Maps are available for inspection at the Village of Malta, 449 Main Street, Malta, Ohio.
Village of McConnelsville, Morgan County, Ohio: Maps are available for inspection at Village Hall, 9 West Main Street, McConnelsville, Ohio.

(Catalog of Federal Domestic Assistance No. 83.100, "Flood Insurance.")

Dated: July 28, 2004.

David I. Maurstad,

Acting Director, Mitigation Division, Emergency Preparedness and Response Directorate.

[FR Doc. 04–17633 Filed 8–2–04; 8:45 am]

BILLING CODE 9110–12–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0, 1, 2, 90 and 95

[WT Docket No. 01–90; ET Docket No. 98–95; RM–9096; FCC 03–324]

Dedicated Short Range Communication Services and Mobile Service for Dedicated Short Range Communications of Intelligent Transportation Service in the 5.850–5.925 GHz Band (5.9 GHz Band)

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document the Commission adopts licensing and service rules for the Dedicated Short Range Communications Service (DSRCS) in the Intelligent Transportation Systems (ITS) Radio Service in the 5.850–5.925 GHz band (5.9 GHz band). This action promotes a nationwide solution to the transportation safety challenges faced by all Americans and follows the Commission's earlier allocation of this radio spectrum for DSRCS.

DATES: Effective October 4, 2004. The incorporation by reference of a certain publication listed in the regulations is approved by the Director of the Federal Register as of October 4, 2004.

FOR FURTHER INFORMATION CONTACT: Zenji Nakazawa via phone at (202) 418–0680, via e-mail at *Zenji.Nakazawa@fcc.gov,* via TTY (202) 418–7233, Wireless Telecommunications Bureau, Federal Communications Commission, Washington, DC 20554.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order,* FCC 03–324, adopted on December 17, 2003, and released on February 10, 2004. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center, 445 12th Street, SW., Washington, DC 20554. The complete text may be purchased from the Commission's copy contractor, Qualex International, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. The full text may also be downloaded at: *http://www.fcc.gov.* Alternative formats are available to persons with disabilities by contacting Brian Millin at (202) 418–7426 or TTY (202) 418–7365 or at *brian.millin@fcc.gov.*

1. In the *Report and Order,* the Commission makes the following major decisions: (i) The U.S. Department of Transportation envisions DSRC units in every new motor vehicle for life-saving communications. To ensure interoperability and robust safety/public safety communications among these DSRC devices nationwide, the Commission adopts the standard supported by most commenters and developed under an accredited standard setting process (ASTM E2213–03 or "ASTM–DSRC"); (ii) the Commission concludes that it is possible to license both public safety and non-public safety use of the 5.9 GHz band. Accordingly, it adopts open eligibility for licensing and technical rules, most of which are embodied in the ASTM–DSRC standard, aimed at creating a framework that ensures priority for public safety communications; (iii) the Commission will license DSRC Roadside Units (RSUs), communication units that are fixed along the roadside, under subpart M (Intelligent Transportation Radio Service) of part 90 of the Commission's Rules. Licensees will receive non-exclusive geographic-area licenses authorizing operation on seventy megahertz of the 5.9 GHz band. It also adopts a framework whereby licensees would register RSUs by site and segment(s); (iv) the Commission licenses On-Board Units (OBUs), in-vehicle communications units, by rule under new subpart L of Part 95 of our Rules.

I. Final Regulatory Flexibility Analysis (FRFA)

2. As required by the Regulatory Flexibility Act of 1980, as amended (RFA) (*see* 5 U.S.C. 603. The RFA, *see* 5 U.S.C. 601–612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Pub. L. 104–121, Title II, 110 Stat. 847 (1996)) an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the *Notice of Proposed Rule Making* (*NPRM*), 68 FR 1999, January 15, 2003, in this proceeding, WT Docket. No. 01–90. The Commission sought written public comment on the proposals in the NPRM, including comment on the IRFA. No comments were submitted specifically in response to the IRFA. This present FRFA conforms to the RFA.

Need for, and Objectives of the Proposed Rules

3. In the *Report and Order,* we adopt licensing, service, and operating rules for the 5.850–5.925 GHz band for use by Dedicated Short Range Communications (DSRC) Services in the provision of Intelligent Transportation Systems (ITS) services. DSRC communications are used for the wireless transfer of data over short distances between roadside

and mobile units, between mobile units, and between portable and mobile units to perform operations related to the improvement of traffic flow, traffic safety, and other intelligent transportation service applications in a variety of environments. This action is taken in response to the Transportation Equity Act for the 21st Century, which requires the Commission, in consultation with the Secretary of the United States Department of Transportation (DOT), to consider the spectrum needs for DSRC. This action will assist DOT's goal of using advanced electronics and technology to increase the safety and efficiency of the nation's surface transportation system.

Summary of Significant Issues Raised by Public Comments in Response to the IRFA

4. No comments were submitted specifically in response to the IRFA. Generally, the comments supported permitting both public safety and non-public safety uses in the 5.9 GHz band, with non-public safety uses secondary. Commenters supported the adoption of the ASTM–DSRC Standard into the Commission's Rules. They further supported site-based licensing, frequency coordination, and the use of the Universal Licensing System.

Description and Estimate of the Number of Small Entities to Which Rules Will Apply

5. 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. The RFA defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act. A small business concern is one which: (i) Is independently owned and operated; (ii) is not dominant in its field of operation; and (iii) satisfies any additional criteria established by the Small Business Administration (SBA). A small organization is generally "any not-for-profit enterprise which is independently owned and operated and is not dominant in its field." Nationwide, as of 1992, there were approximately 275,801 small organizations. The term "small governmental jurisdiction" is defined as "governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand." As of 1997, there were about 87,453 governmental jurisdictions in the United States. This number includes 39,044 county governments, municipalities, and townships, of which 37,546 (approximately 96.2%) have populations of fewer than 50,000, and of which 1,498 have populations of 50,000 or more. Thus we estimate the number of small governmental jurisdictions overall to be 84,098 or fewer.

6. The rules we adopt today will affect users of public safety radio services. These rules may also affect manufacturers of radio communications equipment. We also note that nationwide, there are approximately 22.4 million small businesses, total, according to the SBA data.

Small Businesses Sharing Spectrum With Public Safety Radio Services and Governmental Entities

7. As a general matter, Public Safety Radio Services include police, fire, local government, forestry conservation, highway maintenance, and emergency medical services. Private entities that use DSRC-based ITS applications may be licensed in the 5.9 GHz band on a secondary basis to public safety radio services.

Wireless Service Providers

8. The SBA has developed a small business size standard for wireless small businesses within the two separate categories of paging 1 and cellular and other wireless telecommunications. Under both SBA categories, a wireless business is small if it has 1,500 or fewer employees. According to the Commission's most recent data, 1,761 companies reported that they were engaged in the provision of wireless service. Of these 1,761 companies, an estimated 1,175 have 1,500 or fewer employees and 586 have more than 1,500 employees. Consequently, the Commission estimates that most wireless service providers are small entities that may be affected by the rules and policies adopted herein.

9. The Commission has not developed a definition of small entities specifically applicable to Dedicated Short-Range Communications Manufacturers (DSRC Manufacturers). However, the SBA has established a small business size standard for Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing. Under this standard, firms are considered small if they have 750 or fewer employees. Census data for 1997 indicate that, for that year, there were a total of 1,215 establishments in this category. Of those, there were 1,150 that had employment under 500, and an additional 37 that had employment of 500 to 999. The percentage of wireless equipment manufacturers to total manufacturers in this category is approximately 61.35%, so we estimate that the number of wireless equipment manufacturers with employment under 500 was actually closer to 706, with an additional 23 establishments having employment of between 500 and 999. Given the above, we estimate that the majority of wireless communications equipment manufacturers are small.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

10. Applicants for licenses to provide DSRC operations in the 5.9 GHz band those licensees must submit license applications through the Universal Licensing System using Form 601, and follow the service rules at 47 CFR part 90. These licenses are not subject to spectrum auctions although, they will be subject to licensing and regulatory fees.

Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

11. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its determinations, which may include the following four alternatives, among others: (i) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (ii) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (iii) the use of performance, rather than design standards; and (iv) an exemption from coverage of the rule, or any part thereof, for small entities. Regarding our decision to permit open eligibility for licensing in the 5.9 GHz, see *Report and Order* at paragraphs 50–51. We do not believe that there will be any significant effect on small entities. Any interested and qualified entity may apply for a license. Regarding our decision to use non-exclusive geographic area licensing, see *Report and Order* at paragraphs 57 through 59. We do not believe that there will be any significant adverse effect on small entities. We believe that this licensing approach will actually benefit small entities by enabling them to obtain licenses to provide a DSRC service. We further believe this decision benefits small entities by eliminating the costs associated with frequency coordination. Because of the short range of this service (less than 1000 meters), resulting in relatively lower costs, we believe that small entities will be

attracted to this service. Regarding our decision to require the use of the ASTM–DSRC Standard, see *Report and Order* paragraphs 18 through 22. We do not believe that there will be any adverse effect on small entities. We believe that this decision will benefit small entities. We required the ASTM–DSRC Standard for all DSRC operations in the 5.9 GHz band, which we anticipate will, in turn, reduce the cost of the DSRC devices.

Report to Congress

12. The Commission will send a copy of the *Report and Order,* including this FRFA, in a report to be sent to Congress pursuant to the Congressional Review Act. In addition, the Commission will send a copy of this *Report and Order,* including this FRFA, to the Chief Counsel for Advocacy of the Small Business Administration.

II. Ordering Clauses

13. Accordingly, it is ordered that, pursuant to Sections 1, 4(i), 302, 303(f) and (r), and 332 of the Communications Act of 1934, as amended, 47 U.S.C. 1, 154(i), 302, 303(f) and (r), and 332, this *Report and Order* is adopted.

14. It is further ordered that parts 0, 1, 2, 90, and 95 of the Commission's Rules are amended as specified in rule changes of the *Report and Order,* effective October 4, 2004.

15. It is further ordered that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, shall send a copy of this *Report and Order,* including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the U.S. Small Business Administration.

List of Subjects

47 CFR Part 0

Reporting and recordkeeping requirements.

47 CFR Parts 1 and 90

Incorporation by Reference, Radio, Reporting and recordkeeping requirements.

47 CFR Parts 2 and 95

Communications equipment, Incorporation by Reference, Radio, Reporting and recordkeeping requirements.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Rule Changes

■ For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR parts 0, 1, 2, 90 and 95 as follows:

PART 0—COMMISSION ORGANIZATION

■ 1. The authority citation for part 0 continues to read as follows:

Authority: Sections 5, 48 Stat. 1068, as amended; 47 U.S.C. 155, 225, unless otherwise noted.

■ 2. Section 0.331 is amended by revising paragraph (d) introductory text to read as follows:

§ 0.331 Authority delegated.

* * * * *

(d) *Authority concerning rulemaking proceedings.* The Chief, Wireless Telecommunications Bureau shall not have the authority to act upon notices of proposed rulemaking and inquiry, final orders in rulemaking proceedings and inquiry proceedings, and reports arising from any of the foregoing except such orders involving ministerial conforming amendments to rule parts, or orders conforming any of the applicable rules to formally adopted international conventions or agreements where novel questions of fact, law, or policy are not involved. In addition, revisions to the airport terminal use list in § 90.35(c)(61) of this chapter and revisions to the Government Radiolocation list in § 90.371(b) of this chapter need not be referred to the Commission. Also, the addition of new Marine VHF frequency coordination committee(s) to § 80.514 of this chapter need not be referred to the Commission if they do not involve novel questions of fact, policy or law, as well as requests by the United States Coast Guard to:

* * * * *

PART 1—PRACTICE AND PROCEDURE

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

Authority: 47 U.S.C. 47 U.S.C. 151, 154(i), 154(j), 155, 225, 303(r), 309 and 325(e).

■ 4. Paragraph (d) of § 1.946 is amended by adding the following sentence at the end of paragraph (d) to read as follows:

§ 1.946 Construction and coverage requirements.

* * * * *

(d) * * * This notification requirement is not applicable to authorizations subject to post-license registration requirements under the Dedicated Short-Range Communication Service (DSRCS), subpart M of part 90 of this chapter.

* * * * *

PART 2—FREQUENCY ALLOCATIONS AND RADIO MATTERS; GENERAL RULES AND REGULATIONS

■ 5. The authority citation for part 2 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, and 336, unless otherwise noted.

■ 6. Section 2.106, the Table of Frequency Allocations, is amended by revising page 57 to read as follows:

§ 2.106 Table of Frequency Allocations

* * * * *

BILLING CODE 6712–01–P

International Table			United States Table		FCC Rule Part(s)
Region 1	Region 2	Region 3	Federal Government	Non-Federal Government	
5570-5650 MARITIME RADIONAVIGATION MOBILE except aeronautical mobile 5.446A 5.450A RADIOLOCATION 5.450B			5570-5600 MARITIME RADIONAVIGATION US65 RADIOLOCATION G56 US50 G131	5570-5600 MARITIME RADIONAVIGATION US65 RADIOLOCATION US50	RF Devices (15) Maritime (80) Private Land Mobile (90)
			5600-5650 MARITIME RADIONAVIGATION US65 METEOROLOGICAL AIDS RADIOLOCATION G56	5600-5650 MARITIME RADIONAVIGATION US65 METEOROLOGICAL AIDS RADIOLOCATION	
5.450 5.451 5.452			5.452 US50 G131	5.452 US50	
5650-5725 RADIOLOCATION MOBILE except aeronautical mobile 5.446A 5.450A Amateur Space research (deep space) 5.282 5.451 5.453 5.454 5.455			5650-5925 RADIOLOCATION G2	5650-5830 Amateur 5.150 5.282	RF Devices (15) ISM Equipment (18) Amateur (97)
5725-5830 FIXED-SATELLITE (Earth-to-space) RADIOLOCATION Amateur 5.150 5.451 5.453 5.455 5.456	5725-5830 RADIOLOCATION Amateur 5.150 5.453 5.455				
5830-5850 FIXED-SATELLITE (Earth-to-space) RADIOLOCATION Amateur Amateur-satellite (space-to-Earth) 5.150 5.451 5.453 5.455 5.456	5830-5850 RADIOLOCATION Amateur Amateur-satellite (space-to-Earth) 5.150 5.453 5.455			5830-5850 Amateur Amateur-satellite (space-to-Earth) 5.150	ISM Equipment (18) Amateur (97)
5850-5925 FIXED FIXED-SATELLITE (Earth-to-space) MOBILE 5.150	5850-5925 FIXED FIXED-SATELLITE (Earth-to-space) MOBILE Amateur Radiolocation 5.150	5850-5925 FIXED FIXED-SATELLITE (Earth-to-space) MOBILE Radiolocation 5.150	5.150 US245	5850-5925 FIXED-SATELLITE (Earth-to-space) US245 MOBILE NG160 Amateur 5.150	ISM Equipment (18) Private Land Mobile (90) Personal Radio (95) Amateur (97)
5925-6700 FIXED FIXED-SATELLITE (Earth-to-space) MOBILE			5925-6425	5925-6425 FIXED NG41 FIXED-SATELLITE (Earth-to-space)	International Fixed (23) Satellite Commun. (25) Fixed Microwave (101)

* * * * *

PART 90—PRIVATE LAND MOBILE RADIO SERVICES

■ 7. The authority citation for part 90 continues to read as follows:

Authority: Sections 4(i), 11, 303(g), 303(r) and 332(c)(7) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 161, 303(g), 303(r), 332(c)(7).

■ 8. Section 90.7 is amended by revising the definition of "Dedicated Short Range Communications Services" and adding the definitions of "Communications Zone," "On-Board Unit (OBU)," "Roadside Unit (RSU)," and "Roadway bed surface" in alphabetical order to read as follows:

§ 90.7 Definitions.

* * * * *

Dedicated Short-Range Communications Services (DSRCS). The use of radio techniques to transfer data over short distances between roadside and mobile units, between mobile units, and between portable and mobile units to perform operations related to the improvement of traffic flow, traffic safety, and other intelligent transportation service applications in a variety of environments. DSRCS systems may also transmit status and instructional messages related to the units involved.

* * * * *

Communications zone, The service area associated with an individual fixed Roadside Unit (RSU). The communications zone is determined based on the RSU equipment class specified in section 90.375.

* * * * *

On-Board unit (OBU). An On-Board Unit is a DSRCS transceiver that is normally mounted in or on a vehicle, or which in some instances may be a portable unit. An OBU can be operational while a vehicle or person is either mobile or stationary. The OBUs receive and contend for time to transmit on one or more radio frequency (RF) channels. Except where specifically excluded, OBU operation is permitted wherever vehicle operation or human passage is permitted. The OBUs mounted in vehicles are licensed by rule under part 95 of this chapter and communicate with Roadside Units (RSUs) and other OBUs. Portable OBUs are also licensed by rule under part 95 of this chapter. OBU operations in the Unlicensed National Information Infrastructure (UNII) Bands follow the rules in those bands.

* * * * *

Roadside unit (RSU). A Roadside Unit is a DSRC transceiver that is mounted along a road or pedestrian passageway. An RSU may also be mounted on a vehicle or is hand carried, but it may only operate when the vehicle or hand-carried unit is stationary. Furthermore, an RSU operating under this part is restricted to the location where it is licensed to operate. However, portable or hand-held RSUs are permitted to operate where they do not interfere with a site-licensed operation. A RSU broadcasts data to OBUs or exchanges data with OBUs in its communications zone. An RSU also provides channel assignments and operating instructions to OBUs in its communications zone, when required.

Roadway bed surface. For DSRCS, the road surface at ground level.

■ 9. Section 90.20 is amended by adding the following in the table at paragraph (c)(3) before the entry referencing the 10,550 to 10,680 band, and adding a new paragraph (d)(86) to read as follows:

§ 90.20 Public Safety Pool.

* * * * *

(c) * * *

(3) *Frequencies.*

PUBLIC SAFETY POOL FREQUENCY TABLE

Frequency or band	Class of station(s)	Limitations	Coordinator
	Megahertz		
* * * * * * *			
5850–5925	Base or mobile	86	Not applicable.
* * * * * * *			

* * * * *

(d) * * *

(86) Subpart M of this part contains rules for assignment of frequencies in the 5850–5925 MHz band.

* * * * *

■ 10. Section 90.35 is amended by adding the entry of "5850–5925" before the entry referencing the 10,550 to 10,680 band in paragraph (b)(3), and adding a new paragraph (c)(90) to read as follows:

§ 90.35 Industrial/Business Pool.

* * * * *

(b) * * *

(3) *Frequencies.*

INDUSTRIAL/BUSINESS POOL FREQUENCY TABLE

Frequency or band	Class of station(s)	Limitations	Coordinator
* * * * * * *			
5850–5925	....do	90	Not applicable.
* * * * * * *			

* * * * *

(c) * * *

(90) Subpart M of this part contains rules for assignment of frequencies in the 5850–5925 MHz band.

■ 11. Section 90.149 is amended by adding paragraph (b) to read as follows:

§ 90.149 License term.

* * * * *

(b) Non-exclusive geographic area licenses for DSRCS Roadside Units (RSUs) in the 5850–5925 MHz band will be issued for a term not to exceed ten years from the date of original issuance

or renewal. The registration dates of individual RSUs (see § 90.375) will not change the overall renewal period of the single license.

* * * * *

■ 12. Section 90.155 is amended by adding paragraph (i) to read as follows:

§ 90.155 Time in which station must be placed in operation.

* * * * *

(i) DSRCS Roadside Units (RSUs) in the 5850–5925 MHz band must be placed in operation within 12 months from the date of registration (see § 90.375) or the authority to operate the RSUs cancels automatically (see § 1.955 of this chapter). Such registration date(s) do not change the overall renewal period of the single license.

■ 13. Section 90.157 is revised to read as follows:

§ 90.157 Discontinuance of station operation.

(a) A station license shall cancel automatically upon permanent discontinuance of operations. Unless stated otherwise in this part or in a station authorization, for the purposes of this section, any station which has not operated for one year or more is considered to have been permanently discontinued.

(b) For DSRCS Roadside Units (RSUs) in the 5850–5925 MHz band, it is the DSRCS licensee's responsibility to delete from the registration database any RSUs that have been discontinued.

■ 14. Section 90.175(j) is amended by revising paragraph (j)(16) to read as follows:

§ 90.175 Frequency coordination requirements.

* * * * *

(j) * * *

(16) Applications for DSRCS licenses (as well as registrations for Roadside Units) in the 5850–5925 GHz band.

* * * * *

■ 15. Section 90.179 is amended by revising paragraph (f) to read as follows:

§ 90.179 Shared use of radio stations.

* * * * *

(f) Above 800 MHz, shared use on a for-profit private carrier basis is permitted only by SMR, Private Carrier Paging, LMS, and DSRCS licensees. See subparts M, P, and S of this part.

* * * * *

■ 16. Section 90.205 is amended by revising paragraph (p) to read as follows:

§ 90.205 Power and antenna height limits.

* * * * *

(p) *5850–5925 MHz.* Power and height limitations are specified in subpart M of this part.

* * * * *

■ 17. Section 90.210 is amended by revising the entry for "5850–5925 MHz" and adding footnote 4 in the table and by revising paragraphs (k)(3) introductory text and (k)(4) to read as follows:

§ 90.210 Emission masks.

* * * * *

APPLICABLE EMISSION MASKS

Frequency band (MHz)	Mask for equipment with audio low pass filter	Mask for equipment without audio low pass filter
*	*	*
5850–5925 [4]		

[4] DSRCS Roadside Units equipment in the 5850–5925 MHz band is governed under subpart M of this part.

* * * * *

(k) * * *

(3) *Other transmitters.* For all other transmitters authorized under subpart M that operate in the 902–928 MHz band, the peak power of any emission shall be attenuated below the power of the highest emission contained within the licensee's sub-band in accordance with the following schedule:

* * * * *

(4) In the 902–928 MHz band, the resolution bandwidth of the instrumentation used to measure the emission power shall be 100 kHz, except that, in regard to paragraph (2) of this section, a minimum spectrum analyzer resolution bandwidth of 300 Hz shall be used for measurement center frequencies with 1 MHz of the edge of the authorized subband. The video filter bandwidth shall not be less than the resolution bandwidth.

* * * * *

■ 18. Section 90.213 is amended by revising footnote 10 of the table to read as follows:

§ 90.213 Frequency stability.

* * * * *

[10] Except for DSRCS equipment in the 5850–5925 MHz band, frequency stability is to be specified in the station authorization. Frequency stability for DSRCS equipment in the 5850–5925 MHz band is specified in subpart M of this part.

* * * * *

■ 19. Subpart M, is amended by adding the following undesignated center heading before § 90.371 to read as follows:

* * * * *

Regulations Governing the Licensing and Use of Frequencies in the 5850–5925 MHz Band for Dedicated Short-Range Communications Service (DSRCS)

* * * * *

■ 20. Section 90.371 is amended by revising paragraphs (a) and (b) introductory text and adding paragraph (c) to read as follows:

§ 90.371 Dedicated short-range communications service (DSRCS).

(a) These provisions pertain to systems in the 5850–5925 MHz band for Dedicated Short-Range Communications Service (DSRCS). DSRCS systems use radio techniques to transfer data over short distances between roadside and mobile units, between mobile units, and between portable and mobile units to perform operations related to the improvement of traffic flow, traffic safety, and other intelligent transportation service applications in a variety of environments. DSRCS systems may also transmit status and instructional messages related to the units involved. DSRCS Roadside Units are authorized under this part. DSRCS On-Board Units are authorized under part 95 of this chapter.

(b) DSRCS Roadside Units (RSUs) operating in the band 5850–5925 MHz shall not receive protection from Government Radiolocation services in operation prior to the establishment of the DSRCS station. Operation of DSRCS RSU stations within 75 kilometers of the locations listed in the table below must be coordinated through the National Telecommunications and Information Administration.

* * * * *

(c) NTIA may authorize additional Government Radiolocation services. Once a new Federal assignment is made, the Commission's Universal Licensing System database will be updated, accordingly, to protect the new Federal assignment and the list in paragraph (b) of this section will be updated as soon as practicable.

■ 21. Add § 90.373 to read as follows:

§ 90.373 Eligibility in the DSRCS.

The following entities are eligible to hold an authorization to operate Roadside units in the DSRCS:

(a) Any territory, possession, state, city, county, town or similar governmental entity.

(b) Any entity meeting the eligibility requirements of §§ 90.33 or 90.35.

■ 22. Add § 90.375 to read as follows:

§ 90.375 RSU license areas, communication zones and registrations

(a) DSRCS Roadside Units (RSUs) in the 5850–5925 MHz band are licensed on the basis of non-exclusive geographic areas. Governmental applicants will be issued a geographic area license based on the geo-political area encompassing the legal jurisdiction of the entity. All other applicants will be issued a geographic area license for their proposed area of operation based on county(s), state(s) or nationwide.

(b) Applicants who are approved in accordance with FCC Form 601 will be granted non-exclusive licenses for all non-reserved DSRCS frequencies (*see* § 90.377). Such licenses serve as a prerequisite of registering individual RSUs located within the licensed geographic area described in paragraph (a) of this section. Licensees must register each RSU in the Universal Licensing System (ULS) before operating such RSU. RSU registrations are subject, *inter alia*, to the requirements of § 1.923 of this chapter as applicable (antenna structure registration, environmental concerns, international coordination, and quiet zones). Additionally, RSUs at locations subject to NTIA coordination (*see* § 90.371(b) may not begin operation until NTIA approval is received. Registrations are not effective until the Commission posts them on the ULS.

(c) Licensees must operate each RSU in accordance with the Commission's Rules and the registration data posted on the ULS for such RSU. Licensees must register each RSU for the smallest communication zone needed (for the DSRC-based intelligent transportation systems application) using one of the following four communication zones:

RSU class	Max. output power (dBm) [1]	Communications zone (meters)
A	0	15
B	10	100
C	20	400
D	28.8	1000

[1] The ASTM-DSRC Standard is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and approved by The Director of the Federal Register. Copies may be inspected at the Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554 or 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.* Copies of the ASTM E2213–03 DSRC Standard can be obtained from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428–2959. Copies may also be obtained from ASTM via the Internet at *http://www.astm.org.* The ASTM-DSRC Standard limits output power to 28.8 dBm but allows more power to overcome cable losses to the antenna as long as the antenna input power does not exceed 28.8 dBm and the EIRP does not exceed 44.8 dBm. However, specific channels and categories of uses have additional limitations under the ASTM-DSRC Standard.

■ 23. Add § 90.377 to read as follows:

§ 90.377 Frequencies available; maximum EIRP and antenna height, and priority communications.

(a) Licensees shall transmit only the power (EIRP) needed to communicate with an OBU within the communications zone and must take steps to limit the Roadside Unit (RSU) signal within the zone to the maximum extent practicable.

(b) Frequencies available for assignment to eligible applicants within the 5850–5925 MHz band for RSUs and the maximum EIRP permitted for an RSU with an antenna height not exceeding 6 meters above the roadway bed surface are specified in the table. Where two EIRP limits are given, the higher limit is permitted only for state or local governmental entities.

Channel No.	Frequency range (MHz)	Max. EIRP [1] (dBm)	Channel use
170	5850–5855		Reserved.
172	5855–5865	33	Service Channel.
174	5865–5875	33	Service Channel.
175	5865–5885	23	Service Channel. [2]
176	5875–5885	33	Service Channel.
178	5885–5895	33 / 44.8	Control channel.
180	5895–5905	23	Service Channel.
181	5895–5915	23	Service Channel. [2]
182	5905–5915	23	Service Channel.
184	5915–5925	33 / 40	Service Channel.

[1] An RSU may employ an antenna with a height exceeding 6 meters but not exceeding 15 meters provided the EIRP specified in the table above is reduced by a factor of 20 log(Ht/6) in dB where Ht is the height of the radiation center of the antenna in meters above the roadway bed surface. The EIRP is measured as the maximum EIRP toward the horizon or horizontal, whichever is greater, of the gain associated with the main or center of the transmission beam. The RSU antenna height shall not exceed 15 meters above the roadway bed surface.

[2] Channel Nos. 174/176 may be combined to create a twenty megahertz channel, designated Channel No. 175. Channels 180/182 may be combined to create a twenty-megahertz channel, designated Channel No. 181.

(c) Except as provided in paragraphs (d) and (e) of this section, non-reserve DSRCS channels are available on a shared basis only for use in accordance with the Commission's Rules. All licensees shall cooperate in the selection and use of channels in order to reduce interference. This includes monitoring for communications in progress and any other measures as may be necessary to minimize interference. Licensees of RSUs suffering or causing harmful interference within a communications zone are expected to cooperate and resolve this problem by mutually satisfactory arrangements. If the licensees are unable to do so, the Commission may impose restrictions including specifying the transmitter power, antenna height and direction, additional filtering, or area or hours of operation of the stations concerned. Further the use of any channel at a given geographical location may be

denied when, in the judgment of the Commission, its use at that location is not in the public interest; the use of any channel may be restricted as to specified geographical areas, maximum power, or such other operating conditions, contained in this part or in the station authorization.

(d) *Safety/public safety priority.* The following access priority governs all DSRCS operations:

(1) communications involving the safety of life have access priority over all other DSRCS communications;

(2) subject to a Control Channel priority system management strategy (see ASTM E2213–03 DSRC Standard at § 4.1.1.2(4)) DSRCS communications involving public safety have access priority over all other DSRC communications not listed in paragraph (d)(1) of this section. Roadside Units (RSUs) operated by state or local governmental entities are presumptively engaged in public safety priority communications.

(e) *Non-priority communications.* DSRCS communications not listed in paragraph (d) of this section are non-priority communications. If a dispute arises concerning non-priority communications, the licensee of the later-registered RSU must accommodate the operation of the early registered RSU, *i.e.*, interference protection rights are date-sensitive, based on the date that the RSU is first registered (see § 90.375) and the later registered RSU must modify its operations to resolve the dispute in accordance with paragraph (f) of this section.

(f) Except as otherwise provided in the ASTM-DSRC Standard, as incorporated by reference pursuant to 5 U.S.C. 552(a) and 1 CFR part 51 and approved by the Director of the Federal Register, copies may be inspected at the Federal Communications Commission, 445 12th Street, SW, Washington, DC 20554 or 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.* Copies of the ASTM E2213–03 DSRC Standard can be obtained from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428–2959. Copies may also be obtained from ASTM via the Internet at *http://www.astm.org.* Except as provided in the ASTM–DSRC Standard for the purposes of paragraph (e) of this section objectionable interference will be considered to exist when the Commission receives a complaint and the difference in signal strength between the earlier-registered RSU and the later-registered RSU (anywhere within the earlier-registered RSU's communication zone) is 18 dB or less (co-channel). Later-registered RSUs causing objectionable interference must correct the interference immediately unless written consent is obtained from the licensee of the earlier-registered RSU.

■ 24. Add § 90.379 to read as follows:

§ 90.379 ASTM E2213–03 DSRC Standard (ASTM–DSRC Standard).

Roadside Units operating in the 5850–5925 MHz band shall comply with the following technical standard, which is incorporated by reference: American Society for Testing and Materials (ASTM) E2213–03, "Standard Specification for Telecommunications and Information Exchange Between Roadside and Vehicle Systems—5 GHz Band Dedicated Short Range Communications (DSRC) Medium Access Control (MAC) and Physical Layer (PHY) Specifications" published September 2003 (ASTM E2213–03 DSRC Standard). The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be inspected at the Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554 or 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.* Copies of the ASTM E2213–03 DSRC Standard can be obtained from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428–2959. Copies may also be obtained from ASTM via the Internet at *http://www.astm.org.*

■ 25. Add Section 90.383 to read as follows:

§ 90.383 RSU sites near the U.S./Canada or U.S./Mexico border.

Until such time as agreements between the United States and Canada or the United States and Mexico, as applicable, become effective governing border area use of the 5850–5925 MHz band for DSRCS, authorizations to operate Roadside Units (RSUs) are granted subject to the following conditions:

(a) RSUs must not cause harmful interference to stations in Canada or Mexico that are licensed in accordance with the international table of frequency allocations for Region 2 (see § 2.106 of this chapter) and must accept any interference that may be caused by such stations.

(b) Authority to operate DSRCS Roadside Units is subject to modifications and future agreements between the United States and Canada or the United States and Mexico, as applicable.

■ 26. Section 90.425(d) is amended by adding paragraph (d)(10) to read as follows:

§ 90.425 Station identification.

* * * * *

(d) * * *

(10) It is a Roadside Unit in a DSRCS system.

* * * * *

PART 95—PERSONAL RADIO SERVICES

■ 1. The authority citation for part 95 continues to read as follows:

Authority: Sections 4, 303, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303.

■ 2. Section 95.401 is amended by adding paragraph (g) to read as follows:

§ 95.401 (CB Rule 1) What are the Citizens Band Radio Services?

* * * * *

(g) Dedicated Short-Range Communications Service On-Board Units (DSRCS–OBUs). The rules for this service are contained in subpart L of this part. DSRCS–OBUs may communicate with DSRCS Roadside Units (RSUs), which are authorized under part 90 of this chapter. DSRCS, RSU, and OBU are defined in § 90.7 of this chapter.

■ 27. Section 95.601 is revised to read as follows:

§ 95.601 Basis and purpose.

This section provides the technical standards to which each transmitter (apparatus that converts electrical energy received from a source into RF (radio frequency) energy capable of being radiated) used or intended to be used in a station authorized in any of the Personal Radio Services must comply. This section also provides requirements for obtaining certification for such transmitters. The Personal Radio Services are the GMRS (General Mobile Radio Service)—subpart A, the Family Radio Service (FRS)—subpart B, the R/C (Radio Control Radio Service)—subpart C, the CB (Citizens Band Radio Service)—subpart D, the Low Power Radio Service (LPRS)—subpart G, the Wireless Medical Telemetry Service (WMTS)—subpart H, the Medical Implants Communication Service (MICS)—subpart I, the Multi-Use Radio

Service (MURS)—subpart J, and Dedicated Short-Range Communications Service On-Board Units (DSRCS–OBUs)—subpart L.

■ 28. Section 95.603 is amended by adding a new paragraph (h) to read as follows:

§ 95.603 Certification required.

* * * * *

(h) Each Dedicated Short-Range Communications Service On-Board Unit (DSRCS–OBU) that operates or is intended to operate in the DSRCS (5.850–5.925 GHz) must be certified in accordance with subpart L of this part and subpart J of part 2 of this chapter.

■ 29. Section 95.605 is revised to read as follows:

§ 95.605 Certification procedures.

Any entity may request certification for its transmitter when the transmitter is used in the GMRS, FRS, R/C, CB, IVDS, LPRS, MURS, or MICS following the procedures in part 2 of this chapter. Medical implant transmitters shall be tested for emissions and EIRP limit compliance while enclosed in a medium that simulates human body tissue in accordance with the procedures in § 95.639(g). Frequency stability testing for MICS transmitters shall be performed over the temperature range set forth in § 95.628. Dedicated Short-Range Communications Service On-Board Units (DSRCS–OBUs) must be certified in accordance with subpart L of this part and subpart J of part 2 of this chapter.

■ 30. Section 95.631 is amended by adding a new paragraph (k) to read as follows:

§ 95.631 Emission types.

* * * * *

(k) DSRCS–OBUs are governed under subpart L of this part.

■ 31. Section 95.633 is amended by adding paragraph (g) to read as follows:

§ 95.633 Emission bandwidth.

* * * * *

(g) DSRCS–OBUs are governed under subpart L of this part.

■ 32. Section 95.635 is amended by adding a DSRC–OBU designation to the Table in paragraph (b) and by adding paragraph (f) to read as follows:

§ 95.635 Unwanted radiation.

* * * * *

(b) * * *

Transmitter	Emission type	Applicable paragraphs (b)
*	*	* * *
DSRCS–OBU	As specified in paragraph (f) of this section.	

* * * * *

(f) DSRCS–OBUs are governed under subpart L of this part.

■ 33. Section 95.637 is amended by adding paragraph (f) to read as follows:

§ 95.637 Modulation standards.

* * * * *

(f) DSRCS–OBUs are governed under subpart L of this part.

■ 34. Section 95.639 is amended by adding a new paragraph (i) to read as follows:

§ 95.639 Maximum transmitter power.

* * * * *

(i) DSRCS–OBUs are governed under subpart L of this part, except the maximum output power for portable DSRCS–OBUs is 1.0 mW. For purposes of this paragraph, a portable is a transmitting device designed to be used so that the radiating structure(s) of the device is/are within 20 centimeters of the body of the user.

■ 35. Add § 95.643 after the existing undesignated center heading "Certification Requirements" to read as follows:

§ 95.643 DSRCS–OBU certification.

Sections 95.645 through 95.655 do not apply to certification of DSRCS–OBUs. DSRCS–OBUs must be certified in accordance with subpart L of this part and subpart J of part 2 of this chapter.

■ 36. Part 95 is amended by adding a new Subpart L to read as follows:

Subpart L—Dedicated Short Range Communications Service On-Board Units (DSRCS–OBUs)

Sec.

Subpart L—Dedicated Short-Range Communications Service On-Board Units (DSRCS–OBUs)

§ 95.1501 Scope.

This subpart sets out the regulations governing Dedicated Short-Range Communications Service On-Board Units (DSRCS–OBUs) in the 5850–5925 MHz band. DSRCS Roadside Units (RSUs) are authorized under part 90 of this chapter and DSRCS, RSU, and OBU are defined in § 90.7 of this chapter.

§ 95.1503 Eligibility.

All entities for which the Commission has licensing authority are authorized by rule to operate an FCC certified On-Board Unit in accordance with the rules contained in this subpart. No individual FCC license will be issued. (The FCC does not have authority to license foreign governments or their representatives, nor stations belonging to and operated by the United States Government.)

§ 95.1505 Authorized locations.

Operation of DSRCS On-Board Units is authorized anywhere CB station operation is permitted under § 95.405.

§ 95.1507 Station identification.

A DSRCS On-Board Unit is not required to transmit an FCC station identification announcement.

§ 95.1509 ASTM E2213–03 DSRC Standard.

On-Board Units operating in the 5850–5925 MHz band shall comply with the following technical standards, which are incorporated by reference: American Society for Testing and Materials (ASTM) E2213–03, Standard Specification for Telecommunications and Information Exchange Between Roadside and Vehicle Systems—5 GHz Band Dedicated Short Range Communications (DSRC) Medium Access Control (MAC) and Physical Layer (PHY) Specifications published September 2003 (ASTM E2213–03 DSRC Standard). The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 C.F.R. part 51. Copies may be inspected at the Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554 or 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*. Copies of the ASTM E2213–03 DSRC Standard can be obtained from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428–2959. Copies may also be obtained from ASTM via the Internet at *http://www.astm.org*.

§ 95.1511 Frequencies available.

(a) The following table indicates the channel designations of frequencies available for assignment to eligible

applicants within the 5850–5925 MHz band for On-Board Units (OBUs): [1]

Channel no.	Channel use	Frequency range (MHz)
170	Reserved	5850–5855
172	Service Channel	5855–5865
174	Service Channel	5865–5875
175	Service Channel [2]	5865–5885
176	Service Channel	5875–5885
178	Control channel	5885–5895
180	Service Channel	5895–5905
181	Service Channel [2]	5895–5915
182	Service Channel	5905–5915
184	Service Channel	5915–5925

[2] Channel Nos. 174/176 may be combined to create a twenty megahertz channel, designated Channel No. 175. Channels 180/182 may be combined to create a twenty-megahertz channel, designated Channel No. 181.

(b) Except as provided in paragraph (c) of this section, non-reserve DSRCS channels are available on a shared basis only for use in accordance with the Commission's Rules. All licensees shall cooperate in the selection and use of channels in order to reduce interference. This includes monitoring for communications in progress and any other measures as may be necessary to minimize interference. Licensees suffering or causing harmful interference within a communications zone are expected to cooperate and resolve this problem by mutually satisfactory arrangements. If the licensees are unable to do so, the Commission may impose restrictions including specifying the transmitter power, antenna height and direction, additional filtering, or area or hours of operation of the stations concerned. Further the use of any channel at a given geographical location may be denied when, in the judgment of the Commission, its use at that location is not in the public interest; the use of any channel may be restricted as to specified geographical areas, maximum power, or such other operating conditions, contained in this part or in the station authorization.

(c) *Safety/public safety priority.* The following access priority goveins all DSRCS operations:

(1) Communications involving the safety of life have access priority over all other DSRCS communications;

(2) Subject to a Control Channel priority system management strategy (*see* ASTM E2213–03 DSRC Standard at § 4.1.1.2(4)) DSRCS communications involving public safety have access priority over all other DSRC communications not listed in paragraph (c)(1) of this section. On-Board Units (OBUs) operated by state or local governmental entities are presumptively engaged in public safety priority communications.

(d) *Non-priority communications.* DSRCS communications not listed in paragraph (c) of this section are non-priority communications. If a dispute arises concerning non-priority DSRCS–OBU communications with Roadside Units (RSUs), the provisions of §§ 90.377(e) and (f) of this chapter will apply. Disputes concerning non-priority DSRCS–OBU communications not associated with RSUs are governed by paragraph (b) of this section.

[1] The maximum output power for portable DSRCS–OBUs is 1.0 mW. See § 95.639(i).

[FR Doc. 04–16087 Filed 8–02–04; 8:45 am]
BILLING CODE 6712–01–C

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 04–2131; MB Docket No. 04–79, RM–10873, RM–10874; MB Docket No. 04–83, RM–10878; MB Docket No. 04–85, RM–10880, RM–10881; MB Docket No. 04–86, RM–10882, RM–10883, RM–10884, RM–10885; MB Docket No. 04–87, RM–10886; MB Docket No. 04–88, RM–10887; MB Docket No. 04–89, RM–10888; MB Docket No. 04–90, RM–10889; MB Docket No. 04–91, RM–10890, RM–10891; MB Docket No. 04–92, RM–10892, RM–10893; MB Docket No. 04–93, RM–10894; MB Docket No. 04–94, RM–10895; MB Docket No. 04–95, RM–10896]

Radio Broadcasting Services; Anniston, AL, Asbury, IA, Horseshoe Beach, FL, Keosauqua, IA, Live Oak, FL, Moville, IA, Olathe, CO, Rudd, IA, Somerton, AZ, Sutter Creek, CA, Weiser, ID, Westley, CA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Audio Division grants thirteen reservation proposals requesting to amend the FM Table of Allotments by reserving certain vacant FM allotments for noncommercial educational use in Anniston, Alabama, Asbury, Iowa, Horseshoe Beach, Florida, Keosauqua, Iowa, Live Oak, Florida, Moville, Iowa, Olathe, Colorado, Rudd, Iowa, Somerton, Arizona, Sutter Creek, California, Weiser, Idaho, Westley, California. *See* 69 FR 18860, published April 9, 2004. At the request of American Family Association, the Audio Division grants a petition requesting to reserve vacant Channel 261C3 at Anniston, Alabama for noncommercial educational use. The reference coordinates for Channel *261C3 at Anniston are 33–40–51 North Latitude and 85–48–56 West Longitude. At the request of Radio Bilingue, Inc., the Audio Division grants a petition requesting to reserve vacant Channel 260C3 at Somerton, Arizona for noncommercial educational use. The reference coordinates for Channel *260C3 at Somerton are 32–35–0 North Latitude and 114–35–5 West Longitude. At the request of American Family Association and Calvary Chapel of Amador County, the Audio Division grants petitions requesting to reserve vacant Channel 298A at Sutter Creek, California for noncommercial educational use. The reference coordinates for Channel *298A at Sutter Creek are 38–23–30 North Latitude and 120–48–06 West Longitude. *See* **SUPPLEMENTARY INFORMATION**, *infra*.

DATES: Effective September 7, 2004.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC. 20554.

FOR FURTHER INFORMATION CONTACT: Rolanda F. Smith, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MB Docket Nos. 04–79, 04–83, 04–85, 04–86, 04–87, 04–88, 04–89, 04–90, 04–91, 04–92, 04–93, 04–94, and 04–95 adopted July 14, 2004 and released July 20, 2004. The full text of this Commission decision is available for inspection and copying during regular business hours at the FCC's Reference Information Center, Portals II, 445 Twelfth Street, SW., Room CY-A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY-B402, Washington, DC, 20554, telephone 1–800–378–3160, or via e-mail *http://www.BCPIWEB.com.* The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the General Accounting Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

At the request of American Family Association, Radio Bilingue, Inc., and Starboard Media Foundation, Inc., the Audio Division grants petitions requesting to reserve vacant Channel 238A at Westley, California for noncommercial educational use. The reference coordinates for Channel *238A at Westley are 37–28–13 North Latitude and 121–11–14 West Longitude. At the request of Calvary Chapel of Montrose, the Audio Division grants a petition to reserve vacant Channel 270C2 at Olathe, Colorado for noncommercial educational use. The reference coordinates for Channel

*270C2 at Olathe are 38–36–18 North Latitude and 107–58–54 West Longitude. At the request of Calvary Chapel of Montrose, the Audio Division grants a petition requesting to reserve vacant Channel 293C at Olathe, Colorado for noncommercial educational use. The reference coordinates for Channel *293C at Olathe are 38–37–3 North Latitude and 107–58–33 West Longitude. At the request of Living Proof, Inc., the Audio Division grants a petition requesting to reserve vacant Channel 234C3 at Horseshoe Beach, Florida for noncommercial educational use. The reference coordinates for Channel *234C3 at Horseshoe Beach are 29–26–28 North Latitude and 83–17–15 West Longitude. At the request of Starboard Media Foundation, Inc., the Audio Division grants a petition requesting to reserve vacant Channel 259A at Live Oak, Florida for noncommercial educational use. The reference coordinates for Channel *259A at Live Oak are 30–13–12 North Latitude and 82–54–0 West Longitude. At the request of American Family Association and Starboard Media Foundation, Inc., the Audio Division grants petitions requesting to reserve vacant Channel 238A at Asbury, Iowa for noncommercial educational use. The reference coordinates for Channel *238A at Asbury are 42–30–18 North Latitude and 90–40–46 West Longitude. At the request of University of Iowa and Starboard Media Foundation, Inc., the Audio Division grants petitions requesting to reserve vacant Channel 271C3 at Keosauqua, Iowa for noncommercial educational use. The reference coordinates for Channel *271C3 at Keosauqua are 40–43–48 North Latitude and 91–57–48 West Longitude. At the request of Starboard Media Foundation, Inc., the Audio Division grants a petition requesting to reserve vacant Channel 246A at Moville, Iowa for noncommercial educational use. The reference coordinates for Channel *246A at Moville are 42–29–11 North Latitude and 96–0–36 West Longitude. At the request of American Family Association, the Audio Division grants a petition requesting to reserve vacant Channel 268A at Rudd, Iowa for noncommercial educational use. The reference coordinates for Channel *268A at Rudd are 43–7–34 North Latitude and 92–54–20 West Longitude. At the request of Boise Community Radio Project, Inc., the Audio Division grants a petition requesting to reserve vacant Channel 280C1 at Weiser, Idaho for noncommercial educational use. The reference coordinates for Channel *280C1 at Weiser are 44–20–39 North Latitude and 117–7–14 West Longitude.

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

■ For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR Part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1.The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Alabama, is amended by adding Channel *261C3 and by removing Channel 261C3 at Anniston.

■ 3. Section 73.202(b), the Table of FM Allotments under Arizona, is amended by adding Channel *260C3 and by removing Channel 260C3 at Somerton.

■ 4. Section 73.202(b), the Table of FM Allotments under California, is amended by adding Channel *298A and by removing Channel 298A at Sutter Creek; and by adding Channel *238A and by removing Channel 238A at Westley.

■ 5. Section 73.202(b), the Table of FM Allotments under Colorado, is amended by adding Channel *270C2 and by removing Channel 270C2 at Olathe; and by adding Channel *293C and by removing Channel 293C at Olathe.

■ 6. Section 73.202(b), the Table of FM Allotments under Florida, is amended by adding Channel *234C3 and by removing Channel 234C3 at Horseshoe Beach; and by adding Channel *259A and by removing Channel 259A at Live Oak.

■ 7. Section 73.202(b), the Table of FM Allotments under Idaho, is amended by adding Channel *280C1 and by removing Channel 280C1 at Weiser.

■ 8. Section 73.202(b), the Table of FM Allotments under Iowa, is amended by adding Channel *238A and by removing Channel 238A at Asbury; by adding Channel *271C3 and by removing Channel 271C3 at Keosauqua; by adding Channel *246A and by removing Channel 246A at Moville; and by adding Channel *268A and by removing Channel 268A at Rudd.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 04–17545 Filed 8–2–04; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 040726215–4215–01; I.D. 071604D]

[RIN 0648–AS48]

Fisheries Off West Coast States and in the Western Pacific; Pacific Coast Groundfish Fishery; Pacific Whiting; Routine Management Measure; Closure Authority

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Emergency rule; request for comments.

SUMMARY: This emergency rule establishes routine management measure authority, under the Pacific Coast Groundfish Fishery Management Plan (Pacific Coast Groundfish FMP), to close the Pacific whiting (whiting) primary season fisheries by sector before the sector's whiting allocation is reached in order to minimize impacts on overfished species. This action is necessary to establish a mechanism that can be used to quickly close the commercial whiting primary season fisheries if NMFS estimates that the incidental catch of an overfished species is too high.

DATES: This rule is effective August 3, 2004, through January 31, 2005. Comments must be received no later than 5 p.m., local time on September 2, 2004. Copies of the Record of Decision (ROD), final regulatory flexibility analysis (FRFA), and the Small Entity Compliance Guide for the annual harvest specifications for 2004 are available from D. Robert Lohn, Administrator, Northwest Region (Regional Administrator), NMFS, 7600 Sand Point Way, NE, Seattle, WA 98115–0070.

ADDRESSES: You may submit comments on this emergency rule by I.D. 071604D, by any of the following methods:

- E-mail: *WhitingRoutineClosure.nwr@noaa.gov*. Include the I.D. number in the subject line of the message.
- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.
- Mail: D. Robert Lohn, Administrator, Northwest Region, NMFS, 7600 Sand Point Way NE, Seattle, WA 98115–0070, Attn: Becky Renko.

• Fax: 206–526–6736

Copies of the Final Environmental Impact Statement (FEIS) for the harvest specifications and management measures for the 2004 groundfish fishery is available from Donald McIsaac, Executive Director, Pacific Fishery Management Council (Council), 7700 NE Ambassador Place, Portland, OR 97220, phone: 503–820–2280.

FOR FURTHER INFORMATION CONTACT: Becky Renko (Northwest Region, NMFS) 206–526–6150.

SUPPLEMENTARY INFORMATION:

Electronic Access

This rule is accessible via the Internet at the Office of the **Federal Register**'s website at: *http://www.gpoaccess.gov/fr/index.html.* Background information and documents are available at the NMFS Northwest Region website at *http://www.nwr/noaa.gov/1susufsh/gdfsh01.htm* and at the Council's website at *http://www.pcouncil.org.*

Regulations at § 660.323 (b) authorize the use of routine management measures in the groundfish fishery off Washington, Oregon, and California for the purpose of rebuilding and protecting overfished or depleted stocks. This action is consistent with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) guidance on overfished species management.

Routine Management Measures

The regulatory measures available to manage the West Coast groundfish fisheries include, but are not limited to, harvest guidelines, quotas, landing limits, frequency limits, gear restrictions (escape panels or ports, codend mesh size, etc.), time/area closures, prohibited species, bag and size limits, permits, other forms of effort control, allocation, reporting requirements, and onboard observers. Routine management measures are those regulatory measures that the Council determines are likely to be adjusted on an annual or more frequent basis.

Routine management measures are necessary to meet the varied and interwoven mandates of the Magnuson-Stevens Act and the Pacific Coast Groundfish FMP. These mandates include: implementing the overfished species rebuilding plans, reducing bycatch, preventing overfishing, allowing the harvest of healthy stocks as much as possible while protecting and rebuilding overfished and depleted stocks, and distributing equitably the burden of rebuilding among the sectors. Routine management measures may be used to address a resource problem with an overfished species.

Measures are classified as routine through a rulemaking process. For a measure to be classified as routine, the Council will determine that the measure is appropriate to address a particular management issue. Once a measure is classified as routine, it may be modified thereafter by recommendation of the Council at a single Council meeting, providing it is used for the same intended purpose as the original measure. This allows for a swift adjustment of management measures to respond to updated information received during the fishing year.

Inseason Management of Overfished Species

NMFS made catch projections prior to the start of the fishing year for all West Coast groundfish fisheries to determine whether the Council's preferred management measures would keep harvests of overfished species within their 2004 OYs. These projections included incidental catch estimates of overfished species for the various commercial and recreational directed groundfish fisheries, the tribal fisheries, non-groundfish fisheries, and research activities. As the 2004 fishing year has progressed and new fisheries' data have become available, NMFS has modified and updated the estimates of overfished species total catch.

The Whiting Fishery

The 2004 non-tribal commercial OY for whiting is 215,500 mt (this is calculated by deducting the 32,500 mt tribal allocation and 2,000 mt for research catch and bycatch in non-groundfish fisheries from the 250,000 mt total catch OY). Regulations at 50 CFR 660.323(a)(4) divide the commercial whiting OY into separate allocations for the catcher-processor, mothership, and shore-based sectors. The catcher-processor sector is composed of vessels that harvest and process whiting. The mothership sector is composed of motherships and catcher vessels that harvest whiting for delivery to motherships. Motherships are vessels that process, but do not harvest, whiting. The shore-based sector is composed of vessels that harvest whiting for delivery to land-based processors.

Each commercial sector receives a portion of the commercial OY. For 2004, the catcher-processors received 34 percent (73,270 mt); motherships received 24 percent (51,720 mt); and the shore-based sector received 42 percent (90,510 mt).

Regulations at 50 CFR 660.323(a)(3)(i) describe the primary season for each sector. For catcher-processors, the primary season is the period(s) when at-sea processing is allowed and the fishery is open for the catcher-processor sector. For motherships, the primary season is the period when at-sea processing is allowed and the fishery is open for the mothership sector. The primary season for the shore-based sector is the period when the large-scale target fishery is conducted (when trip limits under § 660.323(b) are not in effect). Before and after the primary seasons, per-trip limits are in effect for whiting. When a sector's allocation is reached, the primary season for that sector is ended.

In 2004, the primary seasons for the non-tribal mothership and catcher-processor sectors began May 15. The shore-based season in most of the Eureka area (between 42° and 40°30′ N. lat.) began on April 1, and the fishery south of 40°30′ N. lat. opened April 15. The shore-based fishery north of 42° N. lat. began on June 15.

As in previous years, most shore-based whiting vessels were issued exempted fishing permits (EFPs) for landing unsorted whiting during the primary season. EFPs allow vessels delivering to shore-based harvesters to delay sorting the catch until offload. Delaying sorting until offload, allows state biologists and industry-hired monitors to collect information on the incidental catch of prohibited species at the processing facilities. Beginning in 2004, all EFP participants have been required to carry video cameras for monitoring full retention at sea. To provide total catch data for monitoring the at-sea processing sectors of the fishery, all at-sea processing vessels voluntarily carry two NMFS-trained observers while participating in the fishery. Total catch data from the whiting fisheries are available more swiftly for use in management decisions than data from many other West Coast groundfish fisheries.

Canary Rockfish Catch in the 2004 Whiting Fisheries

During the early season shore-based fishery off California and the first 2 weeks of the at-sea catcher-processor and mothership fisheries, the incidental catch of canary rockfish was relatively low. However, in early June a single tow taken from the Heceta Bank area, by a vessel in the mothership sector, was estimated to contain 3.9 mt of canary rockfish. This single haul exceeded the 0.9–mt total catch projection for the mothership sector. As of June 9, 2004, the total catch estimate for canary rockfish in the catcher-processor and non-tribal mothership sectors was 4.2 mt, as compared with the projected 2.2

mt. Through June 9, 2004, only 35 percent of the whiting allocation for catcher-processor and non-tribal mothership sectors had been taken. At this time, the primary season fisheries are open for all sectors of the whiting fishery.

In response to the elevated catches of canary rockfish in the whiting fishery, the Council requested that NMFS implement an emergency rule that allows appropriate sectors of the commercial whiting fishery to be closed if the canary rockfish impacts reach 7.3 mt. Therefore, NMFS is publishing this emergency rule to established routine management measure authority, under the Pacific Coast Groundfish FMP, in order to close the whiting primary season fisheries by sector before the sector's whiting allocation is reached and to minimize impacts on overfished species. After implementation of this emergency rule, NMFS plans to use this authority, if appropriate, to implement the new routine management measure recommended by the Council. That is, if NMFS estimates, using the best available data, that 7.3 mt of canary rockfish have been taken in the 2004 whiting fisheries, NMFS will take inseason action and publish a **Federal Register** document to close appropriate sectors of the commercial fisheries.

In addition to the Council's recommendation that NMFS establish routine management measure authority to close the whiting primary season fisheries in order to minimize the impacts on overfished species, the Council also recommended asking the whiting vessel owners to voluntarily avoid areas of known high canary rockfish bycatch. This recommendation applied to all sectors of the whiting fishery.

After the Council's June meeting, commercial whiting fishery data, NMFS trawl survey information, Washington State exempted fishing permit data findings, and other NMFS submersible research data were compiled in an effort to identify areas where high canary rockfish bycatch is likely to occur. On June 23, 2004, NMFS made these maps available to the participants in the whiting fishery to identify geographic locations that are known as areas of high canary rockfish bycatch, and that should be avoided.

Classification

This emergency rule establishes routine management measure authority to close the whiting primary season fisheries by sector before the attainment of the sector allocations in order to address bycatch concerns of overfished species. It is issued under the authority of the Magnuson-Stevens Act and is consistent with the regulations implementing the Pacific Coast Groundfish FMP at 50 CFR part 660.

The Assistant Administrator for Fisheries (AA), NMFS, finds good cause to waive the requirement to provide prior notice and comment on this action pursuant to 5 U.S.C. 553(b)(3)(B) because providing prior notice and opportunity for public comment would be impracticable. The data upon which these recommendations were based were provided to the Council at its June 2004 meeting. There was insufficient time after the meeting to draft this document and to undergo a proposed and final rulemaking before this action needs to be in effect, as explained below. Prior notice and comment would be impracticable because affording prior notice and opportunity for public comment would take too long, thus impeding the Agency's function of managing fisheries to approach, without exceeding, OYs for federally managed species.

Canary rockfish was declared overfished on January 4, 2000 (65 FR 221). A rebuilding plan was adopted into regulation in early 2004 (April 13, 2004, 69 FR 19347). In accordance with the newly adopted rebuilding plan, the coastwide OY for canary rockfish was set very low for 2004. The total projected catch of canary rockfish for the 2004 primary whiting fishery is 7.3 mt. In response to the elevated catches of canary rockfish during early June and concerns that the OY may be exceeded, the Council requested that NMFS develop this emergency rule to allow appropriate sectors of the primary whiting fishery to be closed if the canary rockfish impacts reach 7.3 mt.

Under the Pacific Coast Groundfish FMP and implementing regulations where protection of an overfished stock is required, closed areas or seasons may be used in any commercial fisheries and for any gear type. This action provides a mechanism to close the whiting fisheries before the attainment of the whiting allocations to keep the harvest of an overfished species within their OYs. The whiting fisheries are generally very fast paced and vessels tend to incidentally catch overfished species at sporadic and unpredictable rates. As of July 27, 2004, inseason whiting fisheries data indicates that 5.46 mt of the 7.3 mt of canary rockfish available to the whiting fisheries has been taken. Inseason data also indicates that the shore-based sector of the fishery may attain its whiting allocation and need to be closed as soon as August 17, 2004. If this emergency rule were delayed for a public notice and comment period, the 7.3 mt of canary rockfish available to the fisheries could easily be taken before the completion of the public comment period. Therefore, delaying this rule could result in unexpectedly high bycatch of canary rockfish such that the annual OY, established for rebuilding is exceeded, or that many other portions of the groundfish fishery would have to be closed to make up for bycatch in the whiting fishery.

For the reasons described above, pursuant to 5 U.S.C. 553(d)(3), the AA also finds good cause to waive the 30–day delay in effectiveness, so that this rule may become effective as soon as possible to enable the whiting fishery to close when the 7.3 mt canary rockfish bycatch amount is reached.

This emergency rule has been determined to be not significant for purposes of Executive Order 12866.

This emergency rule is exempt from the procedures of the Regulatory Flexibility Act because the rule is issued without opportunity for prior public comment.

This emergency rule is consistent with the requirements of Executive Order 13175 because it was developed after meaningful consultation with the tribal representative on the Council.

List of Subjects in 50 CFR Part 660

Administrative practice and procedure, American Samoa, Fisheries, Fishing, Guam, Hawaiian Natives, Indians, Northern Mariana Islands, Reporting and recordkeeping requirements.

Dated: July 28, 2004.

William T. Hogarth,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

■ For the reasons set out in the preamble, 50 CFR part 660 is as follows:

PART 660—FISHERIES OFF WEST COAST STATES AND IN THE WESTERN PACIFIC

■ 1. The authority citation for part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 660.323, paragraph (b)(1)(i) is added to read as follows and paragraph (b)(1)(ii) is added and reserved:

§ 660.323 Pacific whiting allocations, allocation attainment, and inseason allocation reapportionment.

* * * * *

(b) * * *

(1) * * *

(i) *Differential trip landing limits and frequency limits based on gear type, closed seasons.* Trip landing and frequency limits that differ by gear type and closed seasons may be imposed or

adjusted on a biannual or more frequent basis for the purpose of rebuilding and protecting overfished or depleted stocks. To achieve the rebuilding of an overfished or depleted stock, the Pacific whiting primary seasons described at § 660.323(3)(i) may be closed for any or all of the fishery sectors identified at § 660.323(4)(i)(A) before the sector allocation is reached.

* * * * *

[FR Doc. 04–17667 Filed 8–2–04; 8:45 am]
BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 031124287–4060–02; I.D. 072804E]

Fisheries of the Exclusive Economic Zone Off Alaska; "Other Species" in the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Prohibition of Retention.

SUMMARY: NMFS is prohibiting retention of Community Development Quota (CDQ) reserve amount of "other species" in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2004 CDQ reserve amount of "other species" in this area.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), July 31, 2004, through 2400 hrs, A.l.t., December 31, 2004.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2004 CDQ reserve amount specified for "other species" in the BSAI is 2,040 metric tons (mt) as established by the 2004 harvest specifications for groundfish of the BSAI (69 FR 9242, February 27, 2004).

In accordance with § 679.20(d)(2), the Administrator, Alaska Region, NMFS, has determined that the 2004 CDQ reserve amount of "other species" in the BSAI has been reached. Therefore, NMFS is requiring that further catches of the CDQ reserve amount of "other species" in the BSAI be treated as a prohibited species in accordance with § 679.21(b).

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such a requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the prohibition of retention of CDQ reserve amount of "other species" in the BSAI.

The AA also finds good cause to waive the 30–day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 28, 2004.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 04–17643 Filed 7–29–04; 2:02 pm]
BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 69, No. 148
Tuesday, August 3, 2004

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150–AH35

Incorporation by Reference of American Society of Mechanical Engineers Boiler and Pressure Vessel Code Cases

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to incorporate by reference the latest revisions of two previously incorporated regulatory guides (RGs) which address NRC review and approval of Code cases published by the American Society of Mechanical Engineers (ASME). The Code cases listed in these RGs have been reviewed by the NRC and found to be acceptable for use as alternatives to requirements in the ASME Boiler and Pressure Vessel Code (BPV Code) pertaining to the construction and inservice inspection of nuclear power plant components.

DATES: Submit comments by October 18, 2004. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only of comments received on or before this date.

ADDRESSES: You may submit comments by any one of the following methods. Please include the following number [RIN 3150–AH35] in the subject line of your comments. Comments on rulemakings 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.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: *SECY@nrc.gov*. If you do not receive a reply confirming that we have received your comments, contact us directly at (301) 415–1966. You may also submit comments via the NRC's rulemaking Web site at *http://ruleforum.llnl.gov*. This site provides the capability to upload comments as files (any format), if your web browser supports that function. Address questions about our rulemaking Web site to Carol Gallagher at (301) 415–5905; e-mail *CAG@nrc.gov*. Comments can also be submitted via the Federal eRulemaking Portal at *http://www.regulations.gov*.

Hand deliver comments to: 11555 Rockville Pike, Rockville, MD 20852, between 7:30 a.m. and 4:15 p.m. on Federal workdays, telephone (301) 415–1966.

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415–1101.

Copies of the draft RGs specified in this rulemaking and other publicly available documents related to this proposed rule, including public comments received, can be viewed electronically on public computers in the NRC Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike, Rockville, MD 20852, Room O–1 F21, and open to the public on Federal workdays from 7:45 a.m. until 4:15 p.m. The PDR reproduction contractor will make copies of documents for a fee. Selected documents, including public comments on the proposed rule, can be viewed and downloaded electronically via the NRC's rulemaking Web site at *http://ruleforum.llnl.gov*.

Publicly available NRC documents created or received in connection with this rulemaking are also available electronically via the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html*. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS, or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at (800) 397–4209, (301) 415–4737 or by e-mail at *PDR@nrc.gov*.

Further information about obtaining documents relevant to this rulemaking, including a list of ADAMS accession numbers, can be found in the "Availability of Documents" Section under the **SUPPLEMENTARY INFORMATION** heading.

FOR FURTHER INFORMATION CONTACT: Harry S. Tovmassian, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–3092, e-mail *HST@nrc.gov*.

SUPPLEMENTARY INFORMATION:

Background

The ASME develops and publishes the BPV Code, which contains the requirements for the design, construction, and inservice inspection (ISI) of nuclear power plant components, and the Code for Operation and Maintenance of Nuclear Power Plants (OM Code), which contains Code requirements for inservice testing (IST) of nuclear power plant components. In response to BPV and OM Code user requests, the ASME develops Code cases which provide alternatives to BPV and OM Code requirements under special circumstances.

Discussion

The NRC staff reviews ASME BPV Code Cases [1], rules upon the acceptability of each Code case, and publishes its findings in RGs. The RGs are revised periodically as new Code cases are published by the ASME. On July 8, 2003 (68 FR 40469), the NRC published a final rule which initiated the practice of incorporating by reference in 10 CFR 50.55a the RGs listing acceptable and conditionally acceptable ASME Code cases. Thus, NRC RG 1.84, Revision 32, Design, Fabrication, and Materials Code Case Acceptability, ASME Section III; NRC RG 1.147, Revisions 0 through 13, Inservice Inspection Code Case Acceptability, ASME Section XI, Division 1; and NRC RG 1.192, Operation and Maintenance Code Case Acceptability, ASME OM Code were incorporated into NRC's regulations. This was done because the previous practice of generally referencing the RGs

[1] The NRC staff also reviews OM Code Cases; however, the regulatory guide listing NRC-approved OM Code Cases is not being revised at this time because no new OM Code Cases have been published by the ASME.

in a footnote to 10 CFR 50.55a did not meet the notice and comment requirements of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*).

This proposed rule would incorporate by reference the latest revisions of the NRC RGs that list acceptable and conditionally acceptable ASME BPV Code Cases. When finalized, RG 1.84, Revision 33, will supersede Revision 32. The proposed rule would incorporate by reference Revision 33 in place of Revision 32, which is currently incorporated by reference in § 50.55a. The final RG 1.147, Revision 14 will supplement Revisions 0–13. The proposed rule would add Revision 14 to the series of RG 1.147 revisions currently incorporated by reference in § 50.55a.

Concurrent with this proposed action, the NRC is publishing draft revisions of the RGs listing acceptable ASME BPV Code Cases for public comment. Interested parties may submit comments to the NRC on the draft revisions in accordance with the instructions published in the **Federal Register** notices announcing the availability of the draft guides (DGs). Comments on the DGs will be considered as part of the RG publication process and will not be addressed in this proposed rulemaking.

Evaluation of Code Cases

When the NRC staff evaluates the ASME Code cases to be incorporated by reference in its RGs, it determines which of the new, revised, or reaffirmed Code cases are acceptable, conditionally acceptable, or unacceptable. When the NRC published the July 8, 2003, rulemaking (68 FR 40469) incorporating by reference RGs 1.84 and 1.147, the regulatory analysis accompanying that action contained a section listing those Code cases which were deemed acceptable or conditionally acceptable. For those Code cases found to be conditionally acceptable, a summary of the basis for the limitations or conditions placed on the application of the Code case was provided. In order to clearly explain NRC's rationale for limitations placed on Code cases and to enhance public participation in the entire rulemaking process, the NRC has prepared a separate draft document entitled "Evaluation of Code Cases in Supplement 12 to the 1998 Edition and Supplement 1 Through Supplement 6 to the 2001 Edition," which now contains this information. Copies of this draft document are available to the public as indicated in the "Availability of Documents" section of this preamble. The public is invited to provide comments on this draft document. Comments should be sent using one of the methods detailed under the **ADDRESSES** heading of the preamble to this proposed rule.

It should be noted that draft RG 1.147 lists Code Cases N–416–3 and N–504–2 as unconditionally acceptable. However, the American Society of Mechanical Engineers recently addressed a revision to Code Case N–504–2. Also, the NRC staff is currently considering a proposed licensee action which would use Code Case N–416–3 in an unanticipated manner. Based on these industry actions, the NRC has determined that conditions are required for the use of Code Cases N–416–3 and N–504–2. This matter is discussed in detail in Paragraph 4.7 of "Evaluation of Code Cases in Supplement 12 to the 1998 Edition and Supplement 1 Through Supplement 6 to the 2001 Edition." Because the industry actions occurred after the draft guide had been published but prior to its release, the NRC is proposing to condition the use of these two Code cases in the final guide unless public comments are received that indicate that the staff's proposed technical bases for the conditions are not applicable, incorrect, unnecessary to provide reasonable assurance of adequate protection to public health and safety and common defense and security, or otherwise not justified in light of the increase in protection to public health and safety or common defense and security that would be provided by imposition of the conditions.

Paragraph-by-Paragraph Discussion

This proposed rule would amend 10 CFR 50.55a to incorporate by reference RG 1.84, Revision 33, in place of Revision 32 and add RG 1.147, Revision 14, to the list of RG 1.147 revisions currently incorporated by reference.

1. Paragraph 50.55a(b)

In § 50.55a(b), (b)(4), and (b)(5), references to the revision number for RG 1.84 would be changed from "Revision 32" to "Revision 33," and references to the revision numbers for RG 1.147 would be changed from "through Revision 13" to "through Revision 14." Revision 33 of RG 1.84 would be incorporated by reference in § 50.55a in place of Revision 32. Revision 14 of RG 1.147 would be incorporated by reference in § 50.55a in addition to all previous revisions, which would remain incorporated by reference.

2. Paragraphs 50.55a(f)(2), (f)(3)(iii)(A), (f)(3)(iv)(A), (f)(4)(ii), (g)(2), (g)(3)(i), (g)(3)(ii), (g)(4)(i), and (g)(4)(ii)

In these paragraphs, the phrase indicating that revisions of RG 1.147 "through Revision 13" are the versions that are incorporated by reference in § 50.55a(b) would be modified to read "through Revision 14."

Plain Language

The Presidential memorandum entitled "Plain Language in Government Writing" (63 FR 31883; June 10, 1998), directed that the Government's writing be in plain language. The NRC requests comments on the proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent using one of the methods detailed under the **ADDRESSES** heading of the preamble to this proposed rule.

Availability of Documents

The NRC is making the documents identified below available to interested persons through one or more of the following:

Public Document Room (PDR). The NRC's Public Document Room is located at 11555 Rockville Pike, Public File Area O–1 F21, Rockville, MD 20082. Copies of publicly available documents related to this rulemaking can be viewed electronically on public computers in the PDR. The PDR reproduction contractor will make copies of documents for a fee.

Rulemaking Web site (Web). The NRC's interactive rulemaking Web site is located at *http://ruleforum.llnl.gov.* Selected documents may be viewed and downloaded electronically via this Web site.

Public Electronic Reading Room (ADAMS). The NRC's Public Electronic Reading Room is located at *http://www.nrc.gov/reading-rm/adams.html.* Through this site, the public can gain access to ADAMS, which provides text and image files of NRC's public documents.

Document	PDR	Web	ADAMS
Proposed Rule—Draft Regulatory Analysis	x	x	ML040480048
Proposed Rule—Draft Evaluation of Code Cases	x	x	ML040480074
Proposed RG 1.84, Rev. 33 (DG–1124)	x	x	ML040850299

Document	PDR	Web	ADAMS
Proposed RG 1.147, Rev. 14 (DG–1125)	x	x	ML040850346
RG 1.84, Revision 32	x		ML030730417
RG 1.147, Revisions 0 to 12	x		ML031560264
RG 1.147, Revision 13	x		ML030730423
Final Rule: Incorporation by Reference of ASME OM and BPV Code Cases (68 FR 40469; July 8, 2003).	x		ML031830007

Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113 (15 U.S.C. 3701 *et seq.*), requires agencies to use technical standards developed or adopted by voluntary consensus standards bodies unless the use of such standards is inconsistent with applicable law or is otherwise impractical. In this action, the NRC would amend its regulations to incorporate by reference RGs that list ASME BPV Code cases which have been approved by the NRC. ASME Code cases, which are ASME–approved alternatives to the provisions of ASME Code editions and addenda, constitute national consensus standards, as defined in Public Law 104–113 and Office of Management and Budget (OMB) Circular A–119. They are developed by bodies whose members (including the NRC and utilities) have broad and varied interests.

The NRC reviews each Section III and Section XI Code Case published by the ASME to ascertain whether its application is consistent with the safe operation of nuclear power plants. Those Code cases found to be generically acceptable are listed in the RGs which are incorporated by reference in § 50.55a(b). Those that are found to be unacceptable are listed in RG 1.193, entitled Code Cases not Approved for Use; but licensees may still seek NRC's approval to apply these Code cases through the relief request process permitted in § 50.55a(a)(3). Other Code cases, which the NRC finds to be conditionally acceptable, are also listed in the RGs which are incorporated by reference along with the modifications and limitations under which they may be applied. If the NRC did not provide for the conditional acceptance of ASME Code Cases, these Code cases would be disapproved outright. The effect would be that licensees would need to submit a larger number of relief requests which would represent an unnecessary additional burden for both the licensee and the NRC. The NRC believes that this situation fits the definition of "impractical," as it applies to Public Law 104–113. For these reasons, the NRC believes that the treatment of ASME BPV Code cases, and modifications and conditions placed on them, in this proposed rule does not conflict with any policy on agency use of consensus standards specified in OMB Circular A–119.

Finding of No Significant Environmental Impact: Environmental Assessment

The Commission has determined under the National Environmental Policy Act of 1969, Public Law 97–190 (42 U.S.C. 4321 *et seq.*), as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment, and, therefore, an environmental impact statement is not required. The basis for this determination is that this rulemaking would not significantly increase the probability or consequences of accidents; no changes would be made in the types of effluents that may be released off site; and there would be no significant increase in public radiation exposure. Therefore, there are no significant radiological impacts associated with the action. Thus, the NRC determines that there would be no significant off site impact to the public from this action.

The NRC has sent a copy of this proposed rule to every State Liaison Officer and requested their comments on this environmental assessment.

Paperwork Reduction Act Statement

This proposed rule decreases the burden on licensees by allowing the use of alternative Code cases. The public burden reduction for this information collection is estimated to average more than five hours per licensee. Additionally, there is an estimated industry-wide reduction of 141 hours for the anticipated reduction in the number of relief requests to use the alternative Code cases. Because the burden for this information collection is insignificant, OMB clearance is not required. Existing requirements were approved by the OMB, approval number 3150–0011.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection unless the requesting document displays a currently valid OMB control number.

Regulatory Analysis

The ASME Code cases listed in the RGs to be incorporated by reference provide voluntary alternatives to the provisions in the ASME BPV Code for design, construction, and inservice inspection of the structures, systems and components used in nuclear power plants. Implementation of these Code cases is not required. Licensees use NRC-approved ASME Code cases to reduce regulatory burden or gain additional operational flexibility. It would be difficult for the NRC to provide these advantages independent of the ASME Code case publication process without a considerable additional resource expenditure by the agency. The NRC has prepared a regulatory analysis addressing the qualitative benefits of the alternatives considered in this proposed rulemaking and comparing the costs associated with each alternative. The regulatory analysis is available for inspection on public computers in the NRC Public Document Room, located at One White Flint North, 11555 Rockville Pike, Rockville, MD 20852, Room O–1 F21. Copies of the draft regulatory analysis are also available to the public as indicated under the "Availability of Documents" section of this preamble.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, Public Law 96–354 (5 U.S.C. 605(b)), the Commission certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule would affect only the licensing and operation of nuclear power plants. The companies that own these plants do not fall within the scope of the definition of "small entities" as set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

Backfit Analysis

The provisions in this proposed rulemaking would permit, but would not require, licensees to apply Code cases that have been reviewed and approved by the NRC, sometimes with modifications or conditions. Therefore, the implementation of an approved Code case would be voluntary and would not constitute a backfit. Thus, the Commission finds that these amendments would not involve any provisions that constitute a backfit as defined in 10 CFR 50.109(a)(1), that the backfit rule would not apply to this proposed rule, and that a backfit analysis is not required.

List of Subjects in 10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire protection, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Part 50.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for Part 50 continues to read as follows:

Authority: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 50.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 50.10 also issued under secs. 101, 185, 68 Stat. 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and appendix Q also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80–50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. Section 50.55a is amended by revising the introductory text of paragraphs (b), (b)(4), and (b)(5), and paragraphs (f)(2), (f)(3)(iii)(A), (f)(3)(iv)(A), (f)(4)(ii), (g)(2), (g)(3)(i), (g)(3)(ii), (g)(4)(i) and (g)(4)(ii) to read as follows:

§ 50.55a Codes and standards.

* * * * *

(b) The ASME Boiler and Pressure Vessel Code and the ASME Code for Operation and Maintenance of Nuclear Power Plants, which are referenced in paragraphs (b)(1), (b)(2), and (b)(3) of this section, were approved for incorporation by reference by the Director of the Office of the Federal Register pursuant to 5 U.S.C. 552(a) and 1 CFR part 51. NRC Regulatory Guide 1.84, Revision 33 [temporarily designated DG–1124], "Design, Fabrication, and Materials Code Case Acceptability, ASME Section III;" NRC Regulatory Guide 1.147, Revision 0 (February 1981), including Revision 1 through Revision 13 and Revision 14 [temporarily designated DG–1125], "Inservice Inspection Code Case Acceptability, ASME Section XI, Division 1;" and Regulatory Guide 1.192, "Operation and Maintenance Code Case Acceptability, ASME OM Code," (June 2003), have been approved for incorporation by reference by the Director of the Office of the Federal Register pursuant to 5 U.S.C. 552(a) and 1 CFR part 51. These regulatory guides list ASME Code cases which the NRC has approved in accordance with the requirements in paragraphs (b)(4), (b)(5), and (b)(6). Copies of the ASME Boiler and Pressure Vessel Code and the ASME Code for Operation and Maintenance of Nuclear Power Plants may be purchased from the American Society of Mechanical Engineers, Three Park Avenue, New York, NY 10016. Single copies of NRC Regulatory Guides 1.84, Revision 33; 1.147, Revision 14; and 1.192 may be obtained free of charge by writing the Reproduction and Distribution Services Section, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; or by fax to 301–415–2289; or by email to *distribution@nrc.gov*. Revisions 0–13 of NRC Regulatory Guide 1.147 are available electronically under accession number ML031560264 in the NRC's Agencywide Document Access and Management System (ADAMS) at *http://www.nrc.gov/reading-rm/adams.html*. For assistance in accessing documents located in ADAMS contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737 or e-mail *PDR@nrc.gov*. Copies of the ASME Codes and NRC Regulatory Guides incorporated by reference in this section may be inspected at the NRC Technical Library, Two White Flint North, 11545 Rockville Pike, Rockville, MD 20852–2738, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

* * * * *

(4) Design, Fabrication, and Materials Code Cases. Licensees may apply the ASME Boiler and Pressure Vessel Code cases listed in NRC Regulatory Guide 1.84, Revision 33, without prior NRC approval subject to the following:

* * * * *

(5) Inservice Inspection Code Cases. Licensees may apply the ASME Boiler and Pressure Vessel Code cases listed in Regulatory Guide 1.147 through Revision 14, without prior NRC approval subject to the following:

* * * * *

(f) * * *

(2) For a boiling or pressurized water-cooled nuclear power facility whose construction permit was issued on or after January 1, 1971, but before July 1, 1974, pumps and valves which are classified as ASME Code Class 1 and Class 2 must be designed and be provided with access to enable the performance of inservice tests for operational readiness set forth in editions and addenda of Section XI of the ASME Boiler and Pressure Vessel Code incorporated by reference in paragraph (b) of this section (or the optional ASME Code cases listed in NRC Regulatory Guide 1.147, through Revision 14, or 1.192 that are incorporated by reference in paragraph (b) of this section) in effect six months before the date of issuance of the construction permit. The pumps and valves may meet the inservice test requirements set forth in subsequent editions of this Code and addenda which are incorporated by reference in paragraph (b) of this section (or the optional ASME Code cases listed in NRC Regulatory Guide 1.147, through Revision 14, or 1.192 that are incorporated by reference in paragraph (b) of this section), subject to the applicable limitations and modifications listed therein.

(3) * * *

(iii) * * *

(A) Pumps and valves, in facilities whose construction permit was issued before November 22, 1999, which are

classified as ASME Code Class 2 and Class 3 must be designed and be provided with access to enable the performance of inservice testing of the pumps and valves for assessing operational readiness set forth in the editions and addenda of Section XI of the ASME Boiler and Pressure Vessel Code incorporated by reference in paragraph (b) of this section (or the optional ASME Code cases listed in NRC Regulatory Guide 1.147, through Revision 14, that are incorporated by reference in paragraph (b) of this section) applied to the construction of the particular pump or valve or the Summer 1973 Addenda, whichever is later.

* * * * *

(iv) * * *

(A) Pumps and valves, in facilities whose construction permit was issued before November 22, 1999, which are classified as ASME Code Class 2 and Class 3 must be designed and be provided with access to enable the performance of inservice testing of the pumps and valves for assessing operational readiness set forth in the editions and addenda of Section XI of the ASME Boiler and Pressure Vessel Code incorporated by reference in paragraph (b) of this section (or the optional ASME Code cases listed in NRC Regulatory Guide 1.147, through Revision 14, that are incorporated by reference in paragraph (b) of this section) applied to the construction of the particular pump or valve or the Summer 1973 Addenda, whichever is later.

* * * * *

(4) * * *

(ii) Inservice tests to verify operational readiness of pumps and valves, whose function is required for safety, conducted during successive 120-month intervals must comply with the requirements of the latest edition and addenda of the Code incorporated by reference in paragraph (b) of this section 12 months before the start of the 120-month interval (or the optional ASME Code cases listed in NRC Regulatory Guide 1.147, through Revision 14, or 1.192 that are incorporated by reference in paragraph (b) of this section), subject to the limitations and modifications listed in paragraph (b) of this section.

* * * * *

(g) * * *

(2) For a boiling or pressurized water-cooled nuclear power facility whose construction permit was issued on or after January 1, 1971, but before July 1, 1974, components (including supports) which are classified as ASME Code Class 1 and Class 2 must be designed and be provided with access to enable the performance of inservice examination of such components (including supports) and must meet the preservice examination requirements set forth in editions and addenda of Section XI of the ASME Boiler and Pressure Vessel Code incorporated by reference in paragraph (b) of this section (or the optional ASME Code cases listed in NRC Regulatory Guide 1.147, through Revision 14, that are incorporated by reference in paragraph (b) of this section) in effect six months before the date of issuance of the construction permit. The components (including supports) may meet the requirements set forth in subsequent editions and addenda of this Code which are incorporated by reference in paragraph (b) of this section (or the optional ASME Code cases listed in NRC Regulatory Guide 1.147, through Revision 14, that are incorporated by reference in paragraph (b) of this section), subject to the applicable limitations and modifications.

(3) * * *

(i) Components (including supports) which are classified as ASME Code Class 1 must be designed and be provided with access to enable the performance of inservice examination of these components and must meet the preservice examination requirements set forth in the editions and addenda of Section XI of the ASME Boiler and Pressure Vessel Code incorporated by reference in paragraph (b) of this section (or the optional ASME Code cases listed in NRC Regulatory Guide 1.147, through Revision 14, that are incorporated by reference in paragraph (b) of this section) applied to the construction of the particular component.

(ii) Components which are classified as ASME Code Class 2 and Class 3 and supports for components which are classified as ASME Code Class 1, Class 2, and Class 3 must be designed and be provided with access to enable the performance of inservice examination of these components and must meet the preservice examination requirements set forth in the editions and addenda of Section XI of the ASME Boiler and Pressure Vessel Code incorporated by reference in paragraph (b) of this section (or the optional ASME Code cases listed in NRC Regulatory Guide 1.147, through Revision 14, that are incorporated by reference in paragraph (b) of this section) applied to the construction of the particular component.

* * * * *

(4) * * *

(i) Inservice examinations of components and system pressure tests conducted during the initial 120-month inspection interval must comply with the requirements in the latest edition and addenda of the Code incorporated by reference in paragraph (b) of this section on the date 12 months before the date of issuance of the operating license (or the optional ASME Code cases listed in NRC Regulatory Guide 1.147, through Revision 14, that are incorporated by reference in paragraph (b) of this section), subject to the limitations and modifications listed in paragraph (b) of this section.

(ii) Inservice examination of components and system pressure tests conducted during successive 120-month inspection intervals must comply with the requirements of the latest edition and addenda of the Code incorporated by reference in paragraph (b) of this section 12 months before the start of the 120-month inspection interval (or the optional ASME Code cases listed in NRC Regulatory Guide 1.147, through Revision 14, that are incorporated by reference in paragraph (b) of this section), subject to the limitations and modifications listed in paragraph (b) of this section.

* * * * *

Dated at Rockville, Maryland, this 21st day of July, 2004.

For the Nuclear Regulatory Commission.

Luis A. Reyes,

Executive Director for Operations.

[FR Doc. 04–17609 Filed 8–2–04; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–18670; Directorate Identifier 2002–NM–83–AD]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model DC–10–10, and DC–10–10F Airplanes; Model DC–10–15 Airplanes; Model DC–10–30 and DC–10–30F (KC–10A and KDC–10) Airplanes; Model DC–10–40 and DC–10–40F Airplanes; and Model MD–10–10F and MD–10–30F Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede an existing airworthiness directive (AD) for certain McDonnell Douglas transport category airplanes.

That AD currently requires implementation of a program of structural inspections to detect and correct fatigue cracking in order to ensure the continued airworthiness of these airplanes as they approach the manufacturer's original fatigue design life goal. This proposed AD would require the implementation of a program of structural inspections of baseline structure to detect and correct fatigue cracking in order to ensure the continued airworthiness of these airplanes as they approach the manufacturer's original fatigue design life goal. This proposed AD is prompted by a significant number of these airplanes approaching or exceeding the design service goal on which the initial type certification approval was predicated. We are proposing this AD to detect and correct fatigue cracking that could compromise the structural integrity of these airplanes.

DATES: We must receive comments on this proposed AD by September 17, 2004.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, room PL–401, Washington, DC 20590.
- Fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

You can get the service information identified in this proposed AD from Boeing Commercial Airplanes, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024).

You may examine the contents of this AD docket on the Internet at *http://dms.dot.gov,* or at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Ron Atmur, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5224; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION:

Docket Management System (DMS)

The FAA has implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, new AD actions are posted on DMS and assigned a docket number. We track each action and assign a corresponding directorate identifier. The DMS AD docket number is in the form "Docket No. FAA–2004–99999." The Transport Airplane Directorate identifier is in the form "Directorate Identifier 2004–NM–999–AD." Each DMS AD docket also lists the directorate identifier ("Old Docket Number") as a cross-reference for searching purposes.

Comments Invited

We invite you to submit any written relevant data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES.** Include "Docket No. FAA–2004–18670; Directorate Identifier 2002–NM–83–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of our docket Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *http://dms.dot.gov.*

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications that affect you. You can get more information about plain language at *http://www.faa.gov/language* and *http://www.plainlanguage.gov.*

Examining the Docket

You may examine the AD docket in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

On November 6, 1995, we issued Airworthiness Directive (AD) 95–23–09, amendment 39–9429 (60 FR 61649, December 1, 1995), for certain McDonnell Douglas transport category airplanes. That AD requires implementation of a program of structural inspections to detect and correct fatigue cracking in order to ensure the continued airworthiness of these airplanes as they approach the manufacturer's original fatigue design life goal. That AD was prompted by data submitted by the manufacturer indicating that certain revisions to the program are necessary in order to clarify some principal structural elements (PSE) and some non-destructive inspection (NDI) procedures. We issued that AD to prevent fatigue cracking that could compromise the structural integrity of those airplanes.

Supplemental Inspection Documents (SIDs) ADs

In the early 1980's, as part of our continuing work to maintain the structural integrity of older transport category airplanes, we concluded that the incidence of fatigue cracking may increase as these airplanes reach or exceed their design service goal (DSG). A significant number of these airplanes were approaching or had exceeded the DSG on which the initial type certification approval was predicated. In light of this, and as a result of increased utilization, longer operational lives, and the high levels of safety expected of the currently operated transport category airplanes, we determined that a supplemental structural inspection program (SSIP) was necessary to ensure a high level of structural integrity for all airplanes in the transport fleet.

Issuance of Advisory Circular

As a follow-on from that determination, we issued Advisory Circular (AC) No. 91–56, "Supplemental Structural Inspection Program for Large Transport Category Airplanes," dated May 6, 1981. That AC provides guidance material to manufacturers and

operators for use in developing a continuing structural integrity program to ensure safe operation of older airplanes throughout their operational lives. This guidance material applies to transport airplanes that were certified under the fail-safe requirements of part 4b ("Airplane Airworthiness, Transport Categories") of the Civil Air Regulations of the Federal Aviation Regulations (FAR) (14 CFR part 25), and that have a maximum gross weight greater than 75,000 pounds. The procedures set forth in that AC are applicable to transport category airplanes operated under subpart D ("Special Flight Operations") of part 91 of the FAR (14 CFR part 91); part 121 ("Operating Requirements: Domestic, Flag, and Supplemental Operations"); part 125 ("Certification and Operations: Airplanes having a Seating Capacity of 20 or More Passengers or a Maximum Payload of 6,000 Pounds or More"); and part 135 ("Operating Requirements: Commuter and On-Demand Operations") of the FAR (14 CFR parts 121, 125, and 135). The objective of the SSIP was to establish inspection programs to ensure timely detection of fatigue cracking.

Aging Aircraft Safety Act (AASA)

In October 1991, Congress enacted Title IV of Public Law 102–143, the AASA of 1991, to address aging aircraft concerns. That Act instructed the FAA administrator to prescribe regulations that will ensure the continuing airworthiness of aging aircraft.

SSID Team

In April 2000 the Transport Airplane Directorate (TAD) chartered a SSID Team to develop recommendations to standardize the SID/SSID ADs regarding the treatment of repairs, alterations, and modifications (RAMs). The report can be accessed at *http://www.faa.gov/certification/aircraft/transport.htm*.

FAA Responses to AASA

In addition to the SSID Team activity, there are other on-going activities associated with FAA's Aging Aircraft Program. This includes, among other initiatives, our responses to the AASA.

On November 1, 2002, as one of the responses to the AASA, we issued the Aging Airplane Safety Interim Final Rule (AASIFR) (67 FR 72726, December 6, 2002). The applicability of that rule addresses airplanes that are operated under part 121 of the FAR (14 CFR part 121), all U.S. registered multi-engine airplanes operated under part 129 of the FAR (14 CFR part 129), and all multi-engine airplanes used in scheduled operations under part 135 of the FARs (14 CFR part 135). The AASIFR requires the maintenance programs of those airplanes to include damage tolerance-based inspections and procedures that include all major structural RAMs. Currently, the ASSIFR requires that these procedures be established and incorporated within four years after December 8, 2003, the effective date specified by the AASIFR.

Public Technical Meeting

The TAD also held a public meeting regarding standardization of the FAA approach to RAMs in SID/SSID ADs on February 27, 2003, in Seattle, Washington. We presented our views and heard comments from the public concerning issues regarding the standardization of the requirements of ADs for certain transport category airplanes that mandate SSIDs, and that address the treatment of RAMs for those certain transport category airplanes. Our presentation included a plan for the standardization of SID/SSID ADs, the results of the SSID Team findings, and the TAD vision of how SID/SSID ADs may support compliance to the AASIFR. We also asked for input from operators on the issues addressing RAMs in SID/SSID ADs. One of the major comments presented at the public meeting was that operators do not have the capability to accomplish the damage tolerance assessments, and they will have to rely on the manufacturers to perform those assessments. Furthermore, the operators believe that the timeframes to accomplish the damage tolerance assessments will not permit manufacturers to support the operators. Another major comment presented was from the Airworthiness Assurance Working Group (AAWG) of the Aviation Rulemaking Advisory Committee (ARAC). The AAWG requested that we withdraw the damage tolerance requirements from the final rule and task AAWG to develop a new RAM damage tolerance based program with timelines to be developed by ARAC. The public meeting presentations can be accessed at *http://www.faa.gov/certification/aircraft/transport.htm*.

Explanation of Relevant Service Information

We have reviewed Boeing Report No. L26–012, "DC–10 Supplemental Inspection Document (SID)," Volume I, Revision 6, dated February 2002. The SID provides a description of PSEs and NDI procedures and thresholds with repetitive inspection intervals for inspections of PSEs. For the purposes of this proposed AD, a PSE is defined as an element that contributes significantly to the carrying of flight, ground or pressurization loads, and the integrity of that element is essential in maintaining the overall structural integrity of the airplane. Certain planning data (inspection threshold and repetitive inspections) and reporting requirements defined in Section 2 of Volume III–94, of the SID have been removed and are now included in Volume 1 of Revision 6 of the SID. We have determined that accomplishment of the actions specified in the service information will adequately address the unsafe condition.

We also have reviewed McDonnell Douglas Report No. MDC 91K0264, "DC–10/KC–10 Aging Aircraft Repair Assessment Program Document," Revision 1, dated October 2000, which provides procedures to determine the appropriate inspection or replacement program for certain repairs to the fuselage pressure boundary. These repairs and inspection/replacement programs are acceptable alternative methods of compliance for the repair and repair inspection programs specified in this proposed AD.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require implementation of a structural inspection program of baseline structure to detect and correct fatigue cracking in order to ensure the continued airworthiness of airplanes as they approach the manufacturer's original fatigue design life goal.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other products of this same type design. Therefore, we are proposing this AD, which would supersede AD 95–23–09. This proposed AD would continue to require revision of the FAA-approved maintenance program. This proposed AD would also require implementation of a structural inspection program of baseline structure to detect and correct fatigue cracking in order to ensure the continued airworthiness of airplanes as they approach the manufacturer's original fatigue design life goal. The following paragraphs summarize certain specific actions proposed in this AD.

Editorial Clarification of References

Paragraph (g) of AD 95–23–09 requires, among other things, that the maintenance program be revised to include the inspection threshold and

repetitive inspections (planning data) defined in Section 2 of Volume III–94 of the SID. Paragraph (g)(4) of AD 95–23–09 also requires inspection results to be reported per Section 2 of Volume III–94. Those planning and data reporting requirements are now contained in Section 4 of Volume I, Revision 6, dated February 2002. Therefore, this NPRM proposes use of the information in Section 4 of Volume 1 of Revision 6, and reference to Volume III has been removed in the new requirements of this proposed AD.

Revision of the Maintenance Program

Paragraph (i) of the proposed AD would require a revision of the maintenance inspection program that provides for inspection(s) of the PSE per Boeing Report No. L26–012, "DC–10 Supplemental Inspection Document (SID)," Volume 1, Revision 6, dated February 2002. PSEs are also defined and specified in the SID. All references in this proposed AD to the "SID" are to Revision 6, dated February 2002.

Supplemental Inspection Program (SIP)

Paragraph (j) of the proposed AD would specify that the SIP be implemented on a PSE-by-PSE basis before structure exceeds its 75% fatigue life threshold ($^3/_4N_{th}$), and its full fatigue life threshold (N_{th}). The threshold value is defined as the life of the structure measured in total landings, when the probability of failure reaches one in a billion. The DC–10 SID program is not a sampling program. All airplanes would be inspected once prior to reaching both PSE thresholds (once by $^3/_4N_{th}$ and once by N_{th}). In order for the inspection to have value, no PSE would be inspected prior to half of the fatigue life threshold, $^1/_2N_{th}$. The additional $^3/_4N_{th}$ threshold aids in advancing the threshold for some PSEs as explained in Section 3 of Volume I of the SID. Inspection of each PSE should be accomplished in accordance with the NDI procedures set forth in Section 2 of Volume II, Revision 8, dated November 2003.

Once threshold N_{th} is passed, the PSE would be inspected at repetitive intervals not to exceed ΔNDI/2 as specified in Section 3 of Volume I of the SID per the NDI procedure, which is specified in Section 2 of Volume II of the SID. The definition of ΔNDI/2 is half of the life for a crack to grow from a given NDI detectable crack size to instability.

SIP Inspection Requirements

Paragraph (k) of this proposed AD also would require, for airplanes that have exceeded the N_{th}, that each PSE be inspected prior to reaching the established thresholds ($^3/_4N_{th}$ and N_{th}) or within 18 months after the effective date of this AD. The entire PSE must be inspected regardless of whether or not it has been repaired, altered, or modified. If any PSE is repaired, altered, or modified, it must be reported as "discrepant." A discrepant report indicates that a PSE could not be completely inspected because the NDI procedure could not be accomplished due to differences on the airplane from the NDI reference standard (*i.e.*, RAMs).

Reporting Requirements

Paragraph (l) of this proposed AD would require that all negative, positive, or discrepant findings of the inspection accomplished in paragraph (b) of the AD be reported to Boeing at the times specified, and in accordance with, the instructions contained in Section 3 of Volume 1 of the SID.

Corrective Action

Paragraph (m) of this proposed AD would require that any cracked structure detected during any inspection required per paragraph (g) of this AD be repaired before further flight. Additionally, paragraph (i) of this AD would require accomplishment of follow-on actions as specified in paragraphs (i)(1), (i)(2), and (i)(3) of this proposed AD, at the times specified below.

1. Within 18 months after repair, accomplish a Damage Tolerance Assessment (DTA) that defines the threshold for inspection and submit the assessment for approval to the Manager, Los Angeles Aircraft Certification Office (ACO), FAA.

2. Prior to reaching 75% of the threshold, submit the inspection methods and repetitive inspections intervals for the repair for approval by the Manager of the Los Angeles ACO.

3. Prior to the threshold, the inspection method and repetitive inspection intervals are to be incorporated into the FAA-approved structural maintenance or inspection program for the airplane.

For the purposes of this proposed AD, the FAA anticipates that submissions of the DTA of the repair, if acceptable, should be approved within six months after submission.

Transferability of Airplanes

Paragraph (n) of this proposed AD specifies the requirements of the inspection program for transferred airplanes. Before any airplane that is subject to this proposed AD can be added to an air carrier's operations specifications, a program for the accomplishment of the inspections required by this proposed AD must be established. Paragraph (n) of the proposed AD would require accomplishment of the following:

1. For airplanes that have been inspected per this proposed AD, the inspection of each PSE must be accomplished by the new operator per the previous operator's schedule and inspection method, or per the new operator's schedule and inspection method, at whichever time would result in the earlier accomplishment date for that PSE inspection. The compliance time for accomplishment of this inspection must be measured from the last inspection accomplished by the previous operator. After each inspection has been performed once, each subsequent inspection must be performed per the new operator's schedule and inspection method.

2. For airplanes that have not been inspected per this proposed AD, the inspection of each PSE must be accomplished either prior to adding the airplane to the air carrier's operations specification, or per a schedule and an inspection method approved by the FAA. After each inspection has been performed once, each subsequent inspection must be performed per the new operator's schedule.

Accomplishment of these actions will ensure that: (1) An operator's newly acquired airplanes comply with its SSIP before being operated; and (2) frequently transferred airplanes are not permitted to operate without accomplishment of the inspections defined in the SSID.

Inspections Accomplished Previously

Paragraph (o) of this proposed AD merely provides approval of Boeing Report No. L26–012, "DC–10 Supplemental Inspection Document (SID)," Volume I, Revision 4, dated June 1993, and Revision 5, dated October 1994; and Volume II, Revision 6, dated October 1997, and Revision 7, dated August 2002; as acceptable for compliance with the requirements of paragraph (j) of this proposed AD for inspections accomplished prior to the effective date of the proposed AD.

Acceptable for Compliance

Paragraph (p) of this proposed AD also provides approval of McDonnell Douglas Report No. MDC 91K0264, "DC–10/KC–10 Aging Aircraft Repair Assessment Program Document," Revision 1, dated October 2000, as an acceptable means compliance with the requirements of paragraphs (i) and (m) of this proposed AD for repairs and inspection/replacement for certain repairs to the fuselage pressure shell

accomplished prior to the effective date of the proposed AD.

Change to Existing AD

This proposed AD would retain certain requirements of AD 95–23–09. Since AD 95–23–09 was issued, the AD format has been revised, and certain paragraphs have been rearranged. As a result, the corresponding paragraph identifiers have changed in this proposed AD, as listed in the following table:

REVISED PARAGRAPH IDENTIFIERS

Requirement in AD 95–23–09	Corresponding requirement in this proposed AD
paragraph (a)	paragraph (f).
paragraph (b)	paragraph (g).
paragraph (c)	paragraph (h).

Interim Action

This is considered to be interim action. We are currently considering requiring damage tolerance-based inspections and procedures that include all major structural RAMs, which may result in additional rulemaking. That rulemaking may include appropriate recommendations from the previously mentioned FAA team and a public meeting on how to address RAMs.

Costs of Compliance

There are about 419 McDonnell Douglas transport category airplanes worldwide of the affected design. This proposed AD would affect about 249 airplanes of U.S. registry and 13 U.S. operators.

The incorporation of the SID program into an operator's maintenance program, as required by AD 95–23–09, and retained in this proposed AD takes about 1,290 work hours per airplane, at an average labor rate of $65 per work hour. Based on these figures, the cost to the 13 affected U.S. operators to incorporate the SID program is estimated to be $1,090,050.

The recurring inspection costs, as required by AD 95–23–09, are estimated to be 365 work hours per airplane per year, at an average labor rate of $65 per work hour. Based on these figures, the recurring inspection costs required by AD 95–23–09 are estimated to be $23,725 per airplane, or $5,907,525 for the affected U.S. fleet.

Since no new recurring inspection procedures have been added to the program by this new proposed AD action, there is no additional economic burden on affected operators to perform any additional recurrent inspections.

Additionally, the number of required work hours for each proposed inspection (and the SID program), as indicated above, is presented as if the accomplishment of those actions were to be conducted as "stand alone" actions. However, in actual practice, these actions for the most part will be accomplished coincidently or in combination with normally scheduled airplane inspections and other maintenance program tasks. Further, any costs associated with special airplane scheduling are expected to be minimal.

Regulatory Findings

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

For the reasons discussed above, I certify that the proposed regulation:

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

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

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

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by removing amendment 39–9429 (60 FR 61649 FR, December 1, 1995) and adding the following new airworthiness directive (AD):

McDonnell Douglas: Docket No. FAA–2004–18670; Directorate Identifier 2002–NM–83–AD.

Comments Due Date

(a) The Federal Aviation Administration must receive comments on this airworthiness directive (AD) action by September 17, 2004.

Affected ADs

(b) This AD supersedes AD 95–23–09, amendment 39–9429.

Applicability: (c) This AD applies to all McDonnell Douglas Model DC–10–10, and DC–10–10F airplanes; Model DC–10–15 airplanes; Model DC–10–30 and DC–10–30F (KC–10A and KDC–10) airplanes; Model DC–10–40 and DC–10–40F airplanes; and Model MD–10–10F and MD–10–30F airplanes; certificated in any category.

Unsafe Condition

(d) This AD was prompted by a significant number of these airplanes approaching or exceeding the design service goal on which the initial type certification approval was predicated. We are issuing this AD to detect and correct fatigue cracking that could compromise the structural integrity of these airplanes.

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

Restatement of Certain Requirements of AD 95–23–09

(f) Within 6 months after November 24, 1993 (the effective date of AD 93–17–09, amendment 39–8680), incorporate a revision into the FAA-approved maintenance inspection program which provides for inspection(s) of the Principal Structural Elements (PSE's) defined in Section 2 of Volume I of McDonnell Douglas Report No. L26–012, "DC–10 Supplemental Inspection Document (SID)," Revision 3, dated December 1992, in accordance with Section 2 of Volume III–92, dated October 1992, of the SID. The non-destructive inspection (NDI) techniques set forth in Section 2 and Section 4 of Volume II, Revision 3, dated December 1992, of the SID provide acceptable methods for accomplishing the inspections required by this paragraph. All inspection results (negative or positive) must be reported to McDonnell Douglas, in accordance with the instructions contained in Section 2 of Volume III–92, dated October 1992, of the SID. Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120–0056.

(1) For those Fleet Leader Operator Sampling (FLOS) PSE's that do not have a Normal Maintenance Visual Inspection specified in Section 4 of Volume II, Revision 3, dated December 1992, of the SID, the procedure for general visual inspection is as follows: Perform an inspection of the general PSE area for cleanliness, presence of foreign objects, security of parts, cracks, corrosion, and damage.

(2) For PSE's 53.10.031E/.032E, 53.10.047E/.048E, and 57.10.029E/.030E: The ENDDATE for these PSE's is October 1993.

(For these PSE's, disregard the June 1993 ENDDATE specified in Section 2 of Volume III–92, dated October 1992, of the SID.)

(g) Within 6 months after December 1, 1995 (the effective date of AD 95–23–09, amendment 39–9429), replace the revision of the FAA-approved maintenance inspection program required by paragraph (f) of this AD with a revision that provides for inspection(s) of the PSE's defined in Section 2 of Volume I of McDonnell Douglas Report No. L26–012, "DC–10 Supplemental Inspection Document (SID)," Revision 5, dated October 1994, in accordance with Section 2 of Volume III–94, dated November 1994, of the SID. The NDI techniques set forth in Section 2 of Volume II, Revision 5, dated October 1994, of the SID provide acceptable methods for accomplishing the inspections required by this paragraph.

(1) Prior to reaching the threshold (N_{th}), but no earlier than one-half of the threshold ($N_{th}/2$), specified for all PSE's listed in Volume III–94, dated November 1994, of the SID, inspect each PSE sample in accordance with the NDI procedures set forth in Section 2 of Volume II, Revision 5, dated October 1994. Thereafter, repeat the inspection for that PSE at intervals not to exceed DNDI/2 of the NDI procedure that is specified in Volume III–94, dated November 1994, of the SID.

(2) This AD does not require visual inspections of FLOS PSE's on airplanes listed in Volume III–94, dated November 1994, of the SID planning data at least once during the specified inspection interval, in accordance with Section 2 of Volume III–94, dated November 1994, of the SID.

(3) For PSE's 53.10.055/.056E, 55.10.013/.014B, 53.10.005/.006E, 53.10.031/.032E, 53.10.047/.048E, 57.10.029/.030E: The EDATE for these PSE's is June 1998. (For these PSE's, disregard the June 1996 EDATE specified in Section 2, of Volume III–94, dated November 1994, of the SID.)

(4) All inspection results (negative or positive) must be reported to McDonnell Douglas in accordance with the instructions contained in Section 2 of Volume III–94, dated November 1994, of the SID. Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120–0056.

(h) Any cracked structure detected during the inspections required by paragraph (f) or (g) of this AD must be repaired before further flight, in accordance with a method approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA.

Note 1: Requests for approval of any PSE repair that would affect the FAA-approved maintenance inspection program required by this AD should include a damage tolerance assessment for that PSE repair.

New Requirements of This AD

Revision of the Maintenance Inspection Program

(i) Within 12 months after the effective date of this AD, incorporate a revision into the FAA-approved maintenance inspection program that provides for inspection(s) of the PSEs, in accordance with Boeing Report No. L26–012, "DC–10 Supplemental Inspection Document (SID)," Volume I, Revision 6, dated February 2002." Unless otherwise specified, all further references in this AD to the "SID" are to Revision 6, dated February 2002.

Non-Destructive Inspections (NDIs)

(j) For all PSEs listed in Section 2 of Volume I of the SID, perform an NDI for fatigue cracking of each PSE in accordance with the NDI procedures specified in Section 2 of Volume II, Revision 8, dated November 2003, of the SID, at the times specified in paragraph (j)(1), (j)(2), or (j)(3) of this AD, as applicable.

(1) For airplanes that have less than three quarters of the fatigue life threshold ($^3/_4N_{th}$) as of the effective date of the AD: Perform an NDI for fatigue cracking no earlier than one-half of the threshold ($^1/_2N_{th}$) but prior to reaching three-quarters of the threshold ($^3/_4N_{th}$), or within 18 months after the effective date of this AD, whichever occurs later. Inspect again prior to reaching the threshold (N_{th}), but no earlier than ($^3/_4N_{th}$). Thereafter, after passing the threshold (N_{th}), repeat the inspection for that PSE at intervals not to exceed ΔNDI/2.

(2) For airplanes that have reached or exceeded three-quarters of the fatigue life threshold ($^3/_4N_{th}$), but less than the threshold (N_{th}), as of the effective date of the AD: Perform an NDI prior to reaching the threshold (N_{th}), or within 18 months after the effective date of this AD, whichever occurs later. Thereafter, after passing the threshold (N_{th}), repeat the inspection for that PSE at intervals not to exceed ΔNDI/2.

(3) For airplanes that have reached or exceeded the fatigue life threshold (N_{th}) as of the effective date of the AD: Perform an NDI within 18 months after the effective date of this AD. Thereafter, repeat the inspection for that PSE at intervals not to exceed ΔNDI/2.

Discrepant Findings

(k) If any discrepancy (*e.g.*, differences on the airplane from the NDI reference standard, such as PSEs that have been repaired, altered, or modified) is detected during any inspection required by paragraph (j) of this AD, accomplish the action specified in paragraph (k)(1) or (k)(2) of this AD, as applicable.

(1) If a discrepancy is detected during any inspection performed prior to $^3/_4N_{th}$ or N_{th}: The area of the PSE affected by the discrepancy must be inspected prior to N_{th} per a method approved by the Manager, Los Angeles ACO, FAA.

(2) If a discrepancy is detected during any inspection performed after N_{th}: The area of the PSE affected by the discrepancy must be inspected prior to the accumulation of an additional ΔNDI/2, measured from the last non-discrepant inspection finding, per a method approved by the Manager of the Los Angeles ACO.

Reporting Requirements

(l) All negative, positive, or discrepant (discrepant finding examples are described in paragraph (k) of this AD) findings of the inspections accomplished under paragraph (o) of this AD must be reported to Boeing, at the times specified in, and in accordance with the instructions contained in, Section 4 of Volume I of the SID. Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120–0056.

Corrective Actions

(m) Any cracked structure of a PSE detected during any inspection required by paragraph (j) of this AD must be repaired before further flight in accordance with an FAA-approved method. Accomplish follow-on actions described in paragraphs (m)(1), (m)(2), and (m)(3) of this AD, at the times specified.

(1) Within 18 months after repair, perform a damage tolerance assessment (DTA) that defines the threshold for inspection of the repair and submit the assessment for approval to the Manager of the Los Angeles ACO.

(2) Prior to reaching 75% of the threshold as determined in paragraph (j)(1) of this AD, submit the inspection methods and repetitive inspection intervals for the repair for approval by the Manager of the Los Angeles ACO.

(3) Prior to the threshold as determined in paragraph (j)(1) of this AD, incorporate the inspection method and repetitive inspection intervals into the FAA-approved structural maintenance or inspection program for the airplane.

Note 2: For the purposes of this AD, we anticipate that submissions of the DTA of the repair, if acceptable, should be approved within six months after submission.

Note 3: Advisory Circular AC 25.1529–1, "Instructions for Continued Airworthiness of Structural Repairs on Transport Airplanes," dated August 1, 1991, is considered to be additional guidance concerning the approval of repairs to PSEs.

Inspection for Transferred Airplanes

(n) Before any airplane that has exceeded the fatigue life threshold (N_{th}) can be added to an air carrier's operations specifications, a program for the accomplishment of the inspections required by this AD must be established per paragraph (n)(1) or (n)(2) of this AD, as applicable.

(1) For airplanes that have been inspected per this AD, the inspection of each PSE must be accomplished by the new operator per the previous operator's schedule and inspection method, or the new operator's schedule and inspection method, at whichever time would result in the earlier accomplishment date for that PSE inspection. The compliance time for accomplishment of this inspection must be measured from the last inspection accomplished by the previous operator. After each inspection has been performed once, each subsequent inspection must be performed per the new operator's schedule and inspection method.

(2) For airplanes that have not been inspected per this AD, the inspection of each PSE required by this AD must be

accomplished either prior to adding the airplane to the air carrier's operations specification, or per a schedule and an inspection method approved by the Manager, Los Angeles ACO. After each inspection has been performed once, each subsequent inspection must be performed per the new operator's schedule.

Inspections Accomplished Before the Effective Date of This AD

(o) Inspections accomplished prior to the effective date of this AD per Boeing Report No. L26–012, "DC–10 Supplemental Inspection Document (SID);" Volume I, Revision 4, dated June 1993, or Revision 5, dated October 1994; Volume II, Revision 6, dated October 1997, or Revision 7, dated August 2002; and Volume III–94, dated November 1994; are acceptable for compliance with the requirements of paragraph (j) of this AD.

Acceptable for Compliance

(p) McDonnell Douglas Report No. MDC 91K0264, "DC–10/KC–10 Aging Aircraft Repair Assessment Program Document," Revision 1, dated October 2000, provides inspection/replacement programs for certain repairs to the fuselage pressure shell. These repairs and inspection/replacement programs are considered acceptable for compliance with the requirements of paragraphs (i) and (m) of this AD for repairs subject to that document.

Alternative Methods of Compliance (AMOCs)

(q) The Manager, Los Angles Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(r) AMOCs approved previously per AD 95–23–09, amendment 39–9429, are approved as AMOCs with the actions required by paragraph (j) of this AD.

Issued in Renton, Washington, on July 23, 2004.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–17592 Filed 8–2–04; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 90

[ET Docket No. 04–243; FCC 04–156]

Narrowbanding for Private Land Mobile Radio Service

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document proposes to revise our transition plan for Private Land Mobile Radio (PLMR) licensees in the 150.05–150.8 MHz, 162–174 MHz, and 406.1–420 MHz bands. This action will provide for an orderly transition from wideband to narrowband operations, increase spectrum efficiency, maintain compatibility with Federal operations, permit PLMR licensees to operate using existing equipment with greater confidence that their critical operations will not be suddenly required to cease transmissions, and significantly reduce the probability that wideband PLMR operations will interfere with new Federal operations.

DATES: Written comments are due September 2, 2004, and reply comments are due September 17, 2004.

ADDRESSES: Office of the Secretary, Federal Communications Commission, 445 12th Street, SW., TW–A325, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Tom Mooring, Office of Engineering and Technology, (202) 418–2450, TTY (202) 418–2989, e-mail: *Tom.Mooring@fcc.gov*.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rulemaking*, ET Docket No. 04–243; FCC 04–156, adopted June 30, 2004, and released July 6, 2004. The full text of this document is available for inspection and copying during regular business hours in the FCC Reference Center (Room CY–A257), 445 12th Street, SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room, CY–B402, Washington, DC 20554. The full text may also be downloaded at: *http://www.fcc.gov*. Alternative formats are available to persons with disabilities by contacting Brian Millin at (202) 418–7426 or TTY (202) 418–7365.

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments on or before September 2, 2004, and reply comments on or before September 17, 2004. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. See Electronic Filing of *Documents in Rulemaking Proceedings*, 63 FR 24121 (May 1, 1998). Comments filed through the ECFS can be sent as an electronic file via the Internet to *http://www.fcc.gov/e-file/ecfs.html*. Generally, only one copy of an electronic submission must be filed. If multiple docket or rulemaking numbers appear in the caption of this proceeding, however, commenters must transmit one electronic copy of the comments to each docket or rulemaking number referenced in the caption. In completing the transmittal screen, commenters should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions for e-mail comments, commenters should send an e-mail to *ecfs@fcc.gov*, and should include the following words in the body of the message, "get form <your e-mail address." A sample form and directions will be sent in reply. Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, commenters must submit two additional copies for each additional docket or rulemaking number.

All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). The Commission's contractor, Natek, Inc., will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class mail, Express Mail, and Priority Mail should be addressed to 445 12th Street, SW., Washington, DC 20554.

Summary of the Notice of Proposed Rulemaking

1. This proceeding was initiated in order to revise the procedures by which certain PLMR service operations on the Hydrological and Meteorological (Hydro), Forest Fire-Fighting and Conservation, and Public Safety channels, as well as Medical Radiocommunication Systems, are to transition to narrower, more spectrally efficient channels in a process commonly known as "narrowbanding." These PLMR operations occupy spectrum in the 150.05–150.8 MHz, 162–174 MHz, and 406.1–420 MHz bands that is allocated for Federal Government (Federal) use and, in many cases, is shared on the condition that

interference is not caused to Federal operations. The National Telecommunications and Information Administration (NTIA) is transitioning Federal operations in this spectrum to 12.5 kHz (so-called "narrowband") channels on a January 1, 2005 and January 1, 2008 timetable (depending on the band), whereas our rules currently permit non-Federal Government (non-Federal) licensees to operate channels in excess of 12.5 kHz (so-called "wideband" operations) in these bands for as long as 2018. Because NTIA has adopted a more rapid narrowbanding schedule in these Federal bands than the Commission has required for our licensees, this transition has the potential to impact non-Federal operations in these bands.

2. Our proposals draw on the general principles embodied in the Commission's *Reframing Proceeding,* 60 FR 43720, August 23, 1995, which set forth a plan to transition PLMR operations from 25 kHz channels to narrower channels. In that proceeding, the Commission recognized that narrowbanding can promote efficient spectrum use and can help accommodate increasing PLMR demand. The instant proceeding is made necessary by NTIA's separate narrowbanding efforts, and is designed to allow for compatible use of Federal spectrum by both Federal and non-Federal users.

Federal Use of the Bands

3. Since January 1, 1995, all new Federal systems in the 162–174 MHz band have been required to operate within a 12.5 kHz channel. After January 1, 2005, all Federal systems in the band must operate within a 12.5 kHz channel. For operations in the 406.1–420 MHz band, NTIA has required that, by January 1, 2008, all assignments and equipment must operate within to a 12.5 kHz channel. In order to remain on a wideband channel in the 406.1–420 MHz band after that date, NTIA requires that a waiver request be recommended for approval by the IRAC's Frequency Assignment Subcommittee (FAS) and approved by NTIA. Even if a waiver is approved, the assignment may be revoked within 180 days of a formal notice, under certain conditions. Finally, we note that some Federal operations such as wireless microphones, military equipment used for tactical and/or training operations, and NOAA weather radio stations are exempt from the Federal narrowbanding requirements.

Non-Federal Use of the Bands

4. Although these bands are allocated for Federal Government use and are administered by NTIA, limited non-Federal use of these bands is authorized by virtue of seven United States footnotes: US8, US11, US13, US216, US223, US300, and US312. We describe the services the Commission has authorized to operate in these bands pursuant to these footnotes, as well as the relationship of non-Federal Government users in the bands to Federal Government users. In many cases, non-Federal Government users in these bands operate on a non-interference basis in conjunction with, or in support of, Federal functions. Moreover, many of the channels authorized by these footnotes are subject to the 12.5 kHz channel plan that the Commission adopted in the *Narrowbanding Second Report and Order,* 68 FR 42296, July 17, 2003.

5. As an initial matter, we note that our current narrowbanding schedule, which sets a January 1, 2005, date by which all new certified equipment must be designed to operate on channels of 6.25 kHz or less, applies to PLMR operations and does not make an exception for the operations on Federal channels discussed in the NPRM. Because NTIA has not yet addressed if or when it will require Federal users on these bands to operate on 6.25 kHz-wide channels, we seek comment on whether we should exempt equipment designed for use in these Federal bands from our current 6.25 kHz certification requirement. Specifically, commenters should address whether such a policy would be either beneficial or detrimental to enabling sharing between PLMR licensees and Federal users.

Hydro Channels (US13)

6. *Background.* On February 24, 2000, NTIA updated the *NTIA Manual* to implement a revised channel plan that specifies new and modified narrowband channels for hydrologic and meteorological operations in the 162–174 and 406.1–420 MHz bands. Specifically, in the 169–172 MHz band segment (in which 20 Hydro channels are currently located), 16 channels were added to the Hydro Channel Plan and the three previously grandfathered channels were removed. In the 406–416 MHz band segment (in which eight Hydro channels are currently located), seven channels were added to the Hydro Channel Plan and three channels were removed. NTIA has designated two of the existing channels—406.125 MHz and 406.175 MHz—to be paired with two of the new channels—415.125 MHz and 415.175 MHz—to allow for paired Hydro operations. A review of our databases indicates that the Commission has licensed 219 fixed stations on the six channels being removed from the Hydro Channel Plan and has issued 1053 licenses for those Hydro channels that are designated for narrowband operations. NTIA requests that existing wideband Hydro systems in the 169–172 MHz and 406–416 MHz segments adhere to the new Hydro Channel Plan and convert to narrowband equipment before January 1, 2005 and January 1, 2008, respectively.

7. *Proposal.* The Commission proposed to revise its rules to reflect an updated Hydro Channel Plan that is consistent with the channel plan shown in the NTIA Manual. The Commission's proposal would increase the number of Hydro channels from 28 single frequency channels (plus three grandfathered channels) to 44 single frequency channels and two sets of paired channels—for a total of 48 frequencies. Within the 162–174 MHz band, we propose to add 16 channels to the Hydro Channel Plan and to remove the three grandfathered channels—169.575 MHz, 170.375 MHz, and 171.975 MHz. Within the 406–416 MHz band, we propose to add seven channels to the Hydro Channel Plan, pair two of the new channels with two existing channels in the band, and remove three channels—409.675 MHz, 409.725 MHz, and 412.625 MHz. By doing so, we would align non-Federal use of the Hydro channels with Federal use under NTIA's narrowbanding plan. Under the provisions of footnote US13, non-Federal stations operate in cooperation with Federal stations. Consistency between Federal and non-Federal band plans furthers the public interest and safety by maintaining a ready flow of hydrologic and metrological data between non-Federal and Federal entities.

8. The Commission's previously adopted rules that require Hydro operations in the 169–172 MHz segment to transition to narrowband equipment well into the future (currently, January 1, 2013, for systems operating in the Industrial/Business Pool and by January 1, 2018, for systems operating in the Public Safety Pool). Thus, our narrowbanding schedule differs from NTIA's plan, which calls for Federal operations to use narrowband equipment by 2005. Because there could be extended periods during which existing non-Federal 25 kHz equipment may not be compatible with Federal operations using the new 12.5 kHz channels, we propose to establish the following procedure for incumbent

licensees in the Hydro channels: First, existing stations (including those stations that expand existing operations) will be permitted to continue to operate with an authorized bandwidth in excess of 12.5 kHz until the 2013 and 2018 transition dates that are currently in effect, so long as no harmful interference is caused to a Federal assignment in the band. Second, because new Federal assignments may be authorized after January 1, 2005, it will be necessary for our licensees to work with the Hydro Committee to minimize the potential for interference between stations. The Hydro Committee coordinates all requests for use of hydrologic channels and provides comment on such request to the FCC and NTIA (*i.e.*, the FAS Secretariat), and thus is in the best position to promote the best cooperative use of these channels. Ultimately, because assignments are determined by the NTIA and the FCC, a non-Federal license in the 169–172 MHz band segment is subject to termination if interference is caused to the Federal assignment.

9. The Commission has not previously adopted narrowbanding requirements for the 406–416 MHz band. For existing non-Federal operations on the 406.125 MHz, 406.175 MHz, 412.725 MHz, and 412.775 MHz channels (*i.e.* the four Hydro channels currently authorized in footnote US13 that will remain in the revised Hydro Channel Plan), we propose to require narrowband operations by the same dates as the Hydro channels in the 169–172 MHz band segment. Thus, these licensees would be permitted to use existing equipment until the Commission's overall narrowbanding requirements take effect (again, currently January 1, 2013, for systems in the Industrial/Business Pool, and by January 1, 2018, for systems in the Public Safety Pool). Because new Federal assignments may be authorized after January 1, 2005, it will be necessary for our licensees to work with the Hydro Committee to minimize the potential for interference between stations. The Hydro Committee coordinates all requests for use of Hydro channels and provides comment on such request to the FCC and NTIA (*i.e.*, the FAS Secretariat), and thus is in the best position to promote the best cooperative use of these channels. Ultimately, because assignments are determined by the NTIA and the FCC, a non-Federal license in the 406–416 MHz band segment will be subject to termination if interference is caused to the Federal assignment.

10. The Commission tentatively concluded that we should implement a modified procedure for those Hydro channels that we propose to remove from the Hydro Channel Plan. In the 162–174 MHz band, one licensee—the State of California—has been authorized 15 fixed stations on the frequency 169.575 MHz under the 1962 grandfathering rules. There are no non-Federal licensees operating on the other two channels in the band. A total of 13 non-Federal licensees are authorized to operate on the three 406–416 MHz band channels: (1) six licensees are authorized to operate 112 fixed stations at 409.675 MHz; (2) three licensees are authorized to operate ten fixed stations at 409.725 MHz; and (3) four licensees are authorized to operate 97 fixed stations at 412.625 MHz. In each of these cases, we propose that licensees modify their equipment and station licenses and migrate to a center frequency under the new Hydro Channel Plan on a timetable as advised by the Hydro Committee and approved by the NTIA and the FCC. As such, we note that Commission licensees should be prepared to cease or relocate operations by January 1, 2005, for stations on the frequency 169.575 MHz and by January 1, 2008, for stations on the frequencies 409.675 MHz, 409.725 MHz, and 412.625 MHz, in the event that they cause harmful interference to Federal facilities. Regardless of how long the Hydro Committee allows existing licensees to continue operations, we propose that in no case will licensees be permitted to operate on these channels after January 1, 2013 (for non-public safety systems) and January 1, 2018 (for public safety systems).

11. For all new Hydro stations, we propose that a license issued on or after January 1, 2005 (for stations in the 162–174 MHz band) or January 1, 2008 (for stations in the 406–416 MHz band), limit operations to a channel no wider than 12.5 kHz, except that we could authorize wideband operations if the Hydro Committee recommends that an application be granted, and NTIA approves the request. Because equipment meeting this channel bandwidth has been available for more than eight years, new licensees should be able to meet this requirement.

12. To implement these proposals, the Commission anticipates revising § 90.265(a) of its rules to reflect the new Hydro Channel Plan and our proposal for transitioning to narrowband channels. Although Hydro channels are used by state and local government entities, they are not listed as being available to Public Safety Pool eligibles in part 90 of its rules. Therefore, we also propose to amend §§ 90.20(c), 90.20(d)(48), and 90.265(a) of the Commission's rules to correct this oversight. The Commission proposes to amend the Industrial/Business Pool Frequency Table in part 90 of its rules by revising the entry for the 406–413 MHz band to read "406–416 MHz" to encompass the new Hydro frequencies at 415.125 MHz and 415.175 MHz. Furthermore, the Commission proposes to revise footnote US13 of § 2.106 to incorporate the new band plan. These revisions are included in the proposed rules.

13. Because non-Federal operations on these channels must not cause interference to Federal operations, we believe that the proposed modifications are necessary in light of the NTIA narrowbanding efforts. Due to the nature and use of the Hydro channels, we expect that the Hydro Committee will continue to promote effective non-Federal use of the band, and will work to foster an effective transition for all licensees. The Commission seeks comment on these proposals, including any difficulties that public safety licensees may have with complying with the proposed policy for transitioning existing operations to narrowband channels. The Commission also request comments on how these proposals would affect Federal operations in the bands.

Forest Fire-Fighting and Conservation Channels (US8)

14. *Background.* Footnote US8 states that the use of nine channels in the 162–174 MHz band may be authorized for stations in the fixed and land mobile services that are operated by non-Federal forest fire-fighting agencies on the condition that no harmful interference will be caused to Federal stations. In addition, two of these channels may also be used by non-Federal conservation agencies for mobile relay operation only. These nine channels are available to Public Safety Pool eligibles in Section 90.20 of our Rules and are reserved primarily for assignment to state licensees.

15. NTIA has required that all new Federal fixed and land mobile operations in the 162–174 MHz band use 12.5 kHz channels since 1995 and has established January 1, 2005, as the date by which all such Federal operations in this band must use narrowband equipment. Our rules permit existing licensees on these channels to use wideband equipment much longer—currently, until January 1, 2018. Because additional Federal agencies will soon commence to operate on the new channels, there is an increased likelihood of interference

between these Federal and non-Federal operations.

16. *Proposal.* Because these nine frequencies were provided for cooperative forest fire-fighting and conservation operations between Federal, state, and local entities, we propose to maintain that relationship. Because our rules provide a much longer transition to narrowband channels than NTIA's plan, we propose to allow operations under existing licenses (and expansions under existing licenses) to continue with an authorized bandwidth in excess of 12.5 kHz until the Commission's general narrowband transition date (currently 2018) or until notified by the Commission that harmful interference is anticipated to or from a Federal assignment proposed on or after January 1, 2005, whichever comes first. To minimize the potential of harmful interference between stations, the FCC will work with NTIA under the auspices of the FAS to provide advanced notice to our licensees that a proposed Federal assignment has been filed with NTIA. After the Federal entity begins operations, however, the non-Federal license will be subject to termination if interference is caused to Federal operations.

17. The Commission proposed that, after January 1, 2005, all new non-Federal stations meet the narrowband standards, unless a waiver has been recommended by the sponsoring Federal agency and approved by NTIA. Although the *Narrowbanding Second Report and Order* 68 FR 42296, July 17, 2003, had established a January 13, 2004, cut-off date for filing wideband applications, it is unclear how long the current stay of those rules will remain in effect or whether the underlying rules will be changed upon reconsideration. Nevertheless, because the forest fire-fighting and conservation channels operate on a secondary basis to Federal operations, we believe that we must move forward with the narrowbanding of these channels in order to improve compatibility with Federal operators and minimize the potential for interference. Thus, if the general narrowbanding requirement for PLMR licenses in the 150–174 MHz band takes effect prior to January 1, 2005, we propose to apply that date instead.

18. The Commission observed that these channels are used sporadically and many are located in rural areas, and so we believe that there is a realistic possibility that some existing licensees will be able to continue to operate on their current channels beyond NTIA's January 1, 2005, schedule without causing harmful interference. Accordingly, we see no need to alter the Commission's previously adopted rules that allow incumbent forest firefighting and conservation operations in the 162–174 MHz band to transition to narrowband equipment by January 1, 2018. However, because there could be up to a 13-year period during which non-Federal forest firefighting/conservation operations using 25 kHz equipment may not be compatible with Federal operations using the new 12.5 kHz channels, the procedures described in the NPRM will provide licensees with notice of anticipated interference to or from new Federal operations and an opportunity to prepare to cease operations. The Commission believes that these proposals balance the competing needs of all users, and seek comment on this plan. The Commission also request comments on the compatibility of older 25 kHz channel equipment with narrowband equipment currently available.

19. The Commission note that, under current practice, applications for use of these channels are accompanied by a letter of concurrence by the sponsoring Federal agency (*e.g.* the Department of Agriculture). We tentatively conclude that this practice aids the coordination of assignments between NTIA and the Commission, and we therefore propose to modify our rules to codify this procedure.

20. Finally, the Commission proposes to move the existing limitations that are contained in § 90.20 of its rules into a new subsection of § 90.265, revise limitation 49 under § 90.20 to provide a cross-reference to § 90.265, and remove what will then be redundant statements of limitation for these channels in § 90.20. Section 90.265 of the Commission's rules already describes procedures by which we license two services permitted on Federal bands pursuant to United States footnotes—Hydro operations and wireless microphones. We believe it would be convenient and consistent to expand this section to include similarly situated services including, *inter alia*, the Forest Fire-Fighting and Conservation channels. We seek comment on these proposals, including any difficulties that public safety licensees may have with complying with the proposed policy for transitioning assignments to 12.5 kHz channels. We also request comment on how these proposals would affect Federal operations in the band.

Public Safety Channels (US11)

21. *Background.* Footnote US11 authorizes public safety radio services use of two channels on 166.25 MHz and 170.15 MHz for locations within 150 miles of New York City, on the condition that harmful interference is not caused to present or future Federal stations in the 162–174 MHz band. A recent review of our licensing database shows that the Commission has authorized 30 fixed stations, 1295 mobile stations, and 95 pagers on the frequency 166.25 MHz, and 23 fixed stations, 640 mobile stations, and 160 pagers on the frequency 170.15 MHz.

22. Consistent with NTIA's 12.5 kHz Plan for Federal fixed and land mobile operations in the 162–174 MHz band, we have required that non-Federal operations on the two public safety channels authorized in footnote US11 be narrowed to 12.5 kHz channels. However, the NTIA plan calls for Federal licensees to meet a January 1, 2005, deadline to operate on narrowband channels, whereas our rules require public safety licensees in the band to migrate to 12.5 kHz technology by January 1, 2018. The prospect that Federal agencies will soon commence to operate on the new channels increases the likelihood of interference between Federal and non-Federal operations in the band.

23. *Proposal.* Because the non-interference considerations discussed in the NPRM apply to these channels, we propose to allow operations under existing licenses (and expansions under existing licenses) to continue with an authorized bandwidth in excess of 12.5 kHz until the Commission's narrowband transition date (currently 2018) or until notified by the Commission that harmful interference is anticipated to or from a Federal assignment proposed on or after January 1, 2005, whichever comes first. To minimize the potential of harmful interference between stations, the FCC will work with NTIA under the auspices of the Frequency Assignment Subcommittee (FAS) of the Interdepartment Radio Advisory Committee (IRAC) to provide advanced notice to our licensees that a proposed Federal assignment has been filed with NTIA. After the Federal entity begins operations, however, the non-Federal license will be subject to termination if interference is caused to the Federal assignment. The Commission also proposed that new stations meet the narrowband standards no later than January 1, 2005, unless a waiver has been granted by NTIA. However, if the general narrowbanding requirement for PLMR licenses in the 150–174 MHz band takes effect prior to January 1, 2005, we propose to apply that date instead.

24. The Commission proposed modifications to its rules to accurately reflect non-Federal licensees' role in

this shared band. It proposed to create a new paragraph in § 90.265 of the rules to describe these public safety channels, and to revise the limitation in § 90.20(d)(47) of the rules to serve as a cross-reference. The Commission proposed to state in its rules that operations are on a secondary basis to any Federal station, in order to give effect to the restriction embodied in footnote US11 that non-Federal operations on 166.250 MHz and 170.150 MHz may operate on the condition that no harmful interference is caused to Government stations "present or future" in the Federal band. The Commission also believes that footnote US11 can be modified to remove an outdated reference to wideband operations that are no longer permitted and to simplify the description of public safety and remote pickup broadcast operations in the band. Finally, the Commission asks whether new applications for use of these channels should be accompanied by a letter of concurrence by a sponsoring Federal agency, as we do with the Forest Fire-Fighting and Conservation channels. We note that similar coordination letters appear to have served non-Federal users well in ensuring smooth processing of license applications.

25. The Commission believes that these proposed modifications will properly account for NTIA's scheduled narrowbanding of Federal operations in the band. The Commission seeks comment on these proposals, including any difficulties that public safety licensees may have with complying with the proposed policy for transitioning footnote US11 assignments to 12.5 kHz channels. The Commission also request comment on how these proposals would affect Federal operations, which are scheduled to use only narrowband equipment after January 1, 2005. Further, the Commission seeks comment on the compatibility of older 25 kHz channel equipment with narrowband equipment currently available.

Medical Radiocommunication Systems (US216)

26. *Background.* Footnote US216 makes several frequencies available to both Federal and non-Federal Medical Radiocommunication Systems on a primary basis. Such use dates back to a 1974 *Report and Order,* in which the Commission established new medical radiocommunication frequencies pursuant to a NTIA report. Medical Radiocommunication Systems operate in frequency bands that are designated for Federal use, as well as bands designated for non-Federal use. Five medical radiocommunication frequencies specified in part 90 of the rules, 150.775 MHz, 150.7825 MHz, 150.790 MHz, 150.7975 MHz, and 163.250 MHz, operate in the Federal bands and are the subject of the discussion herein. Three of these frequencies, 150.775 MHz, 150.790 MHz, and 163.250 MHz, are listed in US216, while the other two, 150.7825 MHz and 150.7975 MHz, are not.

27. *Proposal.* The Commission proposed to require that non-Federal operations in the Federal bands as listed in footnote US216 (150.775 MHz, 150.790 MHz and 163.25 MHz) be narrowed to a 12.5 kHz channel to maintain their primary status. The establishment of a narrowbanding plan for non-Federal users operating on these frequencies will complement NTIA's 12.5 kHz Plan to establish narrowband channels for Federal fixed and land mobile operations in the 150.05–150.8 MHz and 162–174 MHz bands. The Commission further propose to cease licensing stations on the frequencies of 150.7825 MHz and 150.7975 MHz. These frequencies, which were never incorporated into footnote US216, lie within the Federal military band, and additional authorizations would limit the operational deployment of vital military systems. We propose to permit existing stations that are authorized as of effective date of the Report and Order in this proceeding to use the frequencies 150.7825 MHz and 150.7975 MHz indefinitely. We seek comment on these proposals.

28. The Commission proposed to retain the same narrowbanding timetable we previously established in the *Narrowbanding Second R&O* with respect to stations operating on the Federal frequencies: 150.775 MHz, 150.790 MHz, and 163.250 MHz. Under this plan, existing public safety operations using these frequencies, including expansions of existing systems, must use narrowband equipment no later than January 1, 2018. With respect to use of the Federal frequencies in the Medical Radiocommunciation Systems bands, the Commission recognizes that our plan differs from that of NTIA, and that existing non-Federal entities will be able to operate on wideband channels both throughout and after NTIA's transition period for Federal users in the band. The Commission tentatively concluded that such a timetable is warranted because the application of our general narrowbanding dates to these channels will allow us to provide a migration period that is sufficiently long in duration to meet the unique funding and planning needs of public safety entities. The Commission further notes that these three frequencies are shared by Federal and non-Federal entities on a co-primary basis. Thus, use of these three frequencies differs from the other frequency bands, in which non-Federal licensees operate on a secondary basis to Federal users and must be prepared to migrate or cease operations once Federal licensees begin using narrowband equipment. Because of this distinction, the Commission believe that these non-Federal licensees should be treated in a similar manner to all other primary land mobile licensees under its jurisdiction. By doing so, we will be able to provide valuable migration time to existing non-Federal Medical Radiocommunication Systems licensees. In addition, this approach will preserve our traditional first-in-time policy by which the first licensed entity does not have to modify its operations but instead maintains a primary status in relation to subsequently licensed entities. Under this policy, an existing wideband non-Federal licensee will be entitled to protection from interference from new Federal entities and non-Federal licensees that subsequently begin operations in the band, and will not need to modify existing operations to prevent interference to these new entrants. For all of these reasons, we tentatively conclude that existing licensees be permitted to use their existing equipment until January 1, 2018, and that such operations be protected from interference from new or modified Federal and non-Government operations in the band until that date.

29. With respect to new stations operating on the frequencies 150.775 MHz, 150.790 MHz, and 163.250 MHz, the Commission proposed to adopt a narrowbanding timetable that is aligned with NTIA's narrowbanding plan. New stations operating at 163.250 MHz must meet the narrowband standards no later than January 1, 2005, and new stations operating at 150.775 MHz and 150.790 MHz must meet the narrowband standards no later than January 1, 2008. However, if the general narrowbanding requirement for PLMR licenses in the 150–174 MHz band takes effect prior to January 1, 2008, we propose to apply that date instead for new operations at 150.775 MHz, 150.790 MHz, and 163.25 MHz. Because equipment meeting this channel bandwidth has been available for more than eight years, we anticipate that new licensees should be able to meet these requirements. We further note that, unlike existing licensees, new licensees will not have the burden of planning for, budgeting, and

transitioning from legacy wideband systems. These requirements support the longer transition period we are affording existing licensees.

30. The Commission also take this opportunity to propose several clarifications to its part 90 rules relating to Medical Radiocommunication Systems. In § 90.20 of the rules, the Commission proposed to add a new limitation on the use of the frequencies 150.775 MHz, 150.790 MHz, and 163.250 MHz that would implement, on a going-forward basis, the footnote US216 requirement that the use of these channels be limited to medical radio communications systems, as well as to remove existing limitation 19 for these channels. In addition, and in order to give effect to the medical use limitation, we propose that the coordinator for the frequencies 152.0075 MHz and 163.250 MHz (as listed in the fourth column of the Public Safety Pool Frequency Table) be changed from Special Emergency Coordinator (PS) to Emergency Medical Coordinator (PM). The Commission notes that the coordinator for the frequencies 150.775 MHz and 150.790 MHz is specified as PM in the current rules, and tentatively conclude that we should follow the same approach for the frequencies 152.0075 MHz and 163.250 MHz. The Commission seek comment on this proposal. The Commission also proposed to modify footnote US216 to list the available frequencies in lieu of the 152–152.0150 MHz and 163.2375–163.2625 MHz bands. The Commission note that our proposal would result in a single medical paging frequency, 152.0075 MHz, operating in the primary non-Federal band. The Commission seeks comment as to how we should treat this frequency, and whether it should be limited to narrowband operations in the same manner and time frame we require for medical paging operations at 163.25 MHz. Finally, we note that the use of frequencies 150.775 MHz and 150.790 MHz are limited to mobile use only and that no power restrictions are currently specified for these channels in part 90 of the rules, despite NTIA's provisions that these channels are to be used for hand-held units restricted to 2.5 watts of power. The Commission seeks comment on the practical effect of this discrepancy and what actions, if any, we should take to reconcile the difference between our Rules and NTIA's provisions for these channels.

31. The modifications the Commission proposed are designed to balance the needs of incumbent non-Federal users in light of proposed new Federal narrowband operations in the band, and we seek comment on these proposals. The Commission especially solicit information from the medical, the emergency medical, and the special emergency radiocommunication services community regarding the use of the two mobile frequencies (150.775 MHz and 150.790 MHz), the two "offset" frequencies (150.7825 MHz and 150.7975 MHz), and the two paging-only frequencies (152.0075 MHz and 163.25 MHz) in order to develop a full record regarding both the current use of and any future needs for these frequencies—including any related use by non-medical, public safety entities. The Commission also seek information about the need for these frequencies in relation to other frequencies available under part 90 of the Commission's rules.

Other Users (US117, US223, US300, and US312)

32. *Stolen Vehicle Recovery Systems (US312).* Footnote US312 states that the frequency 173.075 MHz may be authorized on a primary basis to non-Federal stations in the Police Radio Service for Stolen Vehicle Recovery Systems (SVRS) and limits the maximum authorized bandwidth for SVRS to 20 kHz. This frequency is listed in the Public Safety Pool Frequency Table and its use is limited to SVRS as prescribed in § 90.20(e)(6) of the Rules. This part 90 rule also states that the SVRS frequency is available on a shared basis with Federal operations. LoJack, currently the only SVRS operator on this frequency in the United States, operates its network in cooperation with federal, state and local law enforcement agencies in 20 states and the District of Columbia. A review of our licensing database finds that public safety licensees are authorized to operate 125 fixed stations as part of the SVRS network.

33. NTIA's 12.5 kHz plan for the 162–174 MHz band calls for Federal agencies to be licensed on the adjacent frequencies 173.0625 MHz and 173.0875 MHz. The Commission note that these frequencies are only 12.5 kHz away from the SVRS center frequency, and therefore it is possible that because new federal entities will be operating much closer in frequency to the SVRS channel than Federal entities have in the past, wideband SVRS operations could encounter interference situations that could prove burdensome to identify and resolve. However, we also note that there has been significant investment in SVRS by the general public and that SVRS equipment has been deployed by numerous law enforcement agencies. Taking these facts into account, the Commission seeks comment as to whether it would be advisable to establish a narrowband transition plan for SVRS users at 173.075 MHz. Specifically, we ask that commenters provide detailed information regarding the availability of narrowband SVRS equipment. In addition, the Commission seeks information that would allow us to determine whether we could craft an effective process that would both preserve the utility of the LoJack system and account for new Federal entrants in the band. For example, how readily could narrowband SVRS technology be made available to operate on the 173.075 MHz frequency? What is the expected life cycle of existing SVRS equipment? Taking into account the availability of equipment and the installed base, what is a reasonable transition plan by which the LoJack network could move to narrowband equipment? For example, would the January 1, 2018 transition date already adopted for the Public Safety Radio Pool be appropriate?

34. Because rules for a separate Police Radio Service were removed when the Commission created the Public Safety Radio Pool, it proposed to update footnote US312 to account for this fact. We also note that some Federal frequencies will continue to operate on wideband channels for the indefinite future. The Commission seeks comment on this matter.

35. *Ship and Public Coast (US223) and Wireless Microphones (US300).* Footnote US223 makes a channel available for public coast station use in limited areas near the Canadian border. Because Ship and Public Coast operations do not fall under the same rules as PLMR, operations under footnote US223 do not need to be modified to support NTIA's narrowbanding timetable, and therefore we propose no changes to these frequencies as part of this proceeding. Footnote US300 specifies eight frequencies that are available for wireless microphone operations on a secondary basis to Federal and non-Federal operations. Because wireless microphones operate at very low power (50 mW output power), there is a minimal likelihood that they will cause interference to high-power land mobile operations. Thus, we propose no changes to the frequencies allocated for wireless microphones as part of footnote US300.

36. *Radio Astronomy Protection (US117).* Footnote US117 states that, in the 406.1–410 MHz band, all new authorizations are limited to a transmitter output power of 7 watts per kHz of necessary bandwidth and that new fixed station authorizations near four RAS observatories are subject to

prior coordination. NTIA has reviewed footnote US117 and recommends that it be revised. Specifically, NTIA proposes that footnote US117 be revised to limit transmitter output power of stations in the fixed and mobile services operating in the 406.1–410 MHz band to 125 watts and to update the RAS site coordination information.

37. With regards to stations in the fixed and mobile services that operate in the 406.1–410 MHz band, the Commission notes that non-Federal use is currently limited to four Hydro channels (406.125 MHz, 406.175 MHz, 409.675 MHz, and 409.725 MHz). A staff review of our licensing records found that most of the non-Federal fixed stations operating on these four Hydro channels have a transmitter output power of 50 watts or less and that the maximum output power that the Commission has authorized is 100 watts. Moreover, we note that, in the proposed Hydro Channel Plan, non-Federal use of the 406.1–410 MHz band would be limited to two Hydro channels (406.125 MHz and 406.175 MHz).

38. The Commission proposed to revise footnote US117, as requested by NTIA, in order to promote more effective protection of RAS reception in the 406.1–410 MHz band. Specifically, in the 406.1–410 MHz band, the proposed revision of footnote US117 would limit the transmitter output power of stations in the fixed and mobile services to 125 watts; would revise the list of RAS sites to include the National Radio Astronomy Observatory at Socorro, New Mexico and to delete two RAS sites no longer observing in this band; and would revise the coordination areas for the Arecibo and Table Mountain Observatories. The Commission request comment on this proposal.

Initial Regulatory Flexibility Analysis

39. As required by the Regulatory Flexibility Act of 1980, as amended (RFA),[1] the Commission has prepared this present Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in this Notice of Proposed Rulemaking (NPRM). Written public comments are requested on this IRFA and must be filed by the deadlines for comments on the NPRM. The Commission will send a copy of the NPRM, including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration.[2]

A. Need for, and Objectives of, the Proposed Rules

40. In the 150.05–150.8 MHz, 162–174 MHz, and 406.1–420 MHz bands, the National Telecommunications and Information Administration (NTIA) is transitioning Federal Government (Federal) operations in the fixed and land mobile services from wideband (25 kHz) to narrowband (12.5 kHz) channels at a more rapid schedule than the Commission has adopted for Private Land Mobile Radio (PLMR) operations in these bands. Because there could be extended periods during which existing PLMR wideband operations may not be compatible with narrowband Federal operations, the Commission is proposing to revise its current narrowbanding plan for these bands to take into account that many PLMR operations in the above Federal bands are authorized on the condition that they not cause interference to Federal operations.

41. The Commission's objectives in making the PLMR proposals contained in this NPRM are to provide for a more orderly transition from wideband to narrowband operations, increase spectrum efficiency, maintain compatibility with Federal operations, permit licensees to operate using existing equipment for the maximum amount of time possible, and significantly reduce the probability that wideband operations will interfere with new Federal operations.

B. Legal Basis

42. This action is authorized under sections 1, 4(i), 302, 303(f) and (r), 332, and 337 of the Communications Act of 1934, as amended, 47 U.S.C. 1, 4(i), 154(i), 302, 303(f) and (r), 332, 337.

C. Description and Estimate of the Number of Small Entities to Which the Proposed Rule Will Apply

43. 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.[3] The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small business concern" under Section 3 of the Small Business Act, unless the Commission has developed one or more definitions that are appropriate for its activities.[4] Under the Small Business Act, a "small business concern" is one that: (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).[5]

44. A small organization is generally "any not-for-profit enterprise which is independently owned and operated and is not dominant in its field."[6] Nationwide, as of 1992, there were approximately 275,801 small organizations.[7] The definition of "small governmental entity" is one with populations of 1 fewer than 50,000.[8] There are approximately 85,006 governmental entities in the nation.[9] This number includes such entities as states, counties, cities, utility districts and school districts. There are no figures available on what portion of this number have populations of fewer than 50,000. However, this number includes 38,978 counties, cities and towns, and of those, 37,556, or ninety-six percent, have populations of fewer than 50,000.[10] The Census Bureau estimates that this ratio is approximately accurate for all governmental entities. Thus, of the 85,006 governmental entities, we estimate that ninety-six percent, or about 81,600, are small entities that may be affected by our rules.

45. PLMR systems serve an essential role in a range of industrial, business, land transportation, and public safety activities. These radios are used by companies of all sizes operating in all U.S. business categories, and are often used in support of the licensee's primary (non-telecommunications) business operations. For the purpose of determining whether a licensee of a PLMR system is a small business as defined by the SBA, we could use the definition for "Cellular and Other Wireless Telecommunications." This definition provides that a small entity is any such entity employing no more than 1,500 persons.[11] The Commission does not require PLMR licensees to disclose information about number of employees, so the Commission does not

[1] *See* 5 U.S.C. 603. The RFA, *see* 5 U.S.C. 601–"612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Public Law 104–121, Title II, 110 Stat. 857 (1996).

[2] 5 U.S.C. 603(a).

[3] *Id.* at 603(b)(3).

[4] *Id.* at 601(3).

[5] *Id.* at 632.

[6] Id. at 601(4).

[7] Department of Commerce, U.S. Bureau of the Census, 1992 Economic Census, Table 6 (special tabulation of data under contract to Office of Advocacy of the U.S. Small Business Administration).

[8] 5 U.S.C. 601(5).

[9] 1992 Census of Governments, U.S. Bureau of the Census, U.S. Department of Commerce.

[10] *Id.*

[11] *See* 13 CFR 121.201, NAICS code 517212.

have information that could be used to determine how many PLMR licensees constitute small entities under this definition. Moreover, because PMLR licensees generally are not in the business of providing cellular or other wireless telecommunications services but instead use the licensed facilities in support of other business activities, we are not certain that the Cellular and Other Wireless Telecommunications category is appropriate for determining how many PLMR licensees are small entities for this analysis. Rather, it may be more appropriate to assess PLMR licensees under the standards applied to the particular industry subsector to which the licensee belongs.[12]

46. The proposals in this NPRM would affect the following PLMR licensees: (1) Industrial/Business Pool and state and local government licensees that are authorized to make hydrological and meteorological (Hydro) measurements under footnote US13; (2) forest firefighting agencies, which are primarily state government licensees, and forest conservation agencies that are authorized under footnote US8; (3) Public Safety Pool licensees that are authorized under footnote US11; and (4) hospital, medical centers, nursing homes, etc. that operate Medical Radiocommunication Systems, which are authorized under footnote US216. These United States footnotes are fully discussed in the NPRM.

47. *Hydro Channel Users.* The Commission has authorized 9 licensees to operate 219 fixed stations on the six channels that would be removed from the Hydro Channel Plan: (1) one licensee (the State of California) is authorized to operate 15 fixed stations on the frequency 169.575 MHz; (2) six licensees are authorized to operate 112 fixed stations at 409.675 MHz; (3) three licensees are authorized to operate ten fixed stations at 409.725 MHz; (4) four licensees are authorized to operate 97 fixed stations at 412.625 MHz; and (5) there are no licensees authorized to operate on the frequencies 170.375 MHz and 171.975 MHz. The Commission has issued 1053 licenses (there is at least one station per license) for the remaining Hydro channels that are being narrowbanded. We believe that some of the Hydro channel licensees are small businesses or small governmental entities.

48. *Forest Firefighting and Conservation Agencies.* The Commission has authorized 21 licensees to operate 414 fixed stations and 45,630 mobile stations on the nine channels that are available to forest firefighting agencies; two of these frequencies are also available for use by conservation agencies. By Commission rule, these frequencies are reserved primarily for assignment to state licensees. Assignments to other licensees may be made only where the frequencies are required for coordinated operation with the state system to which the frequency is assigned. The 21 licensees consist of 19 states and state agencies, the County of Los Angeles, and a non-profit organization. This small organization may be impacted by our proposals.

49. *Public Safety Licensees.* The Commission has granted 27 licensees authorization to operate wideband equipment on the frequencies 166.25 MHz and 170.15 MHz. By Commission rule, these frequencies are to be assigned to stations in the Public Safety Pool that are at points within 240 kilometers of New York City. Specifically, the Commission has granted 15 licensees authorization to operate 1295 mobile stations, 95 pagers, and 30 fixed stations using the frequency 166.25 MHz. The Commission has granted 12 licensees authorization to operate 899 mobile stations, 165 pagers, and 22 fixed stations on the frequency 170.15 MHz. We believe that many of these public safety licensees are small governmental entities.

50. *Medical Radiocommunication Systems.* The Commission has issued 499 licenses for the frequency 150.775 MHz and 418 licenses for the frequency 150.79 MHz. By Commission rule, these 150 MHz channels are used only by mobile stations. For example, these frequencies may be used for voice transmissions from a portable (hand-held) unit to an ambulance. The Commission has issued 520 licenses for the frequency 163.25 MHz. By Commission rule, the frequency 163.25 MHz can be assigned only for one-way paging. We believe that most of the hospitals, medical centers, and nursing homes that operate medical radiocommunication systems are small businesses or small governmental entities.

51. The Commission seeks comment on this analysis. In providing such comment, commenters are requested to provide information regarding how many total and small business entities would be affected.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

52. If adopted, the proposed rules would require that:

- PLMR licensees employing wideband channels for Hydro, forest fire-fighting, conservation, and public safety operations modify or discontinue operations if, after January 1, 2005, these wideband operations cause interference to new Federal operations in the 162–174 MHz band, or if, after January 1, 2008, these wideband operations cause interference to new Federal operations in the 150.05–150.8 MHz and 406.1–420 MHz bands;
- Hydro channel licensees operating on the center frequencies 169.575 MHz, 409.675 MHz, 409.725 MHz, and 412.625 MHz cease operations not later than January 1, 2013 for Industrial/Business Pool licensees and not later than January 1, 2018 for Public Safety Pool licensees;
- PLMR applicants requesting authority to operate Hydro, forest fire-fighting, conservation, public safety, and medical radiocommunication stations in the 162–174 MHz band use narrowband channels after January 1, 2005; and that these applicants use narrowband channels after January 1, 2008 in the 150.05–150.8 MHz and 406–416 MHz bands; and
- New Hydro stations that would operate on the center frequencies 406.125 MHz and 406.175 MHz be limited to a transmitter output power of 125 watts and required to coordinate with the Radio Astronomy Observatory at Socorro, New Mexico.

53. If a licensee is required to modify its operations, we believe that the licensee would either buy new narrowband equipment or that the licensee would hire a vendor to modify some or all of its wideband equipment. We are uncertain of the exact costs relating to the narrowbanding requirements. We request comment on the costs related to narrowbanding and whether these costs would be borne as part of the licensee's normal depreciation and replacement cycle. We are especially interested in comments dealing with whether small entities would be affected disproportionately.

E. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

54. 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,

[12] *See generally* 13 CFR 121.201.

standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.[13]

55. So long as incompatibilities are not created with Federal narrowband operations, we propose to allow incumbent Public Safety Pool licensees to use existing equipment until January 1, 2018, and to allow incumbent Industrial/Business Pool licensees to use existing equipment until January 1, 2013. The Commission proposed that the 14 licensees of the six Hydro channels being deleted from the Hydro Channel Plan modify their equipment and station licenses and migrate to a center frequency listed in the new Hydro Channel Plan on a timetable as advised by the Hydro Committee and approved by NTIA and the Commission. The Commission proposed to grandfather indefinitely those incumbent stations that operate on the frequencies 150.7825 MHz and 150.7975 MHz.

56. The Commission request comment on whether it should exempt equipment designed for use in these Federal bands from our current 6.25 kHz equipment certification requirement, which is scheduled to commence on January 1, 2005. The purpose in providing this alternative is to determine whether such a policy would be beneficial or detrimental to enabling sharing between PLMR licensees and Federal users.

F. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

57. None.

Ordering Clauses

58. Pursuant to sections 1, 4(i), 7(a), 301, 302(a), 303(f), 303(g), 303(r), 307, 308, 309(j), 316, 332, 334, and 336 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 157(a), 301, 302(a), 303(f), 303(g), 303(r), 307, 308, 309(j), 316, 332, 334, and 336, the Notice of Proposed Rulemaking is hereby Adopted.

59. The Commission's Consumer Information and Governmental Affairs Bureau, Reference Information Center, Shall Send a copy of the Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in Parts 2 and 90

Radio, Telecommunications.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

Proposed Rule Changes

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR parts 2 and 90 as follows:

PART 2—FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS

1. The authority citation for part 2 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, and 336, unless otherwise noted.

2. Section 2.106 is amended by revising footnotes US11, US13, US117, US216, and US312 to read as follows:

§ 2.106 Table of Frequency Allocations.

* * * * *

United States (US) Footnotes

* * * * *

US11 On the condition that harmful interference is not caused to present or future Federal Government stations in the band 162–174 MHz, the frequencies 166.25 MHz and 170.15 MHz may be authorized to non-Federal Government stations, as follows: (1) eligibles in the Public Safety Radio Pool may be authorized to operate in the fixed and land mobile services for locations within 150 miles (241.4 km) of New York City; and (2) remote pickup broadcast stations may be authorized to operate in the land mobile service for locations within the continental United States, excluding Alaska, locations within 150 miles of New York City, and the Tennessee Valley Authority Area. (TVA Area). The TVA Area is bounded on the west by the Mississippi River, on the north by the parallel of latitude 37°30′ N., and on the east and south by that arc of the circle with center at Springfield, Illinois, and radius equal to the airline distance between Springfield, Illinois, and Montgomery, Alabama, subtended between the foregoing west and north boundaries.

US13 The following center frequencies, each with a channel bandwidth not greater than 12.5 kHz, are available for assignment to non-Federal Government fixed stations for the specific purpose of transmitting hydrological and meteorological data in cooperation with Federal agencies, subject to the condition that harmful interference will not be caused to Federal Government stations:

HYDRO CHANNELS (MHz)

169.425	170.2625	171.100	406.1250
169.4375	170.275	171.1125	406.1750
169.450	170.2875	171.125	412.6625
169.4625	170.300	171.825	412.6750
169.475	170.3125	171.8375	412.6875
169.4875	170.325	171.850	412.7125
169.500	171.025	171.8625	412.7250
169.5125	171.0375	171.875	412.7375
169.525	171.050	171.8875	412.7625
170.225	171.0625	171.900	412.7750
170.2375	171.075	171.9125	415.1250
170.250	171.0875	171.925	415.1750

New assignments on the frequencies 406.125 MHz and 406.175 MHz are to be primarily for paired operations with the frequencies 415.125 MHz and 415.175 MHz, respectively.

* * * * *

US117 In the band 406.1–410 MHz: (a) Stations in the fixed and mobile services shall be limited to a transmitter output power of 125 watts; (b) non-Federal Government use shall be limited to the radio astronomy service and to the fixed service, as provided by footnote US13; and (c) new authorizations for stations, other than mobile stations, shall be subject to prior coordination by the applicant in the following areas:

[13] 5 U.S.C. 603(c).

1. *Arecibo Observatory of the National Astronomy and Ionosphere Center.* Within Puerto Rico and the U.S. Virgin Islands, contact: Spectrum Manager, Arecibo Observatory, P.O. Box 995, Arecibo, Puerto Rico 00613, Phone: 787–878–2612, Fax: 787–878–1816.

2. *Very Large Array (VLA) of the National Radio Astronomy Observatory (NRAO).* Within a 350 kilometer radius that is centered on 34°04′44″ North Latitude, 107°37′04″ West Longitude, contact: Spectrum Manager, National Radio Astronomy Observatory, P.O. Box O, 1003 Lopezville Road, Socorro, New Mexico 87801, Phone: 505–835–7000, Fax: 505–835–7027.

3. *Table Mountain Observatory of the Department of Commerce* (407–409 MHz only). Within a 10 kilometer radius that is centered on 40°07′50″ North Latitude, 105°14′40″ West Longitude, contact: Radio Frequency Coordinator, Department of Commerce, 325 Broadway, Boulder, Colorado 80303, Phone: 303–497–6548, Fax: 303–497–3384.

* * * * *

US216 The use of the frequencies 150.775 MHz, 150.79 MHz, 152.0075 MHz, and 163.25 MHz, and the bands 462.9375–463.1875 MHz and 467.9375–468.1875 MHz may be authorized for both Federal and non-Federal Government Medical Radiocommunication Systems on a primary basis.

* * * * *

US312 The frequency 173.075 MHz may be authorized on a primary basis to non-Federal Government stations in the Public Safety Radio Pool, limited to police licensees, for stolen vehicle recovery systems (SVRS). SVRS may operate with an authorized bandwidth not to exceed 20 kHz.

* * * * *

PART 90—PRIVATE LAND MOBILE RADIO SERVICES

3. The authority citation for part 90 continues to read as follows:

Authority: Sections 4(I), 11, 303(g), 303(r), and 332(c)(7) of the Communications Act of 1934, as amended, 47 U.S.C. 154(I), 161, 303(g), 303(r), 332(c)(7).

4. Section 90.20 is amended by revising entries to the table in paragraph (c)(3), (d)(47), (d)(48), and (d)(49), by removing and reserving paragraphs (d)(50), and (d)(51), and by adding paragraphs (d)(86) and (d)(87) to read as follows:

§ 90.20 Public Safety Pool.

* * * * *

(c) * * *

(3) *Frequencies.*

PUBLIC SAFETY POOL FREQUENCY TABLE

Frequency or band	Class of station(s)	Limitations	Coordinator
*	*	*	*
	Megahertz		
*	*	*	*
150.775	Mobile	86	PM
150.7825 ..	do	87	PM
150.790	do	86	PM
150.7975 ..	do	87	PM
*	*	*	*
152.0075 ..	Base	13, 30, 86	PM
*	*	*	*
163.250	do	13, 86	PM
166.250	do	47	PF
169–172 ...	Mobile or operational fixed	48	
170.150	Base or mobile	47	PF
170.425	do	9, 49	PO
170.475	do	9, 49	PO
170.575	do	9, 49	PO
171.425	do	9, 49	PO
171.475	do	9, 49	PO
171.575	do	9, 49	PO
172.225	do	9, 49	PO
172.275	do	9, 49	PO
172.375	do	9, 49	PO
*	*	*	*
406–416 ...	Operational fixed	48	
*	*	*	*

(d) * * *

* * * * *

(47) This frequency may be assigned to stations in the Public Safety Pool in accordance with the provisions of § 90.265.

(48) Frequencies in this band will be assigned only for transmitting hydrological or meteorological data or for low power wireless microphones in accordance with the provisions of § 90.265.

(49) This frequency may be assigned only for forest fire-fighting and conservation activities in accordance with the provisions of § 90.265.

(50) [Reserved]

(51) [Reserved]

* * * * *

(86) This frequency will be assigned only for Medical Radiocommunication Systems in accordance with the provisions of § 90.265.

(87) Use of this frequency shall be limited to stations licensed as of [effective upon publication of the Report and Order in this proceeding].

5. Section 90.35(b)(3) is amended by removing the entry for "406–413" and adding in its place "406–416" to read as follows:

§ 90.35 Industrial/Business Pool.

* * * * *

(b) * * *

(3) *Frequencies.*

INDUSTRIAL/BUSINESS POOL FREQEUNCY TABLE

Frequency or band	Class of station(s)	Limitations	Coordinator
* * * * * * *			
Megahertz			
* * * * * * *			
406–416	Operational fixed	53	
* * * * * * *			

6. Section 90.203 is amended by revising paragraph (j) introductory text, and the first sentence in paragraphs (j)(3), and (j)(5), and by revising (j)(7) to read as follows:

§ 90.203 Certification required.

* * * * *

(j) Except where otherwise specially provided for, transmitters operating on frequencies in the 150–174 MHz and 406–512 MHz bands must comply with the following:

* * * * *

(3) Applications for part 90 certification of transmitters designed to operate on frequencies in the 150–174 MHz and/or 406–512 MHz bands, received on or after February 14, 1997, must include a certification that the equipment meets a spectrum efficiency standard of one voice channel per 12.5 kHz of channel bandwidth. * * *

* * * * *

(5) Applications for part 90 certification of transmitters designed to operate on frequencies in the 150–174 MHz and/or 406–512 MHz bands, received on or after January 1, 2005, must include a certification that the equipment meets a spectrum efficiency standard of one voice channel per 6.25 kHz of channel bandwidth. * * *

* * * * *

(7) All transmitters that are designed for one-way paging operations, except those operating on the frequency 163.25 MHz, will be certified with a 25 kHz channel bandwidth and are exempt from the spectrum efficiency requirements of paragraphs (j)(3) and (j)(5) of this section.

* * * * *

7. Section 90.209 is amended by removing the entry "421–512 [2]", in the table following paragraph (b)(5), and adding in its place "406–512 [2]" to read as follows:

§ 90.209 Bandwidth limitations.

* * * * *

(b) * * *

(5) * * *

STANDARD CHANNEL SPACING BANDWIDTH

Frequency band (MHz)	Channel Spacing (kHz)	Authorized bandwidth (kHz)
* * * * * * *		
406–512 [2]	[1] 6.25	[1 3] 20/11.25/6
* * * * * * *		

* * * * *

8. Section 90.217 is amended by adding paragraph (e) to read as follows:

§ 90.217 Exemption from technical standards.

* * * * *

(e) Transmitters used for wireless microphone operations and operating on frequencies allocated for Federal Government use must comply with the requirements of § 90.265(b).

9. Section 90.265 is amended by revising the section heading and paragraph (a) introductory text and the table preceding paragraph (a)(1) and by adding paragraphs (a)(5) through (a)(9), (c), (d), and (e) to read as follows:

§ 90.265 Assignment and use of frequencies in the bands allocated to Federal Government use.

(a) The following center frequencies are available for assignment to fixed stations in the Public Safety Pool or the Industrial/Business Pool, subject to the provisions of this section:

HYDRO CHANNELS (MHz)

169.4250	170.2625	171.1000	406.1250
169.4375	170.2750	171.1125	406.1750
169.4500	170.2875	171.1250	412.6625
169.4625	170.3000	171.8250	412.6750
169.4750	170.3125	171.8375	412.6875

HYDRO CHANNELS (MHZ)—Continued

169.4875	170.3250	171.8500	412.7125
169.5000	171.0250	171.8625	412.7250
169.5125	171.0375	171.8750	412.7375
169.5250	171.0500	171.8875	412.7625
170.2250	171.0625	171.9000	412.7750
170.2375	171.0750	171.9125	415.1250
170.2500	171.0875	171.9250	415.1750

* * * * *

(5) After January 1, 2005 for the 169–172 MHz band and January 1, 2008 for the 406–416 MHz band, channels for new operations are limited to an authorized bandwidth not to exceed 11.25 kHz. After those dates, existing systems with an authorized bandwidth of greater than 11.25 kHz (including those systems that expand existing operations) may continue to operate with a bandwidth greater than 11.25 kHz until January 1, 2013 (for Business/Industrial Pool licensees), and until January 1, 2018 (for Public Safety Pool licensees). Such operations are limited by § 90.265(a)(6) and (a)(7).

(6) After January 1, 2005, if a licensee of a channel in the band 169–172 MHz which uses equipment with an authorized bandwidth greater than 11.25 kHz cannot resolve an interference complaint to the satisfaction of an impacted Federal agency or is advised to do so by the Hydro Committee as approved by the FCC, then the licensee must cease operation on the frequency upon notification by the Commission.

(7) After January 1, 2008, if a licensee of a channel in the band 169–172 MHz which uses equipment with an authorized bandwidth greater than 11.25 kHz cannot resolve an interference complaint to the satisfaction of an impacted Federal agency or is advised to do so by the Hydro Committee as approved by the FCC, then the licensee must cease operation on the frequency upon notification by the Commission.

(8) After [effective upon publication of the Report and Order in this proceeding], new assignments on the frequencies 406.125 MHz and 406.175 MHz are to be primarily for paired operations with the frequencies 415.125 MHz and 415.175 MHz, respectively and limited to an authorized bandwidth not to exceed 11.25 kHz when paired.

(9) Existing stations may continue to use the center frequencies 169.575 MHz, 409.675 MHz, 409.725 MHz, and 412.625 MHz until January 1, 2013 for Business/Industrial Pool licensees and until January 1, 2018 for Public Safety Pool licensees, subject to the requirements of § 90.265(a)(6) and (a)(7).

* * * * *

(c) The following center frequencies are available for assignment to licensees engaged in forest fire-fighting and conservation activities, subject to the provisions of this section:

FOREST FIRE-FIGHTING AND CONSERVATION CHANNELS (MHZ)

170.425	171.425	172.225
170.475	171.475	172.275
170.575	171.575	172.375

(1) These frequencies will be assigned on a secondary basis to any U.S. Government station.

(2) The frequencies 170.425 MHz, 170.475 MHz, 170.575 MHz, 171.425 MHz, 171.575 MHz, 172.225 MHz, and 172.275 MHz will be assigned only to licensees directly responsible for the prevention, detection, and suppression of forest fires.

(3) The frequencies 171.475 MHz and 172.275 MHz will be assigned to licensees directly responsible for the prevention, detection, and suppression of forest fires; or to licensees engaged in forest conservation activities for mobile relay operation only.

(4) The frequencies 170.425 MHz, 170.575 MHz, 171.475 MHz, 172.225 MHz, and 172.375 MHz will be assigned for use only in areas west of the Mississippi River.

(5) The frequencies 170.475 MHz, 171.425 MHz, 171.575 MHz, and 172.275 MHz will be assigned for use only in areas east of the Mississippi River.

(6) All applications for use of these frequencies must be accompanied by a letter of concurrence by the Federal Government, Department of Agriculture.

(7) After January 1, 2005, channels for new operations are limited to an authorized bandwidth not to exceed 11.25 kHz. Between January 1, 2005, and January 1, 2018, existing systems with an authorized bandwidth of greater than 11.25 kHz (including those systems that expand existing operations) may continue to operate with a bandwidth greater than 11.25 kHz, subject to the limitations set forth in § 90.265(c)(8).

(8) After January 1, 2005, if a licensee that uses equipment with an authorized bandwidth greater than 11.25 kHz cannot resolve an interference complaint from an impacted Federal agency, then the licensee must cease operation on the frequency upon notification by the Commission.

(d) The frequencies 166.250 MHz and 170.150 MHz are available for assignment to licensees engaged in public safety activities, subject to the provisions of this section:

(1) These frequencies are available for assignment to stations in the Public Safety Pool, only at points within 241.4 km. (150 mi.) of New York, N.Y.;

(2) Operations on these channels is on a secondary basis to any Federal Government station; and

(3) After January 1, 2005, if a licensee that uses equipment with an authorized bandwidth greater than 11.25 kHz cannot resolve an interference complaint from an impacted Federal agency, then the licensee must cease operation on the frequency upon notification by the Commission.

(4) After January 1, 2005, channels for new operations are limited to an authorized bandwidth not to exceed 11.25 kHz. Between January 1, 2005, and January 1, 2018, existing systems with an authorized bandwidth of greater than 11.25 kHz (including those systems that expand existing operations) may continue to operate with a bandwidth greater than 11.25 kHz, subject to the limitations set forth in § 90.265(d)(3).

(e) The following frequencies are available for use by Medical Radiocommunication Systems:

(1) The frequencies 150.775 MHz, 150.790 MHz, and 163.250 MHz, subject to following provisions:

(i) After [effective upon publication of the Report and Order in this proceeding], new assignments for these frequencies shall be authorized only for Medical Radiocommunication Systems.

(ii) After January 1, 2005, new operations on the frequency 163.25 MHz are limited to an authorized bandwidth not to exceed 11.25 kHz.

(iii) After January 1, 2008, new operations on the frequencies 150.775 MHz and 150.790 MHz are limited to an authorized bandwidth not to exceed 11.25 kHz.

(iv) Existing systems with an authorized bandwidth of greater than 11.25 kHz (including those systems that expand existing operations) may continue to operate on a primary basis with a bandwidth greater than 11.25 kHz until January 1, 2018. After January 1, 2018, stations that use the frequencies 150.775 MHz, 150.790 MHz, or 163.25 MHz shall be limited to an authorized bandwidth not to exceed 11.25 kHz.

(2) The frequency 152.0075 MHz and frequencies within the bands 462.9375–463.1875 MHz and 467.9375 MHz-468.1875 MHz, subject to the limitations specified in § 90.20 of this chapter.

[FR Doc. 04–17074 Filed 8–2–04; 8:45 am]
BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 04–2267; MB Docket No. 04–266, RM–11005; MB Docket No. 04–267, RM–11008; MB Docket No. 04–268; RM–11009; MB Docket No. 04–269, RM–11010; MB Docket No. 04–270 RM–11012; MB Docket No. 04–271; RM–11013; MB Docket No. 04–272; RM–11014; MB Docket No. 04–273, RM–11015; MB Docket No. 04–274; RM–11016; MB Docket No. 04–275; RM–11017; MB Docket No. 04–276; RM–11033; MB Docket No. 04–277; RM–11034; MB Docket No. 04–278; RM–11035; MB Docket No. 04–279; RM–11036; MB Docket No. 04–280; RM–11037]

Radio Broadcasting Services; Coalinga, CA; Coupeville, WA; Harrisonburg, LA; Mecca, CA; Mooreland, OK; Randsburg, CA; Port Isabel, TX; Richland Springs, TX; Ringwood, OK; Rosepine, LA; San Joaquin, CA; Taos, NM; Taos Pueblo, NM, Wasco, CA; Waynoka, OK

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document proposes 15 allotments to Coalinga, California, Coupevile, Washington, Harrisonburg, Louisiana, Mecca, California, Mooreland, Oklahoma, Randsburg, California, Port Isabel, Texas, Richland Springs, Texas, Ringwood, Oklahoma, Rosepine, Louisiana, San Joaquin, California, Taos Pueblo, New Mexico, Taos, New Mexico, Wasco, California, and Waynoka, Oklahoma. *See* **SUPPLEMENTARY INFORMATION**, *infra*.

DATES: Comments must be filed on or before September 16, 2004, and reply comments on or before October 1, 2004.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, his counsel, or consultant, as follows: Charles Crawford, 4553 Bordeaux Avenue, Dallas Texas 75205 (Petitioner for the Harrisonburg, LA; Rosepine, LA, Waynoka, OK; Richland Springs, TX; Ringwood, OK; and Mooreland, OK proposals); Dana J. Puopolo, 2134 Oak Street, Unit C, Santa Monica, California, 90405 (Petitioner for the Mecca, CA; Taos, NM; Port Isabel, TX; Randsburg, CA; Taos Pueblo, NM; and Coupeville, WA proposals); Linda A. Davidson, 2134 Oak Street, Unit C, Santa Monica, California 90405 (Petitioner for the San Joaquin, CA; and Wasco, CA proposals); and Robert Eurich, President, 105 Mountain Air, Inc., 7179 N. Van Ness, Fresno, California 93711 (Petitioner for the Coalinga, CA proposal).

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 04–266; MB Docket No. 04–267; MB Docket No. 04–268; MB Docket No. 04–269; MB Docket No. 04–270; MB Docket No. 04–271; MB Docket No. 04–272; MB Docket No. 04–273; MB Docket No. 04–274; MB Docket No. 04–275, MB Docket No. 04–276; MB Docket No. 04–277; MB Docket No. 04–278; MB Docket No. 04–279; and MB Docket No. 04–280; adopted July 21, 2004, and released July 26, 2004. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 Twelfth Street, SW., Washington, DC. This document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or *http://www.BCPIWEB.com*.

The Audio Division requests comments on a petition filed by Charles Crawford proposing the allotment of Channel 232A at Harrisonburg, Louisiana, as the community's first local aural transmission service. Channel 232A can be allotted to Harrisonburg in compliance with the Commission's minimum distance separation requirements with a site restriction of 4.9 kilometers (3.0 miles) northeast to avoid short-spacings to the licensed sites of Station WEMX(FM), Channel 231C1, Kentwood, Louisiana, and Station KSMB(FM), Channel 233C, Lafayette, Louisiana. The coordinates for Channel 232A at Harrisonburg are 31–48–18 North Latitude and 91–47–26 West Longitude.

The Audio Division requests comments on a petition filed by Dana J. Puopolo proposing the allotment of Channel 274A at Mecca, California, as the community's second local FM transmission service. Channel 274A can be allotted to Mecca in compliance with the Commission's minimum distance separation requirements at city reference coordinates. The coordinates for Channel 274A at Mecca are 33–34–18 North Latitude and 116–04–35 West Longitude. Since Mecca is located within 320 kilometers (199 miles) of the U.S.-Mexican border, concurrence of the Mexican government has been requested.

The Audio Division requests comments on a petition filed by Dana J. Puopolo proposing the allotment of Channel 288A at Taos, New Mexico, as the community's fifth local FM transmission service. Channel 288A can be allotted to Taos in compliance with the Commission's minimum distance separation requirements with a site restriction of 8.3 kilometers (5.2 miles) northwest to avoid a short-spacing to the proposed allotment of Channel 287C at Des Moine, New Mexico. The coordinates for Channel 288A at Taos are 36–26–55 North Latitude and 105–39–00 West Longitude.

The Audio Division requests comments on a petition filed by Linda A Davidson proposing the allotment of Channel 299A at San Joaquin, California, as the community's second local FM transmission service. Channel 299A at can be allotted to San Joaquin in compliance with the Commission's minimum distance separation requirements with a site restriction of 2.1 kilometers (1.2 miles) west to avoid a short-spacing to the licensed site for Station KZOL(FM), Channel 300B1, North Fork, California. The coordinates for Channel 299A at San Joaquin California are 36–36–00 North Latitude and 120–12–36 West Longitude.

The Audio Division requests comments on a petition filed by Charles Crawford proposing the allotment of Channel 281A at Rosepine, Louisiana, as the community's first local aural transmission service. Channel 281A can be allotted to Rosepine in compliance with the Commission's minimum distance separation requirements with a site restriction of 5.5 kilometers (3.4 miles)west to avoid a short-spacing to the licensed site of Station KJLO-FM, Channel 281C, Monroe, Louisiana The coordinates for Channel 281A at Rosepine are 30–55–24 North Latitude and 93–20–24 West Longitude.

The Audio Division requests comments on a petition filed by Charles Crawford proposing the allotment of

Channel 231C2 at Waynoka, Oklahoma, as the community's first local aural transmission service. Channel 231C2 can be allotted to Waynoka in compliance with the Commission's minimum distance separation requirements with a site restriction of 28.8 kilometers (17.9 miles) north to avoid a short-spacing to the proposed allotment site for Channel 233A, Cherokee, Oklahoma. The coordinates for Channel 231C2 at Waynoka are 36–49–25 North Latitude and 98–59–50 West Longitude.

The Audio Division requests comments on a petition filed by Linda A. Davidson proposing the allotment of Channel 224A at Wasco, California, as the community's first local FM transmission service. Channel 224A can be allotted to Wasco in compliance with the Commission's minimum distance separation requirements at city reference coordinates. The coordinates for Channel 224A at Wasco are 35–35–37 North Latitude and 119–20–35 West Longitude.

The Audio Division requests comments on a petition filed by Charles Crawford proposing the allotment of Channel 299A at Richland Springs, Texas, as potentially the community's third local FM transmission service. To accommodate the allotment, petitioner also requests the modification of the reference coordinates for vacant Channel 299A at Hamilton, Texas. Channel 299A can be allotted to Richland Springs in compliance with the Commission's minimum distance separation requirements with a site restriction of 14.7 kilometers (9.1 miles) southwest to avoid a short-spacing to the proposed allotment site for Channel 296A, Brady, Texas. The coordinates for Channel 299A at Richland Springs are 31–09–42 North Latitude and 99–02–03 West Longitude. Additionally, the modified reference coordinates (31–49–57 NL and 98–07–00 WL) for vacant Channel 299A, Hamilton, Texas, requires a site restriction of 14.3 kilometers (8.9 miles) north of the community. Since Richland Springs is located within 320 kilometers (199 miles) of the U.S.-Mexican border, concurrence of the Mexican government has been requested.

The Audio Division requests comments on a petition filed by Dana J. Puopolo proposing the allotment of Channel 288A at Port Isabel, Texas, as the community's second local FM transmission service. Channel 288A can be allotted to Port Isabel in compliance with the Commission's minimum distance separation requirements with a site restriction of 10.0 kilometers (6.3 miles) southeast of the community. The coordinates for Channel 288A at Port Isabel are North Latitude 25–59–25 and 97–09–59. Since Port Isabel is located within 320 kilometers (199 miles) of the U.S—Mexican border, concurrence of the Mexican government has been requested.

The Audio Division requests comments on a petition filed by 105 Mountain Air, Inc., proposing the allotment of Channel 265A at Coalinga, California, as the community's third local FM transmission service. Channel 265A can be allotted to Coalinga in compliance with the Commission's minimum distance separation requirements with a site restriction of 8.1 kilometers (5.1 miles) west to avoid a short-spacing to the licensed site for Station KWYE(FM), Channel 266A, Fresno, California. The coordinates for Channel 265A at Coalinga are 36–08–22 North Latitude and 120–27–00 West Longitude.

The Audio Division requests comments on a petition filed by Dana J. Puopolo proposing the allotment of Channel 271A at Randsburg, California, as the community's first local commercial FM transmission service. Channel 271A can be allotted to Randsburg in compliance with the Commission's minimum distance separation requirements at city reference coordinates. The coordinates for Channel 271A at Randsburg are 35–22–06 North Latitude and 117–39–25 West Longitude. Since Randsburg is located within 320 kilometers of the U.S.-Mexican border, concurrence of the Mexican government has been requested.

The Audio Division requests comments on a petition filed by Charles Crawford proposing the allotment of Channel 285A at Ringwood, Oklahoma, as the community's first local aural transmission service. Channel 285A can be allotted to Ringwood in compliance with the Commission's minimum distance separation requirements with a site restriction of. 10.0 kilometers (6.2 miles) northeast to avoid a short-spacing to the licensed site for Station WWLS-FM, Channel 285A, Bethany, Oklahoma. The coordinates for Channel 285A at Ringwood are North Latitude 36–26–13 and 98–09–31 West Longitude.

The Audio Division requests comments on a petition filed by Dana J. Puopolo proposing the allotment of Channel 292C3 at Taos Pueblo, New Mexico, as the community's first local aural transmission service. Channel 292C3 can be allotted to Taos Pueblo in compliance with the Commission's minimum distance separation requirements with at city reference coordinates. The coordinates for Channel 292C3 at Taos Pueblo are 36–26–19 North Latitude and 105–32–38 West Longitude.

The Audio Division requests comments on a petition filed by Charles Crawford proposing the allotment of Channel 254A at Mooreland, Oklahoma, as the community's third local FM transmission service. Channel 254A can be allotted to Mooreland in compliance with the Commission's minimum distance separation requirements with a site restriction of 13.9 kilometers (8.6 miles) northwest of the community. The coordinates for Channel 254A at Mooreland are 36–30–30 North Latitude and 99–20–00 West Longitude.

The Audio Division requests comments on a petition filed by Dana J. Puopolo proposing the allotment of Channel 266A at Coupeville, Washington, as the community's first local aural transmission service. Channel 266A can be allotted to Coupeville in compliance with the Commission's minimum distance separation requirements with a site restriction of 9.5 kilometers (5.9 miles) north to avoid a short-spacing to the licensed site for Station KPLZ-FM, Channel 268C, Seattle, Washington. The coordinates for Channel 266AA at Coupeville are 48–18–00 North Latitude and 122–42–00 West Longitude. Since Coupeville is located within 320 kilometers (200 miles) of the U.S-Canadian border, and the allotment is short-spaced to the licensed site for Channel 266C, New Westminster, British Columbia, and the allotment site for Channel 266A, River Jordan, British Columbia, concurrence of the Canadian government for this allotment has been requested as a specially negotiated, short-spaced allotment.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under California, is amended by adding Channel 265A at Coalinga; by adding Channel 274A at Mecca; by adding Randsburg, Channel 271A; by adding Channel 299A at San Joaquin; and by adding Wasco, Channel 224A.

3. Section 73.202(b), the Table of FM Allotments under Louisiana, is amended by adding Harrisonburg, Channel 232A; and by adding Rosepine, Channel 281A.

4. Section 73.202(b), the Table of FM Allotments under New Mexico, is amended by adding Channel 288A at Taos; and by adding Taos Pueblo, Channel 292C3.

5. Section 73.202(b), the Table of FM Allotments under Oklahoma, is amended by adding Channel 254A at Mooreland; by adding Ringwood, Channel 285A; and by adding Waynoka, Channel 231C2.

6. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding Channel 288A at Port Isabel; and by adding Channel 299A at Richland Springs.

7. Section 73.202(b), the Table of FM Allotments under Washington, is amended by adding Coupeville, Channel 266A.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Divison, Media Bureau.

[FR Doc. 04–17674 Filed 8–2–04; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 04–2261, MB Docket No. 04–281, RM–11041]

Television Broadcast Service and Digital Television Broadcast Service; Mobile, AL

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition filed by Paxson Communications Corporation, Television Capital Corporation of Mobile, Fant Broadcast Development, L.L.C. and Marri Broadcasting, L.P. (collectively, the "Applicants"), proposing substitution of DTV channel 18 for NTSC channel 61 at Mobile. DTV Channel 18 can be allotted to Mobile at reference coordinates 30–36–45 N. and 87–38–43 W. with a power of 396, a height above average terrain HAAT of 552 meters.

DATES: Comments must be filed on or before September 20, 2004, and reply comments on or before October 5, 2004.

ADDRESSES: The Commission permits the electronic filing of all pleadings and comments in proceeding involving petitions for rule making (except in broadcast allotment proceedings). *See Electronic Filing of Documents in Rule Making Proceedings,* GC Docket No. 97–113 (rel. April 6, 1998). Filings by paper can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. The Commission's contractor, Natek, Inc., will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class mail, Express Mail, and Priority Mail should be addressed to 445 12th Street, SW., Washington, DC 20554. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows:

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 04–281, adopted July 22, 2004, and released July 29, 2004. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. This document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 301–816–2820, facsimile 301–816–0169, or via-e-mail *joshir@erols.com.*

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

This document does not contain proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. 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 Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. *See* 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, *see* 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Digital television broadcasting, Television.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.606 [Amended]

2. Section 73.606(b), the Table of Television Allotments under Alabama is amended by removing Channel 61 at Mobile.

§ 73.622 [Amended]

3. Section 73.622(b), the Table of Digital Television Allotments under Alabama is amended by adding DTV channel 18 at Mobile.

Federal Communications Commission.

Barbara A. Kreisman,

Chief, Video Division, Media Bureau.

[FR Doc. 04–17677 Filed 8–2–04; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 69, No. 148
Tuesday, August 3, 2004

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

Office of the Secretary

Notice of the Forestry Research Advisory Council Meeting

AGENCY: Research, Education, and Economics, USDA.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. App 2, the United States Department of Agriculture announces a meeting of the Forestry Research Advisory Council. The meeting will be open to the public.

DATES: The Forestry Research Advisory Council will meet on August 25, 2004, from 8:30 a.m. to 4 p.m., and on August 26, 2004, from 8 a.m. to noon. A complete agenda will be available prior to the meeting. To obtain a copy call the Contact Person identified below.

ADDRESSES: The meeting will take place at the Mandarin Oriental Hotel, Portrait Conference Room, 1330 Maryland Avenue, SW., Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Catalino A. Blanche, FRAC Coordinator, Mail Stop 2210, 1400 Independence Avenue, SW., Washington, DC 20250; telephone: (202) 401–4190; fax: (202) 401–1706; e-mail: *cblanche@csrees.usda.gov.*

SUPPLEMENTARY INFORMATION: Section 1441(C) of the Agriculture and Food Act of 1981 requires the establishment of the Forestry Research Advisory Council to provide advice to the Secretary of Agriculture on accomplishing efficiently the purposes of the Act of October 10, 1962 (16 U.S.C. 582a, *et seq.*), known as the McIntire-Stennis Act of 1962. The Council also provides advice related to the Forest Service research program, authorized by the Forest and Rangeland Renewable Resources Research Act of 1978 (Pub. L. 95–307, 92 Stat. 353, as amended; 16 U.S.C. 1600 (note)). The Council is composed of 20 voting members from: federal and state agencies, forest industries, forestry schools and state agricultural experiment stations, and volunteer public groups.

The purposes of the meeting are: (a) To hear reports from the Forest Service, USDA, Cooperative State Research, Education and Extension Service, USDA, forest industries, the National Association of Professional Forestry Schools and Colleges, and (b) to formulate advice on Federal and state forestry research for the Secretary of Agriculture.

Done at Washington, DC this 27th day of July, 2004.

Joseph J. Jen,

Under Secretary, Research, Education, and Economics.

[FR Doc. 04–17625 Filed 8–2–04; 8:45 am]

BILLING CODE 3410–22–P

DEPARTMENT OF AGRICULTURE

Food Service

Shasta County Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Shasta County Resource Advisory Committee (RAC) will meet at the USDA Service Center in Redding, California, September 15, 2004. The purpose of this meeting is to discuss proposed projects under Title II of the Secure Rural Schools and Community Self-Determination Act of 2000.

DATES: September 15, 2004.

ADDRESSES: The meetings will be held at the USDA Service Center, 3644 Avtech Parkway, Redding, California 96002.

FOR FURTHER INFORMATION CONTACT: Michael R. Odle, Asst. Public Affairs Officer and RAC Coordinator.

SUPPLEMENTARY INFORMATION: The meetings are open to the public. Public input sessions will be provided and individuals will have the opportunity to address the Shasta County Resource Advisory Committee.

Dated: Dated: July 27, 2004.

J. Sharon Heywood,

Forest Supervisor, Shasta-Trinity National Forest.

[FR Doc. 04–17613 Filed 8–2–04; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Southern California Tree Mortality Emergency; Riverside, San Bernardino, and San Diego, Counties, CA

AGENCY: Natural Resources Conservation Service, USDA

ACTION: Notice of a finding of no significant impact.

SUMMARY: Pursuant to Section 102(2)(c) of the National Environmental Policy Act of 1969, the Council on Environmental Quality regulations (40 CFR Part 1500), and the Natural Resources Conservation Service regulations (7 CFR Part 650), the Natural Resources Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for proposed federal assistance for the Southern California Tree Mortality Emergency in Riverside, San Bernardino, and San Diego Counties, California.

FOR FURTHER INFORMATION CONTACT: Charles K. Davis, State Conservation Engineer, Natural Resources Conservation Service, 430 G Street, Davis, California 95616–4164, telephone (530) 792–5622.

SUPPLEMENTARY INFORMATION: The environmental assessment of this federally assisted action indicates that it will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Charles W. Bell, State Conservationist, has determined that the preparation and review of an environmental impact statement are not needed for this action.

The proposed work involves removal of dead and dying trees and excess brush that have created an imminent threat of catastrophic wildfire. The work will be done in locations where that threat has resulted in a hazard to life and property.

The Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various Federal, State, and local agencies. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting

Charles K. Davis, State Conservation Engineer.

Dated: July 27, 2004.

Helen R. Flach,

Assistant State Conservationist.

[FR Doc. 04–17624 Filed 8–2–04; 8:45 am]

BILLING CODE 3410–16–M

BROADCASTING BOARD OF GOVERNORS

Privacy Act of 1974: Notice of Systems of Records

AGENCY: Broadcasting Board of Governors (BBG).

ACTION: Notice of systems of records.

SUMMARY: This document is a compilation of the Broadcasting Board of Governors' Systems of Records maintained under the Privacy Act of 1974 (5 U.S.C. 552a), as amended. The Broadcasting Board of Governors (BBG) is a relatively new Agency and this is its first compilation of systems notices.

The compilation of the BBG's System of Records is made in compliance with the President's Memorandum of May 14, 1998 on Privacy and Personal Information in Federal Records. The President directed Federal agencies to review their information practices and ensure that they are conducted in accordance with privacy law and policy, because ensuring that the Federal government protects the privacy of personal information is a priority of the Administration. Office of Management and Budget (OMB) clearance is pending.

DATES: Effective date: This notice is effective 30 days from the date of publication. Persons wishing to comment on the systems or amended systems may do so through the above date at the address listed below.

ADDRESSES: For further information contact: Joseph Gatewood, Office of General Counsel, BBG, Suite 3349, 330 Independence Ave., SW., Washington DC 20237. Telephone (202) 260–4404. Any requests for information should make sure to identify the request as in reference to BBG's Privacy Act Systems of Records.

SUPPLEMENTARY INFORMATION: The BBG has never published a System of Records under the Privacy Act of 1974 (5 U.S.C. 552a), as amended, because it is a new agency that was created on October 1, 1999.

The Privacy Act created a statutory framework governing how the Federal government collects, maintains, uses and disseminates information about certain individuals.

Increased computerization of Federal records permits information to be used and analyzed in ways that could diminish individual privacy in the absence of additional safeguards. Therefore, we are assuring that the use of new information technologies sustains, and does not erode, the protections provided in the collection, use, retention and disclosure of personal information. The personal information will be handled in compliance with the requirements of the Privacy Act.

The Privacy Act provides that, upon request, an individual has the right to access any record maintained on that person in an agency's system of records. Under the Privacy Act, a "system of records" is a group of any records under the control of an agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

The Privacy Act further provides that an individual may make a request to gain access to his/her records or to any records pertaining to him that is contained within an agency's system of records, and that the individual may permit another individual to accompany him/her to review the record and have a copy made at the individual's expense. The agency may require that the individual requesting access to the records furnish a written statement authorizing discussion of the individual's record in the accompanying person's presence. The individual may request amendment of a record pertaining to him/her within the agency's system of records if the individual believes that the record is not accurate, relevant, timely or complete. In order for a request to be considered, the individual will clearly note the specific and precise portion of each record that the individual disagrees. The agency will then consider the individual's request, and determine whether it is appropriate to amend the record. If the agency deems amendment of the record appropriate, the agency will amend the record and so notify the individual. If the agency deems amendment of the record inappropriate, the agency will issue a refusal to the individual within 30 days of the individual's request that states the reason's for the refusal and the procedures established by the agency for the individual to request review of the agency's determination. Accompanying the agency's refusal will be the name(s) and addresses of the designated agency official(s) to whom the individual may request review of the agency's decision not to amend the record. Use of the Privacy Act as a mechanism to obtain access to files compiled in anticipation of a civil action or proceeding is forbidden.

The Privacy Act requires each agency to publish in the **Federal Register** a description denoting the type and character of each system of records that the agency maintains, and the routine uses that are contained in each system, as a means to notify individuals regarding the purposes for which personally identifiable information is disclosed and to assist the individual to more easily find such files within the Agency.

The BBG's publication of a system of records will readily enable individuals to determine if there are records maintained about the individual in the Agency's systems of records. Additionally, the publication of the Agency's systems notices will emphasize to Agency personnel the importance of protecting and regulating the collection, maintenance, use and dissemination of personal information.

OMB clearance is pending; the "Notice of Systems of Records" was submitted to OMB on July 7, 2004. The authority for maintaining these systems is the Privacy Act of 1974, 5 U.S.C. 552a, as amended.

Dated: July 27, 2004.

Carol Booker,

Acting General Counsel.

Table of Contents

(Complaint Files)
BBG–17—OCR—Office of Civil Rights (General Files)
BBG–18—OCR—Office of Civil Rights (Minority Groups)
BBG–19—P/K—Office of External Affairs (Clearance Files for Speaking, Teaching and Writing, and Approval Files for Outside Employment)

Statement of General Routine Uses Applicable to All BBG System of Records Files

The following routine uses apply to and are incorporated by reference into each system of records (BBG–1 through BBG–19) set forth in this Notice:

1. Disclosure for Law Enforcement Purposes

Information may be disclosed to the appropriate Federal, State, local, tribal or foreign agency responsible for investigating, prosecuting, enforcing, reviewing or implementing a statute, rule, regulation, license or order, if the information is relevant to a potential violation or civil or criminal law or regulation within the apparent jurisdiction of the entity.

2. Disclosure Incident to Requesting Information

Information may be disclosed to any source from which additional information is requested (to the extent necessary to identify the individual, inform the source of the purpose of the request, and to identify the type of information requested), when necessary to obtain information related to an agency decision concerning retention of the individual, or other personnel action (except hiring), retention or issuance of a security clearance, the letting of a contract, subcontract, cooperative agreement, grant, or other financial arrangement, or other benefit.

3. Disclosure to Requesting Agency

Information may be disclosed to a Federal, State, local, foreign, tribal or other public authority of the fact that this system of records contains information relevant to the retention of an employee, the retention or granting of a security clearance, the letting or retention of a contract, subcontract, cooperative agreement, grant or other financial arrangement, or the issuance or retention of a license or other benefit. The other agency or organization may then make a request supported by the written consent of the individual if it so chooses. No disclosure will be made unless the agency has a good faith belief that the information has been determined to be sufficiently reliable to support a referral to another office within the agency or to another Federal agency for criminal, civil, administrative, personnel, or regulatory action.

4. Disclosure to the Office of Management and Budget

Information may be disclosed to the Office of Management and Budget at any stage in the legislative coordination and clearance process in connection with legislation as set forth in OMB Circular No. A–19.

5. Disclosure to Congressional Offices

Information may be disclosed to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual.

6. Disclosure to the Department of Justice or for Litigation or Other Proceedings

Information may be disclosed to the Department of Justice, or in a proceeding before a court, adjudicative body, or other administrative body before which the Agency is authorized or required to appear. Such disclosures may occur in circumstances in which the Agency determines that litigation is likely to affect the Agency or any of its components, and the Agency is a party to the litigation or has an interest in such litigation, the Department of Justice or the Agency is deemed to be relevant and necessary to the litigation, and the use of the records is compatible with the purpose for which the records or information were collected. Information may also be disclosed in connection with litigation or settlement discussions regarding claims by or against the Agency, including public filing with a court, arbitrator, mediator, administrative body or other deciding or mediating official or body, as relevant and necessary to the discussions or proceedings, and except where court orders are otherwise required under section (b)(11) of the Privacy Act, 5 U.S.C. 552a(b)(11).

7. Disclosure for Hiring or Retention of Employee

Information may be disclosed from this system of records to a Federal, State or local agency in response to a request by the agency in connection with the hiring, retention or investigation of an employee, issuance of a security clearance, letting of a grant or contract, or the issuance of a license, grant or other benefit by the requesting agency, to the extent that such information is deemed relevant to the requesting agency's decision.

8. Disclosure to the Office of Personnel Management

Information may be disclosed to the Office of Personnel Management pursuant to the Agency's responsibility or authority for oversight or evaluation of Federal personnel management.

9. Disclosure to the National Archives or Federal Records Management Centers

Information may be disclosed to the National Archives or Federal Records Management Centers as necessary for purposes of records management or records management inspections.

10. Disclosure for Administrative Claims, Complaints, Appeals

Information may be disclosed to an authorized appeal grievance examiner, formal complaints examiner, equal opportunity employment investigator or official, arbitrator, mediator, opposing counsel or representative, or other person properly engaged in investigation, settlement, litigation or decision regarding an administrative grievance, complaint, claim, or appeal filed by an employee, but only to the extent that the information is relevant and necessary to the proceeding. Agencies that may obtain information under this routine use include, but are not limited to, the Office of Personnel Management, Office of Special Counsel, Merit Systems Protection Board, Federal Labor Relations Authority, Equal Employment Opportunity Commission, and Office of Government Ethics.

11. Disclosure to Contractors, Grantees and Others

Information may be disclosed to contractors, grantees, consultants, or volunteers performing or working on a contract, grant, cooperative agreement, job, service, or other activity for the Agency and who have a need to have access to the information in the performance of their duties or activities for the Agency. Where appropriate, the Agency may require such individuals or entities to comply with the Privacy Act, as provided in 5 U.S.C. 552a(m).

12. Disclosure to Federal Agencies for Purposes of Audit

A record from this system of records may be disclosed to authorized employees of a Federal agency for purposes of audit or program review. Examples of such agencies include, but are not limited to, Offices of Inspector General, General Accounting Office, Department of the Treasury, and Office of Management and Budget.

13. Disclosure to Department of State

A record from this system of records may be disclosed to the Department of State and its posts abroad for the purpose of transmission of information between organizational units of the Agency, or for purposes related to the responsibilities of the Department of State in conducting foreign policy or protecting United States citizens, such as the assignment of employees to positions abroad, the reporting of accidents abroad, evacuation of employees and dependents, and other purposes for which officers and employees of the Department of State have a need for the records in the performance of their official duties.

14. Disclosure to International or Foreign Agencies or Entities

A record in this system of records may be disclosed to a foreign government or international agency when necessary to facilitate the conduct of U.S. relations with that government or agency through the issuance of such documents as visas, country clearances, identification cards, drivers' licenses, diplomatic lists, licenses to import or export personal effects, and other official documents and permits routinely required in connection with the official service or travel abroad of the individual and her or his dependents.

15. Disclosure Under Foreign Assistance Act

A record in this system of records may be disclosed to Federal agencies with which the Agency has entered into an agreement to provide services to assist the Agency in carrying out its functions under the Foreign Assistance Act of 1961, as amended. Such disclosures would be for transmitting information between organizational units of the Agency, for providing to the original employing agency information concerning the services of its employee while under the supervision of the Agency, including performance evaluations, reports of conduct, awards and commendations, and information normally obtained in the course of personnel administration and employee supervision, or for providing other information directly related to the purpose of the inter-agency agreement as set forth therein, and necessary and relevant to its implementation.

16. Disclosure Pursuant to FOIA

A record in this system of records may be disclosed to the Department of Justice to determine whether disclosure thereof is required by the Freedom of Information Act (5 U.S.C. 552). A record in this system of records may be disclosed when the information is subject to exemption under the Freedom of Information Act (5 U.S.C. 552), but the Agency, in its discretion, determines not to assert the exemption.

17. Disclosure to State and Local Tax Authorities

A record from this system of records may be disclosed to state and local tax authorities with which the Secretary of the Treasury has entered into agreements and only to those state and local taxing authorities for which the employee is subject to tax (whether or not tax is withheld).

BBG–1

SYSTEM NAME:

Broadcasting Board of Governors Staff Files—BBG.

SYSTEM LOCATION:

Broadcasting Board of Governors (BBG), Rm. 3360, 330 Independence Ave., SW., Washington, DC 20237.

SECURITY CLASSIFICATION:

None.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who submit or receive official correspondence from the BBG or Board Staff.

CATEGORIES OF RECORDS IN THE SYSTEM:

Correspondence to and from the Board and Board Staff, BBG reports, Board biographical files, Broadcasting Entities (*e.g.*, Voice of America (VOA), International Broadcasting Bureau (IBB), Office of Cuba Broadcasting (OCB), Radio Free Asia (RFA), and Radio Free Europe/Radio Liberty (RFE/RL)).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Federal Records Act of 1950, as amended; 44 U.S.C. 3101–3167; Records Disposal Act of 1943, as amended; 44 U.S.C. 3301–3314.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

To maintain a record of correspondence to and from the BBG Board, both with individuals and institutions outside the Agency and to the BBG Broadcasting entities, reports provided to Congress either by request or on an informational basis, and biographical information on Board members for BBG and public use. Records are used and accessed by Board members and Board staff. Also see Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Information is retained in document form in file folders and in computers.

RETRIEVABILITY:

Manually retrieved by category and name.

SAFEGUARDS:

1. Authorized users: access to files is limited to only authorized BBG employees having a substantiated need for the information.

2. Physical safeguards: all files are protected by office personnel during regular duty hours and during non-duty hours by security doors that can only be accessed by BBG staff employees. Computer information is protected by the use of passwords restricted to authorized users. Files are contained in secure building that can be accessed only by persons showing proper identification credentials.

3. Procedural safeguards: access to records is limited to staff members on a need to know basis, to employees performing their official duties.

RETENTION AND DISPOSAL:

Records are maintained until no longer useful or relevant and then retired or destroyed in accordance with BBG policy and procedures.

SYSTEM MANAGER(S) AND ADDRESS:

BBG Executive Director, Broadcasting Board of Governors, Room 3360, 330 Independence Ave., SW, Washington, DC 20237.

NOTIFICATION PROCEDURES:

Individuals who want to know whether this system of records contains information about them, or who want access to their records, or who want to contest the contents of a record, should make a written request to: FOIA/Privacy Act Officer, Broadcasting Board of Governors (BBG), Suite 3349, 330 Independence Ave., SW, Washington, DC 20237. Individuals' requests should contain the name and address of the system manager (listed above) and the following information to enable their records to be located and identified:

A. Full legal name;

B. Date of Birth;

C. Social Security Number;

D. Last employing organization (include duty station location) and the approximate dates of employment or contact; and

E. Signature.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should follow the

Notification Procedures (listed above). Individuals requesting access will also be required to provide adequate identification, such as driver's license, employee identification card, and/or other identifying document. Additional identification procedures may be required in some instances. To request a file other than your own, you must have a notarized, signed statement giving you express permission to access the file from the individual to whom the file pertains.

CONTESTING RECORD PROCEDURES:

The BBG's rules for access and for contesting contents and appealing determinations by the individual concerned appear at 22 CFR Part 505. The right to contest records is limited to information that is incomplete, irrelevant, erroneous or untimely.

RECORD SOURCE CATEGORIES:

Biographical and ethics information furnished voluntarily by subject individuals, unsolicited correspondence, requests and inquiries from U.S. Government officials and members of the general public to the BBG and BBG staff.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

BBG–2

SYSTEM NAME:

Office of the General Counsel Litigation Files.

SYSTEM LOCATION:

Broadcasting Board of Governors, Office of the General Counsel, Suite 3349, 330 Independence Ave., SW, Washington, DC 20237.

SECURITY CLASSIFICATION:

Some documents within the system may be classified or confidential.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have filed grievances, inquiries or discrimination complaints; employees separated or considered for separation for cause; officers selected out; individuals taking legal actions against the BBG or its employees; tort claimants and accident victims; employees and related persons for whom legislative action is sought; personal property loss claimants; employees and applicants raising legal or administrative issues concerning rights or benefits; individuals whose salaries have been garnished; individuals whose official personnel files have been subpoenaed in connection with divorce, custody or other litigation.

CATEGORIES OF RECORDS IN THE SYSTEM:

Investigatory reports; litigation reports; pre-hearing and pre-trial material; evidence for discovery and submission to hearing officers and courts; pleadings; briefs; transcripts; decisions and other related documents.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Federal Records Act, as amended, 44 U.S.C. 3101.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF THE ROUTINE USES:

To represent the BBG in claims and other legal actions; to issue legal opinions or determinations regarding BBG action and perform all of the BBG's legal representation and advocacy functions.

Information is made available on a need-to-know basis to personnel of the BBG as may be required in the performance of their official duties. The principal users of this information outside of the BBG are the Department of Justice, Department of State, including Office of Inspector General, Office of Personnel Management, Foreign Service Grievance Board, and the Employee Management Relations Committee.

Records contained in these files may be released to agencies outside the BBG who have statutory, regulatory, or other lawful authority to collect, maintain or use such information. Also see Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders, electronic data on computer storage media.

RETRIEVABILITY:

By the name of the individual and the nature of the legal action.

SAFEGUARDS:

Maintained in locked file cabinets and in offices in office suites to which only authorized BBG personnel have access. Computer files are maintained on networked BBG computers that are accessible only through the use of passwords.

RETENTION AND DISPOSAL:

Records may be retained until such time as they are no longer useful, current, or for a period of time until it can be assured that all legal proceedings and matters are final and concluded.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the General Counsel, BBG, Suite 3349, 330 Independence Ave., SW, Washington, DC 20237.

NOTIFICATION PROCEDURES:

Individuals who want to know whether this system of records contains information about them, or who want access to their records, or who want to contest the contents of a record, should make a written request to: FOIA/Privacy Act Officer, BBG, Suite 3349, 330 Independence Ave., SW, Washington, DC 20237. Individuals' requests should contain the name and address of the system manager (listed above) and the following information to enable their records to be located and identified:

A. Full legal name;
B. Date of Birth;
C. Social Security Number;
D. Last employing organization (include duty station location) and the approximate dates of employment or contact; and
E. Signature.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should follow the Notification Procedures (listed above). Individuals requesting access will also be required to provide adequate identification, such as driver's license, employee identification card, and/or other identifying document. Additional identification procedures may be required in some instances. A notarized signature is required if the request is made by written correspondence. To request a file other than your own, you must have a notarized, signed statement giving you express permission to access the file from the individual to whom the file pertains.

CONTESTING RECORD PROCEDURES:

The BBG's rules for access and for contesting the contents of records subject to the Privacy Act, and appealing determinations appear in 22 CFR Part 505. The right to contest records is limited to information that is incomplete, irrelevant, erroneous or untimely.

RECORD SOURCE CATEGORIES:

Information provided by the individual and/or their attorneys or representatives, and by employees of the BBG; information produced in the processing of a claim, grievance, legal action or issue.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552(a)(k)(2) and (k)(5), all investigatory material in the record which meets the criteria of these subsections is exempted from the

notice, access and contest requirements (under 5 U.S.C. 552a(c)(3), (d)(e)(1), (e)(4)(G), (H) and (I) and (f) of the BBG regulations) in order for the BBG's legal staff to properly perform its functions. *See also* 22 CFR 505.15.

BBG–3

SYSTEM NAME:

Freedom of Information and Privacy Act Files—BBG/GC/FP.

SYSTEM LOCATION:

Freedom of Information Act (FOIA)/ Privacy Act (PA) Officer, Office of the General Counsel, Broadcasting Board of Governors, 330 Independence Ave., SW., Suite 3349, Washington, DC 20237.

SECURITY CLASSIFICATION:

Some documents may be classified Confidential and Secret.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have requested documents/records or other information maintained and in the possession of the BBG (pursuant to the Freedom of Information Act) or maintained by the BBG in a System of Records about themselves (pursuant to the Privacy Act of 1974).

CATEGORIES OF RECORDS IN THE SYSTEM:

Official, unofficial or personal information maintained and in possession of the BBG through reports, memoranda, correspondence, etc.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 552 (Freedom of Information Act) and 5 U.S.C. 552a (Privacy Act).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

For processing of requests received pursuant to the FOIA and the Privacy Act. Information is made available on a need to know basis to personnel of the BBG as may be required in the performance of their official duties.

Information in these records is not normally available to individuals or agencies outside the BBG, but records may be released to other government agencies who have statutory or other lawful authority to maintain or view such information.

Also see Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders, and electronic storage on computers.

RETRIEVABILITY:

By name of individual or personal identifier.

SAFEGUARDS:

Records are maintained in secure office area with access only to BBG employees, and in bar locked cabinets and in combination locked storage.. Computer and data base records are maintained on secure BBG computers with access only to authorized individuals with the appropriate password information.

RETENTION AND DISPOSAL:

Retired and destroyed in accordance with record disposition schedules for BBG.

SYSTEM MANAGER(S) AND ADDRESS:

FOIA/Privacy Act Officer, Office of the General Counsel, Broadcasting Board of Governors, 330 Independence Ave., SW., Suite 3349, Washington, DC 20237.

NOTIFICATION PROCEDURES:

Individuals who want to know whether this system of records contains information about them, or who want access to their records, or who want to contest the contents of a record, should make a written request to: FOIA/Privacy Act Officer, BBG, Suite 3349, 330 Independence Ave., SW., Washington, DC 20237. Individuals' requests should contain the name and address of the system manager (listed above) and the following information to enable their records to be located and identified:

A. Full legal name;

B. Date of Birth;

C. Social Security Number;

D. Last employing organization (include duty station location) and the approximate dates of employment or contract; and

E. Signature.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should follow the Notification Procedures (listed above). Individuals requesting access will also be required to provide adequate identification, such as driver's license, employee identification card, and/or other identifying document. Additional identification procedures may be required in some instances. To request a file other than your own, you must have a notarized, signed statement giving you express permission to access the file from the individual to whom the file pertains.

CONTESTING RECORD PROCEDURE:

The BBG's rules for access and for contesting/amending record contents and appealing determinations appear in 22 CFR Part 505. The right to contest records is limited to information that is incomplete, irrelevant, erroneous or untimely.

RECORD SOURCE CATEGORIES:

Compiled as a result of requests under the Freedom of Information Act (FOIA) and the Privacy Act.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Certain records contained within the system of records may be exempted under 5 U.S.C. 552 (k)(1)–(2), (k)(4)–(6).

BBG–4

SYSTEM NAME:

Office of Legal Counsel Ethics Files (Financial Disclosure Reports).

SYSTEM LOCATION:

Office of the General Counsel, BBG, 330 Independence Ave., SW., Suite 3349, Washington, DC 20237.

SECURITY CLASSIFICATION:

None for the system. However, some documents within the system may be classified as confidential or otherwise protected or immunized from disclosure.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Experts or consultants, employees, paid at the Executive Schedule level; employees classified at GS–13, or the Foreign Service Equivalent, or higher, who are in positions of responsibility for a government decision or taking a government action with regard to: Contracting or procurement; administering or monitoring grants or subsidies; regulating or auditing private or other non-Federal enterprise; or required to report employment or financial interests in order to determine potential conflicts of interest or to ensure that BBG decision making is not performed by individuals with an ethical conflict.

CATEGORIES OF RECORDS IN THE SYSTEM:

Statements of personal and family financial and share holdings and other interests in business enterprises; copies of blind trusts and other agreements pertaining to such interests; correspondence regarding potential or actual conflicts of interest, or regarding investigation, insulation or control of individuals to prevent or eliminate potential conflicts of interest; opinions of counsel, including recommendations of waivers.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Executive Order 11222; 5 U.S.C. 7301; 18 U.S.C. 208; Ethics in Government Act of 1948, as amended.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Review by the Ethics Officer and staff for possible conflicts of interest. Provide necessary reference information should allegations of conflicts arise. Also see Statement of General Routine Uses.

On a need-to-know basis, sharing of ethics information among BBG components or employees in their official capacities for the purpose of investigating or addressing allegations of conduct that is related to addressing ethics issues.

Information in Confidential Financial Disclosure Reports is not normally available to individuals or agencies outside of the BBG, but records may be released to other government agencies who have statutory or other lawful authority to maintain such information. Information in Public Financial Disclosure Reports is generally subject to public disclosure.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders and electronic data base and computer entries.

RETRIEVABILITY:

Alphabetically by name and by BBG element or geographic area.

SAFEGUARDS:

Maintained in secure office area with access only to BBG employees, and in bar locked cabinets and in combination locked storage. Computer and data base records are maintained on secure BBG computers with access only to authorized individuals with the appropriate password information.

RETENTION AND DISPOSAL:

Disposed of six years after employee leaves a position for which a report or ethics information is or has been required.

SYSTEM MANAGER AND ADDRESS:

Office of the General Counsel, Broadcasting Board of Governors (BBG), Suite 3349, 330 Independence Ave., SW., Washington, DC 20237.

NOTIFICATION PROCEDURES:

Individuals who want to know whether this system of records contains information about them, or who want access to their records, or who want to contest the contents of a record, should make a written request to: FOIA/Privacy Act Officer, BBG, Suite 3349, 330 Independence Ave., SW., Washington, DC 20237. Individuals' requests should contain the name and address of the system manager (listed above) and the following information to enable their records to be located and identified:

A. Full legal name;

B. Date of Birth;

C. Social Security Number;

D. Last employing organization (include duty station location) and the approximate dates of employment or contact; and

E. Signature.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should follow the Notification Procedures (listed above). Individuals requesting access will also be required to provide adequate identification, such as driver's license, employee identification card, and/or other identifying document. Additional identification procedures may be required in some instances. A notarized signature is required if the request is made by written correspondence. To request a file other than your own, you must have a notarized, signed statement giving you express permission to access the file from the individual to whom the file pertains.

CONTESTING RECORD PROCEDURE:

The BBG's rules for access and for contesting/amending record contents and appealing determinations appear in 22 CFR Part 505. The right to contest records is limited to information that is incomplete, irrelevant, erroneous or untimely.

RECORD SOURCE CATEGORIES:

From the individual who filed the required ethics form or from any individual who provided information pursuant to a complaint or legal request for examination of ethics or conflict of interest issues.

EXEMPTIONS CLAIMED FROM THE SYSTEM:

Certain records contained within the system of records may be exempted from disclosure pursuant to 5 U.S.C. 552 (k)(1)–(2), (k)(4)–(6).

BBG–5

SYSTEM NAME:

IBB Director's Executive Secretariat Files.

SYSTEM LOCATION:

Director's Office, Executive Secretariat, International Broadcasting Bureau, Broadcasting Board of Governors, 330 Independence Ave., SW., Washington, DC 20237.

SECURITY CLASSIFICATION:

Some documents may be classified confidential or secret.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Members of the White House Staff, Members of Congress and their staffs, heads of other executive agencies of the Federal Government and members of the general public.

CATEGORIES OF RECORDS IN THE SYSTEM:

Correspondence addressed to the IBB Director, as well as the BBG, and copies of responses to requests for reports, information and/or assistance of various kinds prepared by the Director or designated representative.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Federal Records Act of 1950, as amended, 44 U.S.C. 3101–3167; Records Disposal Act of 1943, as amended, 44 U.S.C. 3301–3314.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Reference files to provide oversight of the flow of requests of the Director for reports on programming effectiveness of BBG broadcasts; to provide information and/or assistance of various kinds; and to provide and monitor responses to such requests.

Information is made available on a need-to-know basis to personnel of the BBG as may be required in the performance of their official duties.

The information may also be released to other government agencies who have statutory or other lawful authority to maintain or use such information.

Also see Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored on computer maintained by and located within the Secretariat, and maintained as paper records in file folders in the Secretariat.

RETRIEVABILITY:

Records are cross-indexed by individual name, organization, subject file and by computer reference number.

SAFEGUARDS:

Computer records are accessible only to authorized employees of the Director's staff with appropriate password information. Paper records are kept in locked file cabinets that are contained in a secure area. All records are contained in secure building that is accessible only to individuals with appropriate identification.

RETENTION AND DISPOSAL:

Records are maintained indefinitely.

SYSTEM MANAGER(S) AND ADDRESS:

Supervisory Staff Analyst, Executive Secretariat, BBG, 330 Independence Ave., SW., Washington, DC 20237.

NOTIFICATION PROCEDURES:

Individuals who want to know whether this system of records contains information about them, or who want access to their records, or who want to contest the contents of a record, should make a written request to: FOIA/Privacy Act Officer, BBG, Suite 3349, 330 Independence Ave., SW., Washington, DC 20237. Individuals' requests should contain the name and address of the system manager (listed above) and the following information to enable their records to be located and identified:

A. Full legal name;
B. Date of Birth;
C. Social Security Number;
D. Last employing organization (include duty station location) and the approximate dates of employment or contact; and
E. Signature.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should follow the Notification Procedures (listed above). Individuals requesting access will also be required to provide adequate identification, such as driver's license, employee identification card, and/or other identifying document. Additional identification procedures may be required in some instances. A notarized signature is required if the request is made by written correspondence. To request a file other than your own, you must have a notarized, signed statement giving you express permission to access the file from the individual to whom the file pertains.

CONTESTING RECORD PROCEDURES:

The BBG's rules for access, contesting record contents and appealing determinations appear in 22 CFR Part 505. The right to contest records is limited to information that is incomplete, irrelevant, erroneous or untimely.

RECORD SOURCE CATEGORIES:

Unsolicited correspondence from U.S. Government Officials and members of the general public addressed to the Director concerning VOA, Worldnet, RFE/RL, RFA, or Office of Cuba Broadcasting.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Certain records contained in this system of records may be exempted from 5 U.S.C. 552(a)(k)(1)–(2), (k)(4)–(6); See 22 CFR 505.15.

BBG–6

SYSTEM NAME:

M/A—Office of Administration Travel Card Program Files.

SYSTEM LOCATION:

Office of Administration, Broadcasting Board of Governors, 330 Independence Ave., SW., Washington, DC 20237.

SECURITY CLASSIFICATION:

None.

CATEGORIES OF INDIVDUALS COVERED BY THE SYSTEM:

IBB/BBG employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records and information pertaining to IBB/BBG employees who participate in the Government Travel Charge Card Program.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Travel and Transportation Reform Act of 1998, Public Law 105–264, dated October 19, 1998, 112 STAT. 2350; 5 U.S.C. 5707; 40 U.S.C. 486, Sec. 2.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Used by the staff of the Office of Administration to prepare various reports. The information may be released to other government agencies that have Statutory or other lawful authority to maintain, examine or compile such information.

Also see Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records maintained in file folders and lists maintained in computers.

RETRIEVABILITY:

By name of employee.

SAFEGUARDS:

Paper records are maintained in file cabinets in office space that is restricted to authorized BBG employees. Computer records are maintained in systems accessible only by authorized users with appropriate password information. All records are contained in a secure building with access limited to individuals with appropriate identification.

RETENTION AND DISPOSAL:

To date, these records have no disposal authority.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Administrative Operations Division, IBB, Broadcasting Board of Governors, 330 Independence Ave., SW., Washington, DC 20237.

NOTIFICATION PROCEDURES:

Individuals who want to know whether this system of records contains information about them, or who want access to their records, or who want to contest the contents of a record, should make a written request to: FOIA/Privacy Act Officer, BBG, Suite 3349, 330 Independence Ave., SW., Washington, DC 20237. Individuals' requests should contain the name and address of the system manager (listed above) and the following information to enable their records to be located and identified:

A. Full legal name;
B. Date of Birth;
C. Social Security Number;
D. Last employing organization (include duty station location) and the approximate dates of employment or contact; and
E. Signature.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should follow the Notification Procedures (listed above). Individuals requesting access will also be required to provide adequate identification, such as driver's license, employee identification card, and/or other identifying document. Additional identification procedures may be required in some instances. A notarized signature is required if the request is made by written correspondence. To request a file other than your own, you must have a notarized, signed statement giving you express permission to access the file from the individual to whom the file pertains.

CONTESTING RECORD PROCEDURES:

The BBG's rules for access and for contesting contents and appealing determinations by the individual concerned appear in 22 CFR Part 505. The right to contest records is limited to information that is incomplete, irrelevant, erroneous or untimely.

RECORD SOURCE CATEGORIES:

Information obtained from individuals in the context of applications for approval of travel credit card. Delinquent and Misuse report.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

BBG–7

SYSTEM NAME:

M/A—Office of Administration (Employee Parking).

SYSTEM LOCATION:

Office of Administration, International Broadcasting Bureau (IBB), Broadcasting Board of Governors (BBG), 330 Independence Ave., SW., Washington, DC 20237.

SECURITY CLASSIFICATION:

None.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

IBB/BBG employees assigned to BBG controlled parking spaces; employees waiting for assignment of vacated parking spaces.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Regulations regarding the use of Federally-controlled parking spaces at 41 CFR Part 101.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Assignment of parking space to BBG executives; to assure fairness in the assignment of parking spaces to employees and to give priority to certain individuals, e.g. the handicapped and individuals in car pools.

Information is made available to authorized BBG personnel as may be required in the performance of their official duties.

The information may also be released to other government agencies who have statutory or other lawful authority to maintain, examine or compile such information.

Also see Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS BY THE SYSTEM:

STORAGE:

Paper records maintained in file folders and lists maintained in computers.

RETRIEVABILITY:

By name of employee.

SAFEGUARDS:

Paper records are maintained in file cabinets in office space that is restricted to authorized BBG employees. Computer records are maintained in systems accessible only by authorized users with appropriate password information. All records are contained in a secure building with access limited to individuals with appropriate identification.

RETENTION AND DISPOSAL:

Records are destroyed within 18 months of time when employee relinquishes the assigned parking space or is separated from the BBG.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Administration, IBB, Broadcasting Board of Governors, 330 Independence Ave., SW., Washington, DC 20237.

NOTIFICATION PROCEDURES:

Individuals who want to know whether this system of records contains information about them, or who want access to their records, or who want to contest the contents of a record, should make a written request to: FOIA/Privacy Act Officer, BBG, Suite 3349, 330 Independence Ave., SW., Washington, DC 20237. Individuals' requests should contain the name and address of the system manager (listed above) and the following information to enable their records to be located and identified:

A. Full legal name;

B. Date of Birth;

C. Social Security Number;

D. Last employing organization (include duty station location) and the approximate dates of employment or contact; and

E. Signature.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should follow the Notification Procedures (listed above). Individuals requesting access will also be required to provide adequate identification, such as driver's license, employee identification card, and/or other identifying document. Additional identification procedures may be required in some instances. A notarized signature is required if the request is made by written correspondence. To request a file other than your own, you must have a notarized, signed statement giving you express permission to access the file from the individual to whom the file pertains.

CONTESTING RECORD PROCEDURES:

The BBG's rules for access and for contesting contents and appealing determinations by the individual concerned appear in 22 CFR Part 505. The right to contest records is limited to information that is incomplete, irrelevant, erroneous, or untimely.

RECORD SOURCE CATEGORIES:

Information obtained from individuals in the context of application for and administration of BBG parking spaces, and responses generated to this information by various BBG personnel.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

BBG–8

SYSTEM NAME:

M/A—Office of Administration (Office Travel Records).

SYSTEM LOCATION:

Office of Administration, IBB, Broadcasting Board of Governors, 330 Independence Avenue, SW., Washington, DC 20237.

SECURITY CLASSIFICATION:

None.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Past and present BBG employees and private citizens who have traveled under BBG auspices or as a result of BBG travel orders.

CATEGORIES OF RECORDS IN THE SYSTEM:

Travel documents and correspondence relating to shipment and storage of personal effects and property; records of active passports and visa requests from foreign embassies; records of temporary duty travel.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Supplemental Appropriation Act of 1995, Public Law 663, section 1331 (31 U.S.C. 200); Section 367, the Revised Statutes, as amended; Anti-Deficiency Act (31 U.S.C. 665).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Used by the staff of the Office of Administration to provide reimbursement for travel services provided to BBG travelers and the packing, storing, or shipment of their household effects and automobiles; to obtain passports and visas for BBG employees and other BBG travelers; and to prepare various reports on BBG travel activities. Also see Statement of General Routine Uses.

Information in these records is not normally available to individuals or agencies outside the BBG, but records may be released to other government agencies that have lawful authority to maintain, collect, view or compile such information.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS BY THE SYSTEM:

STORAGE:

Paper records maintained in file folders in storage files, loose leaf binders, and cards. Electronic records maintained in computers.

RETRIEVABILITY:

Alphabetically by name.

SAFEGUARDS:

Passports and related material and all classified material are kept in bar-locked cabinets. Other records are kept in unlocked files that are under surveillance and supervision of authorized employees during the working day, and by security guards after official working hour. Computer records are maintained in areas controlled by authorized BBG employees and are accessible by authorized individuals using password information. All records are within a secure building that is accessible only to individuals with appropriate identification.

RETENTION AND DISPOSAL:

Temporary duty travel authorizations are maintained for four years and then sent to the Federal records center. Records of personal property are maintained for six years. Passport records are kept for ten years for employees and five years for non-employee travelers.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Administrative Operations Division, IBB, Broadcasting Board of Governors, 330 Independence Ave., SW., Washington, DC 20237.

NOTIFICATION PROCEDURES:

Individuals who want to know whether this system of records contains information about them, or who want access to their records, or who want to contest the contents of a record, should make a written request to: FOIA/Privacy Act Officer, BBG, Suite 3349, 330 Independence Ave., SW., Washington, DC 20237. Individuals' requests should contain the name and address of the system manager (listed above) and the following information to enable their records to be located and identified:

A. Full legal name;
B. Date of Birth;
C. Social Security Number;
D. Last employing organization (include duty station location) and the approximate dates of employment or contact; and
E. Signature.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should follow the Notification Procedures (listed above). Individuals requesting access will also be required to provide adequate identification, such as driver's license, employee identification card, and/or other identifying document. Additional identification procedures may be required in some instances. A notarized signature is required if the request is made by written correspondence. To request a file other than your own, you must have a notarized, signed statement giving you express permission to access the file from the individual to whom the file pertains.

CONTESTING RECORD PROCEDURE:

The BBG's rules for access and for contesting record contents and appealing determinations appear in 22 CFR Part 505. The right to contest records is limited to information that is incomplete, irrelevant, erroneous or untimely.

RECORD SOURCE CATEGORIES:

Travel request forms initiated by various BBG components. Information regarding personal items obtained from the traveler and from transportation carriers. Passport information received from the Department of State's Passport Office.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

BBG–9

SYSTEM NAME:

M/CON—Office of Contracts (Vendor Data-Base File Extracts).

SYSTEM LOCATION:

Office of Contracts (M/CON), International Broadcasting Bureau (IBB), Broadcasting Board of Governors (BBG), 330 "C" Street, SW., Washington, DC 20237.

SECURITY CLASSIFICATION:

None.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Actual and prospective BBG contractors or grantees; individuals with whom the BBG contracts for talent, including Purchase Order Vendors (POV) and individuals retained for Expert Consultant Services.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information on individuals as either past, current, or potential future vendor(s) to the BBG is contained in and can be extracted as electronic or paper records from M/CON's computer data base files. Such records may contain an individual's name, business/Internet address(s) and type, telephone/facsimile numbers, security clearances, college/higher education diplomas and degrees, specialized Government training, awards, and personal data from previous contracts, product/service code, and/or North America Industry and Classification System (NAICS) code.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Federal Acquisition Regulation (45 CFR 14.205–1(c) and 53.21(e)).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

To prepare BBG Solicitation Mailing Lists for competitive procurements; to determine potential contractor responsibility information such as financial status, annual billing amounts, technical experience, past performance, relevant experience, and other contractor qualification information. Information in the system of records is made available on a need to know basis to BBG personnel as required in the performance of their official duties. Information may be released to other Government agencies who have lawful authority to maintain, view or compile such information. The principal user of this information outside the BBG is the General Services Administration.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Information is initially entered into M/CON's computer system from either Requisition or Contract forms or from the former Standard Form 129 (Solicitation Mailing List Application). Once the data is entered into the computer system, the SF–129 paper documents copies are then destroyed.

RETRIEVABILITY:

By the name of the individual.

SAFEGUARDS:

1. *Authorized Users:* Contracting personnel and other authorized BBG personnel.
2. *Physical Safeguards:* Access to computer records is limited via password only to authorized personnel; all records are contained within a secure building with access only to individuals with appropriate identification.
3. *Procedural Safeguards:* All authorized users of the information stored in these systems protect the information from public view and unauthorized personnel. Data stored in computers are accessed through the use of passwords available only to authorized personnel.
4. *Implementation Guidelines*: BBG Manual of Operations and Administration (MOA) III 500; Records Management Handbook (Domestic) Section 560–565.

RETENTION AND DISPOSAL:

A routine update of information is conducted approximately every five (5)

years. Outdated information is disposed of internally.

SYSTEM MANAGER(S) AND ADDRESS:

Senior Procurement Executive, Office of Contracts (M/CON), International Broadcasting Bureau (IBB), Broadcasting Board of Governors (BBG), 330 "C" Street SW., Washington, DC 20237.

NOTIFICATION PROCEDURES:

Individuals who want to know whether this system of records contains information about them, or who want access to their records, or who want to contest the contents of a record, must submit a written request to: FOIA/Privacy Act Officer, BBG, 330 Independence Avenue SW., Washington, DC 20237. Individual requests shall contain the name and address of the System Manager (listed above) and the following information to enable their records to be located and identified:

A. Full legal name that would be the vendor name used in the contract;

B. Date of Birth;

C. Social Security Number;

D. Last employing organization (include duty station location) and the approximate dates of employment or contract; and

E. Signature.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should follow the Notification Procedures (listed above). Individuals requesting access will also be required to provide adequate identification, such as driver's license, employee identification card, and/or other identifying document. Additional identification procedures may be required in some instances. To request a file other than your own, you must have a notarized, signed statement giving you express permission to access the file from the individual to whom the file pertains.

CONTESTING RECORD PROCEDURES:

The BBG's rules for access and for contesting record contents and appealing determinations appear in 22 CFR Part 505. The right to contest records is limited to information that is incomplete, irrelevant, erroneous or untimely.

RECORD SOURCE CATEGORIES:

Information is provided by individuals, companies, and other organizations.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

BBG–10

SYSTEM NAME:

M/CON—Office of Contracts (Acquisition and Procurement Workforce Information System).

SYSTEM LOCATION:

Office of Contracts (M/CON), International Broadcasting Bureau (IBB), Broadcasting Board of Governors (BBG), 330 "C" Street SW., Washington, DC 20237.

SECURITY CLASSIFICATION:

None.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

BBG employees involved with acquisition and procurement activities, including but not limited to warranted Contracting Officers, Contracting Specialists, Purchasing Agents, Procurement Analysts, and Authorized Representatives of the Contracting Officer (AR/CO).

CATEGORIES OF RECORDS IN THE SYSTEM:

Records containing information regarding an individual's capacity or ability to serve or be involved with BBG procurement activities, including but not limited to Name, Office Symbol, Position Title, Series and Grade, Service Computation Date, Supervisory Designation, Functional Description of Present Position, Education, Training, Procurement Experience, Professional Organizations, Honors, Awards, Career Objectives.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for this system is derived from the Federal Records Act, 44 U.S.C. 3101, and Federal Acquisition Regulation (FAR), Subpart 1–6 (Career Development, Contracting Authority, and Responsibilities).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Identification of employees who have met standards of experience, education, and training for appointment as warranted Contracting Officers and Authorized Representatives of Contracting Officers (AR/CO). Additional purposes are to comply with applicable FAR requirements, and procurement education and training requirements of the Clinger-Cohen Act (Pub. L. 104–106) and the Office of Federal Procurement Policy (OFPP) Letters 92–03 and 97–01 pertaining to mandatory training requirements for the career development of Federal acquisition and procurement workforce personnel. Information is also used to analyze overall BBG procurement system performance regarding such areas as functional workforce structure and size, and system-wide and individual training needs. Information is available for performance of official duties. Information may be released to other Government agencies who have lawful authority to maintain, view or compile such information. Also, see Statement of General Routine Uses.

POLICIES AND PRACTICES AND STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Information is maintained in paper form in files and in Office of Contracts computer storage.

RETRIEVABILITY:

Records are retrieved by BBG employee's name, office, job series and grade.

SAFEGUARDS:

1. *Authorized Users:* Office of Contracts personnel and BBG employees with express authorization.

2. *Physical safeguards:* Files are kept in binders and in desktop PCs in the Policy and Procedures Staff offices in the Office of Contracts. During non-duty hours the binders and PC is kept in a locked office. Computer records are maintained in office space that is controlled by BBG employees and in computers in which only authorized users may access via passwords. All records are contained within a secure building with access only to individuals with appropriate identification.

3. *Procedural safeguards:* All users of the personal information in connection with the performance of their official duties protect information from public view and from unauthorized personnel entering the office space where the records are kept. Access to records is strictly limited to Office of Contracts (M/CON) personnel.

4. *Implementation guidelines*: BBG Manual of Operations and Administration (MOA) III–500; Records Management Handbook (Domestic) Sections 560–565.

RETENTION AND DISPOSAL:

Files will be retained as long as the individual remains an employee of the BBG and is assigned to an Office of Contracts (M/CON) Headquarters or Field Procurement Activity procurement position (*i.e.*, Contracting Officer, Purchasing Agent) or the employee is designated as an Authorized Representative of the Contracting Officer (AR/CO) for the term of the specific contract to which the AR/

CO designation is applicable. Records will be destroyed within a reasonable time upon the employee's separation from the BBG, revocation or expiration of the employee's contracting warrant or AR/CO designation, or completion of the contract to which the AR/CO designation is applicable.

SYSTEM MANAGER(S) AND ADDRESS:

Senior Procurement Executive, Office of Contracts (M/CON), International Broadcasting Bureau (IBB), Broadcasting Board of Governors (BBG), 330 "C" Street SW., Washington, DC 20237.

NOTIFICATION PROCEDURES:

Individuals who want to know whether this system of records contains information about them, or who want access to their records, or who want to contest the contents of a record, must submit a written request to: FOIA/Privacy Act Officer, BBG, 330 Independence Avenue SW., Washington, DC 20237. Individual requests shall contain the name and address of the System Manager (listed above) and the following information to enable their records to be located and identified:

A. Full legal name that would be the vendor name used in the contract;

B. Date of Birth;

C. Social Security Number;

D. Last employing organization (include duty station location) and the approximate dates of employment or contract; and

E. Signature.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should follow the Notification Procedures (listed above). Individuals requesting access will also be required to provide adequate identification, such as driver's license, employee identification card, and/or other identifying document. Additional identification procedures may be required in some instances. To request a file other than your own, you must have a notarized, signed statement giving you express permission to access the file from the individual to whom the file pertains.

CONTESTING RECORD PROCEDURES:

The BBG's rules for access and for contesting record contents and appealing determinations appear in 22 CFR Part 505. The right to contest records is limited to information that is incomplete, irrelevant, erroneous or untimely.

RECORD SOURCE CATEGORIES:

Information is provided by individuals, companies, and other organizations.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

BBG–11

SYSTEM NAME:

M/CON—Office of Contracts—(Suspension and Debarment Information System).

SYSTEM LOCATION:

Office of Contracts (M/CON), International Broadcasting Bureau (IBB), Broadcasting Board of Governors (BBG), 330 "C" Street SW., Washington, DC 20237.

SECURITY CLASSIFICATION:

Some documents may be classified at the "Confidential" level of security classification, and they may also be considered as "Procurement Sensitive" information.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have been suspended, proposed for debarment, or debarred from Federal procurement, non-procurement, and assistance programs, and individuals who have been the subject of agency review, audit or inquiry to determine whether they should be debarred and/or suspended from Federal procurement/non-procurement and assistance programs.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records include information on individuals and firms excluded, suspended, or considered for exclusion or suspension or other lawful disqualification from Federal acquisition (including procurement and non-procurement programs) or assistance programs as a result of suspension or debarment proceedings initiated by BBG or pursuant to information forwarded to or received by the BBG from another agency pursuant to lawful function or from the GSA's List of Parties Excluded from Federal Procurement or nonprocurement Programs. Such information includes, but is not limited to, names and addresses, and other identifying information such as Social Security numbers or taxpayer identification numbers, of individuals covered by the system of records. Such information also includes evidence obtained in support of: criminal, civil or administrative action and closure, interim decisions, compliance agreements, audits, and final determinations. Examples of evidence contained in files include correspondence, inspection reports, memoranda of interviews, contracts and cooperative and assistance agreements, judgment, plea and conviction documents, and corporate information. Computer generated records may include data regarding categories and status of cases.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Federal Property and Administrative Services Act of 1949, 41 U.S.C. 251 *et seq.*, Office of Federal Procurement Policy Act., 41 U.S.C. 401 *et seq.*; Executive Order 12549 (Feb. 18, 1986) and Executive Order 12689 (Aug. 16, 1989); Federal Acquisition Regulation 9.404; and 22 CFR 513.500 and 513.505.

PURPOSE:

To assist the BBG in assembling information on, conducting, and documenting debarment and suspension proceedings to ensure that Federal contracts, cooperative agreements and Federal assistance, loans, and benefits are awarded to responsible business entities and individuals.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Records may be disclosed to the General Services Administration (GSA) to compile and maintain the "List of Parties Excluded from Federal Procurement or Nonprocurement Programs" in accordance with FAR 9.404 and 22 CFR 513.500 and 513.505; to organizations or individuals suspended, proposed for debarment or debarred in BBG proceedings; to the legal representatives of such organizations; and to the legal representatives of individuals suspended, proposed for debarment or debarred in BBG proceedings; to a Federal, State or local agency, financial institution, or other entity to verify an individual's eligibility for engaging in a covered transaction, including covered, primary and lower-tier covered transactions as defined at 22 CFR 513.110; to Federal, State or local agencies, in response to requests or subpoenas, or for the purpose(s) of (a) assisting them in administering Federal acquisition, loan and benefit programs or regulatory programs or monies; (b) assisting them in discharging their duties to ensure that Federal contracts and assistance, loans, benefits programs and monies are awarded to responsible individuals and organizations; or (c) ensuring that Federal, State or local regulatory responsibilities are met; to the public, upon request, and to

publishers of computerized legal research systems, but such disclosures shall be limited to interim or final decisions and settlement agreements. Also see Statement of General Routine Uses.

POLICIES AND PRACTICES AND STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File-folders, computer data-bases and other electronic media.

RETRIEVABILITY:

By name of the individual or firm and by file number.

SAFEGUARDS:

Computer records are maintained in a secure, password protected computer system. Paper records are maintained by authorized individuals in locked file cabinets and in secure locked offices. All records are maintained in secure, access-controlled areas. All records are contained within a secure building with access only to individuals with appropriate identification.

RETENTION AND DISPOSAL:

Investigative and advocacy files are maintained until such time after all litigation or appeal ceases and no further activity is likely to occur. Audit files are retained throughout the term of any compliance agreement or settlement, or until such time as all litigation activity is final and ceases. The official administrative record is retained in the office until six months after the period of debarment or exclusion expires, or until all provisions of any compliance agreement or settlement agreement have been completely fulfilled. The official administrative record is then transferred to the Federal Records Center (FRC) for storage. Files relating to cases closed without action are also transferred to the FRC within one year after the decision to close the matter.

SYSTEM MANAGER(S) AND ADDRESS:

Senior Procurement Executive, Office of Contracts (M/CON), International Broadcasting Bureau (IBB), Broadcasting Board of Governors (BBG), 330 "C" Street SW., Washington, DC 20237.

NOTIFICATION PROCEDURES:

Individuals who want to know whether this system of records contains information about them, or who want access to their records, or who want to contest the contents of a record, must make a written request to: FOIA/Privacy Act Officer, BBG, 330 Independence Avenue, SW., Washington, DC 20237. Individuals' requests must contain the name and address of the system manager (listed above) and the following information to enable their records to be located and identified:

A. Full legal name;

B. Date of Birth;

C. Social Security Number;

D. Last employing organization (include duty station location) and the approximate dates of employment or contact; and

E. Signature.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should follow the Notification Procedures (listed above). Individuals requesting access will also be required to provide adequate identification, such as driver's license, employee identification card, and/or other identifying document. Additional identification procedures may be required in some instances. To request a file other than your own, you must have a notarized, signed statement giving you express permission to access the file from the individual to whom the file pertains.

CONTESTING RECORD PROCEDURES:

The BBG's rules for access and for contesting record contents and appealing determinations appear at 22 CFR Part 505. The right to contest records is limited to information that is incomplete, irrelevant, erroneous or untimely.

RECORD SOURCE CATEGORIES:

BBG and other Federal officials, State and local government officials, private parties, business and other entities who may have information relevant to an inquiry, and individuals who have been suspended, proposed for debarment, or debarred, and their legal representatives.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Certain records contained within this system of records may be exempted by 5 U.S.C. 552(a)(k)(2); (k)(4); and (k)(5).

BBG—12

SYSTEM NAME:

M/P—Office of Personnel.

SYSTEM LOCATION:

Office of Personnel, International Broadcasting Bureau, Broadcasting Board of Governors, 330 Independence Avenue, SW., Washington, DC 20237.

SECURITY CLASSIFICATION:

Some documents are classified Confidential.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

BBG employees and overseas American employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records and information pertaining to the recruitment, testing and appointment of employees. Records include application forms; fiscal documents related to expenses; documents regarding post appointment; changes in employee skills, qualifications and experience; copies of SF–50 forms and payroll change slips.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Law 80–402, the United States Information and Exchange Act of 1948, as amended (22 U.S.C. 1431 *et seq.*); the U.S. International Broadcasting Act of 1994, as amended (22 U.S.C. 6201, *et seq.*); and the Foreign Affairs Consolidation Act of 1998 (Pub. L. 105–277).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Official Personnel Files contains long-term records necessary or relevant to documenting employee status and service, as required by the United States Office of Personnel Management's (OPM's) instructions and designated in OPM's Guide to Personnel Record Keeping.

Information is made available as required by BBG personnel in performance of their official duties. The principal users of this information outside the BBG are personnel officers in other government agencies as a result of a transfer, detail or hiring processes relating to the individual to whom the records pertain, and investigators performing official functions. The information may also be released to other government agencies who have a statutory or other lawful authority to maintain such information.

Also see Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Documents are maintained in Standard Form 66 for all Official Personnel Files (OPFs), additional information is contained in computer data base.

RETRIEVABILITY:

OPFs are manually retrieved by name.

SAFEGUARDS:

OPFs are maintained in a security approved locked storage room and in

computers accessed by individuals only with appropriate password information.

Access to OPFs is limited to authorized BBG employees and other authorized individuals, such as security or EEO investigators, with a substantiated official need for access to the information to perform their duties. Computer files are maintained in secure office area with access to authorized individuals with appropriate password information. All files are stored in a secure building with access only to individuals with appropriate identification.

RETENTION AND DISPOSAL:

Files are maintained as long as employee remains at BBG. Records of former employees are transferred to their destination agency or to the Federal Records Center, as appropriate.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Operations and Benefits Division, Office of Personnel, Broadcasting Board of Governors, International Broadcasting Bureau, 330 Independence Ave., SW., Washington, DC 20237.

NOTIFICATION PROCEDURES:

Individuals who want to know whether this system of records contains information about them, or who want access to their records, or who want to contest the contents of a record, should make a written request to: FOIA/Privacy Act Officer, BBG, Suite 3349, 330 Independence Ave., SW., Washington, DC 20237. Individuals' requests should contain the name and address of the system manager (listed above) and the following information to enable their records to be located and identified:

A. Full legal name;
B. Date of Birth;
C. Social Security Number;
D. Last employing organization (include duty station location) and the approximate dates of employment or contact; and
E. Signature.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should follow the Notification Procedures (listed above). Individuals requesting access will also be required to provide adequate identification, such as driver's license, employee identification card, and/or other identifying document. Additional identification procedures may be required in some instances. A notarized signature is required if the request is made by written correspondence. To request a file other than your own, you must have a notarized, signed statement giving you express permission to access the file from the individual to whom the file pertains.

CONTESTING RECORD PROCEDURES:

The BBG's rules for access, contesting record contents and appealing determinations appear at 22 CFR Part 505. The right to contest records is limited to information that is incomplete, irrelevant, erroneous or untimely.

RECORD SOURCE CATEGORIES:

Information is retrieved from employee application forms; from employees' supervisors (documentation relating to employees' experience, training, evaluation, performance, review, and recommendation for promotion, etc.; and from organizational personnel and fiscal elements (e.g. SF–50—Notification of Personnel Actions, payroll change slips, etc.).

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Certain records contained within this system of records may be exempted by 5 U.S.C. 552(a)(k)(1); (k)(2); (k)(4); (k)(5); and (k)(6).

BBG–13

SYSTEM NAME:

M/PT—Office of Personnel (Training and Development Division).

SYSTEM LOCATION:

Training and Development Division, Office of Personnel, Broadcasting Board of Governors, International Broadcasting Bureau, 330 C St., SW., Washington, DC 20237.

SECURITY CLASSIFICATION:

None.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

BBG employees receiving training.

CATEGORIES OF RECORDS IN THE SYSTEM:

Employee training applications, biographic data, educational background, training records, training program outlines, evaluations of training courses.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Law 80–402, the United States Information and Educational Exchange Act of 1948, as amended (22 U.S.C. 1431, *et seq.*); the U.S. International Broadcasting Act of 1994, as amended (22 U.S.C. 6201, *et seq.*); and the Foreign Affairs Consolidation Act of 1998 (Pub. L. 105–277).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

Background material used to determine eligibility for training; justification for training reports and record-keeping; evaluation and selection of lecturers and contractors to provide training; preparation of reports to Congress and other government agencies on training provided and training costs, as well as projected training needs and costs.

Information is made available on a need to know basis to personnel of the BBG as may be required in the performance of their official duties. The principal users of this information outside the BBG are personnel officers in other government agencies as a result of transfer, detail, or reassignment of the individual to whom the record pertains, other agencies considering employees for detail or transfer, and investigators performing their job functions.

The information may also be released to other government agencies who have statutory or other lawful authority to maintain such information. Also see Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records stored in file folders and file cabinets. Computer records stored on computer drives.

RETRIEVABILITY:

Manually retrieved by name, by computer generated lists of training statistics, or by training course title or description.

SAFEGUARDS:

Access to files is limited only to authorized BBG employees having an official use or need for the information. All files are maintained in locked offices during non-duty hours and are protected by office personnel when being used during duty hours. All files are contained within a secure building with access only to individuals with appropriate identification. All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office.

RETENTION AND DISPOSAL:

Training records maintained until employee is separated or until records are no longer needed. Budget records and cost statistics are kept for three to five years.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Training and Development Division, Office of Personnel, Broadcasting Board of Governors, International Broadcasting Bureau, 330 C St., SW., Washington, DC 20237.

NOTIFICATION PROCEDURES:

Individuals who want to know whether this system of records contains information about them, or who want access to their records, or who want to contest the contents of a record, should make a written request to: FOIA/Privacy Act Officer, BBG, Suite 3349, 330 Independence Ave., SW., Washington, DC 20237. Individuals' requests should contain the name and address of the system manager (listed above) and the following information to enable their records to be located and identified:

A. Full legal name;

B. Date of Birth;

C. Social Security Number;

D. Last employing organization (include duty station location) and the approximate dates of employment or contact; and

E. Signature.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should follow the Notification Procedures (listed above). Individuals requesting access will also be required to provide adequate identification, such as driver's license, employee identification card, and/or other identifying document. Additional identification procedures may be required in some instances. A notarized signature is required if the request is made by written correspondence. To request a file other than your own, you must have a notarized, signed statement giving you express permission to access the file from the individual to whom the file pertains.

CONTESTING RECORD PROCEDURES:

The BBG's rules for access and for contesting record contents and appealing determinations appear in 22 CFR Part 505. The right to contest records is limited to information that is incomplete, irrelevant, erroneous or untimely.

RECORD SOURCE CATEGORIES:

The employee; training applications and records; training officers and other individuals involved in personnel management; supervisors; trainee evaluations.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Certain records contained within this system of records may be exempted by 5 U.S.C. 552(a)(k)(2); (k)(4); (k)(5); and (k)(6).

BBG–14

SYSTEM NAME:

M/SEC—Office of Security (Personnel Security and Integrity Records).

SYSTEM LOCATION:

Office of Security, Broadcasting Board of Governors, International Broadcasting Bureau, 330 C St., SW., Washington, DC 20237. Retired records stored at Washington National Records Center, 4205 Suitland Road, Suitland, MD 20409.

SECURITY CLASSIFICATION:

Most records are unclassified, but the system may include records that are confidential and secret.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All persons currently or formerly employed by BBG in the United States; all persons currently or formerly employed by BBG in other countries; some foreign nationals currently or formerly employed outside the United States; some contractors or individuals whose services are utilized by BBG; former applicants to BBG; some prospective spouses of BBG employees; persons who have significant relationship with persons whose services were utilized or considered for utilization by the BBG; some persons who were significantly involved in non-security related administrative inquiries conducted by the M/SEC; some persons of counterintelligence interest whose names appeared in the press or are contained in documents furnished by other agencies of the United States.

CATEGORIES OF RECORDS IN THE SYSTEM:

Application and security forms provided by subjects; reports of investigation and background check, including those conducted by the Office of Security and other Government agencies; Personnel Security Worksheet Records evaluating investigative material; security clearance and security approval forms; intra-office, intra-Agency and inter-agency correspondence relating to investigations; security and suitability determinations and administrative matters; correspondence to and from Federal and non-Federal law enforcement and counterintelligence agencies; correspondence to and from State and local law enforcement jurisdictions, credit bureaus, private employers, schools, businesses, and individuals relating to investigative inquiries; records regarding briefings, interviews and de-briefings; security certifications to other agencies, contact reports, and security violations; photographs and finger print cards; Cross Reference Sheets and Records of Release of Information; records from Security Identification Card System. Not all files contain all of the above-listed elements.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The authority of the Office of Security to collect and maintain security data is derived from the following: Executive Order 10450 of April 27, 1953, as amended; Executive Order 10865 of January 17, 1961, as amended; Executive Order 12968 of August 2, 1995; and Title 5 of the Code of Federal Regulations.

PURPOSE:

To collect, record and maintain information deemed necessary to make security and suitability determinations regarding applicants for employment with and employees of the IBB and BBG; to make security determinations regarding the advisability of employee assignments; to make security assessments regarding the advisability of contracts and other financial arrangements such as cooperative agreements, and positions with IBB and BBG; to make security determinations regarding the advisability of certain promotions, as required by regulation; to make determinations regarding employees' receipt of special clearances as required by regulation; to make determinations whether certain non-citizen employees of IBB or BBG abroad should be granted security approval; to disclose information to the Office of Inspector General, U.S. Attorneys' Offices, and other Federal, State and local law enforcement entities as necessary for these offices to carry out their investigative and law enforcement functions; to provide information to officials within IBB and BBG components and management elements as necessary to assist in the performance of their official duties.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Data may be disclosed to Foreign Service Board of Examiners as necessary to determine qualifications and suitability of applicants; data may be disclosed to the Department of State as necessary to determine whether an applicant or employee should be granted or maintain medical clearance; data may be disclosed to other Government agencies as necessary for those agencies to determine whether employees should be granted special clearances required in connection with IBB or BBG duties; data may be

disclosed in advising duly authorized security officers or other agencies of significant security information related to a BBG or IBB employee or applicant. Data may be disclosed to the Office of Personnel or to the Office of Personnel Management that significant security or suitability information was developed or obtained regarding an applicant or employee. IBB/BBG investigative material having counterintelligence or national security significance may be disclosed to other U.S. Government agencies with responsibilities in these areas. Records may be used by the Director of the Office of Security or his/her lawful agent in correspondence and contacts with officials of other Government agencies when, in the judgment of the Director, it becomes necessary to inform other Government agencies of information uncovered or available to the Office of Security.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records kept in file folders; computer data stored on computers and electronic media.

SAFEGUARDS:

Authorized Users: Employees of the Records Management Unit and employees of the Office of Security.

Physical Safeguards: Files and computers are maintained in a secure area which, during working hours, is staffed by authorized users. Room is locked and alarmed during non-duty hours. Files in possession of other authorized users are kept in approved safe or locked cabinets when not in use and during non-duty hours. Computer records are maintained on secure computers with strict password access. Entire building is secured during non-duty hours, with security guards on duty.

Procedural/Technical Safeguards: Records Management Unit personnel furnish files to other authorized users in exchange for properly executed "Chargeout Record" form. Record Management Unit is provided properly executed "Recharge" form if file is passed from one authorized user to another. All personnel having routine access to records have top secret security clearances.

Citation of Implementing Guidelines: Executive Order 12958, and the Privacy Act of 1974 (5 U.S.C. 552a).

RETENTION AND DISPOSAL:

Files pertaining to employees, contractors, and other whose relationship with IBB and BBG required a security clearance or certification may be transferred to the Washington National Records Center after the individual leaves the BBG or after the relationship with the BBG ceases. Records may be destroyed upon notification of death or not later than five years after separation or transfer of employee or termination of contract, whichever is applicable. Files pertaining to unsuccessful applicants may be transferred to Washington National Records Center 120 days after non-selection, and destroyed ten years after date of last action; index and cross-index cards may be destroyed as files are destroyed. All destruction of documents pursuant to appropriate security controls.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Security, BBG, 330 C Street, SW., Washington, DC 20237.

NOTIFICATION PROCEDURES:

Individuals who want to know whether this system of records contains information about them, or who want access to their records, or who want to contest the contents of a record, should make a written request to: FOIA/Privacy Act Officer, BBG, Suite 3349, 330 Independence Ave., SW., Washington, DC 20237. Individuals' requests should contain the name and address of the system manager (listed above) and the following information to enable their records to be located and identified:

A. Full legal name;

B. Date of Birth;

C. Social Security Number;

D. Last employing organization (include duty station location) and the approximate dates of employment or contact; and

E. Signature.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should follow the Notification Procedures (listed above). Individuals requesting access will also be required to provide adequate identification, such as driver's license, employee identification card, and/or other identifying document. Additional identification procedures may be required in some instances. A notarized signature is required if the request is made by written correspondence. To request a file other than your own, you must have a notarized, signed statement giving you express permission to access the file from the individual to whom the file pertains.

CONTESTING RECORD PROCEDURES:

The BBG's rules for access and for contesting record contents and appealing determinations appear at 22 CFR Part 505. The right to contest records is limited to information that is incomplete, irrelevant, erroneous or untimely.

RECORD SOURCE CATEGORIES:

Biographic, personal history and other relevant information furnished by the subject individual on application and security forms or furnished by the subject during personal interviews or contained in reports of investigation conducted by the Office of Security, the Office of Personnel Management, Department of State, Office of Inspector General, Federal Bureau of Investigation, Department of Homeland Security and other Federal, State and local Government agencies or entities. Biographical, personal history and other relevant information obtained from credit bureaus, current and former employers, supervisors, co-workers, schools, teachers, rental and real estate agencies, landlords, neighbors, references, and acquaintances. Biographical, personal history and other relevant information, which may or may not be in the form of a photograph obtained from birth certificates, medical records and professional organization and society records. Counterintelligence and security reports that are furnished by other Federal agencies; various public records and indices such as those produced by Congressional committees, other elements and employees of BBG, employees of other Government agencies, non-government entities, and members of the public who may furnish information to the Office of Security in the interests of national security, the integrity or preservation of the federal service, good citizenship or desire to assist others, whistleblower activity, or concern regarding potentially unlawful, unethical, or improper activities.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

5 U.S.C. 552a(k)(1), (k)(2), and (k)(5); 5 U.S.C. 552a(c)(3), 552a(d), 552a(e)(1), (e)(4)(H)–(I), and (f). See 22 CFR 505.15.

BBG–15

SYSTEM NAME:

OCB—Office of Cuba Broadcasting.

SYSTEM LOCATION:

Director's Office, Office of Cuba Broadcasting, Broadcasting Board of Governors, 4201 NW 77th Avenue, Miami, Florida 33166.

SECURITY CLASSIFICATION:

None.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Employees and interns.

CATEGORIES OF RECORDS IN THE SYSTEM:

Leave slips and statements, performance appraisals, position descriptions, manager's notes.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Federal Records Act of 1950, as amended, 44 U.S.C. 3101.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

To track employee information for use by managers.

STORAGE:

Stored in file folders and on computers.

RETRIEVABILITY:

Retrieved by name.

SAFEGUARDS:

In secure areas and cabinets that are only accessible by managers. Computer information is maintained on secure computers with access limited by password.

RETENTION AND DISPOSAL:

Maintained until employee is separated from the BBG. Records of former employees are transferred to their destination agency or to the Federal Records Center, as appropriate.

SYSTEM MANAGER(S) AND ADDRESSS:

Director's Office, Office of Cuba Broadcasting, Broadcasting Board of Governors, 4201 NW 77th Avenue, Miami, Florida 33166.

NOTIFICATION PROCEDURES:

Individuals who want to know whether this system of records contains information about them, or who want access to their records, or who want to contest the contents of a record, should make a written request to: FOIA/Privacy Act Officer, BBG, Suite 3349, 330 Independence Ave., SW., Washington, DC 20237. Individuals' requests should contain the name and address of the system manager (listed above) and the following information to enable their records to be located and identified:

A. Full legal name;
B. Date of Birth;
C. Social Security Number;
D. Last employing organization (include duty station location) and the approximate dates of employment or contact; and
E. Signature.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should follow the Notification Procedures (listed above). Individuals requesting access will also be required to provide adequate identification, such as driver's license, employee identification card, and/or other identifying document. Additional identification procedures may be required in some instances. A notarized signature is required if the request is made by written correspondence. To request a file other than your own, you must have a notarized, signed statement giving you express permission to access the file from the individual to whom the file pertains.

CONTESTING RECORD PROCEDURES:

The BBG's rules for access and for contesting record contents and appealing determinations appear at 22 CFR Part 505. The right to contest records is limited to information that is incomplete, irrelevant, erroneous, or untimely.

RECORD SOURCE CATEGORIES:

Information is provided by individuals and managers.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

BBG–16

SYSTEM NAME:

Office of Civil Rights Complaint Files—OCR.

SYSTEM LOCATION:

Office of Civil Rights, Broadcasting Board of Governors, 301 4th Street, SW., Washington, DC 20237.

SECURITY CLASSIFICATION:

None.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Any employee with BBG who has a belief he/she has been discriminated against in some manner, or an individual who believes he/she has been retaliated against for a past filing of a discrimination complaint, and who has consulted with an Office of Civil Rights Counselor of the BBG or a member of OCR staff about the alleged discrimination.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 200e–16; 29 U.S.C. 633a; 29 U.S.C. 206(d).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

To record statements and actions taken regarding employees' and employment applicants' claims of discrimination. Principal users of this information outside the BBG are the Department of Justice, the Merit Systems Protection Board, and the Equal Employment Opportunity Commission. The information contained in this system may also be released to other government agencies having statutory or other lawful authority to maintain, compile, view or receive such information.

Information is made available on a need to know basis to BBG personnel as required for the performance of their official duties. Also see Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Partially automated system. Most information is stored in paper folders, with additional information stored on computers.

SAFEGUARDS:

Access is limited to OCR staff and contract EEO investigators. Records are stored in cabinets with bar locks and on computers protected with passwords known only to authorized OCR officials. Files are not removed from OCR offices, complainant and/or the complainant's representative are provided with copies of file materials, and copies may also be provided to other government agencies in accordance with the exercise of these agencies' statutory, regulatory or other official authorized functions.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Civil Rights, Broadcasting Board of Governors, 310 4th Street, SW., Washington, DC 20237.

NOTIFICATION PROCEDURES:

Individuals who want to know whether this system of records contains information about them, or who want access to their records, or who want to contest the contents of a record, should make a written request to: FOIA/Privacy Act Officer, BBG, Suite 3349, 330 Independence Ave., SW, Washington, DC 20237. Individuals' requests should contain the name and address of the system manager (listed above) and the following information to enable their records to be located and identified:

A. Full legal name;
B. Date of Birth;
C. Social Security Number;
D. Last employing organization (include duty station location) and the approximate dates of employment or contact; and
E. Signature.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should follow the Notification Procedures (listed above). Individuals requesting access will also

be required to provide adequate identification, such as driver's license, employee identification card, and/or other identifying document. Additional identification procedures may be required in some instances. A notarized signature is required if the request is made by written correspondence. To request a file other than your own, you must have a notarized, signed statement giving you express permission to access the file from the individual to whom the file pertains.

CONTESTING RECORD PROCEDURES:

The BBG's rules for access and for contesting record contents and appealing determinations appear at 22 CFR Part 505. The right to contest records is limited to information that is incomplete, irrelevant, erroneous, or untimely.

RECORD SOURCE CATEGORIES:

Personal interviews, affidavits, statements, BBG Personnel and Employment records, transcripts of hearings and litigation proceedings, correspondence.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

BBG—17

SYSTEM NAME:

OCR—Office of Civil Rights General Files (General Files).

SYSTEM LOCATION:

Office of Civil Rights, Broadcasting Board of governors (BBG), 301 4th St, SW., Washington, DC 20237

SECURITY CLASSIFICATION:

Some documents may be classified Confidential.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Employees of the BBG, applicants for positions in the BBG, organizations and institutes of higher education applying for grants from the BBG, recruitment contacts, prominent individuals who may be appropriate contacts for promotion panels, speakers, electronic media experts, and other individuals with whom the office is in contact, such as contractors and consultants.

CATEGORIES OF RECORDS IN THE SYSTEM:

Copies of applications, resumes, correspondence and bibliographical information regarding the individuals covered by the system, including memoranda to the files of employees covered by the system who seek counseling. General administrative files, including those dealing with travel, budget training and personnel matters. Various affirmative action plans, correspondence with BBG officials and others, such as correspondence with other agencies and individuals requesting information. Chron files and historical files outlining a variety of actions taken by the office and others in the area of EEO and Civil Rights. Computer generated lists of employees, and statistical studies of various parts of the BBG. Medical records of applicants and employees with disabling conditions and compliance records containing information about the EEO status of BBG grantee organizations and action taken on their applications.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

29 CFR Parts 1613 *et seq.*

PURPOSE(S):

To enable the office to carry out activities designed to recruit, hire, train, promote, assign and otherwise provide equal employment opportunity to employees of and applicants for employment in the BBG Compliance Review files containing information about grant applicant's implementation of Titles VI, VII, and IX of the Civil Rights Act of 1964, as amended, the Rehabilitation Act of 1974, as amended, and the Age Discrimination in Employment Act, as amended; to enable the office to monitor and implement Federal regulations as stipulated in these statutes.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USE:

Information in this system is made available on a need-to-know basis to Personnel Officers of the BBG as may be required in the performance of their duties. It may also be provided to Congressional Committees, individual Members of Congress, the White House, the Department of Justice, the Office of Personnel Management, the Equal Employment Opportunity Commission and to other government entities that have statutory or other lawful authority to maintain such information. Compliance Review information may also be released to grant applicants on request. Also see Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

The system is partially automated. Some information is also maintained on discs, and some in paper folders.

RETRIEVABILITY:

Records are retrieved by name and types of activities, i.e., affirmative action plans, travel, training, etc.

SAFEGUARDS:

1. *Authorized users:* OCR staff members and contract EEO investigators who are authorized to have access to the system of records in the performance of their duties.

2. *Physical safeguards:* Bar-locked safes, files contained in secure building requiring appropriate identification to enter.

3. *Procedural safeguards:* Separate maintenance of tables linking codes, data encryption, security software providing restricted commands programs, employee training, procedures for recording and reporting security violations, computer log-on codes. Contract investigator has security clearance and is supervised by an OCR staff member.

4. *Implementation guidelines:* BBG Manual of Operations and Administration (MOA) V–A (Domestic) Section 560–565.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Civil Rights, Broadcasting Board of Governors (BBG), 301 4th Street, SW., Washington, DC 20237.

NOTIFICATION PROCEDURES:

Individuals who want to know whether this system of records contains information about them, or who want access to their records, or who want to contest the contents of a record, should make a written request to: FOIA/Privacy Act Officer, BBG, Suite 3349, 330 Independence Ave., SW., Washington, DC 20237. Individuals' requests should contain the name and address of the system manager (listed above) and the following information to enable their records to be located and identified:

A. Full legal name;
B. Date of Birth;
C. Social Security Number;
D. Last employing organization (include duty station location) and the approximate dates of employment or contact; and
E. Signature.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should follow the Notification Procedures (listed above). Individuals requesting access will also be required to provide adequate identification, such as driver's license, employee identification card, and/or other identifying document. Additional identification procedures may be

required in some instances. A notarized signature is required if the request is made by written correspondence. To request a file other than your own, you must have a notarized, signed statement giving you express permission to access the file from the individual to whom the file pertains.

CONTESTING RECORD PROCEDURES:

The BBG's rules for access and for contesting contents and appealing determinations by the individual concerned appear in 22 CFR Part 505. The right to contest records is limited to information that is incomplete, irrelevant, erroneous or untimely.

RECORD SOURCE CATEGORIES:

Correspondence, memos of conversations, BBG records of personnel actions, published biographical sources.

EXEMPTIONS CLAIMED FOR THIS SYSTEM:

None.

BBG—18

SYSTEM NAME:

OCR—Office of Civil Rights (Minority Groups).

SYSTEM LOCATION:

Office of Civil Rights, Broadcasting Board of Governors (BBG), 301 4th St, SW., Washington, DC 20237.

SECURITY CLASSIFICATION:

None.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All employees of BBG and some applicants for employment in BBG.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records are categorized by name, race, sex, national origin, age, grade or wage level. Handicap or lack thereof and may contain medical records.

AUTHORITY FOR MAINTENANCE IN THE SYSTEM:

29 CFR 1613.301; 29 CFR 1613.302.

PURPOSE(S):

To compile statistical records of women, minorities, and individuals with disabling conditions who are considered for employment, hired, promoted, assigned, training, awarded, disciplined, and/or separated or who resign from the BBG, to measure EEO progress and to identify problems.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USE:

Information is made available on a need-to-know basis to personnel of the BBG as may be required in the performance of their official duties, including implementing affirmative action plans and in processing complaints of discrimination. Information is not normally available to individuals or agencies outside the BBG, but records may be released to other government agencies having a statutory or other lawful authority to maintain such information. The principal users of this information outside of BBG are the Equal Employment Opportunity Commission, the Office of Personnel Management, the Department of Justice, the Department of State, and Congress. Also see Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper and computer records.

RETRIEVABILITY:

By name, race, sex, age, handicap, national origin, agency location, date of entry or separation, date of last promotion, grade or wage level.

SAFEGUARDS:

1. *Authorized users:* Members of the OCR staff and certain authorized members of the Office of Personnel, Policy and Services staff.

2. *Physical safeguards:* Bar-locked safes, security guard patrol (off-duty hours); access to building limited to individuals with appropriate identification.

3. *Procedural safeguards:* Computer passwords; Separate maintenance of tables linking codes, data encryption, security software providing restricted commands programs, employee training, procedures for recording and reporting security violations. Contractors are supervised by employees with a security clearance.

4. *Implementation guidelines:* BBG Manual of Operations and Administration (MOA) V–A (Domestic) Section 560–565. The source of security standards is 29 CFR 1613.301 *et seq.*

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Civil Rights, Broadcasting Board of Governors (BBG), 301 4th Street, SW., Washington, DC 20237.

NOTIFICATION PROCEDURES:

Individuals who want to know whether this system of records contains information about them, or who want access to their records, or who want to contest the contents of a record, should make a written request to: FOIA/Privacy Act Officer, BBG, Suite 3349, 330 Independence Ave., SW., Washington, DC 20237. Individuals' requests should contain the name and address of the system manager (listed above) and the following information to enable their records to be located and identified:

A. Full legal name;

B. Date of Birth;

C. Social Security Number;

D. Last employing organization (include duty station location) and the approximate dates of employment or contact; and

E. Signature.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should follow the Notification Procedures (listed above). Individuals requesting access will also be required to provide adequate identification, such as driver's license, employee identification card, and/or other identifying document. Additional identification procedures may be required in some instances. A notarized signature is required if the request is made by written correspondence. To request a file other than your own, you must have a notarized, signed statement giving you express permission to access the file from the individual to whom the file pertains.

CONTESTING RECORD PROCEDURES:

The BBG's rules for access and for contesting contents and appealing determinations by the individual concerned appear in 22 CFR Part 505. The right to contest records is limited to information that is incomplete, irrelevant, erroneous or untimely.

RECORD SOURCE CATEGORIES:

From the employee or applicant concerned, BBG personnel data, visual inspection of the employee or application.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Not applicable.

BBG–19

SYSTEM NAME:

P/K—Office of External Affairs (Clearance Files for Speaking, Teaching and Writing, and Approval Files for Outside Employment).

SYSTEM LOCATION:

Broadcasting Board of Governors (BBG), International Broadcasting Bureau (IBB), Office of External Affairs, Room 3131, 330 Independence Ave, SW., Washington, DC 20237.

SECURITY CLASSIFICATION:

None.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Employees of the IBB, the Voice of America, the Office of Cuba

Broadcasting (Radio and Television Marti), WORLDNET Television, Office of engineering and Technical Operations.

CATEGORIES OF RECORDS IN THE SYSTEM:

Correspondence addressed to the Director of the Office of External Affairs requesting clearance for outside speaking, teaching, or writing, or requesting approval for outside employment. Correspondence from office, language service, and division directors to the Director of the Office of External Affairs regarding employees' requests for clearance or approval. Correspondence from the Office of External Affairs to and from the BBG Office of the General Counsel and Ethics Officer. Responses to IBB and BBG employees on clearance or approval from the Director of the Office of External Affairs.

AUTHORITY FOR MAINTENANCE OF SYSTEM:

Federal Records Act of 1950, as amended, 44 U.S.C. 3101–3167, Records Disposal Act of 1943, as amended, 44 U.S.C. 3301–3314.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Files are routinely used by the Director of the Office of External Affairs or his/her delegate to determine record of current or previous requests for clearance and/or approval and the disposition of those requests. Files may be used by representatives of the Labor Relations offices in the course of investigations. Also see General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper and computer records are stored in a locked office within the Office of External Affairs.

RETRIEVABILITY:

Records are kept in hard copy or computer chronologically by year of the request. A small number of files are kept by individual identifier.

SAFEGUARDS:

General access to files is permitted only to administrative staffs and other top management officials having a need-to-know such information in the normal performance of their duties. Computer records are protected by password access for authorized users. All records are located within secure building with access restricted to individuals showing appropriate identification.

RETENTION AND DISPOSAL:

Files are retained in the Office of External Affairs, and are used periodically for reference purposes.

SYSTEM MANAGER(S) AND ADDRESS:

Director of External Affairs, International Broadcasting Bureau (IBB), Broadcasting Board of Governors, 330 Independence Ave., SW., Washington, DC 20237.

NOTIFICATION PROCEDURES:

Individuals who want to know whether this system of records contains information about them, or who want access to their records, or who want to contest the contents of a record, should make a written request to: FOIA/Privacy Act Officer, BBG, Suite 3349, 330 Independence Ave., SW., Washington, DC 20237. Individuals' requests should contain the name and address of the system manager (listed above) and the following information to enable their records to be located and identified:

A. Full legal name;

B. Date of Birth;

C. Social Security Number;

D. Last employing organization (include duty station location) and the approximate dates of employment or contact; and

E. Signature.

RECORDS ACCESS PROCEDURE:

Requests from individuals should be addressed to the FOIA/Privacy Act Officer, Office of the General Counsel, 330 Independence Ave, SW., Suite 3349, Washington, DC 20237.

CONTESTING RECORDS PROCEDURES:

The rules for access and for contesting contents and appealing determinations by the individual concerning appeal are found in CFR Part 505. The right to contest records is limited to information that is incomplete, irrelevant, erroneous or untimely.

RECORD SOURCE CATEGORIES:

Information is received from employees seeking advance clearance for outside speaking, teaching or writing on matters of official concern, or approval for outside employment; from supervisors of such employees; from the Office of the General Counsel; from the IBB Designated Ethics Officer, and from the Director of the Office of External Affairs in making the determination on requests for clearance and/or approval.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 04–17554 Filed 8–2–04; 8:45 am]

BILLING CODE 8230–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of opportunity to request administrative review of antidumping or countervailing duty order, finding, or suspended investigation.

Background

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspension of investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended, may request, in accordance with section 351.213 (2002) of the Department of Commerce (the Department) Regulations, that the Department conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

Opportunity to Request a Review: Not later than the last day of August 2004, interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in August for the following periods:

	Period
Antidumping Duty Proceeding	
Argentina: Oil Country Tubular Goods, A–357–810	8/1/03–7/31/04
Argentina: Seamless Line and Pressure Pipe, A–357–809	8/1/03–7/31/04
Australia: Corrosion-Resistant Carbon Steel Flat Products, A–602–803	8/1/03–7/31/04
Belgium: Cut-to-Length Carbon Steel Plate, A–423–805	8/1/03–7/31/04
Brazil: Cut-to-Length Carbon Steel Plate, A–351–817	8/1/03–7/31/04
Brazil: Seamless Line and Pressure Pipe, A–351–826	8/1/03–7/31/04

	Period
Canada: Corrosion-Resistant Carbon Steel Flat Products, A–122–822	8/1/03–7/31/04
Canada: Pure Magnesium, A–122–814	8/1/03–7/31/04
Chile: Fresh Atlantic Salmon [1] A–337–803	7/1/03–6/30/04
Czech Republic: Carbon and Alloy Seamless Standard, Line, and Pressure Pipe (Under 4½ Inches), A–851–802	8/1/03–7/31/04
Finland: Cut-to-Length Carbon Steel Plate, A–405–802	8/1/03–7/31/04
France: Corrosion-Resistant Carbon Steel Flat Products, A–427–808	8/1/03–7/31/04
France: Industrial Nitrocellulose, A–427–009	8/1/03–7/31/04
Germany: Corrosion-Resistant Carbon Steel Flat Products, A–428–815	8/1/03–7/31/04
Germany: Cut-to-Length Carbon Steel Plate, A–428–816	8/1/03–7/31/04
Germany: Seamless Line and Pressure Pipe, A–428–820	8/1/03–7/31/04
Italy: Grain Oriented Electrical Steel, A–475–811	8/1/03–7/31/04
Italy: Oil Country Tubular Goods, A–475–816	8/1/03–7/31/04
Italy: Granular Polytetrafluoroethylene Resin, A–475–703	8/1/03–7/31/04
Japan: Brass Sheet & Strip, A–588–704	8/1/03–7/31/04
Japan: Corrosion-Resistant Carbon Steel Flat Products, A–588–824	8/1/03–7/31/04
Japan: Oil Country Tubular Goods, A–588–835	8/1/03–7/31/04
Japan: Granular Polytetrafluoroethylene Resin, A–588–707	8/1/03–7/31/04
Japan: Tin Mill Products, A–588–854	8/1/03–7/31/04
Mexico: Carbon and Alloy Seamless Standard, Line, and Pressure Pipe (Over 4½ Inches), A–201–827	8/1/03–7/31/04
Mexico: Gray Portland Cement and Cement Clinker, A–201–802	8/1/03–7/31/04
Mexico: Cut-to-Length Carbon Steel Plate, A–201–809	8/1/03–7/31/04
Mexico: Oil Country Tubular Goods, A–201–817	8/1/03–7/31/04
Poland: Cut-to-Length Carbon Steel Plate, A–455–802	8/1/03–7/31/04
Republic of Korea: Corrosion-Resistant Carbon Steel Flat Products, A–580–816	8/1/03–7/31/04
Republic of Korea: Oil Country Tubular Goods, A–580–825	8/1/03–7/31/04
Republic of Korea: Structural Steel Beams, A–580–841	8/1/03–7/31/04
Romania: Carbon and Alloy Seamless Standard, Line, and Pressure Pipe (Under 4½ Inches), A–485–805	8/1/03–7/31/04
Romania: Cut-to-Length Carbon Steel Plate, A–485–803	8/1/03–7/31/04
Spain: Cut-to-Length Carbon Steel Plate, A–469–803	8/1/03–7/31/04
Sweden: Cut-to-Length Carbon Steel Plate, A–401–805	8/1/03–7/31/04
The People's Republic of China: Petroleum Wax Candles, A–570–504	8/1/03–7/31/04
The People's Republic of China: Sulfanilic Acid, A–570–815	8/1/03–7/31/04
The United Kingdom: Cut-to-Length Carbon Steel Plate, A–412–814	8/1/03–7/31/04
Turkey: Aspirin, A–489–602	8/1/03–7/31/04
Vietnam: Frozen Fish Fillets, A–552–801	1/31/03–7/31/04
Countervailing Duty Proceedings	
Belgium: Cut-to-Length Carbon Steel Plate, C–423–806	1/1/03–12/31/03
Brazil: Cut-to-Length Carbon Steel Plate, C–351–818	1/1/03–12/31/03
Canada: Pure Magnesium, C–122–815	1/1/03–12/31/03
Canada: Alloy Magnesium, C–122–815	1/1/03–12/31/03
France: Corrosion-Resistant Carbon Steel, C–427–810	1/1/03–12/31/03
France: Stainless Steel Sheet and Strip in Coils, C–427–815	1/1/03–12/31/03
Germany: Corrosion-Resistant Carbon Steel, C–428–817	1/1/03–12/31/03
Germany: Cut-to-Length Carbon Steel Plate, C–428–817	1/1/03–12/31/03
Italy: Oil Country Tubular Goods, C–475–817	1/1/03–12/31/03
Italy: Stainless Steel Sheet and Strip in Coils, C–475–825	1/1/03–12/31/03
Mexico: Cut-to-Length Carbon Steel Plate, C–201–810	1/1/03–12/31/03
Republic of Korea: Corrosion-Resistant Carbon Steel Plate, C–580–818	1/1/03–12/31/03
Republic of Korea: Dynamic Random Access Memory Semiconductors, C–580–851	4/7/03–12/31/03
Republic of Korea: Stainless Steel Sheet and Strip in Coils, C–580–835	1/1/03–12/31/03
Republic of Korea: Structural Steel Beams, C–580–841	1/1/03–12/31/03
Spain: Cut-to-Length Carbon Steel Plate, C–469–804	1/1/03–12/31/03
Sweden: Cut-to-Length Carbon Steel Plate, C–401–804	1/1/03–12/31/03
United Kingdom: Cut-to-Length Carbon Steel Plate, C–412–815	1/1/03–12/31/03
Suspension Agreements	
None.	

[1] This case was inadvertently listed in the opportunity notice for July anniversary cases that published on July 1, 2004 (69 FR 39903). On July 25, 2003 (68 FR 44043), the revocation of the antidumping duty order on Fresh Atlantic Salmon from Chile was published in the **Federal Register**. The effective date of the revocation is 07/01/2001.

In accordance with section 351.213(b) of the regulations, an interested party as defined by section 771(9) of the Act may request in writing that the Secretary conduct an administrative review. For both antidumping and countervailing duty reviews, the interested party must specify the individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order or suspension agreement for which it is requesting a review, and the requesting party must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which were produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

As explained in *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 69 FR 23954 (May 6, 2003), the Department has clarified its practice with respect to the collection of final antidumping

duties on imports of merchandise where intermediate firms are involved. The public should be aware of this clarification in determining whether to request an administrative review of merchandise subject to antidumping findings and orders. See also the Import Administration Web site at *http://www.ia.ita.doc.gov.*

Six copies of the request 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. The Department also asks parties to serve a copy of their requests to the Office of Antidumping/Countervailing Enforcement, Attention: Sheila Forbes, in room 3065 of the main Commerce Building. Further, in accordance with section 351.303(f)(l)(i) of the regulations, a copy of each request must be served on every party on the Department's service list.

The Department will publish in the **Federal Register** a notice of "Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation" for requests received by the last day of August 2004. If the Department does not receive, by the last day of August 2004, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, the Department will instruct the U.S. Customs and Border Protection to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of (or bond for) estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

This notice is not required by statute but is published as a service to the international trading community.

Dated: July 26, 2004.

Holly A. Kuga

Senior Office Director, Office 4 for Import Administration.

[FR Doc. 04–17564 Filed 8–2–04; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–831]

Fresh Garlic From the People's Republic of China: Final Results of Antidumping Duty New Shipper Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On May 3, 2004, the Department of Commerce published the preliminary results of new shipper reviews of the antidumping duty order on fresh garlic from the People's Republic of China. The period of review is November 1, 2002, through April 30, 2003. The reviews cover five manufacturers/exporters.

We invited interested parties to comment on our preliminary results. Based on our analysis of the comments received, we have made certain changes to our calculations. The final dumping margins for these reviews are listed in the "Final Results of the Reviews" section below.

DATES: Effective August 3, 2004.

FOR FURTHER INFORMATION CONTACT: Minoo Hatten or Mark Ross, Office of Antidumping/Countervailing Duty Enforcement 5, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–1690 or (202) 482–4794, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 7, 2003, we published in the **Federal Register** the *Notice of Initiation of New Shipper Antidumping Duty Reviews* (68 FR 40242) in which we initiated new shipper reviews of the antidumping duty order on fresh garlic from the People's Republic of China (PRC) for Jinxiang Dong Yun Freezing Storage Co., Ltd. (Dong Yun), Shanghai Ever Rich Trade Company (Ever Rich), Linshu Dading Private Agricultural Products Co., Ltd. (Linshu Dading), Linyi Sanshan Import & Export Trading Co., Ltd. (Linyi Sanshan), Sunny Import & Export Limited (Sunny), Tancheng County Dexing Foods Co., Ltd. (Tancheng), and Taian Ziyang Food Co., Ltd. (Ziyang).

On April 28, 2004, we published a notice rescinding Tancheng's new shipper review of the antidumping duty order on fresh garlic from the PRC. See *Notice of Rescission of Antidumping New Shipper Review of Fresh Garlic from the People's Republic of China*, 69 FR 23171 (April 28, 2004).

On May 3, 2004, the Department of Commerce (the Department) published the preliminary results of the new shipper reviews of the antidumping duty order on fresh garlic from the PRC. See *Fresh Garlic from the People's Republic of China: Preliminary Results of Antidumping Duty New Shipper Reviews*, 69 FR 24123 (May 3, 2004) (Preliminary Results). We invited parties to comment on our preliminary results. We received comments from three respondents, Sunny, Linshu Dading, and Dong Yun. We did not receive comments from the petitioners (the Fresh Garlic Producers Association and its individual members).

On June 28, 2004, we published the final results of the antidumping new shipper review for Linyi Sanshan. See *Fresh Garlic from the People's Republic of China: Final Results of Antidumping Duty New Shipper Review for Linyi Sanshan Import Export Trading Co., Ltd.*, 69 FR 36059 (June 28, 2004).

We have conducted these reviews in accordance with section 751 of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.214 (2003).

Scope of the Order

The products covered by this antidumping duty order are all grades of garlic, whole or separated into constituent cloves, whether or not peeled, fresh, chilled, frozen, provisionally preserved, or packed in water or other neutral substance, but not prepared or preserved by the addition of other ingredients or heat processing. The differences between grades are based on color, size, sheathing, and level of decay.

The scope of this order does not include the following: (a) garlic that has been mechanically harvested and that is primarily, but not exclusively, destined for non-fresh use; or (b) garlic that has been specially prepared and cultivated prior to planting and then harvested and otherwise prepared for use as seed.

The subject merchandise is used principally as a food product and for seasoning. The subject garlic is currently classifiable under subheadings 0703.20.0010, 0703.20.0020, 0703.20.0090, 0710.80.7060, 0710.80.9750, 0711.90.6000, and 2005.90.9700 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this order is dispositive. In order to be excluded from the antidumping duty order, garlic entered under the HTSUS subheadings listed

above that is (1) mechanically harvested and primarily, but not exclusively, destined for non-fresh use or (2) specially prepared and cultivated prior to planting and then harvested and otherwise prepared for use as seed must be accompanied by declarations to U.S. Customs and Border Protection (CBP) to that effect.

Analysis of Comments Received

All issues raised in the case briefs by parties in these reviews are addressed in the Issues and Decision Memorandum, dated July 26, 2004, which is hereby adopted by this notice (*Decision Memo*). A list of the issues which parties raised and to which we respond in the *Decision Memo* is attached to this notice as an Appendix. The *Decision Memo* is a public document on file in the Central Records Unit (CRU), Main Commerce Building, Room B–099, and is accessible on the Web at *http://www.ia.ita.doc.gov/frn*. The paper copy and electronic version of the memorandum are identical in content.

Separate Rates

In our preliminary results, we determined that Sunny, Linshu Dading, Dong Yun, Ever Rich, and Ziyang met the criteria for the application of a separate rate. See *Preliminary Results*, 69 FR at 24124. We have not received any information since the issuance of the *Preliminary Results* that provides a basis for reconsideration of these determinations.

Changes Since the Preliminary Results

Based on comments certain respondents submitted on the *Preliminary Results* and our analysis of information on the record, we have made certain changes to the margin calculations for all respondents. In addition, based on changes due to verification, we have made additional revisions to the margin calculations for Sunny for the final results. These changes are discussed below.

A. Application of Surrogate Financial Ratios

For the final results of these reviews, in calculating the amount of overhead, selling, general and administrative expenses (SG&A), and profit included in normal value, we have determined not to apply the surrogate financial ratios to production costs that include packing expenses. As in the *Preliminary Results*, however, we have calculated separate surrogate values for materials and labor associated directly with packing fresh garlic from the PRC and added these packing expenses to the calculation of normal value. For a more detailed discussion of this issue see *Decision Memo* at Comment 1.

B. Valuation of Garlic Seed

As we discuss in response to Comment 2 of the *Decision Memo*, for the final results of these reviews we have limited the pricing information upon which we have relied for valuation of garlic seed to the National Horticultural Research and Development Foundation prices for the Agrifound Parvati and Yamuna Safed-3 varieties. We selected the pricing information for these varieties because, of all the varieties for which information was submitted, these two match most closely the subject merchandise in terms of bulb diameter and number of cloves per bulb. This limiting of price selection did not change the surrogate value of seed for the final results, since all of the selected prices for the *Preliminary Results* were identical.

C. Valuation of Leased Land

The respondents in these reviews leased the farmland on which the subject merchandise was grown. The need to capture the cost of leasing land in the calculation of normal value for the subject merchandise was brought to our attention by the petitioners in their June 4, 2004, submission in another segment of this proceeding. Consistent with recent PRC case practice, we determined that the cost of leasing land in this proceeding is an important component in the cost build-up of normal value. The cost of leasing land was not included in our calculation of normal value for the *Preliminary Results* and is not reflected in the financial ratios calculated from Parry Agro's income statements (see *Notice of Preliminary Determination of Sales at Less Than Fair Value, Partial Affirmative Preliminary Determination of Critical Circumstances and Postponement of Final Determination: Certain Frozen and Canned Warmwater Shrimp from the People's Republic of China*, 69 FR 42654 (July 16, 2004)). Accordingly, for purposes of the final results of these reviews, we applied a land-lease cost to our calculation of normal value using a methodology similar to that applied in the recently-completed preliminary results of a new shipper review covering the period November 1, 2002, through October 31, 2003. See *Fresh Garlic from the People's Republic of China: Preliminary Results of Antidumping Duty New Shipper Review*, 69 FR 40607 (July 6, 2004) *(July New Shipper Review Prelim)*.

In the *July New Shipper Review Prelim*, the Department applied a surrogate value for land based on a 1996 policy notification issued by the State of Rajasthan, in which the state government set an annual lease rent for cultivable wasteland. In exploring additional publicly-available information concerning the cost of leasing land in India, we located the 2001 Punjab State Development Report administered by the Planning Commission of the government of India ("Punjab Report"). See Memorandum from Susan Lehman to The File titled "Factors Valuations for the Final Results of the New Shipper Reviews," dated July 26, 2004. We find that the "Punjab Report" contains more relevant and contemporaneous information pertaining to the Indian land-lease market for farmland. The subject of the "Punjab Report" is clearly more similar to the type of land leased by the respondents during the period of review (POR). Further, the data contained within the "Punjab Report" is based on actual experience, whereas that contained within the 1996 policy notification we used in the *July New Shipper Review Prelim* was based on parameters that may not have been implemented or that may have since been amended.

Upon review of the record of these new shipper reviews, we find no information undermining the figure contained within the "Punjab Report." As such, based on all available information, we have determined that the figure contained within the "Punjab Report" serves as the most reliable basis for determining a surrogate value for calculating a cost of the farmland used to grow the subject merchandise.

According to the "Punjab Report," the most frequent annual rent for farmland in the State of Punjab was found to be 17,500 rupees per hectare. As this rate was based on information gathered in 2001, we have inflated the annual cost of land and have converted the values to calculate an annual land-lease cost of $25.75/mu (15 mu = 1 hectare).

In order to determine a per-kilogram cost of land, we first determined each companies' production quantity in kilograms per mu by dividing the verified total production quantity by the total amount of farmland leased by each company during the POR, as provided in the land leases. The information used in our calculation was extracted directly from the company-specific responses to our questionnaires. We then divided the annual land-lease cost of $25.75/mu by the company-specific per-mu production quantity, and derived a per-kilogram cost of land. The result of this calculation was applied to the build-up of normal value as an addition to fixed overhead. For the company-specific

calculations, see the July 26, 2004, Final Results Analysis Memorandum for each company.

D. Sunny

For the preliminary results of these reviews, we valued cold storage at the production facility using an electricity surrogate value and added it to normal value. When the subject merchandise was put in cold storage before it was processed (or when it was semi-processed) at a facility away from the production/processing facility prior to shipment, we valued cold storage using a surrogate value for cold storage, which includes electricity expenses, and added it to normal value. When the garlic was fully processed and packed, and placed into a cold-storage facility not located at the production/processing facility prior to the date of shipment from the PRC, we valued it using a cold-storage surrogate value and treated it as a movement expense which we deducted from the U.S. price.

At verification, we examined Sunny's cold-storage activities and found that it rented a cold storage facility away from the production/processing facility for its semi-processed garlic. See Memorandum from Brian Ellman to The File titled "Verification of the Responses of Sunny Import and Export Limited in the Antidumping Duty New Shipper Review of Fresh Garlic from the People's Republic of China," dated May 17, 2004, at pages 10 and 20.

For the *Preliminary Results*, we incorrectly valued the cold storage expenses incurred by Sunny using a surrogate value for electricity. Because Sunny used a rented cold storage facility located away from the production/processing facility to store its semi-processed garlic prior to shipment, we should have valued its cold storage expenses using a surrogate value for cold storage. For the final results, we have corrected this error and have valued Sunny's reported cold storage using a surrogate value for cold storage, which includes electricity expenses, and added it to normal value.

E. Dong Yun

While reviewing Dong Yun's margin-calculation program for the preliminary results, we found that we used the incorrect consumption amounts for direct labor and packing labor. We have corrected this error for these final results. See the Final Results Analysis Memorandum for Dong Yun, dated July 26, 2004, at page 3.

Final Results of the Reviews

We determine that the following dumping margins exist for the period November 1, 2002, through April 30, 2003:

Exporter	Weighted-average percentage margin
Grown by Pizhou Guangda Import and Export Co., Ltd. and Exported by Shanghai Ever Rich Trade Company	0.00
Grown by Jinxing Jinda Agriculture Industrial & Trading Company Ltd. and Exported by Linshu Dading Private Agricultural Products Co., Ltd	0.00
Grown and Exported by Sunny Import and Export Ltd	33.66
Grown and Exported by Taian Ziyang Food Company, Ltd	0.00
Grown and Exported by Jinxiang Dong Yun Freezing Storage Co., Ltd	19.18

Duty Assessment and Cash-Deposit Requirements

The Department will determine, and CBP shall assess, antidumping duties on all appropriate entries. The Department will issue appropriate assessment instructions directly to CBP within 15 days of publication of the final results of these reviews. Further, the following cash-deposit requirements will be effective upon publication of the final results of these new shipper reviews for shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results, as provided by section 751(a)(2)(C) of the Act: (1) For subject merchandise grown by Pizhou Guangda Import and Export Co., Ltd., and exported by Shanghai Ever Rich Trade Company; grown by Jinxing Jinda Agriculture Industrial & Trading Company Ltd., and exported by Linshu Dading Private Agricultural Products Co., Ltd.; or grown and exported by Sunny Import and Export, Ltd., Taian Ziyang Food Company, Ltd., or Jinxiang Dong Yun Freezing Storage Co., Ltd., the cash-deposit rate will be the rate listed above; (2) for all other subject merchandise exported by Shanghai Ever Rich Trade Company, Linshu Dading Private Agricultural Products Co., Ltd., Sunny Import and Export, Ltd., Taian Ziyang Food Company, Ltd., and Jinxiang Dong Yun Freezing Storage Co., Ltd., the cash-deposit rate will be the PRC-wide rate, which is 376.67 percent; (3) for all other PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash-deposit rate will be the PRC-wide rate of 376.67 percent; (4) for all non-PRC exporters of subject merchandise, the cash-deposit rate will be the rate applicable to the PRC exporter that supplied that exporter. These deposit requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

Notification to Interested Parties

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during the review period. Pursuant to 19 CFR 351.402(f)(3) failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO as explained in the administrative protective order itself. 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 the terms of an APO is a sanctionable violation.

Bonding is no longer permitted to fulfill security requirements for shipments from Ever Rich, Linshu Dading, Sunny, Ziyang, and Dong Yun of fresh garlic from the PRC entered, or withdrawn from warehouse, for consumption in the United States on or after the publication of this notice in the **Federal Register**.

These final results of new shipper reviews and notice are issued and published in accordance with sections 751(a)(2)(B) and 777(i) of the Act.

Dated: July 26, 2004.

Jeffrey A. May,

Acting Assistant Secretary for Import Administration.

Appendix

Decision Memo

1. Application of Surrogate Financial Ratios
2. Valuation of Garlic Seed
3. Valuation of Ocean Freight
4. Fixed Overhead Calculation
5. Selling, General and Administrative Expenses and Profit Calculation

[FR Doc. 04–17566 Filed 8–2–04; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–427–818]

Notice of Final Results of Antidumping Duty Administrative Review: Low Enriched Uranium From France

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of final results of antidumping duty administrative review.

SUMMARY: On January 27, 2004, the Department of Commerce (the Department) published the preliminary results of its first administrative review of the antidumping duty order on low enriched uranium (LEU) from France. The review covers one producer of the subject merchandise. The period of review (POR) is July 13, 2001, through January 31, 2003. Based on our analysis of comments received, these final results differ from the preliminary results. The final results are listed below in the Final Results of Review section.

DATES: *Effective Date:* August 3, 2004.

FOR FURTHER INFORMATION CONTACT: Carol Henninger or Constance Handley, at (202) 482–3003 or (202) 482–0631, respectively; AD/CVD Enforcement, Office 1, Group I, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Avenue, NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On January 27, 2004, the Department published in the **Federal Register** the preliminary results of the first administrative review of the antidumping duty order on LEU from France. *See Notice of Preliminary Results of Antidumping Duty Administrative Review: Low Enriched Uranium from France,* 69 FR 3883 (January 27, 2004) (*Preliminary Results*).

We invited parties to comment on the *Preliminary Results*. On February 27, 2004, we received case briefs from the sole respondent, Eurodif S.A., Compagnie Génerale Des Matiéres Nucleaires, S.A. and COGEMA, Inc. (collectively, COGEMA/Eurodif), and the petitioners, the United States Enrichment Corporation and USEC Inc. (collectively, USEC). COGEMA/Eurodif submitted its rebuttal brief on March 5, 2004, and USEC submitted its rebuttal brief on March 16, 2004. Upon request from the Department, USEC and COGEMA/Eurodif submitted additional comments regarding the treatment of countervailing duties on March 2, 2004, and March 9, 2004, respectively. A public hearing was held on March 17, 2004.

Scope of the Order

The product covered by this order is all low enriched uranium (LEU). LEU is enriched uranium hexafluoride (UF_6) with a U^{235} product assay of less than 20 percent that has not been converted into another chemical form, such as UO_2, or fabricated into nuclear fuel assemblies, regardless of the means by which the LEU is produced (including LEU produced through the down-blending of highly enriched uranium).

Certain merchandise is outside the scope of this order. Specifically, this order does not cover enriched uranium hexafluoride with a U^{235} assay of 20 percent or greater, also known as highly enriched uranium. In addition, fabricated LEU is not covered by the scope of this order. For purposes of this order, fabricated uranium is defined as enriched uranium dioxide (UO_2), whether or not contained in nuclear fuel rods or assemblies. Natural uranium concentrates (U_3O_8) with a U^{235} concentration of no greater than 0.711 percent and natural uranium concentrates converted into uranium hexafluoride with a U^{235} concentration of no greater than 0.711 percent are not covered by the scope of this order.

Also excluded from this order is LEU owned by a foreign utility end-user and imported into the United States by or for such end-user solely for purposes of conversion by a U.S. fabricator into uranium dioxide (UO_2) and/or fabrication into fuel assemblies so long as the uranium dioxide and/or fuel assemblies deemed to incorporate such imported LEU (i) remain in the possession and control of the U.S. fabricator, the foreign end-user, or their designed transporter(s) while in U.S. customs territory, and (ii) are re-exported within eighteen (18) months of entry of the LEU for consumption by the end-user in a nuclear reactor outside the United States. Such entries must be accompanied by the certifications of the importer and end-user.

The merchandise subject to this order is currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) at subheading 2844.20.0020. Subject merchandise may also enter under 2844.20.0030, 2844.20.0050, and 2844.40.00. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive.

Analysis of Comments Received

The issues raised in the case briefs by parties to this administrative review are addressed in the *Issues and Decision Memorandum* to James J. Jochum, Assistant Secretary for Import Administration, from Gary Taverman, Acting Deputy Assistant Secretary for Import Administration (*Decision Memorandum*), which is hereby adopted by this notice. A list of the issues addressed in the *Decision Memorandum* is appended to this notice. The *Decision Memorandum* is on file in Room B–099 of the main Commerce building, and a public version of it can also be accessed directly on the Web at *www.ia.ita.doc.gov*. The paper copy and electronic version of the *Decision Memorandum* are identical in content.

Changes Since the Preliminary Results

Based on our analysis of comments received, we have made adjustments to the methodology used in calculating the final dumping margin in this proceeding. The adjustments are discussed in detail in the *Decision Memorandum*.

Final Results of Review

As a result of our review, we determine that the following weighted-average margin exists for the period of July 13, 2001, through January 31, 2003:

Producer—COGEMA/Eurodif
Weighted-Average Margin (Percentage)—5.43

Assessment

The Department will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries, pursuant to 19 CFR 351.212(b). The Department calculated importer-specific duty assessment rates on the basis of 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 assessment rate is above *de minimis*, we will instruct CBP to assess duties on all entries of subject merchandise by that importer. The Department will issue appropriate assessment instructions directly to CBP within 15 days of publication of these final results of review.

Cash Deposits

Furthermore, the following deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of LEU from France entered, or withdrawn from warehouse, for consumption on or after the publication date of these final results, as provided by section 751(a) of the Tariff Act of 1930, as amended (the Act): (1) For companies 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 19.95 percent, the "All Others" rate established in the less-than-fair-value investigation. These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

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 review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred, and in the subsequent assessment of double antidumping duties.

This notice also is the only 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. 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 the terms of an APO is a sanctionable violation.

We are issuing and publishing these results and notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: July 26, 2004.

Jeffrey May,

Acting Assistant Secretary for Import Administration.

Appendix I—Proposed Treatment of Countervailing Duties as a Cost

Background

Section 772(c)(2)(A) of the Tariff Act of 1930, as amended, requires that in calculating dumping margins, the Department must deduct from prices in the United States any "United States import duties" or other selling expenses included in those prices.[1] The issue has been raised whether this provision requires the Department to deduct countervailing duties ("CVDs") imposed under section 772 of the Trade Act of 1974 from U.S. prices in calculating dumping margins.[2]

The Department received extensive comments and has considered them at great length. On the basis of that consideration, it has determined not to deduct CVDs from U.S. prices in calculating dumping margins. The reasons for this decision are set forth below.

Comments in Support of Deducting Countervailing Duties

Commenters in favor of deducting CVDs from U.S. price argue that the plain language of section 772(c)(2)(A) requires such deduction. Section 772(c)(2)(A) states that U.S. price shall be reduced by "the amount, if any, included in such price, attributable to any additional costs, charges, or expenses, and United States import duties, which are incident to bringing the subject merchandise from the original place of shipment in the exporting country to the place of delivery in the United States * * *." These commenters contend that CVDs, in particular CVDs to offset domestic subsidies, are costs, charges, expenses or import duties incidental to bringing merchandise into the United States. Thus, those CVDs must be deducted.

More specifically, these commenters argue that the statutory phrase "United States import duties" encompasses CVDs. They contend that there is no basis for interpreting the term "United States import duties" as referring only to "normal" or "regular" duties. These commenters point out that the Antidumping Act of 1921 (the "1921 Act") identified three types of duties: "special dumping duties," "regular customs duties," and "United States import duties." According to the commenters, "United States import duties" therefore means something different than "normal" or "regular" duties. The commenters assert that this term actually encompasses all duties, special and regular,[3] so that the statutory direction to deduct "U.S. import duties" requires the deduction of CVDs.

Furthermore, these commenters note that section 772(c)(1)(C) requires the Department to increase U.S. price by the amount of any CVD that was imposed to offset an export subsidy. According to these commenters, section 772(c)(1)(C)—and the corresponding exception in section 772(c)(2)(A) for CVDs that fall under 772(c)(1)(C)—would have been superfluous if Congress had not already intended CVDs normally to be deducted from U.S. price. In other words, Congress set a general rule that CVDs are to be deducted from U.S. price, but altered this general rule by creating the exception for CVDs for export subsidies. Thus, these commenters contend that the doctrine of *expressio unius est exclusio alterius*[4] applies. Under this doctrine, the express statutory exception in section 772(c)(2)(A) for CVDs for export subsidies indicates that Congress intended that section to encompass CVDs for non-export subsidies.

According to these commenters, the doctrine of *expressio unius* also applies when one looks at other provisions of section 772. Section 772(c)(2)(B) instructs the Department not to deduct from U.S. price the amount of any export tax, duty or other charge that is imposed by the exporting country to offset a countervailable subsidy. On the other hand, the Department will deduct the amount of any export tax, duty or other charge that is imposed by the exporting country for reasons other than to offset a countervailable subsidy. Thus, according to some commenters,

[1] 19 U.S.C. 1677a(c)(2)(A). This statutory deduction existed prior to the passage of the Uruguay Round Agreements Act (URAA), and the URAA did not modify it in any respect.

[2] *Antidumping Proceedings: Treatment of Section 201 Duties and Countervailing Duties*, 68 FR 53,104 (Sept. 9, 2003).

[3] At the same time, these commenters argue that the 1921 Act's identification of different types of duties is ultimately irrelevant to the issue of deducting CVDs because the 1921 Act only referred to types of dumping duties, not countervailing duties.

[4] "To say one thing is to exclude the alternative."

the statute's scheme for the treatment of measures to offset countervailable subsidies is clear. Section 772(c)(2)(B) addresses export taxes, duties or other charges imposed by the exporting country, whether to offset a countervailable subsidy or for other purposes. Section 772(c)(1)(C) addresses CVDs imposed to offset export subsidies. The only type of offset measure not expressly addressed is a CVD imposed to offset non-export subsidies. Thus, according to these commenters, it is reasonable to conclude that this type of measure is the type addressed in section 772(c)(2)(A) and should be deducted in accordance with that provision.

The commenters supporting deduction of CVDs from U.S. price recognize that the Department's current practice is not to deduct. However, these commenters note that, under a general principle of administrative law, the Department may change its practice as long as it provides a reasoned explanation for such change.[5] This principle applies even when courts have sustained the Department's current practice.

Some commenters argue that deducting CVDs from U.S. price would not constitute a double remedy to the domestic industry, in contrast to the claims of the parties opposing such deductions. Several commenters argue that deducting CVDs is no more double-counting than deducting other costs and expenses incurred by a seller to the United States. Some commenters note that under their proposal, the Department would only deduct CVDs for domestic subsidies when the terms of the sale obligate the seller (or related importer) to pay the costs of the CVDs. Thus, the change in practice would not increase dumping margins to the extent hypothesized by the opposing parties. Moreover, there is no "recursiveness" (double-counting) problem with respect to deduction of CVDs from U.S. price (as there might be if the Department deducted antidumping duties from U.S. price) because recursiveness is only a problem when the same determinant (such as the dumping margin) is present on both sides of the equation. This is not the case with the deduction of CVDs from U.S. price, because the ultimate antidumping duty rate will not affect the CVD rate.

Some commenters also argue that deduction of CVDs from U.S. price is necessary in order to make the Department's practice consistent with Customs' practice. Customs, in determining the dutiable value of a good, deducts the amount of any CVDs.[6] According to some commenters, the fact that the Department does not deduct CVDs from U.S. price results in a U.S. price that is greater than Customs' dutiable value of the good. When the dumping margin is applied to U.S. price, the result is a greater antidumping duty amount than when Customs applies that same margin to the smaller dutiable value. According to these commenters, because Customs collects antidumping duties on the basis of dutiable value, the Department's failure to deduct CVDs from U.S. price results in Customs collecting less than the full amount necessary to offset the margin of dumping found by the Department.

Several commenters claim that deducting CVDs from U.S. price would be consistent with the international obligations of the United States. These commenters note that Article VI(5) of the GATT is inapplicable because it only prohibits the imposition of both antidumping and countervailing duties for the same situation of dumping or export subsidization. It does not address CVDs for non-export subsidies, and therefore it does not prohibit the deduction of CVDs for non-export subsidies from U.S. price. These commenters also contend that such deduction would not violate the obligation of Article VI(2) of the GATT and Article 9.3 of the Antidumping Agreement that the amount of antidumping duties must not exceed the margin of dumping. According to these commenters, the deduction would make an adjustment for a cost of U.S. sales and therefore would have an equivalent effect on both the margin and the amount of duties. Some commenters also note that the laws of major U.S. trading partners authorize the deduction of CVDs when calculating dumping margins. Therefore, under the current practice, U.S. domestic industries are at a disadvantage relative to the industries of other countries.

Finally, some commenters assert that a deduction for CVDs is necessary in order to reflect the true cost of selling in the United States. They note that payment of CVDs is a condition to merchandise entering the United States. Additionally, some commenters contend that certain foreign producers are simply absorbing the costs of CVDs. A deduction for CVDs in antidumping calculations is necessary in order to level the playing field when foreign producers absorb the CVD costs. According to these commenters, the Department should deduct CVD deposits, as well as final assessed CVD amounts, because deposits are also a cost of bringing merchandise into the United States.

Comments in Opposition To Deducting Countervailing Duties

Many commenters argue that the term "United States import duties" in section 772(c)(2)(A) does not include countervailing duties. They claim that "United States import duties" refers only to ordinary duties, not to remedial duties such as CVDs. For example, one commenter argues that the use of the two terms "import duties" and "countervailing duties" in section 772 indicates that Congress intended the terms to have different meanings.

Some commenters point to section 777(c)(2)(B), which prohibits the Department from deducting any export tax, duty or other charge imposed by the exporting country to offset a countervailable subsidy. Because CVDs similarly offset countervailable subsidies, they argue that this shows the Congress did not intend them to be deducted from U.S. prices.

Many commenters note that the Department's long-standing practice has been not to deduct CVDs from U.S. price.[7] They note that the Department has interpreted "United States import duties" as including only ordinary duties and not remedial duties,[8] and that the Court of International Trade (CIT) has upheld this practice.[9]

Some commenters point out that the Department and the CIT rejected the domestic parties' arguments concerning the deduction of CVDs imposed to offset non-export subsidies in *U.S. Steel Group* v. *United States*, 15 F. Supp. 2d 892, 900 (1998). According to these commenters, the domestic parties in *U.S. Steel* argued that section 772(c)(2)(A) sets a general rule that CVDs are to be deducted from U.S.

[5] These commenters cite *Rust* v. *Sullivan*, 500 U.S. 173 (1991), and *NTN Bearing Corp.* v. *United States*, 903 F. Supp. 62 (Ct. Int'l Trade 1995).

[6] The relevant statute, 19 U.S.C. 1401a(b)(3)(B), directs Customs not to include in dutiable value the "customs duties and other Federal taxes currently payable on the imported merchandise by reason of its importation * * *" According to some commenters, the term "customs duties" is not defined—just as the term "United States import duties" is not defined for purposes of section 772(c)(2)(A)—but Customs interprets it to include CVDs.

[7] Some commenters suggest that the Department cannot change its long-standing practice absent a change in law or fact.

[8] Many commenters cite *Certain Cold-Rolled and Corrosion-Resistant Carbon Steel Flat Products from Korea*, 62 FR 18404 (April 15, 1997), in which the Department articulated the distinction between ordinary duties and antidumping or countervailing duties.

[9] *See, e.g., A.K. Steel* v. *United States*, 988 F. Supp. 594 (Ct. Int'l Trade 1997); *Hoogovens Staal BV* v. *United States*, 4 F. Supp. 2d 1213 (Ct. Int'l Trade 1998).

price, and that the exception relating to CVDs imposed to offset export subsidies, contained in section 772(c)(1)(C), is evidence of this general rule. The CIT rejected this interpretation of the relationship between sections 772(c)(1)(C) and 772(c)(2)(A). *Id.* These commenters contend that the result in *U.S. Steel Group* represents the appropriate construction of the relationship between sections 772(c)(1)(C) and 772(c)(2)(A), and that the Department should not adopt a different construction now. According to these commenters, the requirement in section 772(c)(1)(C) to add CVDs imposed to offset export subsidies cannot be used to interpret 772(c)(2)(A) as requiring the subtraction of CVDs imposed to offset non-export subsidies.

One commenter argues that the doctrine of *expressio unius est exclusio alterius* does not support the conclusion that the requirement to add CVDs for export subsidies to U.S. price implies that CVDs for non-export price must be subtracted under section 772(c)(2)(A). This commenter contends that, because section 772(c) expressly provides for either increases or reductions to U.S. price, the statute's silence with respect to non-export subsidy CVDs indicates that Congress intended these CVDs to neither increase nor reduce U.S. price.

Several commenters contend that Congress has been aware of the Department's longstanding practice of not deducting CVDs from U.S. prices and has acquiesced in this practice by never amending the statute. These commenters, argue that the Department's current practice is, therefore, consistent with congressional intent. One commenter also asserts that Congress's rejection of the treatment of antidumping duties as costs during passage of the URAA is further evidence of Congress's acceptance of the Department's current practice.[10] Additionally, several commenters point out that some members of Congress recently have proposed legislation that would require the Department to deduct CVDs from U.S. price. According to these commenters, the necessity of new legislation demonstrates that the current statutory language does not permit deduction of CVDs.

Many commenters argue that the deduction of CVDs from U.S. price would result in a double remedy to domestic industry because the CVDs effectively would be charged twice: once in the original proceeding which imposed the CVDs and once more as a factor in U.S. price, which will have the effect of increasing the dumping margin. These commenters note that the Department recognized the double-counting problem in *Certain Cut-to-Length Carbon Steel Plate from Germany*, 62 FR 18390 (April 15, 1997). According to these commenters, deduction of CVDs would be inconsistent with the remedial purpose of the trade remedy laws and would transform remedial duties into punitive duties. The commenters cite to *A.K. Steel* v. *United States*, 988 F. Supp. 594 (Ct. Int'l Trade 1997) and *U.S. Steel Group*, 15 F. Supp. 2d 892, in which the CIT sustained the Department's decisions not to deduct remedial duties, partly because of the Department's concerns that the deductions would result in double-counting.

Several commenters argue that deducting CVDs from U.S. price would be inconsistent with the international obligations of the United States. They cite to Article VI(5) of the GATT, which prohibits countries from deducting CVDs imposed to offset export subsidization in a dumping calculation. They also cite Article 19.4 of the Agreement on Subsidies and Countervailing Measures, which provides that no CVD shall be levied in excess of the amount of the subsidy found to exist. These commenters contend that deducting a CVD in an antidumping proceeding will have the practical effect of doubling the amount of the CVD, in contravention of Article 19.4. Commenters also argue that deduction of CVDs would create an artificially low export price and consequently an inflated dumping margin, in contravention of Article 9.3 of the Antidumping Agreement. Furthermore, some commenters argue that the fact that the laws of some U.S. trading partners may provide for the deduction of CVDs is irrelevant to the question of whether the United States should adopt this practice. Other commenters assert that a change in the Department's practice would create a domino effect that would have a negative impact on world trade.

Finally, one commenter argues that there would be practical difficulties to deducting CVDs from U.S. price. According to this commenter, the retrospective duty assessment system of the United States would make timely and consistent adjustments for CVDs impossible. This commenter contends that the Department, if it chooses to deduct CVDs, would only be able to deduct final, assessed CVDs. However, CVDs are not final until after all appeals are complete. Consequently, when there are parallel antidumping and countervailing duty proceedings for the same subject merchandise, the Department would not be able to make adjustments to the dumping margin until the appeals of the CVD proceeding are complete. Such a delay would push the final antidumping determination well past the statutory deadlines, according to this commenter.

Discussion

The Department, for the several reasons explained below, has determined to continue its well-established practice of not deducting CVDs from U.S. price in calculating dumping margins. The Department's view remains that CVDs are neither "United States import duties" nor selling expenses within the meaning of section 772(c)(2)(A) of the Act, and therefore should not be deducted from U.S. price.

The Statute and Legislative History. Section 772(c)(2)(A) of the Act requires the Department to reduce export price and constructed export price by:

> The amount, if any, included in such price, attributable to any additional costs, charges, or expenses and *United States import duties*, which are incident to bringing the subject merchandise from the original place of shipment in the exporting country to the place of delivery in the United States.[11]

The Meaning of "United States Import Duties". The term "United States import duties" originated in the 1921 Act.[12] The term was not defined in 1921 or in any subsequent AD or CVD legislation, and the CIT has found its meaning to be "unclear."[13] In this situation, the Department's interpretation of the term is entitled to substantial deference.[14]

The legislative history of the 1921 Act indicates that AD duties, at least, are not the same as ordinary Customs duties. The Senate Report refers to AD duties as "special dumping dut[ies]" and refers to ordinary Customs duties as "United States import duties."[15] Section 211 of the 1921 Act provides that, for the

[10] In *Certain Cut-to-Length Carbon Steel Plate from Germany*, 62 FR 18390, 18395 (April 15, 1997), the Department noted that "[T]he treatment of AD and CVD duties (already paid or to be assessed) as a cost to be deducted from the export price is an issue that was arduously debated during passage of the URAA and ultimately rejected by Congress."

[11] 19 U.S.C. 1677a(c)(2)(A) (emphasis added).

[12] *See*, The 1921 Act, 19 U.S.C. 161(a) (repealed, 1979); and *Nichimen Am., Inc.*, v. *United Stotes*, 938 F.2d 1286, 1289 (Fed. Cir.-1991).

[13] *See*, *AK Steel* v. *United States*, 988 F. Supp. 594, 607 (Ct. Int'l Trade 1997); and *PQ Corp.* v. *United States*, 652 F. Supp. 724, 736 (Ct. Int'l Trade 1987).

[14] *See*, *Chevron U.S.A., Inc.* v. *Noturol Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984).

[15] *See*, S. Rep. No. 67–16, at 4 (1921), discussed in *Certoin Cold-Rolled ond Corrosion-Resistont Corbon Steel Flot Products from Koreo*, 62 FR 18,404, 18,421 (Apr. 15, 1997).

limited purpose of duty drawback, "the special dumping dut[ies] * * * shall be treated in all respects as regular customs duties." [16] If "special dumping duties" really were considered to be just one type of "United States import duty," this special provision would have served no purpose.

That "special dumping duties" were considered to be distinct from normal Customs duties is also indicated by the fact that section 202(a) of the 1921 Act provides that "special dumping duties" may be applied to "duty-free" merchandise.[17] In this context, "duty-free" must mean "free from normal Customs duties." If "duty-free" had meant "free from any import duties," that would have included antidumping duties, so that special dumping duties would have been applied to merchandise exempt from special dumping duties. Plainly, "duty-free" was understood to mean "free from normal Customs duties."

A number of commenters argue that, while Congress did distinguish "special dumping duties" from "regular customs duties" in section 211 of the 1921 Act, it used the different term "United States import duties" in sections 203 and 204 (which were the precursors to section 772). Thus, "United States import duties" must mean something other than either "special dumping duties" or "regular customs duties." Logically, "United States import duties" must be a broader term that encompasses normal Customs duties and CVDs. The problem with this argument is that if "United States import duties" includes CVDs, then it logically must include *all* CVDs and also AD duties, thus requiring their deduction from U.S. prices. With respect to CVDs to offset export subsidies, this flatly contradicts the statute. With respect to AD duties, this would amount to deducting dumping margins from initial U.S. prices in calculating dumping margins.

Another provision of the statute that provides some context is section 779, which provides that, "[f]or purposes of any law relating to the drawback of customs duties, [CVDs and AD duties] imposed by this subtitle shall not be treated as being regular customs duties." [18] While this is restricted in application to duty drawback, it certainly suggests that AD duties and CVDs are distinguishable from regular Customs duties.[19]

The Meaning of "Any Costs, Charges or Expenses" of Importation. A number of commenters argue that CVDs to offset domestic subsidies must be deducted as included in the term "any costs, charges, or expenses" of bringing the merchandise into the United States, the better argument takes account of the fact that the statute refers to any additional "costs, charges, expenses and United States import duties * * *." These comments argue that this language indicates that import duties are considered to be independent of other costs, charges, and expenses. We disagree. While CVDs are a special type of import duty, they are nevertheless a species of import duty, and are thus covered, if at all, by the phrase "United States import duties." Thus, the Department has interpreted the statute as providing for the addition to initial U.S. prices of any additional costs, charges, or expenses and normal United States import duties (but not other import duties).

The Logic and Context of the 1979 Amendments. With respect to CVDs to offset export subsidies, the 1979 amendments to the statute provide a straightforward response to the argument that they should be deducted from initial U.S. prices in calculating dumping margins—they require that CVDs to offset export subsidies be added to initial U.S. prices. We do not interpret the statute to require CVDs to offset export subsidies first to be added to initial U.S. prices and then to permit this addition to be negated by their subsequent subtraction.

Domestic subsidies present a closer question, as the statute does not speak directly to them. The fact that the statute addresses CVDs to offset export subsidies directly, however, and then remains silent about the plainly related issue of CVDs to offset domestic subsidies, is not complete silence—it implies that no adjustment is appropriate. There is no reason why Congress would have provided for the addition of export subsidy CVDs, but not considered the plainly related issue of domestic subsidy CVDs.

Certain domestic parties have argued that the provision for the addition to U.S. prices of CVDs to offset export subsidies, coupled with silence concerning the treatment of CVDs to offset domestic subsidies, indicates that CVDs to offset domestic subsidies should be subtracted from U.S. prices. This logic is flawed. The statute does not require the "non-deduction" from initial U.S. prices of CVDs to offset export subsidies—it requires their addition. There are not one, but two, alternatives to "non-addition"—subtraction and no adjustment. As discussed below with respect to the double counting issue, the logical complement to adding CVDs to offset export subsidies to U.S. price is to make no adjustment with respect to CVDs to offset domestic subsidies.[20]

Some domestic commenters argue that the 1979 amendments indicate that CVDs generally must be deducted from initial prices in the United States. These commenters focus on the fact that, in addition to requiring the addition of export subsidy CVDs to the initial U.S. price under (current) (c)(1)(C), the 1979 Act also amended section (c)(2)(A), specifically excluding export subsidies from the normal deductions from initial U.S. prices.[21] The argument is that this additional change would have been pointless, unless CVDs otherwise were to be deducted from U.S. prices.

(d) * * * The purchase price and the exporter's sales price shall be adjusted by being

(1) increased by—

* * * * *

(D) the amount of any countervailing duty imposed on the merchandise under subtitle A of this title or section 303 of this Act to offset an export subsidy, and

(2) reduced by—

(A) except as provided in paragraph (1)(D), the amount, if any, included in such price, attributable to any additional costs, charges, and expenses, and United States import duties, incident to bringing the merchandise from the place of shipment in the country of exportation to the place of delivery in the United States * * *

Pub. L. 96–39, 93 Stat. 181–82 (1979).

This argument is overstated. First, the second of these two amendments to the statute simply states that expenses are to be deducted from the price in the United States "except as provided in [the paragraph providing for the addition of export subsidies]." While this could be interpreted to mean that CVDs normally are deducted, it also could be interpreted as a simple safeguard to prevent any possible implication that the same expense should be both added to and subtracted

[16] The 1921 Act, 42 Stat. 15. *See*, S. Rep. No. 67–16, at 4 (1921).

[17] The 1921 Act, 42 Stat. 11.

[18] 19 U.S.C. 1677h.

[19] Of course, it can also be argued that no exemption would be necessary if the general rule were not that AD duties and CVDs are generally to be treated as regular Customs duties.

[20] As explained above, the addition of export subsidy CVDs and no adjustment for domestic subsidy CVDs is consistent with a presumption that subsidies are passed through into initial prices, but that CVDs are not. There is no consistent set of presumptions about these matters that can be reconciled with the addition to initial U.S. prices of export subsidy CVDs and the subtraction of domestic subsidy CVDs.

[21] The 1979 amendments changed the statute to read as follows:

from prices in the United States. The House Report is silent on the issue,[22] but the Senate Report supports this second interpretation:

> * * * the addition for countervailing duties assessed on the same merchandise to offset subsidies is clarified to apply only to subsidies which are classified as export subsidies.
>
> * * * * *
>
> The purpose of the amendment regarding additions to purchase price and exporter's sales price with respect to countervailing duties also being assessed because of an export subsidy is designed to clarify that such adjustment is made only to the extent that the exported merchandise * * * benefits from a particular subsidy. The principal [sic] behind adjustments to the price paid in these instances is to achieve comparability between the price[s] which are being compared. *Where the situation is the same * * * [where the subsidy benefits all merchandise sold in both markets] then no adjustment is appropriate.*[23]

Thus, not only does the Senate Report not support the interpretation that CVDs should be deducted from U.S. price, it states that "no adjustment" is appropriate with respect to domestic subsidy CVDs.[24]

Double Counting. The 1979 amendments also demonstrate Congress' intention to avoid double-counting of CVDs and AD duties. Section 772(c)(1)(c) of the Act expressly provides that where an export subsidy has been provided, the Department must increase the U.S. price by "the amount of any countervailing duty imposed on the subject merchandise * * * to offset an export subsidy." 19 U.S.C. section 1677a(c)(1)(C). As the Department has explained, the reason for this is to prevent double-counting:

> Domestic subsidies presumably lower the price of the subject merchandise both in the home and the U.S. markets, and therefore have no effect on the measurement of any dumping that might also occur. Export subsidies, by contrast, benefit only exported merchandise. Accordingly, an export subsidy brings about a lower U.S. price, which could be ascribed to either dumping or export subsidization, as well as the potential for double remedies. Imposing both an export-subsidy CVD and an AD duty, calculated with no adjustment for that CVD, would impose a double remedy specifically prohibited by Article VI.5 of the GATT. Thus, the only reasonable explanation for Congress' decision to provide for the {addition to} U.S. price of export-subsidy CVDs is protection against double remedies. *Cold-Rolled Corrosion Resistant Carbon Steel Flat Products from Korea*, 62 FR at 18,422

The treatment of CVDs that arise out domestic subsidies contrasts with the statutory treatment of CVDs that relate to export subsidies. The reason for the difference in treatment is that export subsidies are assumed to increase dumping margins by lowering the export price, but not the domestic price in the exporting country. Consequently, collecting both a CVD on an export subsidy and also the increase in the dumping margin resulting from that subsidy would constitute a double remedy for the export subsidy. Adding the CVD to the initial U.S. price lowers the margin by the amount the subsidy is presumed to have increased it, thereby preventing a double-remedy. On the other hand, domestic subsidies are assumed not to affect dumping margins, because they lower prices in both the U.S. market and the domestic market of the exporting country equally. As a result, there is no need for an adjustment to prevent a double remedy. Thus, in the most general terms, the statute stands for the proposition that dumping margins should not be calculated so as to double-collect CVDs.

The Courts have specifically upheld this rationale for not deducting CVDs from U.S. prices in calculating dumping margins. As the court explained in *U.S. Steel Group* v. *United States:*

> Logically, the deduction of countervailing duty, whether export or non-export, from the U.S. price used to calculate the antidumping margin, would result in a double remedy for the domestic industry. Commerce has already corrected for subsidies on the subject merchandise in the countervailing duty order, thereby granting the domestic industry a remedy. To deduct such countervailing duties from U.S. price would create a greater dumping margin, in effect a second remedy for the domestic industry. *U.S. Steel Group* v. *United States*, 15 F.Supp. 892, 900 (Ct. Int'l Trade 1998).

Certain commenters have argued that an analysis of the statute must take into account section 772(c)(2)(B), which provides that any export tax specifically imposed to offset a countervailable subsidy may not be deducted from the initial U.S. price.[25] A number of commenters have pointed out that, because export taxes on subsidies are exempt from the normal requirement to deduct the costs of selling in the United States from initial U.S. prices, it would be consistent to give the same exemption to import taxes (CVDs) on those same subsidies. We agree that not deducting CVDs from U.S. prices is consistent with section 772(c)(2)(B). Section 771(6)(C) lists "export taxes, duties, or other charges levied on the export of merchandise to the United States specifically intended to offset the countervailable subsidy received."

The Department's Practice & Relevant Court Decisions. In the 23 years that the Department has administered the AD law, it has never deducted AD duties or CVDs from initial U.S. prices in calculating dumping margins.[26] Nor, apparently, did Treasury ever make such a deduction in the 58 years that it administered the law (from 1921—1979). As the Department has explained:

> It is the Department's longstanding position that AD and CVD duties are not a cost within the meaning of section 772(d). AD and CVD duties are unique. Unlike normal duties which are an assessment against value, AD and CVD duties derive from the margin of dumping or rate of subsidization found. See *Federal Mogul*, supra 813 F.Supp. at 872 (deposits of antidumping duties should not be deducted from USP because such deposits are not analogous to deposits of "normal import duties"). *Final Results of Antidumping Administrative Review: Plate from Germany*, 62 FR 18,390, 18,395 (Apr. 15, 1997).

The Department's interpretation of the statute has been consistently affirmed by the U.S. courts. The CIT has upheld the Department's interpretation of the meaning of section 772(c)(2)(A) of the Act on five occasions, and the court has directly addressed the issue of whether CVDs should be deducted from initial

---

[22] See discussion of United States Price at H. R. Rep. No. 96–317, at 77 (1979).

[23] S. Rep. No. 96–249 at 93 (1979). (Emphasis added).

[24] The 1979 Act Statement of Administrative Action, at 412, states that:

> A new adjustment to "purchase price" and "exporter's sales price" is intended to reflect provisions of Article VI of the General Agreement on Tariffs and Trade, by mandating the addition to "purchase price" or "exporter's sales price" of any countervailing duty actually imposed to offset an export subsidy paid on the same merchandise. * * * The GATT prohibits the assessment of both antidumping and countervailing duties to compensate for the same cause of unfairly low priced imports, whether by dumping or as result of an export subsidy.

[25] 19 U.S.C. 1677a(c)(2)(B) directs the Department to reduce the export price or constructed export price by:

> the amount, if included in such price, of any export tax, duty, or other charge imposed by the exporting country on the exportation of the subject merchandise to the United States, other than an export tax, duty, or other charge described in section 1677(6) (C). [Section 771(6) (C) of the Act].

[26] *See, e.g., Certain Corrosion-Resistant Carbon Steel Flat Products from Korea; Final Results of Antidumping Duty Administrative Review*, 61 FR 18,547 18,564 (Apr. 26, 1996); *Certain Cold-Rolled Carbon Steel Flat Products from the Netherlands; Final Results of Antidumping Duty Administrative Review*, 61 FR 48, 465, 48,469 (Sept. 13, 1996); *Certain Cut-To-Length Carbon Steel Plate from Germany; Final Results of Antidumping Duty Administrative Review*, 62 FR 18,390, 18,395 (Apr. 15, 1997); *Extruded Rubber Thread from Malaysia; Final Results of Antidumping Duty Administrative Review*, 64 FR 12,967, 12,973 (March 16, 1999); and *Certain Welded Carbon Steel Pipes and Tubes from Thailand*, 66 FR 53,388 (Oct. 22, 2001) and accompanying Decision Memorandum at Comment 1. *See Also, Antidumping Duties; Countervailing Duties: Proposed Rule*, 61 FR 7,308, 7,332 (Feb. 27, 1996).

prices in the United States in two decisions.[27] In each case, the Court affirmed the Department's determination not to make the deduction, following the rationale of the earlier decisions upholding the Department's determination not to deduct AD duties from initial U.S. prices.[28]

Throughout this time, Congress has been aware of the Department's firmly-established practice and of the court decisions affirming that practice, and never sought to change the statute in this regard.[29] This creates a strong presumption that the Department's interpretation of the statute is consistent with Congressional intent.[30]

Certain commenters have pointed to two Commerce administrative determinations, in *Fuel Ethanol from Brazil* and *Softwood Lumber from Canada,* in support of their contention that the Department has previously determined to deduct duties from U.S. price. However, the Department's determinations in these two cases are inapposite. First, the Department's 1986 determination in *Fuel Ethanol from Brazil* is not relevant to the issue of the treatment of CVDs. In that determination, the Department deducted special tariffs on imported fuel ethanol from the initial U.S. prices.[31] The tariffs in question were not CVDs. In fact, they were not remedial duties under any trade remedy law. Rather, they were tariffs added to the HTS by Congress to offset a tax subsidy that producers received for fuel-grade ethanol. A contemporary investigation by the International Trade Commission did not find injury to a U.S. industry.[32] Consequently, *Fuel Ethanol from Brazil* is not relevant to the issue of whether CVDs should be subtracted from U.S. prices in calculating dumping margins.

Similarly, the Department's 2002 determination in *Softwood Lumber from Canada* is not relevant to the issue of the treatment of CVDs.[33] That proceeding involved imports of lumber that had been subject to a quota-based fee under the U.S.—Canada Softwood Lumber Agreement. The export fees applied only to exports of lumber from Canada above 14.7 billion board feet. The Department deducted these fees from initial U.S. prices, noting that they did not qualify for the exemption from such deductions for export payments "specifically intended to offset countervailable subsidies." [34] Because that determination involved export fees rather than import duties, and similarly did not address the purpose of CVDs or account for the legislative history discussed above, it does not apply to the issue of whether CVDs should be deducted.

Customs' Practice. Certain commenters argue that CVDs must be deducted from initial U.S. prices because Customs deducts them from the price at which such merchandise is exported in calculating export value under section 302 of the Emergency Tariff Act, which contains identical language to section 772 of the AD law. The argument is that Customs must deduct CVDs in calculating entered value in order to avoid assessing Customs duties on CVDs, which would arguably be double counting. Accordingly, the identical language in the AD law must also be interpreted to require the deduction of CVDs from initial U.S. prices in calculating EP or CEP.

Any differences between the Department's and Customs' approach to valuation are not germane to the Department's interpretation of the statute. Customs law and the AD/CVD laws are distinctly different statutes and are applied for distinctly different purposes. The Courts have often countenanced different approaches and interpretations by the two agencies in interpreting the respective laws which they administer.[35] Thus, the answer is that even identical language in two statutes must be interpreted in context, and that export value was never intended to be exactly the same thing as EP or CEP.

Fair Pricing. Some domestic parties argue that, if CVDs are not passed through into initial U.S. prices, the foreign producers defeat the purpose of the AD law to "level the playing field" in the U.S. market. Thus, they argue, CVDs must be deducted from the initial U.S. price. to create a fair comparison. This argument takes what may well have been an implicit assumption of Congress in creating the AD and CVD laws (although apparently not the 1979 amendments)—that AD duties and CVDs would raise prices in the U.S. market—and turns it into a requirement to be enforced by the AD law. The AD law itself, however, contains no such requirement. It simply directs the Department to determine the export price and the normal value and to assess AD duties in the amount of the difference. In other words, the AD law does not require that merchandise subject to AD duties or CVDs be sold at higher prices in the U.S. market if the producer pays the duties.

The only provision of the statute that even refers to the potential effect of duties on prices in the U.S. market is in the statute's sunset provision, introduced in the Uruguay Round Agreements Act. This directs the Department to determine in CEP situations (in the second and fourth administrative reviews only) whether the foreign producer or exporter "absorbed" the AD duties.[36] There is no comparable provision with respect to CVDs. A finding that absorption occurred does not affect the AD margin, but only the determination of whether dumping would be likely to continue or

---

[27] *See, PQ Corp.* v. *United Stotes,* 652 F. Supp. 724, 737 (Ct. Int'l Trade 1987) (Commerce need not deduct estimated AD deposits from the initial price in the United States); *Federol-Mogul Corp.* v. *United States,* 813 F. Supp. 856, 872 (Ct. Int'l Trade 1993) (Commerce need not deduct estimated AD deposits from the initial price in the United States); *AK Steel Corp.* v. *United States,* 988 F. Supp. 594 (Ct. Int'l Trade 1997) (actual antidumping and countervailing duties need not be deducted from the initial price in the United States); *Hoogovens Stool* v. *United States,* 4 F. Supp.2d 1213, 1220 (Ct. Int'l Trade 1998) (Commerce need not deduct AD duties from the initial price in the United States as either U.S. import duties or as costs); *Bethlehem Steel* v. *United States,* 27 F. Supp.2d 201, 208 (Ct. Int'l Trade 1998) (Commerce need not deduct AD duties from the initial price in the United States as either U.S. import duties or as costs); *U.S. Steel Group* v. *United Stotes,* 15 F. Supp. 2d 892, 898–900 (Ct. Int'l Trade 1998) (Commerce need not deduct either AD nor CVDs from the starting price in the United States in calculating AD duties). *But see, C.J. Tower & Sons* v. *United States,* 71 F. 2d 438 (CCPA 1934), in which the Court of Customs and Patent Appeals stated in another context that special dumping duties were not penalties, but duties for "all purposes."

[28] *U.S. Steel,* at 899 (Ct. Int'l Trade 1998); AK Steel, at 607–608.

[29] *See,* H.R. Rep. No. 103–826(I), at 60–61 (1994); S. Rep. No. 96–249, at 94 (1979).

[30] *See, FDA* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 132 (2000); *United States* v. *Hermanos,* 209 U.S. 337, 339 (1908); *Merrill Lynch, Pierce, Fenner & Smith, Inc.* v. *Curran,* 456 U.S. 353, 381–82 (1982).

[31] *Fuel Ethanol from Brazil; Finol Determination of Soles ot Less Thon Foir Volue,* 51 FR 5572 (Feb. 14, 1986).

[32] *Certain Ethyl Alcohol from Brazil,* Inv. No. 731–TA–248, USITC Pub. 1818 (Final)(March 1986).

[33] *Certain Softwood Lumber Products from Canoda; Notice of Final Determination of Soles ot Less Thon Foir Volue,* 67 FR 15,539 (Apr. 2, 2002), and accompanying decision memorandum, at Comment Nine.

[34] *Id.*

[35] *See, Diversified Prod.* v. *United States,* 572 F. Supp. 883 (Ct. Int'l Trade 1983); *Torrington* v. *United States,* 745 F. Supp. 718, 722 (Ct. Int'l Trade 1990), *aff'd,* 938 F.2d 1276 (Fed. Cir. 1991) (Commerce not bound by customs classifications); *Koyo Seiko* v. *United States,* 955 F. Supp. 1532 (Ct. Int'l Trade 1997) (Customs has a ministerial role in antidumping duty law and * * *. it is solely Commerce's domain to define the class or kind of merchandise.) *Roquette Freres* v. *United States,* 583 F. Supp. 599, 605 (Ct. Int'l Trade 1984) (Commerce not bound by Customs interpretation of term "class or kind").

[36] Section 751(a)(4) of the Act, 19 U.S.C. 1675(a)(4).

recur if the order were revoked.[37] The SAA relating to this very provision states that it is not intended to provide for the treatment of AD duties as a cost in AD calculations.[38]

A related argument is that producers must be forced to cover their full costs of production in the United States, and that the extent to which that cost of production has been lowered by subsidies must be accounted for by deducting CVDs on those subsidies from initial U.S. prices. This argument is mistaken—the AD law does not direct the Department to add foreign government subsidies to foreign producers' costs of production. Presumably, Congress did not intend for the Department to effectively accomplish the same thing by subtracting CVDs from initial U.S. prices.

Conclusion. The Department will continue not to deduct CVDs from U.S. prices in calculating dumping margins because CVDs are not "United States import duties" within the meaning of the statute, and to make such a deduction effectively would collect the CVDs a second time. Accordingly, to the extent that CVDs may reduce dumping margins, this is not a distortion of any margin to be eliminated, but a legitimate reduction in the level of dumping.

Appendix II—Issues in Decision Memorandum

Comment 1: Application of the Major Inputs Rule to Eurodif's Purchases of Electricity
Comment 2: General and Administrative (G&A) expenses
Comment 3: Financial Expenses
Comment 4: Constructed Value (CV) Profit
Comment 5: Goodwill Expenses
Comment 6: Tails Defluorination and Plant Decommissioning
Comment 7: Attribution of Subject Merchandise
Comment 8: Circumstance of Sale (COS) Adjustment
Comment 9: Constructed Export Price (CEP) Offset
Comment 10: Indirect Selling Expenses
Comment 11: CV Selling Expenses
Comment 12: Treatment of Countervailing Duties

[FR Doc. 04–17565 Filed 8–2–04; 8:45 am]
BILLING CODE 3510–DS–P

[37] The Department finds that the duties have been absorbed if the seller pays them, which is consistent with the approach to CVDs taken the 1979 amendments to the AD law. *See, e.g., Stainless Steel Wire Rod from the Republic of Korea; Preliminary Results of Antidumping Duty Administrative Review*, 68 FR 57,879, 57,880 (Oct. 7, 2003); *Freshwater Crawfish Tail Meat from the People's Republic of China; Notice of Final Results of Antidumping Duty Administrative Review*, 68 FR 19,504, 19,505 (Apr. 21, 2003).

[38] Uruguay Round Agreements Act, Statement of Administrative Action at 885.

DEPARTMENT OF COMMERCE

International Trade Administration

(A–570–501)

Natural Bristle Paintbrushes and Brush Heads From the People's Republic of China: Preliminary Determination To Rescind the Antidumping New Shipper Review of Shanghai R&R Import/ Export Co., Ltd.

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On September 30, 2003 the Department of Commerce (the Department) initiated new shipper reviews of the antidumping duty order on natural bristle paintbrushes and brush heads from the People's Republic of China (PRC) covering the period February 1, 2003, through July 31, 2003. *See Natural Bristle Paintbrushes and Brush Heads from the People's Republic of China: Initiation of Antidumping Duty New Shipper Reviews*, 68 FR 57875 (October 7, 2004) (*Initiation Notice*). These new shipper reviews covered two exporters: Shanghai R&R Imp./Exp. Co., Ltd. (Shanghai R&R) and Changshan Import/Export Co., Ltd (Changshan). For the reasons discussed below, we preliminarily intend to rescind the new shipper review of Shanghai R&R. The Department is addressing the preliminary determination for Changshan in a separate notice.

EFFECTIVE DATE: August 3, 2004.

FOR FURTHER INFORMATION CONTACT: Scott Lindsay or Dana Mermelstein at (202) 482–0780 and (202) 482–1391, respectively; Office of AD/CVD Enforcement 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On February 14, 1986, the Department issued an antidumping duty order on natural bristle paintbrushes and brush heads from the PRC. *See Amended Antidumping Duty Order: Natural Bristle Paint Brushes and Brush Heads From the People's Republic of China*, 51 FR 8342 (February 14, 1986). On August 14, 2003, the Department received from Shanghai R&R, an exporter of subject merchandise to the United States, a timely request for a new shipper review under this order. Pursuant to section 351.214(b)(2)(iv) of the Department's regulations, this request included documentation establishing the volume of Shanghai R&R's first shipment to the United States and the date of the first sale to an unaffiliated customer in the United States. On September 30, 2003, the Department initiated this new shipper review covering the period February 1, 2003, through July 31, 2003. *See Initiation Notice.* On January 8, 2004, we received Shanghai R&R's response to the Department's initial questionnaire. On April 29, 2004, the Department received Shanghai R&R's response to the Department's supplemental questionnaire. On June 10, 2004, we received Shanghai R&R's response to the Department's second supplemental questionnaire.

On March 18, 2004, the Department extended the time limit for the completion of the preliminary results to July 26, 2004, in accordance with section 751(a)(2)(B)(iv) of the Tariff Act of 1930, as amended (the Act), and section 351.214(i)(2) of the Department's regulations. *See Notice of Extension of Time Limit for Preliminary Results of Antidumping Duty New Shipper Reviews: Natural Bristle Paintbrushes from the People's Republic of China*, 69 FR 12831 (March 18, 2004).

Verification

As provided in section 782(i) of the Act, we conducted verification of the questionnaire responses of Shanghai R&R. We used standard verification procedures, including on–site inspection of the production and sales facilities, and an examination of relevant sales and financial records. Our verification results are outlined in the *New Shipper Review of Natural Bristle Paintbrushes from the People's Republic of China: Sales Verification Report for Shanghai R&R Import/Export Co., Ltd.*, dated July 21, 2004. A public version of this report is on file in the Central Records Unit located in room B–099 of the Main Commerce Building.

Intent to Rescind Review

With every new shipper review request, the Department has an obligation to analyze the documentation and certifications to establish that they meet the conditions of section 351.214(b)(2)(iv) of the Department's regulations. At the time Shanghai R&R requested this new shipper review, we determined that the regulatory requirements were met and we initiated the new shipper review. At verification, the Department found documentation which brings into question that this sale was in fact made to the importer identified in Shanghai R&R's initial request for review and in all subsequent questionnaire responses. Shanghai R&R's explanation, that mistakes were made in identifying the importer in

certain sales and accounting records, do not persuade us to find that the importer documented in the initial request was correctly identified. Moreover, the discrepancies between Shanghai R&R's submissions and the documents reviewed at verification undermine the accuracy and completeness of Shanghai R&R's claim that it made an entry and a sale to an unaffiliated customer in the United States. As such, we find that our initiation of this new shipper review was based on documents that failed to establish the date of the first sale to an unaffiliated customer in the United States. Therefore, pursuant to section 351.214(b)(2)(iv)(C) of the Department's regulations, the requirements for initiation have not been satisfied.

Accordingly, The Department intends to rescind this new shipper review. Because much of the information pertinent to our preliminary decision to rescind this review is business proprietary, we have set forth our complete analysis in a separate memorandum. *See* Memorandum from Scott Lindsay, Case Analyst, through Barbara E. Tillman, Director of Office of AD/CVD Enforcement VII, to Gary Taverman, Acting Deputy Assistant Secretary for Import Administration, Group I, "*Natural Bristle Paintbrushes and Brush Heads from the People's Republic of China (PRC): Intent to Rescind the New Shipper Review for Shanghai R&R Import/Export Co., Ltd.* (2/1/03 - 7/31/03)," dated July 23, 2004. A public version of this report is on file in the Central Records Unit located in room B–099 of the Main Commerce Building.

Notification

At the completion of this new shipper review, either with a final rescission or a notice of final results, the Department will notify U.S. of Customs and Border Protection that bonding is no longer permitted to fulfill security requirements of shipments with the exporter/producer combination of Shanghai R&R/Zhejiang Linan Maxiao Brush Factory of natural bristle paintbrushes and brush heads from the PRC entered, or withdrawn from warehouse, for consumption in the United States on or after the publication of the final rescission or results notice in the **Federal Register**. After the publication of the final rescission notice, a cash deposit of 351.92 percent *ad valorem* shall be collected for any entries exported by Shanghai R&R. Should the Department reach a final result other than a rescission, an appropriate antidumping duty rate will be calculated for both assessment and cash deposit purposes.

Schedule for Final Results of Review

Pursuant to section 351.309 of the Department's regulations, interested parties may submit written comments in response to this preliminary determination to rescind the review. Normally, case briefs are to be submitted within 30 days after the date of publication of this notice, and rebuttal briefs, limited to arguments raised in case briefs, are to be submitted no later than five days after the time limit for filing case briefs. Parties who submit arguments in this proceeding are requested to submit with the argument: (1) a statement of the issues, and (2) a brief summary of the argument. Case and rebuttal briefs must be served on interested parties in accordance with section 351.303(f) of the Department's regulations.

Also, pursuant to section 351.310 of the Department's regulations, within 30 days of the date of publication of this notice, interested parties may request a public hearing on arguments to be raised in the case and rebuttal briefs. Unless the Secretary specifies otherwise, the hearing, if requested, will be held two days after the date for submission of rebuttal briefs. Parties will be notified of the time and location. The Department will issue the final results of this new shipper review, which will include the results of its analysis of issues raised in the briefs, within 90 days from the date of the preliminary results, unless the time limit is extended.

We are issuing and publishing this determination is accordance with sections 751(a)(2)(B) and 777(i) of the Act.

Dated: July 26, 2004.

Jeffrey A. May,

Acting Assistant Secretary for Import Administration.

[FR Doc. 04–17563 Filed 8–2–04; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

(A–570–504)

Petroleum Wax Candles From the People's Republic of China: Preliminary Intent To Rescind the Antidumping New Shipper Review of Shanghai R&R Import/Export Co. Ltd.

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On September 30, 2003 the Department of Commerce (the Department) initiated three new shipper reviews of the antidumping duty order on petroleum wax candles from the People's Republic of China (PRC) covering the period August 1, 2002, through July 31, 2003. *See Petroleum Wax Candles from the People's Republic of China: Initiation of Antidumping Duty New Shipper Reviews*, 68 FR 57876 (October 7, 2004) (*Initiation Notice*). These new shipper reviews covered three exporters: Shanghai R&R Imp./Exp. Co., Ltd. (Shanghai R&R); Changshan Import/Export Co., Ltd. (Changshan); and Shandong Huihe., Ltd (Shandong). For the reasons discussed below, we preliminarily intend to rescind the new shipper review of Shanghai R&R. The Department is addressing the preliminary determination for Changshan and Shandong in separate notices.

EFFECTIVE DATE: August 3, 2004.

FOR FURTHER INFORMATION CONTACT: Scott Lindsay or Dana Mermelstein at (202) 482–0780 and (202) 482–1391, respectively; Office of AD/CVD Enforcement 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On August 28, 1986, the Department issued an antidumping duty order on petroleum wax candles from the PRC. *See Antidumping Duty Order: Petroleum Wax Candles From the People's Republic of China*, 51 FR 30686 (February 14, 1986) On August 14, 2003, the Department received a timely request for a new shipper review of the antidumping duty order on petroleum wax candles from the PRC from Shanghai R&R, an exporter of subject merchandise to the United States. Pursuant to section 351.214(b)(2)(iv) of the Department's regulations, this request included documentation establishing the volume of Shanghai R&R's first shipment to the United States and the date of the first sale to an unaffiliated customer in the United States. On September 30, 2003, the Department initiated this new shipper review covering the period August 1, 2002, through July 31, 2003. *See Initiation Notice*. On January 7, 2004, we received Shanghai R&R's response to the Department's initial questionnaire. On April 26, 2004, the Department received Shanghai R&R's response to the Department's supplemental questionnaire. On June 14, 2004, we received Shanghai R&R's response to the Department's second supplemental questionnaire.

On March 17, 2004, the Department extended the time limit for the completion of the preliminary results to July 26, 2004, in accordance with section 751(a)(2)(B)(iv) of the Tariff Act of 1930, as amended (the Act), and section 351.214(i)(2) of the Department's regulations. *See Petroleum Wax Candles from the People's Republic of China: Notice of Extension of Time Limit for Preliminary Results of Antidumping Duty New Shipper Reviews*, 69 FR 12641 (March 17, 2004).

On July 21, 2004, the National Candle Association, petitioner, submitted comments regarding the sales under review. We received these comments too late for them to be considered for these preliminary results. These comments will be fully considered and addressed for the final results of this new shipper review.

Verification

As provided in section 782(i) of the Act, we conducted verification of the questionnaire responses of Shanghai R&R. We used standard verification procedures, including on–site inspection of the production and sales facilities, and an examination of relevant sales and financial records. Our verification results are outlined in the *New Shipper Review of Petroleum Wax Candles from the People's Republic of China: Sales Verification Report for Shanghai R&R Import/Export Co., Ltd.*, dated July 15, 2004. A public version of this report is on file in the Central Records Unit located in room B–099 of the Main Commerce Building.

Intent to Rescind Review

With every new shipper review request, the Department has an obligation to analyze the documentation and certifications to establish that they meet the conditions of section 351.214(b)(2)(iv) of the Department's regulations. At the time Shanghai R&R requested this new shipper review, we determined that the regulatory requirements were met and we initiated the new shipper review. At verification, the Department found documentation which brings into question that this sale was in fact made to the importer identified in Shanghai R&R's initial request for review and in all subsequent questionnaire responses. Shanghai R&R's explanation that mistakes were made in identifying the importer in certain sales and accounting records does not persuade us to find that the importer documented in the initial request was correctly identified. As such, we find that our initiation of this new shipper review was based on documents that failed to establish the date of the first sale to an unaffiliated customer in the United States. Therefore, pursuant to section 351.214(b)(2)(iv)(C) of the Department's regulations, the requirements for initiation have not been satisfied.

Accordingly, we preliminarily intend to rescind this new shipper review. Because much of the information pertinent to our preliminary decision to rescind this review is business proprietary, we have set forth our complete analysis in a separate memorandum. *See* Memorandum from Scott Lindsay, Case Analyst, through Barbara E. Tillman, Director of Office of AD/CVD Enforcement VII, to Gary Taverman, Acting Deputy Assistant Secretary for Import Administration, Group I, "*Petroleum Wax Candles from the People's Republic of China (PRC): Preliminary Intent to Rescind the New Shipper Review for Shanghai R&R Import/Export Co., Ltd.* (8/1/02 - 7/31/03)," dated July 23, 2004.

Notification

At the completion of this new shipper review, either with a final rescission or a notice of final results, the Department will notify U.S. Customs and Border Protection that bonding is no longer permitted to fulfill security requirements of shipments with the exporter/producer combination of Shanghai R&R/Qingyuan County Artistic and Candle Factory of petroleum wax candles from the PRC entered, or withdrawn from warehouse, for consumption in the United States on or after the date of publication of the final rescission or results notice in the **Federal Register**. After the publication of the final rescission notice, a cash deposit of 108.30 percent *ad valorem* shall be collected for any entries exported by Shanghai R&R. Should the Department reach a final result other than a rescission, an appropriate antidumping duty rate will be calculated for both assessment and cash deposit purposes.

Schedule for Final Results of Review

Pursuant to section 351.309 of the Department's regulations, interested parties may submit written comments in response to these preliminary results. Normally, case briefs are to be submitted within 30 days after the date of publication of this notice, and rebuttal briefs, limited to arguments raised in case briefs, are to be submitted no later than five days after the time limit for filing case briefs. Parties who submit arguments in this proceeding are requested to submit with the argument: (1) a statement of the issues, and (2) a brief summary of the argument. Case and rebuttal briefs must be served on interested parties in accordance with section 351.303(f) of the Department's regulations.

Also, pursuant to section 351.310 of the Department's regulations, within 30 days of the date of publication of this notice, interested parties may request a public hearing on arguments to be raised in the case and rebuttal briefs. Unless the Secretary specifies otherwise, the hearing, if requested, will be held two days after the date for submission of rebuttal briefs. Parties will be notified of the time and location. The Department will issue the final results of this new shipper review, which will include the results of its analysis of issues raised in the briefs, within 90 days from the date of the preliminary results, unless the time limit is extended.

We are issuing and publishing this determination is accordance with sections 751(a)(2)(B) and 777(i) of the Act.

Dated: July 26, 2004.

Jeffrey A. May,

Acting Assistant Secretary for Import Administration.

[FR Doc. 04–17560 Filed 8–2–04; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

(A–570–504)

Petroleum Wax Candles from the People's Republic of China: Rescission of Antidumping Duty New Shipper Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On September 30, 2003 the Department of Commerce (the Department) initiated three new shipper reviews of the antidumping duty order on petroleum wax candles from the People's Republic of China (PRC) covering the period August 1, 2002, through July 31, 2003. *See Petroleum Wax Candles from the People's Republic of China: Initiation of Antidumping Duty New Shipper Reviews*, 68 FR 57876 (October 7, 2003) (*Initiation Notice*). These new shipper reviews covered three exporters: Shanghai R&R Imp./Exp. Co., Ltd.; Changshan Import/Export Co., Ltd. (Changshan Ltd.); and Shangdong Huihe., Ltd. For the reasons discussed below, we are rescinding the new shipper review of Changshan Ltd.

EFFECTIVE DATE: August 3, 2004.

FOR FURTHER INFORMATION CONTACT: Dara Iserson or Thomas Gilgunn at (202) 482–4052 and (202) 482–4236, respectively; AD/CVD Enforcement, Office 7, Group III, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On August 14, 2003, the Department received a timely request for a new shipper review of the antidumping duty order on petroleum wax candles from the PRC from Changshan Ltd., an exporter of subject merchandise to the United States. This request included a commercial invoice as documentation establishing the volume of Changshan Ltd.'s first shipment to the United States and the date of the first sale to an unaffiliated customer in the United States pursuant to section 351.214(b)(2)(iv) of the Department's regulations. On September 30, 2003, the Department initiated this new shipper review covering the period August 1, 2002, through July 31, 2003. *See Initiation Notice.*

In its December 18, 2003, questionnaire response, Changshan Ltd. provided another version of its commercial invoice which had a different merchandise description and a different date of sale. We also obtained entry documentation from U.S. Customs & Border Protection (CBP) which was placed on the record. After examining all of these documents, the Department sent a letter to Changshan Ltd. on March 18, 2004, requesting that it explain why the copy of the commercial invoice which documented its single new shipper sale in Exhibit 9 of its December 18, 2003, response contained material differences when compared to the commercial invoice Changshan Ltd. included in its August 14, 2003, new shipper review request. (*See* our letter dated March 18, 2004, for a complete discussion of those differences.) Changshan Ltd. submitted its response on April 15, 2004. On May 10, 2004, we asked Changshan Ltd. to explain and provide supporting documentation as to why it submitted documents with the same invoice number, but different dates and different merchandise descriptions. In its May 17, 2004, response, Changshan Ltd. stated that the fact that it had prepared multiple versions of the same commercial invoice for its single new shipper sale was the result of clerical errors and a general lack of experience in preparing commercial documents.

After analyzing these responses and all of the information on the record, the Department issued a memorandum informing the parties that it intended to rescind this new shipper review. (*See Petroleum Wax Candles from the People's Republic of China (PRC); Intent to Rescind the New Shipper Review for Changshan Import/Export Co., Ltd. (8/1/02 - 7/31/03)*, dated June 7, 2004 (*Intent to Rescind Memo.*) In our *Intent to Rescind Memo*, the Department informed the interested parties that we intended to rescind this new shipper review because the initiation of this review was based on documents which failed to establish: 1) the date on which the subject merchandise was first entered, or withdrawn from warehouse, for consumption, or the date on which Changshan Ltd. first shipped the subject merchandise for export to the United States; and 2) the date of the first sale to an unaffiliated customer in the United States. (*See* sections 351.214(b)(2)(iv)(A) and (C) of the Department's regulations.) We provided interested parties an opportunity to comment on the *Intent to Rescind Memo.*

In its June 14, 2004, comments on our *Intent to Rescind Memo*, Changshan Ltd. disagreed with the Department's analysis of its sales documents. Changshan Ltd. made two arguments with respect to the Department's intent to rescind its new shipper review. First, Changshan Ltd. argued that it issued only one invoice for the sale at issue and that any subsequent "revisions" made to that invoice were immaterial. Second, Changshan Ltd. argued that, pursuant to section 351.214(f) of its regulations, the Department can only rescind a new shipper review where the respondent withdraws its request for review where there was no entry or sale within the period of review (POR) and the expansion of the POR would prevent the timely completion of the review. In its June 14, 2004, comments on our *Intent to Rescind Memo*, the National Candles Association, petitioners, provided a statement in support of the Department's decision to rescind this new shipper review. On June 15, 2004, Changshan Ltd. withdrew its request for a new shipper review.

Scope of the Order

The products covered by this order are certain scented or unscented petroleum wax candles made from petroleum wax and having fiber or paper–cored wicks. They are sold in the following shapes: tapers, spirals, and straight–sided dinner candles; rounds, columns, pillars, votives; and various wax–filled containers. The products were classified under the Tariff Schedules of the United States (TSUS) item 755.25, Candles and Tapers. The products are currently classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) item 3406.00.00. Although the HTSUS subheading is provided for convenience and customs purposes, our written description of the scope of this proceeding remains dispositive.

Rescission of Review

With every new shipper review request, the Department has an obligation to analyze the documentation and certifications to establish that they meet the conditions of section 351.214(b)(2)(iv) of the Department's regulations. At the time Changshan Ltd. requested this new shipper review, we determined that the regulatory requirements were met and we initiated the new shipper review. *See Initiation Notice.* Since the initiation, in response to our questions regarding the sale at issue, Changshan Ltd. has submitted documentation which demonstrates that the invoice provided with the request for this new shipper review was neither correct nor accurate. Furthermore, three other versions of this invoice are now on the record of this review. We are not persuaded by Changshan Ltd.'s arguments that only one invoice was issued and the subsequent revisions to this invoice were immaterial. In fact, the discrepancies in the dates on the various versions of the invoice are material to the Department's analysis of whether Changshan Ltd.'s request for a new shipper review fulfills the regulatory requirements necessary for the Department to initiate a new shipper review. *See* sections 351.214(b)(2)(iv)(A) and (C). Changshan Ltd.'s explanations of why the invoices differ and how errors were made do not demonstrate that the invoice which they describe as the "one" invoice is indeed the correct invoice. Moreover, even assuming we found its explanations reasonable, Changshan Ltd. has stated that the invoice which was the basis for the Department's initiation of this new shipper review is not the original or final version of the document, despite Changshan Ltd.'s having provided the required company certifications that the information provided with its request for review were both complete and accurate. See section 351.303(g)(1) of the Department's regulations. As such, we continue to find that our initiation of this new shipper review was based on documents that failed to establish: 1) the date on which the subject merchandise was first entered, or withdrawn from warehouse, for consumption, or the date

on which Changshan Ltd. first shipped the subject merchandise for export to the United States; and 2) the date of the first sale to an unaffiliated customer in the United States. Therefore, pursuant to sections 351.214(b)(2)(iv)(A) and (C) of the Department's regulations, the requirements for initiation have not been satisfied.

We have also considered Changshan Ltd.'s argument that a new shipper review can only be rescinded when the respondent withdraws its request for review or where there was no entry or sale within the POR and the expansion of the POR would prevent the timely completion of the review. However, the Department has the authority to rescind a new shipper review when, as in the instant case, the Department finds that the documentation submitted in support of the request for new shipper review is defective; thus, the regulatory requirements for initiating a new shipper review have not been satisfied. *See, e.g., Honey from the People's Republic of China: Notice of Preliminary Results and Partial Rescission of Antidumping Duty New Shipper Review*, 69 FR 31348 (June 3, 2004) (the Department rescinded the new shipper review because the company failed to provide documentation and certifications establishing the first sale to an unaffiliated customer in the United States); *See, also, Certain Preserved Mushrooms from the People's Republic of China: Preliminary Results of Sixth New Shipper and Preliminary Results and Partial Rescission of Fourth Antidumping Duty Admission Review*; 69 FR 10410 (March 15, 2004) (the Department rescinded the new shipper review with respect to XITIC because it failed to provide proper certifications in accordance with section 351.214(b)(ii)(B) of the Department's regulations based on data contained in its questionnaire response); *Honey from the People's Republic of China: Partial Rescission of Antidumping Duty New Shipper Review*, 68 FR 4760 (January 30, 2003) (the Department rescinded the new shipper review of Sichuan Dubao because the company failed to identify the correct name of the exporter and producer of the subject merchandise). Accordingly, we are rescinding this new shipper review of candles.

Cash Deposit Requirements

The Department will notify CBP that bonding is no longer permitted to fulfill security requirements for shipments from Changshan Ltd. of petroleum wax candles from the PRC that are entered, or withdrawn from warehouse, for consumption in the United States on or after the date of publication of this rescission notice in the **Federal Register**, and that a cash deposit of 108.30 percent *ad valorem* should be collected for any entries of petroleum wax candles exported by Changshan Ltd.

Assessment of Antidumping Duties

The Department will instruct CBP to assess antidumping duties on all appropriate entries. Since we are rescinding this antidumping duty new shipper review with respect to Changshan Ltd., the PRC–wide rate of 108.30 percent in effect at the time of entry applies to all exports of candles from the PRC by Changshan Ltd. entered, or withdrawn from warehouse, for consumption during the POR (August 1, 2002 through July 31, 2003). The Department will issue appropriate assessment instructions directly to CBP within 15 days of publication of this notice of rescission of antidumping duty new shipper review.

Notification to Importers

This notice also serves as a reminder to importers of their responsibility under section 351.402(f)(2) of the Department's regulations 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 notice also serves as a reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with section 351.305(a)(3) of the Department's regulations. Timely written otification of the return/destruction of APO material 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 sanctions.

We are issuing and publishing this determination and notice in accordance with sections 751(a)(2)(B) and 777(i) of the Act.

Dated: July 26, 2004.

Jeffrey A. May,

Acting Assistant Secretary for Import Administration.

[FR Doc. 04–17561 Filed 8–2–04; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

A–570–504

Petroleum Wax Candles from the People's Republic of China: Notice of Preliminary Results of Antidumping Duty New Shipper Review of Shandong Huihe, Ltd.

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On September 30, 2003 the Department of Commerce (the Department) initiated three new shipper reviews of the antidumping duty order on petroleum wax candles from the People's Republic of China (PRC) covering the period August 1, 2002, through July 31, 2003. *See Petroleum Wax Candles from the People's Republic of China: Initiation of Antidumping Duty New Shipper Reviews*, 68 FR 57876 (October 7, 2004) (*Initiation Notice*). These new shipper reviews covered three exporters: Shanghai R&R Imp./Exp. Co., Ltd. (Shanghai R&R); Changshan Import/Export Co., Ltd. (Changshan); and Shandong Huihe., Ltd (Shandong). The Department is addressing the preliminary results for Shanghai R&R and Changshan in separate notices. The review of Shandong covers the period August 1, 2002 through August 15, 2003.

We preliminarily determine that sales have not been made below normal value (NV). The preliminary results are listed below in the section titled "Preliminary Results of Review." If these preliminary results are adopted in our final results, we will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties based on the difference between the export price (EP) and NV. Interested parties are invited to comment on these preliminary results. (*See* the "Preliminary Results of Review" section of this notice.)

EFFECTIVE DATE: August 3, 2004.

FOR FURTHER INFORMATION CONTACT: Dara Iserson or Douglas Kirby. Office of AD/CVD Enforcement VII, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, D.C. 20230; telephone: (202) 482–4052 or (202) 482–3782, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department published in the **Federal Register** an antidumping duty order on petroleum wax candles from the PRC on August 28, 1986. *See Notice*

of Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Petroleum Wax Candles from the People's Republic of China, (51 FR 30686). On August 12, 2003, the Department received from Shandong Huihe a timely request for a new shipper review this in accordance with section 751(a)(2)(B) of the Tariff Act of 1930, as amended (theAct) and section 351.214(c) of the Department's regulations. In its request, Shandong Huihe identified itself as the company that produced the petroleum wax candles exported for its new shipper sale. On September 30, 2003, the Department initiated this new shipper review for the period August 1, 2002 through July 31, 2003. *See Petroleum Wax Candles From the People's Republic of China: Initiation of Antidumping Duty New Shipper Review*, 68 FR 57876 (October 7, 2003).

On October 22, 2003 we issued a questionnaire to Shandong Huihe.[1] On December 16, 2003, we received the company's sections A, C, and D questionnaire response. On April 27, 2004, we issued a supplemental questionnaire to Shandong Huihe. We received the response to this questionnaire on May 11, 2004.

On January 26, 2004, we requested information from the U.S. importer of Shandong Huihe's new shipper sales. We received the importer's response to the questionnaire on May 12, 2004.On June 26, 2004, Shandong Huihe requested that the Department extend the period of review in order to capture the entry of its new shipper sales.

On March 11, 2004, the Department extended the preliminary results of this new shipper review by 120 days until July 26, 2004. *See Petroleum Wax candles from the People's Republic of China: Extension of Time Limit of Preliminary Results of New Shipper Review*, 69 FR 12641 (March 17, 2004).

On July 20, 2004, the National Candle Association, petitioner, submitted comments regarding the sales under review. We received these comments too late for them to be considered for these preliminary results. These comments will be fully considered and addressed for the final results of this new shipper review. In addition, on July 26, 2004, the Department issued a supplemental questionnaire to Shandong Huihe. The response to this questionnaire will be fully analyzed for the final results of this new shipper review.

[1] Section of A of the questionnaire requests general information concerning a company's corporate structure and business practices, the merchandise under this investigation that it sells, and the manner in which it sells that merchandise in all of its markets. Section B requests a complete listing of all home market sales, or, if the home market is not viable, of sales in the most appropriate third-country market (this section is not applicable to respondents in non-market economy (NME) cases). Section C requests a complete listing of U.S. sales. Section D requests information on the factors of production of the merchandise under investigation. Section E requests information on further manufacturing.

Period of Review

Pursuant to section 351.214(g)(1)(i)(A), the standard period of review (POR) in a new shipper proceeding initiated in the month immediately following the anniversary month is the one–year period immediately preceding the anniversary month. Shandong Huihe requested that the Department extend the normal one–year period. The Department's regulations provide it with the discretion to expand the normal POR to include an entry and sale to an unaffiliated customer in the United States of subject merchandise if the expansion of the period would likely not prevent the completion of the review within the time limits set forth in Section 351.214(i)(1). *See Antidumping Duties; Countervailing Duties; Notice of Proposed Rulemaking and Request for Public Comment, 61 FR 7308, 7318 (February 27, 1996); Antidumping Duties; Countervailing Duties; Final Rule*, 62 FR 27296, 27319–20 (May 19, 1997). *See also* 19 CFR 351.214(f)(2)(ii).

Because we determine that this short expansion of the period will not likely prevent the completion of the review within the prescribed time limits, we have expanded the annual review period. Therefore, the POR for Shandong Huihe's new shipper review has been defined as August 1, 2002 through August 15, 2003.

Scope of the Order

The products covered by this order are certain scented or unscented petroleum wax candles made from petroleum wax and having fiber or paper–cored wicks. They are sold in the following shapes: tapers, spirals, and straight–sided dinner candles; rounds, columns, pillars, votives; and various wax–filled containers. The products were classified under the Tariff Schedules of the United States (TSUS) item 755.25, Candles and Tapers. The products are currently classified under the Harmonized Tariff Schedule of the United States (HTSUS) item 3406.00.00. Although the HTSUS subheading is provided for convenience and customs purposes, our written description of the scope of this proceeding remains dispositive.

Verification

As provided in section 782(i) of the Act, we will conduct verification of Shandong Huihe following the issuance of the preliminary results.

Separate Rates

Shandong Huihe has requested a separate, company–specific rate. In its questionnaire responses, the company states that it is an independent legal entity.

To establish whether a company operating in a non–market economy (NME) country is sufficiently independent to be eligible for a separate rate, the Department analyzes each exporting entity under the test established in *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). Under this policy, exporters in NMEs are entitled to separate, company–specific margins when they can demonstrate an absence of government control, both in law and in fact, with respect to export activities. Evidence supporting, though not requiring, a finding of *de jure* absence of government control over export activities includes: 1) an absence of restrictive stipulations associated with an individual exporter's business and export licenses; 2) any legislative enactments decentralizing control of companies; and 3) any other formal measures by the government decentralizing control of companies. *De facto* absence of government control over exports is based on four factors: 1) whether each exporter sets its own export prices independently of the government and without the approval of a government authority; 2) whether each exporter retains the proceeds from its sales and makes independent decisions regarding the disposition of profits or financing of losses; 3) whether each exporter has the authority to negotiate and sign contracts and other agreements; and 4) whether each exporter has autonomy from the government regarding the selection of management.

De Jure Control

With respect to the absence of *de jure* government control over the export activities of the company reviewed, evidence on the record indicates that Shandong Huihe's export activities are not controlled by the government. Shandong Huihe submitted evidence of its legal right to set prices

independently of all government oversight. The business license of the company indicates that it is permitted to engage in the exportation of candles. We find no evidence of *de jure* government control restricting this company's exportation of candles.

The following laws, which have been placed on the record of this review, indicate a lack of *de jure* government control over privately–owned companies, such as Shandong Huihe, and that control over these enterprises rests with the enterprises themselves. The *Administrative Regulations of the People's Republic of China Governing the Registration of Enterprises as Legal Persons*, issued on June 3, 1988, by the State Council of the PRC, the Company Law of the People's Republic of China, issued on December 29, 1993, by the National People's Congress, the *Regulations of the People's Republic of China for Controlling the Registration of Enterprises as Legal Persons*, promulgated by the State Administration for Industry and Commerce on June 13, 1988, and the *General Principles of the Civil Law of the People's Republic of China*, effective on January 1, 1987, all placed on the record of this review, provide that, to qualify as legal persons, companies must have the "ability to bear civil liability independently" and the right to control and manage their businesses. These regulations also state that, as an independent legal entity, a company is responsible for its own profits and losses. *See Notice of Final Determination of Sales at Less Than Fair Value: Manganese Metal from the People's Republic of China*, 60 FR 56045 (November 6, 1995) (*Manganese Metal*). Unless verification shows otherwise, we preliminarily determine that there is an absence of *de jure* control over export activity with respect to this firm.

De Facto Control

With respect to the absence of *de facto* control over export activities, the information provided in the questionnaire responses, which will be reviewed at verification, indicates that the management of Shandong Huihe is responsible for the determination of export prices, profit distribution, marketing strategy, and contract negotiations. Our analysis indicates that there is no government involvement in the daily operations or the selection of management for this company. In addition, we have found that the respondent's pricing and export strategy decisions are not subject to any outside entity's review or approval, and that there are no governmental policy directives that affect these decisions.

There are no restrictions on the use of export earnings. The company's general manager has the right to negotiate and enter into contracts, and may delegate this authority to employees within the company. There is no evidence that this authority is subject to any level of governmental approval. Shandong Huihe has stated that its management is selected by its board of directors and/or its employees and that there is no government involvement in the selection process. Lastly, decisions made by respondent concerning purchases of subject merchandise from other suppliers are not subject to government approval. Consequently, because evidence on the record indicates an absence of government control, both in law and in fact, over its export activities, we preliminarily determine that Shandong Huihe is eligible for a separate rate for purposes of this new shipper review.

Normal Value Comparisons

To determine whether respondent's sales of the subject merchandise to the United States were made at prices below NV, we compare the United States prices to NV, as described in the "United States Price" and "Normal Value" sections of this notice.

United States Price

For Shandong Huihe, we based United States price on EP, in accordance with section 772(a) of the Act, because the first sale to an unaffiliated purchaser was made prior to importation, and constructed export price (CEP) was not otherwise warranted by the facts on the record. We calculated EP based on the packed price from the exporter to the first unaffiliated purchaser in the United States. We deducted foreign inland freight and foreign brokerage and handling from the starting price (gross unit price) in accordance with section 772(c) of the Act.

Normal Value

Section 773(c)(1) of the Act provides that the Department shall determine NV using a factors–of-production methodology if (1) the merchandise is exported from an NME country, and (2) available information does not permit the calculation of NV using home–market prices, third–country prices, or constructed value under section 773(a) of the Act.

In every case conducted by the Department involving the PRC, the PRC has been treated as an NME country. Pursuant to section 771(18)(C)(i) of the Act, any determination that a foreign country is an NME country shall remain in effect until revoked by the administering authority. Shandong Huihe did not contest such treatment in this review. Accordingly, we have applied surrogate values to the factors of production to determine NV. *See Factor Values Memo for the Preliminary Results of the Antidumping Duty New Shipper Review of Petroleum Wax Candles from the People's Republic of China*, July 26, 2004 (*Factor Values Memo*).

We calculated NV based on factors of production in accordance with section 773(c)(4) of the Act and section 351.408(c) of our regulations. Consistent with numerous other cases involving the PRC, we determined that India (1) is comparable to the PRC in level of economic development, and (2) is a significant producer of comparable merchandise. *See* the Memorandum from the Office of Policy regarding surrogate country selection for this review. We valued the factors of production using publicly available information from India. We adjusted the Indian input prices by adding freight expenses to reflect delivered prices.

We valued the factors of production as follows:

To value petroleum wax, we used the average Indian price for paraffin wax derived from rates published in *Chemical Weekly* for the period August 2001 through July 2002. This price was adjusted on a tax–exclusive basis to account for the Indian excise tax of 16 percent and has been inflated through the POR using the wholesale price index (WPI) published by the Reserve Bank of India (RBI) for the chemicals and chemical products industry sector. *See* Reserve Bank of India Bulletin, Table 39 Index Numbers of Wholesale Prices in India by Groups and Sub–Groups (Averages), http://www.rbi.org.in.

To value wicks, we used the average Indian import price for HTS number 5908 from the World Trade Atlas. *See* http://www.gtis.com/. For this unit value, we adjusted the total import value by excluding the value of imports from NME countries, and countries providing their exporters with non–specific export subsidies (South Korea, Thailand, and Indonesia). *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value: Certain Automotive Replacement Glass Windshields From the People's Republic of China*, 67 FR 6482 (February 12, 2002). Also consistent with our policy, we excluded, in a few instances, import data that appeared to be aberrational. *See, e.g., Memorandum to Jeff May, Acting Assistant Secretary for Import Administration, from Barbara Tillman, Acting Deputy Assistant Secretary for Import Administration, Group III,*

Regarding Issues and Decision Memorandum for the Final Determination of the Antidumping Duty Investigation of Saccharin from the People's Republic of China, dated May 20, 2003, at Comment 2, page 5, for a discussion of this issue. We then divided this import value by the total import quantity, which we similarly adjusted to exclude the quantity from NME countries and countries providing non–specific export subsidies, and import data that appeared aberrational. Since this data is contemporaneous with the POR, we did not adjust for inflation.

To value polyethylene wax, we used the average Indian import price for HTS number 34042000 from the World Trade Atlas. *See* http://www.gtis.com/. For this unit value, we divided the total import value (which we adjusted to exclude the value of imports from NME countries, countries with non–specific export subsidies, and import data that appeared aberrational), by the total import quantity (similarly adjusted). Since this data is contemporaneous with the POR, we did not adjust for inflation.

To value coal we used the average Indian import price for HTS number 27011902 from the Wold Trade Atlas. *See* http://www.gtis.com. For this unit value, we divided the total import value (which we adjusted to exclude the value of imports from NME countries, countries with non–specific export subsidies, and import data that appeared aberrational), less the value of imports from NME countries, by the total import quantity (similarly adjusted). Since this data is contemporaneous with the POR, we did not adjust for inflation.

To value electricity, we used the value for electricity published in the first quarter 2001 edition of the International Energy Agency's Energy Prices and Taxes. Because this data is reported for 1997, we used the Reserve Bank of India (RBI) Wholesale Price Index (WPI) inflator for the fuel, power, light and lubricants sector to adjust the reported price for electricity to reflect inflation through the POR. *See* Reserve Bank of India Bulletin, Table 39 Index Numbers of Wholesale Prices in India by Groups and Sub–Groups (Averages), http://www.rbi.org.in.

To value packing materials (inner box, outerbox, and tape), we used average Indian import prices for HTS numbers 48192000, 48191000, and 39191000 respectively from the World Trade Atlas. *See* http://www.gtis.com/. For each of these unit values, we divided the total import value (which we adjusted to exclude the value of imports from NME countries, countries with non–specific export subsidies, and import data that appeared aberrational), by the total import quantity (similarly adjusted). Since this data is contemporaneous with the POR, we did not adjust for inflation.

To value factory overhead, selling, general, and administrative expenses (SG&A), and profit, in accordance with our decision in the most recent administrative review of petroleum wax candles from the PRC, we used information reported in the January 1997 Reserve Bank of India Bulletin, "Statement 1 - Combined Income, Value of Production, Expenditure and Appropriation Accounts, Industry Group–wise" of that report for the Indian metals and chemicals (and products thereof) industries. *See Notice of Final Results and Rescission, in Part, of the Antidumping Duty Administrative Review of Petroleum Wax Candles from the People's Republic of China*, 69 FR 12121 (March 15, 2004) (Candles Final).

For labor, we used the PRC regression–based wage rate at Import Administration's home page, Import Library, Expected Wages of Selected NME Countries, revised in September 2001. *See* http://ia.ita.doc.gov/wages/. Because of the variability of wage rates in countries with similar per capita gross domestic products, section 351.408(c)(3) of the Department's regulations requires the use of a regression–based wage rate. The source of these wage rate data on the Import Administration's web site is the *Yearbook of Labour Statistics 2000*, International Labour Office (Geneva: 2000), Chapter 5B: Wages in Manufacturing.

To value foreign inland freight, in accordance with our decision in the most recent administrative review of petroleum wax candles from the PRC, we used an average of shipping rates for the Mumbai to Pune route from *Chemical Weekly* for the period from February 2002 to June 2002. *See Candles Final*. Because the data were not contemporaneous with the period of review (POR) we inflated the price using the WPI for India taken from the International Monetary Fund's 2003 *International Financial Statistics*.

Currency Conversion

We made currency conversions pursuant to section 351.415 of the Department's regulations at the rates certified by the Federal Reserve Bank. *See* http://ia.ita.doc.gov/exchange/index.html.

Preliminary Results of Review

We preliminarily determine that the following dumping margin exists:

Manufacturer/Exporter	Time Period	Margin (ad valorem)
Shandong Huihe, Ltd.	8/1/02–8/15/03	0.00 percent

Cash Deposit Requirements

At the completion of this new shipper review, the Department will notify the CBP that bonding will no longer be permitted to fulfill the security requirements for shipments of petroleum wax candles produced and exported by Shandong Huihe. If these preliminary results are not modified in the final results of this review, a cash deposit rate of zero will be effective upon the publication of the final results of this new shipper review for all shipments of petroleum wax candles from the PRC produced and exported by Shandong Huihe and entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act. For petroleum wax candles exported, but not produced by Shandong Huihe, we will apply as the cash deposit rate the PRC–wide rate, which is currently 108.30 percent *ad valorem*.

Assessment Rates

If these preliminary results are not changed by the final results, the Department will direct CBP to liquidate, without regard to antidumping duties, Shandong Huihe's entries covered by this review.

Schedule for Final Results of Review

Pursuant to19 CFR 351.224(b), the Department will disclose calculations performed in connection with the preliminary results of this review within five days of the date of publication of this notice. Any interested party may request a hearing within 30 days of publication of this notice in accordance with section 351.310(c) of the Department's regulations. Any hearing would normally be held 37 days after the publication of this notice, or the first

workday thereafter, at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC 20230. Individuals who wish to request a hearing must submit a written request within 30 days of the publication of this notice in the **Federal Register** to the Assistant Secretary for Import Administration, U.S. Department of Commerce, Room 1870, 14th Street and Constitution Avenue, NW, Washington, DC 20230. Requests for a public hearing should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and, (3) to the extent practicable, an identification of the arguments to be raised at the hearing.

Unless otherwise notified by the Department, interested parties may submit case briefs within 30 days of the date of publication of this notice in accordance with 351.309(c)(ii) of the Department's regulations. As part of the case brief, parties are encouraged to provide a summary of the arguments not to exceed five pages and a table of statutes, regulations, and cases cited. Rebuttal briefs, which must be limited to issues raised in the case briefs, must be filed within five days after the case brief is filed. If a hearing is held, an interested party may make an affirmative presentation only on arguments included in that party's case brief and may make a rebuttal presentation only on arguments included in that party's rebuttal brief. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled time.

Unless the time limit is extended, the Department will issue the final results of this new shipper review no later than 90 days after the signature date of the preliminary results. The final results will include the analysis of issues raised in the briefs.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 351.402(f) of the Department's regulations to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during these review periods. 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 new shipper review and this notice are published in accordance with sections 751(a)(2)(B) and 777 (i)(1) of the Act.

Dated: July 26, 2004.

Jeffrey A. May,

Acting Assistant Secretary for Import Administration.

[FR Doc. 04–17562 Filed 8–2–04; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–813]

Stainless Steel Butt-Weld Pipe Fittings From Korea: Extension of Time Limit for the Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Extension of Time Limit for the Preliminary Results of Antidumping Duty Administrative Review.

SUMMARY: The Department of Commerce (the Department) is extending the due date for the preliminary results of review of the antidumping duty order on stainless steel butt-weld pipe fittings from Korea from October 31, 2004 to February 28, 2005.

EFFECTIVE DATE: August 3, 2004.

FOR FURTHER INFORMATION CONTACT: Fred Baker or Robert James, AD/CVD Enforcement Office 8, Group III, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–2924 or (202) 482–0649, respectively.

SUPPLEMENTARY INFORMATION:

Background

On February 23, 1993, the Department published the antidumping duty order on stainless steel butt-weld pipe fittings from Korea. *See Antidumping Duty Order: Certain Welded Stainless Steel Butt-Weld Pipe Fittings from Korea,* 58 FR 11029 (February 23, 1993). On February 27, 2004, Sungkwang Bend Co., Ltd., a producer of the subject merchandise, requested a review of its U.S. sales during the period February 1, 2003 through January 31, 2004. On March 26, 2004, the Department published a notice initiating the requested review. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part,* 69 FR 15788, (March 26, 2004).

Extension of Time Limit for Preliminary Results

The Tariff Act of 1930 (as amended) (the Tariff Act), at section 351(a)(3)(A), provides that the Department will issue the preliminary results of an administrative review of an antidumping duty order within 245 days after the last day of the anniversary month of the date of publication of the order. The Tariff Act provides further that if the Department determines that it is not practicable to complete the review within this time period, the Department may extend the 245-day period to 365 days.

The Department has determined that it is not practicable to complete the preliminary results by the current 245-day deadline of October 31, 2004. There are a number of discrepancies in the submitted data that require additional information and analysis. These discrepancies pertain, *inter alia,* to customer affiliations, computation methodologies, and unreported expenses. We require additional time to analyze the questionnaire response, issue a supplemental questionnaire(s), and conduct a verification. Therefore, in accordance with section 751(a)(3)(A) of the Tariff Act, and 19 CFR 351.213(h)(2), the Department is extending the time limit for the preliminary results by 120 days to February 28, 2005.

This notice of postponement is in accordance with section 751(a)(3)(A) of the Tariff Act.

Dated: February 27, 2004.

Jeffrey A. May,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 04–17640 Filed 8–2–04; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Export Trade Certificate of Review

ACTION: Notice of application.

SUMMARY: The Office of Export Trading Company Affairs ("OETCA"), International Trade Administration, Department of Commerce, has received an application for an Export Trade Certificate of Review. This notice summarizes the conduct for which certification is sought and requests comments relevant to whether the Certificate should be issued.

FOR FURTHER INFORMATION CONTACT: Jeffrey C. Anspacher, Director, Office of Export Trading Company Affairs, International Trade Administration, by

telephone at (202) 482–5131 (this is not a toll-free number) or E-mail at *oetca@ita.doc.gov*.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from state and federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. Section 302(b)(1) of the Export Trading Company Act of 1982 and 15 CFR 325.6(a) require the Secretary to publish a notice in the **Federal Register** identifying the applicant and summarizing its proposed export conduct.

Request for Public Comments

Interested parties may submit written comments relevant to the determination whether a Certificate should be issued. If the comments include any privileged or confidential business information, it must be clearly marked and a nonconfidential version of the comments (identified as such) should be included. Any comments not marked privileged or confidential business information will be deemed to be nonconfidential. An original and five (5) copies, plus two (2) copies of the nonconfidential version, should be submitted no later than 20 days after the date of this notice to: Office of Export Trading Company Affairs, International Trade Administration, U.S. Department of Commerce, Room 1104H, Washington, DC 20230. Information submitted by any person is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). However, nonconfidential versions of the comments will be made available to the applicant if necessary for determining whether or not to issue the Certificate. Comments should refer to this application as "Export Trade Certificate of Review, application number 04–00002." A summary of the application follows.

Summary of the Application

Applicant: Export Trade Association of the Americas ("ETAA"), 561 Ragan Road, Wapato, Washington 98951.

Contact: Chris E. Svendsen, Attorney, Telephone: (509) 453–1319.

Application No.: 04–00002.

Date Deemed Submitted: July 19, 2004.

Members (in addition to applicant): E.W. Brandt & Sons, Inc., Wapato, Washington; and ETAA Distributing, LLC, Wapato, Washington.

ETAA seeks a Certificate to engage in the Export Trade Activities and Methods of Operation described below in the following Export Trade and Export Markets:

Export Trade

1. *Products*

Fresh tree fruits, primarily apples.

2. *Technology Rights*

Technology Rights, including, but not limited to, patents, trademarks, copyrights and trade secrets owned and/or controlled by ETAA and Members that relate to Products.

3. *Export Trade Facilitation Services (as they relate to the export of Products, and Technology Rights)*

All export trade-related services, including, but not limited to, professional services and assistance relating to: government relations; state and federal export programs; foreign trade and business protocol; consulting; international market research and analysis; collection of information on trade opportunities; marketing; negotiations; joint ventures; brokering; handling; export management; export licensing; patent and trademark licensing; common marking and identification; advertising and sales promotion; communication and processing of foreign orders to and for Members; trade documentation and services related to compliance with customs requirements; insurance and financing; trade show exhibitions; organizational development; management and labor strategies; transfer of technology; transportation services, including shipping and warehousing; the formation of shippers' associations; legal assistance; foreign exchange and taking title to goods.

Export Markets

The Export Markets include all parts of the world except the United States (the fifty states of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands).

Export Trade Activities and Methods of Operation

With respect to the export sale of fresh tree fruits, the licensing of Technology Rights, and the provision of Export Trade Facilitation Services, ETAA and/or one or more Members may:

1. Participate in negotiations and enter into agreements with foreign buyers (including governments and private persons) regarding:

(a) The quantities, time periods, prices, and terms and conditions, in connection with actual or potential bona fide export opportunities;

(b) non-tariff trade barriers in the Export Markets; and

(c) the sale, license and/or use of Technology Rights relating to the Products.

2. Advise and cooperate with the United States and foreign governments in:

(a) Establishing procedures pertaining to the regulating of the export of the Member's Products, for example: quantity standards, marketing orders, and the imposition and lifting of tariffs; and

(b) fulfilling the phytosanitary, quality and/or funding requirements pertaining to the export of the Member's products, for example: tariffs, weighing fees and inspections imposed by foreign governments.

3. Allocate export sales among Members in connection with actual or potential bona fide export opportunities.

4. Agree on quantities of Products to be sold.

5. Allocate geographic areas or countries in Export Markets and/or customers in Export Markets among Members.

6. Conduct marketing, promotion and distribution of fresh tree fruits in Export Markets.

7. Conduct quality control studies and inspections of goods for export at point of shipment, point of arrival, and through the retail level in Export Markets.

8. Negotiate and enter into agreements, whether or not exclusive, with providers of Export Trade Facilitation Services for the export of Products.

9. Establish and operate fumigation facilities and administer phytosanitary protocols to qualify the Products for Export Markets.

10. Operate foreign offices and companies to facilitate the sale and distribution of fresh tree fruits in Export Markets.

11. Recover administrative expenses and costs through fees and assessments allocated to each Member on a pro rata share basis or any other non-discriminatory method. Any Member objecting to the method of allocating expenses and costs will be charged based on actual expenses incurred.

12. Products to be exported will be primarily supplied by the ETAA and Members, with instances of Products supplied from non-Member entities. For example: to fill export sales orders, contracts and spot sales, as required.

13. ETAA and Members may exchange and discuss information on the following:

(a) Information about sales and marketing efforts for the Export Markets, activities and opportunities for sales of fresh tree fruits in the Export Markets, selling strategies for the Export Markets, sales for the Export Markets, contract and spot pricing in the Export Markets, projected demands in Export Markets for fresh tree fruits, customary terms of sale in the Export Markets, prices and availability of fresh tree fruits from competitors for sale in the Export Markets, and specifications for fresh tree fruits by customers in the Export Markets;

(b) Information about the export price, quality, quantity, source, and delivery dates of fresh tree fruits available from the Members to export;

(c) Information about terms and conditions of contracts for sale in the Export Markets to be considered and/or bid on by ETAA and Members;

(d) Information about joint bidding or selling arrangements for the Export Markets and allocations of sales resulting from such arrangements among the Members;

(e) Information about expenses specific to exporting to and within the Export Markets, including without limitation, transportation, trans- or intermodal shipments, insurance, inland freights to port, port storage, commissions, export sales, documentation, financing, customs duties and taxes;

(f) Information about United States and foreign legislation and regulations, including federal marketing order programs that may affect sales for the Export Markets;

(g) Information about ETAA or Members' export operations, including without limitation, sales and distribution networks established by ETAA or Members in the Export Markets, and prior export sales by Members (including export price information);

(h) Exchange information with and among the Members as necessary to carry out the Export Trade Facilitation Services, Export Trade Activities and Methods of Operation; and

(i) Information about export customer credit terms and credit history.

Dated: July 28, 2004.

Vanessa M. Bachman,

Acting Director, Office of Export Trading Company Affairs.

[FR Doc. 04–17639 Filed 8–2–04; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 072704D]

Fisheries of the Caribbean, Gulf of Mexico and South Atlantic; Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic Region; Environmental Assessment for Amendment 15

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice announcing the preparation of an environmental assessment (EA).

SUMMARY: NMFS, in cooperation with the Gulf of Mexico and the South Atlantic Fishery Management Councils (Councils), is preparing an EA in accordance with the National Environmental Policy Act (NEPA) for Amendment 15 to the Fishery Management Plan for Coastal Migratory Pelagic Resources (Amendment 15). This notice is intended to inform the public of the change from the preparation of a draft supplemental environmental impact statement (DSEIS) to the preparation of an EA for Amendment 15.

FOR FURTHER INFORMATION CONTACT: Rick Leard; telephone: 813–228–2815 ext. 228; fax: 813–225–7015; e-mail: *Rick.Leard@gulfcouncil.org*; or Steve Branstetter; telephone: 727–570–5796; fax: 727–570–5583; e-mail: *steve.branstetter@noaa.gov*.

SUPPLEMENTARY INFORMATION: On February 13, 2004 (69 FR 7187) and April 9, 2004 (69 FR 18875), NMFS and the Councils published Notices of Intent in the **Federal Register** to prepare a DSEIS and to announce scoping meetings regarding the actions proposed in Amendment 15. Amendment 15 proposes two actions: (1) consideration of alternatives to address limited access in the king mackerel fishery of the Gulf of Mexico and South Atlantic region, and (2) a possible change in the fishing year for Atlantic migratory groups of king and Spanish mackerel.

The fishery for king mackerel operates under a moratorium on the issuance of new commercial vessel permits. The moratorium is scheduled to expire on October 15, 2005. Amendment 15 examines alternatives that would allow the moratorium to expire, extend the existing moratorium for a designated time frame, or establish a more permanent limited access system for the king mackerel fishery.

The current fishing year for Atlantic migratory groups of both king and Spanish mackerel extends from April 1 through March 31. The Councils are considering a potential change in the fishing year from an April 1 opening to either a January 1 opening or a March 1 opening.

Based on comments received during the scoping process, and further analyses of the environmental impacts of the actions proposed in Amendment 15, NMFS and the Councils do not anticipate any significant impacts on the human environment. Consequently, NMFS and the Councils are initially preparing an EA rather than proceeding with the development of a DSEIS. If the EA results in a Finding of No Significant Impact (FONSI), the EA and FONSI will be the final environmental documents required by NEPA. If the EA reveals that significant environmental impacts may be reasonably expected to result from the proposed actions, NMFS and the Councils will develop a DSEIS to further evaluate those impacts.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 29, 2004.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 04–17669 Filed 8–2–04; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 072604A]

RIN 0648–AP02

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Red Snapper Rebuilding Plan

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability of Amendment 22 to the Fishery Management Plan (FMP) for the Reef Fish Resources of the Gulf of Mexico (Amendment 22); request for comments.

SUMMARY: NMFS announces the availability of Amendment 22 prepared by the Gulf of Mexico Fishery Management Council (Council). Amendment 22 would provide the regulatory authority to implement a mandatory observer program for selected commercial and for-hire

(charter vessel/headboat) vessels in the Gulf of Mexico reef fish fishery. This observer program would be an important component of a standardized methodology to collect bycatch information in the fishery. In addition, consistent with the requirements of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), Amendment 22 would establish a stock rebuilding plan, biological reference points, and stock status determination criteria for red snapper in the Gulf of Mexico. The intended effect of these proposed regulations is to end overfishing and rebuild the red snapper resource.

DATES: Written comments must be received no later than 5 p.m., eastern time, on or before October 4, 2004.

ADDRESSES: You may submit comments by any of the following methods:

- E-mail: *0648–AP02.NOA@noaa.gov.* Include in the subject line the following identifier: 0648–AP02.
- Federal e-Rulemaking Portal: *http://www.regulations.gov.*
- Mail: Peter Hood, Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702.

Copies of Amendment 22, which includes a Regulatory Impact Review (RIR), Initial Regulatory Flexibility Analyses (IRFA), and a Supplemental Environmental Impact Statement (SEIS) may be obtained from the Gulf of Mexico Fishery Management Council, The Commons at Rivergate, 3018 U.S. Highway 301 North, Suite 1000, Tampa, FL 33619–2266; telephone: 813–228–2815; fax: 813–225–7015; e-mail: *gulfcouncil@gulfcouncil.org.* Copies of Amendment 22 can also be downloaded from the Council's website at *www.gulfcouncil.org.*

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this rule must be submitted to Robert Sadler, Southeast Region, NMFS, at the St. Petersburg mailing address stated above, and by e-mail to *David_Rostker@omb.eop.gov*, or fax to 202–395–7285.

FOR FURTHER INFORMATION CONTACT: Peter Hood, telephone: 727–570–5305, fax: 727–570–5583, e-mail: *peter.hood@noaa.gov.*

SUPPLEMENTARY INFORMATION: The reef fish fishery in the exclusive economic zone (EEZ) of the Gulf of Mexico is managed under the FMP. The FMP was prepared by the Council and is implemented under the authority of the Magnuson-Stevens Act by regulations at 50 CFR part 622.

Background

In May 2001, the Council submitted to NMFS a regulatory amendment to the FMP, based on NMFS's 1999 stock assessment, that proposed to redefine biological reference points and status determination criteria for the red snapper stock and proposed a plan to rebuild the red snapper stock to the stock biomass capable of producing maximum sustainable yield on a continuous basis (B_{MSY}) by the year 2032. The rebuilding plan proposed in the regulatory amendment was based on analyses provided by NMFS in 2000. Because the incidental catch of juvenile (age 0–age 1) red snapper in the shrimp trawl fishery comprises the vast majority of the total fishing mortality on red snapper, the success of the rebuilding plan is primarily dependent upon potential reductions in shrimp trawl bycatch.

According to NMFS's stock assessment, the number of juvenile red snapper taken incidental to the shrimp trawl fisheries accounted for about 90 percent of the total red snapper harvest prior to the implementation of a April 14, 1998, rule (63 FR 1813) requiring the use of bycatch reduction devices (BRDs), which are estimated to have reduced shrimp trawl bycatch mortality of red snapper by 40 percent. However, the Council's Reef Fish Stock Assessment Panel indicated even greater reductions would be required to rebuild the red snapper stock to B_{MSY} within the maximum recommended 31–year time frame, even if the directed red snapper fishery were eliminated.

NMFS returned the red snapper regulatory amendment to the Council in July 2002, identifying the need to further explore alternative rebuilding plans based on realistic expectations for further reductions in shrimp trawl bycatch, and to more fully evaluate the impacts of these alternatives in a Supplemental Environmental Impact Statement (SEIS). Additionally, NMFS suggested the need to better address the bycatch provisions of the Magnuson-Stevens Act. Amendment 22 was developed in response to NMFS's suggestions.

Biological Reference Points and Stock Status Determination Criteria Proposed in Amendment 22

Consistent with the requirements of the Magnuson-Stevens Act, Amendment 22 would establish the following biological reference points and stock status criteria for Gulf of Mexico red snapper: maximum sustainable yield (MSY); optimum yield (OY); maximum fishing mortality threshold (MFMT) (the fishing mortality rate which, if exceeded, would constitute overfishing); and minimum stock size threshold (MSST) (the stock size below which the stock would be considered overfished).

MSY for red snapper would equal the yield associated with fishing at F_{MSY} (currently estimated at 0.092); thus, MSY would equal 41.13 million lb (18.66 million kg) whole weight (wwt), assuming low maximum recruitment and an initial steepness of 0.90 for the stock-recruitment relationship.

Until the red snapper stock recovers to the target level, B_{MSY}, the harvest for red snapper would be defined as consistent with the rebuilding strategy proposed in Amendment 22. After achieving B_{MSY}, the OY for red snapper would correspond to a fishing mortality rate (F_{OY}) defined as $F_{OY} = 0.75 * F_{MSY} = 0.069$.

Red snapper MSST would equal (1–M) $*B_{MSY}$ = 2.453 billion lb (1.112 billion kg) wwt where B_{MSY} = 2.726 billion lb (1.237 billion kg) wwt and M (natural mortality) = 0.1.

Red snapper MFMT would be equal to F_{MSY} which is currently estimated at 0.092.

Stock Rebuilding Plan

The Magnuson-Stevens Act requires a rebuilding plan to establish a schedule for rebuilding an overfished stock that is as short as possible, and not to exceed 10 years, except in cases where the biology of the stock, other environmental conditions, or management measures under an international agreement dictate otherwise. The National Standard Guidelines provide a formula for calculating the maximum rebuilding schedule in situations where it would take 10 years or longer to rebuild a stock to B_{MSY} in the absence of fishing mortality. Applied to the red snapper stock, this formula defines the maximum recommended rebuilding schedule as 31 years (e.g., time it would take to rebuild the stock to B_{MSY} in the absence of fishing mortality (12 years) plus one mean generation time (19.6 years)). Implicit to establishing a rebuilding plan for a stock is the assumption that overfishing will end sometime during the rebuilding period. When overfishing ends depends on the type of rebuilding schedule selected.

For Gulf of Mexico red snapper, the rebuilding plan would initially maintain total allowable catch at 9.12 million lb (4.14 million kg) wwt, end overfishing between 2009 and 2010, and rebuild the red snapper stock by 2032. The status of the stock would be reviewed and management measures would be adjusted, as necessary, based upon

periodic stock assessments. The next stock assessment is scheduled for late 2004. Annual landings also would be monitored to ensure quotas are not exceeded.

Bycatch Reporting Methodology

The Council is required by the Magnuson-Stevens Act to establish a standardized bycatch reporting methodology for Federal fisheries. Current regulations require commercial and recreational for-hire participants in the Gulf of Mexico reef fish fishery who are selected by the Southeast Science and Research Director (SRD) to maintain and submit a fishing record, including bycatch information, on forms provided by the SRD.

To enhance current bycatch reporting, Amendment 22 would provide for the establishment of a mandatory observer program for the reef fish fishery. NMFS would develop a procedure for the random selection of vessels for which a Federal commercial vessel permit or charter vessel/headboat permit for Gulf of Mexico reef fish has been issued. A vessel selected by NMFS would be required to carry a NMFS-approved observer. The owner or operator of a vessel selected for observer coverage would be required to provide food and accommodations for the observer and provide the observer access to the vessel's equipment, personnel, and physical space sufficient to carry out the observer's duties. The costs associated with observer coverage, other than food and accommodations, would be borne by NMFS. In selecting vessels, NMFS would consider the suitability of the vessel for observer coverage and would ensure that the universe of vessels included is representative of all statistical sub-zones in the Gulf of Mexico. Vessel permits would not be renewed for vessels that fail or refuse to carry observers in accordance with this process. NMFS would initiate full implementation of the observer program as soon as sufficient funding for the program is obtained.

In addition, to further improve bycatch reporting for the headboat sector of the Gulf of Mexico reef fish fishery, NMFS's Marine Recreational Fisheries Statistical Survey (MRFSS) would be enhanced by including headboats, using the same sampling methodology as is currently used for charter vessels. The existing MRFSS catch-and-effort program would be continued to collect bycatch information from the private recreational sector of the fishery.

A proposed rule that would implement measures outlined in Amendment 22 has been prepared. In accordance with the Magnuson-Stevens Act, NMFS is evaluating the proposed rule to determine whether it is consistent with Amendment 22, the FMP, the Magnuson-Stevens Act, and other applicable law. If that determination is affirmative, NMFS will publish the proposed rule in the **Federal Register** for public review and comment.

Written comments received by October 4, 2004, whether specifically directed to the FMP or the proposed rule, will be considered by NMFS in its decision to approve, disapprove, or partially approve Amendment 22. Comments received after that date will not be considered by NMFS in this decision. Written comments received by NMFS on Amendment 22 or the proposed rule during their respective comment periods will be addressed in the final rule.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 27, 2004.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 04–17666 Filed 8–2–04; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 071904A]

Caribbean Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of Public Meetings.

SUMMARY: The Caribbean Fishery Management Council (Council) and its Administrative Committee will hold meetings.

DATES: The meetings will be held on August 17–18, 2004. The Council will convene on Tuesday, August 17, 2004, from 9 a.m. to 5 p.m., and the Administrative Committee will meet from 5:15 p.m. to 6:15 p. m. The Council will reconvene on Wednesday, August 18, 2004, from 9 a.m. to 5 p.m., approximately.

ADDRESSES: The meetings will be held at The Buccaneer Hotel, Estate Shoys, Christinasted, St. Croix, USVI 00824.

FOR FURTHER INFORMATION CONTACT: Caribbean Fishery Management Council, 268 Munoz Rivera Avenue, Suite 1108, San Juan, Puerto Rico 00918–1920; telephone: (787) 766–5926.

SUPPLEMENTARY INFORMATION: The Council will hold its 116th regular public meeting to discuss the items contained in the following agenda:

August 17, 2004

9 a.m. – 5 p.m.

Call to Order

Election of Officials

Adoption of Agenda

Consideration of 115th Council Meeting Verbatim Minutes

Executive Director's Report

Presentations

NOAA/National Ocean Service (NOS) Biogeography Program—Mark Monaco
Trap Studies Update—Ron Hill
Limited Entry Project—Bob Trumble
Update on Socio-Economic Survey of PR and USVI Fishers—Manuel Valdes-Pizzini
Marine Protected Areas (MPAs)—Brock Bernstein
NOAA Fisheries Recreational Strategic Plan—Michael Kelly
East End Marine Park, St. Croix, USVI—Susan Curtis
Coral Reefs Studies Update—Jorge R. Garcia-Sais
Essential Fish Habitat (EFH) Update—Graciela Garcia-Moliner
Sustainable Fisheries Act (SFA) Document en Emergency Action—Grammanik Bank

5:15 p.m. – 6:15 p.m.

Administrative Committee Meeting

Advisory Panel (AP)/Scientific and Statistical Committee (SSC)/Habitat Advisory Panel (HAP) Membership
Budget: 2002, 2003, 2004–05
Pending Travel and Contracts
Other Business

August 18, 2004

9 a.m. – 5 p.m.

Continuation of Discussion on SFA Document and Emergency Action—Grammanik Bank
Enforcement Report
Puerto Rico
U.S. Virgin Islands
NOAA
U.S. Coast Guard

Administrative Committee Recommendations

August 17, 2004

Meetings Attended by Council Members and Staff

Other Business

Next Council Meeting

The meetings are open to the public, and will be conducted in English.

Fishers and other interested persons are invited to attend and participate with oral or written statements regarding agenda issues.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. For more information or request for sign language interpretation and/other auxiliary aids, please contact Mr. Miguel A. Rolon, Executive Director, Caribbean Fishery Management Council (see **FOR FURTHER INFORMATION CONTACT**) at least 5 days prior to the meeting date.

Dated: July 29, 2004.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E4–1719 Filed 8–2–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Public Comment for Enhancement of the initial Integrated Ocean Observing System (IOOS)

AGENCY: National Ocean Service, NOAA, Department of Commerce.

ACTION: Notice of opportunity for written public comment.

SUMMARY: This notice announces the opportunity for public comment on the planning process and plans for developing the U.S. Integrated Ocean Observing System (IOOS). IOOS is the U.S. contribution to the Global Ocean Observing System (GOOS) and the Global Earth Observing System of Systems (GEOSS).

DATES: A conference to complete a phased implementation plan for the IOOS has been scheduled for August 31 through September 1, 2004. Due to limited space, attendance is by invitation only. However, the public is invited to comment in writing on design plans and priorities for IOOS development. Planning documents that the conference will build on can be found at *http://www.ocean.us/documents/componentsIOOS.jsp*. Comments must be submitted by close of business on August 20, 2004 (*w.fields@ocean.us*, or Ms. Windy Fields, Ocean.US, 2300 Clarendon Blvd, Suite 1350, Arlington, VA 22201).

ADDRESSES: The meeting location is undisclosed.

FOR FURTHER INFORMATION CONTACT: For information regarding this notice, please contact Ms. Windy Fields, Ocean.US Telephone: (703) 588–0853. E-mail: *w.fields@ocean.us*.

SUPPLEMENTARY INFORMATION: *See http://www.ocean.us.*

Dated: July 29, 2004

Mary Leach,

Chief Financial Officer, Ocean Services and Coastal Management, National Oceanic and Atmospheric Administration.

[FR Doc. 04–17645 Filed 8–2–04; 8:45 am]

BILLING CODE 3510–JE–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 072904A]

Marine Mammals; File No. 369–1757

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Receipt of application.

SUMMARY: Notice is hereby given that Bruce R. Mate, Ph.D., Hatfield Marine Science Center, Oregon State University, Newport, OR 97365, has applied in due form for a permit to take large whales, and other non-endangered species for purposes of scientific research.

DATES: Written, telefaxed, or e-mail comments must be received on or before September 2, 2004.

ADDRESSES: The application and related documents are available for review upon written request or by appointment: (See **SUPPLEMENTARY INFORMATION**).

Written comments or requests for a public hearing on this application should be mailed to the Chief, Permits, Conservation and Education Division, F/PR1, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular request would be appropriate.

Comments may also be submitted by facsimile at (301)713–0376, provided the facsimile is confirmed by hard copy submitted by mail and postmarked no later than the closing date of the comment period.

Comments may also be submitted by e-mail. The mailbox address for providing email comments is *NMFS.Pr1Comments@noaa.gov*. Include in the subject line of the e-mail comment the following document identifier: File No. 369–1757.

FOR FURTHER INFORMATION CONTACT: Ruth Johnson or Carrie Hubard, (301)713–2289.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR 222–226).

The Applicant requests a permit to conduct the following activities:

(1) Tag 200 each of humpback whales (*Megaptera novaeangliae*), blue whales (*Balaenoptera musculus*), fin whales (*Balaenoptera physalus*), gray whales (*Eschrichtius robustus*), North Atlantic right whales (*Eubalaena glacialis*), southern right whales (*Eubalaena australis*), bowhead whales (*Balaena mysticetus*), sperm whales (*Physeter catodon*) and 60 North Pacific right whales (*Eubalaena japonica*) in U.S. and foreign waters of the North Atlantic (including Gulf of Mexico), North Pacific (including Hawaii), Arctic and Indian Oceans, Beaufort, Bering and Chukchi Seas, and international waters of the Mediteranean Sea over a 5–year period. No more than 50 of each whale species will be tagged in a single year. Up to 200 of each species would be incidentally harassed annually. Satellite-monitored radio tags, GPS-linked satellite tags and acoustic tags will be deployed to monitor the movements and diving behavior of these species. The objectives of the proposed research are to: (a) identify migration routes; (b) identify specific feeding and breeding grounds for each species, if unknown; (c) characterize local movements and dive habits in both feeding and breeding grounds, and during migration; (d) examine the relationships between movements/dive habits and prey distribution, time of day, geographic location, or physical and biological oceanographic conditions; (e) provide surfacing-rate information that can be useful in the

development of more accurate abundance estimations; (f) characterize whale vocalizations; and (g) characterize sound pressure levels to which whales are exposed. Tagged whales will be approached for photo-identification, behavioral observation and assessment of possible tag effects;

(2) Tag 100 killer whales (*Orcinus orca*) over a five-year period not to exceed 20 in a single year. This would occur on an opportunistic basis, should killer whales be encountered during tagging activities with other species. The objectives of this research are to document killer whale movements and seasonal distribution patterns;

(3) Conduct non-invasive Level B harassment (photo-identification and behavioral observation) on the other non-target non-endangered/threatened marine mammal species encountered during tagging activities, in order to contribute to the knowledge of species (or situations) for which little information has been documented; and

(4) Import and export marine mammal biopsy samples and baleen from beach-cast (dead) whales. Baleen will be used for isotopic ratio analysis which may help validate movements between ocean areas with distinctive isotopic ratio signatures. Biopsy samples would be analyzed in different laboratories depending upon the species in question or the specific tests being conducted. Samples would imported/exported on a worldwide basis.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Documents may be reviewed in the following locations:

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713–2289; fax (301)713–0376;

Northwest Region, NMFS, 7600 Sand Point Way NE, BIN C15700, Bldg. 1, Seattle, WA 98115–0700; phone (206)526–6150; fax (206)526–6426;

Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802–1668; phone (907)586–7221; fax (907)586–7249;

Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213; phone (562)980–4001; fax (562)980–4018;

Protected Species Coordinator, Pacific Area Office, NMFS, 1601 Kapiolani Blvd., Rm, 1110, Honolulu, HI 96814–4700; phone (808)973–2935; fax (808)973–2941;

Northeast Region, NMFS, One Blackburn Drive, Gloucester, MA 01930–2298; phone (978)281–9200; fax (978)281–9371; and

Southeast Region, NMFS, 9721 Executive Center Drive North, St. Petersburg, FL 33702–2432; phone (727)570–5301; fax (727)570–5320.

Dated: July 29, 2004.

Patrick Opay,

Acting Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 04–17668 Filed 8–2–04; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF DEFENSE

Office of the Secretary

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by September 2, 2004.

Title, Form, and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS) Subpart 237.70, Mortuary Services, DFARS clause 252.237–7011, Preparation History; DD Form 2063; OMB Number 0704–0231.

Type of Request: Reinstatement.

Number of Respondents: 800.

Responses Per Respondent: 1.

Annual Responses: 800.

Average Burden Per Response: .5 hours.

Annual Burden Hours: 400.

Needs and Uses: This requirement provides for the collection of necessary information from contractors regarding the results of the embalming process under contracts for mortuary services. The information is used to ensure proper preparation of the body for shipment and burial. The contractor uses DD Form 2063 to provide this information.

Affected Public: Business or other for-profit.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Jacqueline Zeiher.

Written comments and recommendations on the proposed information collection should be sent to Ms. Zeiher at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Mr. Robert Cushing.

Written requests for copies of the information collection proposal should be sent to Mr. Cushing, WHS/ESCD/Information Management Division, 1225 South Clark Street, Suite 504, Arlington, VA 22202–4326.

Dated: July 28, 2004.

L.M. Bynum,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 04–17556 Filed 8–2–04; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Submission for OMB Review, Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by September 2, 3004.

Title and OMB Number: Customer Satisfaction Survey—Generic Clearance; OMB Number 0704–0403.

Type of Request: Extension.

Number of Respondents: 790.

Responses per Respondent: 1.

Annual Responses: 790.

Average Burden per Response: 10 minutes.

Annual Burden Hours: 132.

Needs and Uses: This information collection requirement is necessary to assess the level of service the Defense Technical Information Center (DTIC) provides to its current customers. The surveys will provide information on the level of overall customer satisfaction, and on customer satisfaction with several attributes of service that impact the level of overall satisfaction. These customer satisfaction surveys are required to implement Executive Order 12862, "Setting Customer Service Standards." Respondents are DTIC registered users who are components of the Department of Defense, Military Services, other Federal government Agencies, U.S. Government contractors, university involved in Federally funded research, and participants. The information obtained by these surveys will be used to assist agency senior management in determining agency business policies and processes that should be selected for examination,

modification, and reengineering from the customer's perspective. These surveys will also provid statistical and demographic basis for the design of follow-on surveys. Future surveys will be used to assist monitoring of changes in the level of customer satisfaction over time.

Affected Public: Business or other for-profit; not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jacqueline Zeiher.

Written comments and recommendations on the proposed information collection should be sent to Ms. Zeiher at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Mr. Robert Cushing.

Written requests for copies of the information collection proposal should be sent to Mr. Cushing, WHS/ESCD/ Information Management Division, 1225 South Clark Street, Suite 504, Arlington, VA 22202–4326.

Dated: July 28, 2004.

L. M. Bynum,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 04–17557 Filed 8–2–04; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Notice of Availability of Environmental Assessment for the Air Force Memorial

AGENCY: Washington Headquarters Services, DoD.

ACTION: Notice of availability.

SUMMARY: The Department of Defense (DoD) Washington Headquarters Services (WHS) announces that an Environmental Assessment (EA) for the Air Force Memorial is available for public review and comment within 30 days of the date of this publication. The Memorial is planned for the Naval Annex Site, Columbia Pike and Southgate Road, near the Pentagon in Arlington, VA. The Naval Annex is also known as the Navy Annex, Arlington Annex, and Federal Office Building No. 2 (FOB2).

The EA documents an evaluation of the environmental effects of the proposed Memorial in accord with the National Environmental Policy Act of 1969, as amended (NEPA, 42 U.S. Code 4321 to 4370b), Council of Environmental Quality (CEQ) implementing regulations (Title 40, Code of Federal Regulations, Parts 1500–1508), and DoD Instruction 4715.9, Environmental Planning and Analysis. The EA identifies the proposed action, purpose and need for the project, project alternatives, affected environment, environmental consequences, and proposed mitigation measures. Environmental consequences examined include potential impacts on socio-economic conditions, cultural and visual resources, transportation systems, physical and biological resources, utilities and infrastructure, and cumulative impacts.

The Air Force Memorial Foundation (AFMF) proposes to establish the Air Force Memorial on three acres of the Naval Annex Site, as authorized by Congress, to honor the men and women who have served in the U.S. Air Force and its predecessors. The main element of the Memorial would be three curving vertical spires, from 200 to 270 feet high, that symbolize Air Force core values, people, and key mission ingredients. At the base of the spires, complementary elements would include an Honor Guard Sculpture, Contemplation Chamber, Air Force Members Chamber, seating area, pedestrian walkways, and parking area. The proposed action, as directed by Congress, requires demolition of Wing 8 of FOB2.

The EA is available on the Internet at *http://www.dtic.mil/ref/Safety/index.htm* and *http://www.airforcememorial.org* and in paper copy at the following libraries:

- Arlington County Central Library, 1015 N. Quincy Street, Arlington, VA 22201.
- Aurora Hills Library, 735 S. 18th St., Arlington, VA 22202.
- Columbia Pike Library, 816 S. Walter Reed Dr., Arlington, VA 22204.
- Shirlington Library, 2786 S. Arlington Mill Dr., Arlington, VA 22206.

For those with access or escort, copies are also available in the FOB2 Building Managers Office, Room 1030, and in the Pentagon Library Reference Center on the Pentagon Concourse.

DATES: Public comments are invited and must be either e-mailed or postmarked on or before September 2, 2004.

ADDRESSES: To request a copy of the EA or provide comments, contact Dr. Brian Higgins at telephone: 703–697–5066, e-mail: *bhiggins@ref.whs.mil*, or WHS Real Estate and Facilities Directorate, 1155 Defense Pentagon, Room 3B200, Washington, DC 20301–1155. Individuals also may download the EA from the Web sites.

FOR FURTHER INFORMATION CONTACT: For additional information on the EA, contact Dr. Brian Higgins at telephone: 703–697–5066, or e-mail: *bhiggins@ref.whs.mil.*

Dated: July 28, 2004.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 04–17559 Filed 8–2–04; 8:45 am]

BILLING CODE 5006–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

U.S. Notice to Mariners—Change in Distribution Methods

AGENCY: National Geospatial-Intelligence Agency (NGA), Department of Defense.

ACTION: Notice.

SUMMARY: The National Geospatial-Intelligence Agency (NGA) is changing the way we *make U.S. Notice to Mariners* available to the public. We will continue to publish electronic versions of the *U.S. Notice to Mariners* and make them available free of charge via the Internet, but we will no longer mass-roduce and mail copies of each Notice.

DATES: This change takes effect with *U.S. Notice to Mariners*, January 1, 2005.

ADDRESSES: Although we are not requesting them, you may make comments on this change. To make sure that your comments and related material are not entered more than once in the docket, please submit them by only one of the following means:

(1) Electronically through the Web site for the Docket Management System at *webmasternss@nga.mil.*

(2) By mail to: Maritime Division, MS D–44, National Geospatial-Intelligence Agency, 4600 Sangamore Road, Bethesda, Maryland 20816–5003.

(3) By fax: 301–227–4211.

FOR FURTHER INFORMATION CONTACT: For further information about the substance of this notice, contact Mr. Keith Alexander, Maritime Division, MS D–44, National Geospatial-Intelligence Agency, 4600 Sangamore Road, Bethesda, Maryland 20816–5003.

SUPPLEMENTARY INFORMATION: The *U.S. Notice to Mariners* is the oldest, continuous U.S. Government publication, in constant publication with a break every week since 1869. Despite this long and noble record, hard copy production and distribution of the *U.S. Notice to Mariners* is no longer the most efficient means of providing

critical navigational information to mariners. Current computer/communication technology makes worldwide data transfer both rapid and reliable. Thus, mariners will not longer need to wait weeks for time-senstive navigational information as is currently required with mailing hard copy *U.S. Notice to Mariners* around the globe. Additionally, the phase out of hard copy *U.S. Notice to Mariners* production will conserve critical resources. For example, NGA annually produces a volume of *U.S. Notice to Mariners* that, if stacked in a column, would measure roughly 22,000 feet high. Put another way, transitioning from hard copy production and distribution will conserve roughly 2,360 trees per year.

In conclusion, the NGA hard copy transition strategy will reduce the time required for mariners to receive important marine navigational information, elimate costs associated with the printing and distribution of this publication, and conserve natural resources such as pulpwood and the fossil fuels needed to produce paper and transport this weekly product to numerous destinations around the globe.

Dated: July 28, 2004.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 04–17558 Filed 8–2–04; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF ENERGY

Agency Information Collection Renewal

AGENCY: Department of Energy.

ACTION: Notice; comment request.

SUMMARY: The Department of Energy (DOE) intends to renew an information collection package with the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. The Department's Office of Environment, Safety and Health information collection package, OMB No. 1910–5105, allows the Department and its contractors to provide management control and oversight over health and safety programs concerning worker exposure to ionizing radiation.

DATES: Written comments and recommendations for the proposed collections of information must be mailed by September 2, 2004.

ADDRESSES: Comments and recommendations regarding this collection should be mailed to the OMB Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, please advise the OMB Desk Officer of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at (202) 395–6893. In addition, please notify the DOE contact listed in this notice.

FOR FURTHER INFORMATION CONTACT: Persons submitting comments to OMB are requested to send a copy to Dr. Judith D. Foulke, U.S. Department of Energy, Office of Worker Protection Policy and Programs (EH–52), Office of Environment, Safety and Health, Building 270/CC, 1000 Independence Ave., SW., Washington, DC 20585–1290.

Dr. Foulke can be contacted by telephone at (301) 903–5865 or e-mail at *Judy.Foulke@eh.doe.gov*.

Requests for copies of the Department's Paperwork Reduction Act Submission and other information should be directed to Ms. Susan L. Frey, Director, U.S. Department of Energy, Records Management Division, Office of the Chief Information Officer, Germantown Building, IM–11, 1000 Independence Ave., SW., Washington, DC 20585–1290.

Ms. Frey can be contacted by telephone at (301) 903–3666 or e-mail at *Susan.Frey@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: This package contains (1) *Current OMB No.* 1910–5105; (2) *Package Title:* Occupational Radiation Protection; (3) *Summary:* Request for a three-year extension without change, which covers mandatory responses; (4) *Purpose:* The recordkeeping and reporting requirements that comprise this information collection will permit DOE and its contractors to provide management control and oversight over health and safety programs concerning worker exposure to ionizing radiation; (5) *Respondents:* 35 DOE management and operating contractors and 15 other contractors; (6) *Estimated Number of Burden Hours:* 50,000 following each revision of 10 CFR 835 and 5000 for other years.

Statutory Authority: Atomic Energy Act of 1954, 42 U.S.C. 2201, and the Department of Energy Organization Act, 42 U.S. C. 7191 and 7254.

Issued in Washington, DC, on June 15, 2004.

Susan L. Frey,

Director, Records Management Division, Office of the Chief Information Officer.

[FR Doc. 04–17626 Filed 8–2–04; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC04–512–001, FERC–512]

Commission Information Collection Activities, Proposed Collection; Comment Request; Submitted for OMB Review

July 28, 2004.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice.

SUMMARY: In compliance with the requirements of section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507, the Federal Energy Regulatory Commission (Commission) has submitted the information collection described below to the Office of Management and Budget (OMB) for review and reinstatement of this information collection requirement. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below. The Commission did not receive any comments in response to an earlier **Federal Register** notice of February 17, 2004 (69 FR 7460–61) and has noted this in its submission to OMB.

DATES: Comments on the collection of information are due by August 27, 2004.

ADDRESSES: Address comments on the collection of information to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Federal Energy Regulatory Commission Desk Officer. Comments to OMB should be filed electronically, c/o *Pamela_L._Beverly@omb.eop.gov* and include the OMB Control No. as a point of reference. The Desk Officer may be reached by telephone at 202–395–7856. A copy of the comments should also be sent to the Federal Energy Regulatory Commission, Office of the Executive Director, ED–30, Attention: Michael Miller, 888 First Street, NE., Washington, DC 20426. Comments may be filed either in paper format or electronically. Those persons filing electronically do not need to make a paper filing. For paper filings, such comments should be submitted to the

Office of the Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426 and should refer to Docket No. IC04–512–001.

Documents filed electronically via the Internet must be prepared in WordPerfect, MS Word, Portable Document Format, or ASCII format. To file the document, access the Commission's Web site at *http://www.ferc.gov* and click on "Make an E-filing," and then follow the instructions for each screen. First time users will have to establish a user name and password. The Commission will send an automatic acknowledgment to the sender's e-mail address upon receipt of comments. User assistance for electronic filings is available at 202–502–8258 or by e-mail to *efiling@ferc.gov*. Comments should not be submitted to the e-mail address.

All comments are available for review at the Commission 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* or toll-free at (866)208–3676, or for TTY, contact (202)502–8659.

FOR FURTHER INFORMATION CONTACT: Michael Miller may be reached by telephone at (202)502–8415, by fax at (202)273–0873, and by e-mail at *michael.miller@ferc.gov*.

SUPPLEMENTARY INFORMATION:

Description

The information collection submitted for OMB review contains the following:

1. *Collection of Information:* FERC–512, "Application for Preliminary Permit"

2. *Sponsor:* Federal Energy Regulatory Commission

3. Control No. 1902–0073.

The Commission is now requesting that OMB approve a three-year extension of the expiration date, with no changes to the existing collection. The information filed with the Commission is mandatory.

4. *Necessity of the Collection of Information:* Submission of the information is necessary for the Commission to carry out its responsibilities in implementing the statutory provisions of sections 4(f), 5 and 7 of the Federal Power Act (FPA), 16 U.S.C. 797, 798 & 800. The purpose of obtaining a preliminary permit is to maintain priority for an application for a hydropower facility license while the applicant conducts surveys to prepare maps, plans, specifications and estimates; conducts engineering, economic and environmental feasibility studies; and making financial arrangements. The conditions under which the priority will be maintained are set forth on each permit. During the term of the permit, no other application for a preliminary permit or application for a license submitted by another party can be accepted. The term of the permit is three years. The information collected under the designation FERC–512 (preliminary permit) is in the form of a written application. The information is used by Commission staff to determine an applicant's qualifications to hold a preliminary permit, review the proposed hydropower project development for feasibility and to issue a notice of the application in order to solicit public and agency comments. The Commission implements the filing requirements in the Code of Regulations (CFR) under 18 CFR 4.31–33, 4.80–83.

5. *Respondent Description:* The respondent universe currently comprises 50 applications (average per year) subject to the Commission's jurisdiction.

6. *Estimated Burden:* 3,650 total hours, 50 respondents (average per year), 1 response per respondent, and 73 hours per response (average).

7. *Estimated Cost Burden to Respondents:* 3,650 hours / 2080 hours per years × $107,185 per year = $188,089. The cost per respondent is equal to $3,762.

Statutory Authority: Sections 4(f), 5 and 7 of the FPA (16 U.S.C. 797, 798 and 800).

Linda Mitry,

Acting Secretary.

[FR Doc. E4–1718 Filed 8–2–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP04–327–001]

ANR Pipeline Company; Notice of Compliance Filing

July 28, 2004.

Take notice that, on July 23, 2004, ANR Pipeline Company (ANR) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets with an effective date of July 8, 2004:

Substitute Fifteenth Revised Sheet No. 2
Substitute Seventh Revised Sheet No. 102
Substitute Sixth Revised Sheet No. 103
Substitute Third Revised Sheet No. 162.01
Substitute Tenth Revised Sheet No. 191
Substitute Third Revised Sheet No. 191A

ANR states that the filing is being made pursuant to the Commission's Order Accepting Certain Tariff Sheets Subject to Conditions, issued July 8, 2004, in Docket No. RP04–327–000, 108 FERC ¶ 61,028.

ANR states that copies of the filing were served on all customers and state regulatory Commissions.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing 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. Such protests must be filed in accordance with the provisions of section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests 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 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.

Linda Mitry,

Acting Secretary.

[FR Doc. E4–1711 Filed 8–2–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR04–14–000]

Bridgeline Holdings, L.P.; Notice of Petition for Rate Approval

July 28, 2004.

Take notice that on July 16, 2004, Bridgeline Holdings, L.P. (Bridgeline)

filed a petition for rate approval pursuant to section 284.123(b)(2) of the Commission's Regulations. Bridgeline requests the Commission to approve a maximum interruptible rate of $.2360 per MMBtu, a maximum firm usage charge of $.1422 per MMBtu, a monthly reservation charge of $2.85 per MMBtu, and a fuel retention of .84% for transportation service under section 311(a)(2) of the Natural Gas Policy Act.

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. 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 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.

Intervention and Protest Date: 5 p.m. Eastern Time on August 12, 2004.

Linda Mitry,

Acting Secretary.

[FR Doc. E4–1708 Filed 8–2–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP04–414–000]

Colorado Interstate Gas Company; Notice of Proposed Changes in FERC Gas Tariff

July 28, 2004.

Take notice that on July 26, 2004, Colorado Interstate Gas Company (CIG) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No 1, the tariff sheets listed in Appendix A to the filing, to become effective August 27, 2004.

CIG states that these tariff sheets are filed to: (i) dd an index based discount provision to the list of permissible discounts; and (ii) move the list of permissible discounts from the Form of Service Agreements to the General Terms and Conditions (GT&C) of the tariff.

CIG states that copies of its filing have been sent to all firm customers, interruptible customers, and affected state commissions.

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 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 in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). 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 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.

Linda Mitry,

Acting Secretary.

[FR Doc. E4–1715 Filed 8–2–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP04–413–000]

Columbia Gulf Transmission Company, Complainant, v. Tennessee Gas Pipeline Company, Respondent; Notice of Complaint Requesting Fast Track Processing

July 27, 2004.

Take notice that on July 26, 2004, Columbia Gulf Transmission Company (Columbia Gulf) filed a formal complaint against Tennessee Gas Pipeline Company (Tennessee) pursuant to sections 4(a), 5(a), 7(c) and 16 of the Natural Gas Act (NGA), and Rule 206 of the Commission's Rules of Practice and Procedure, alleging that Tennessee is illegally imposing a transportation charge on Columbia Gulf's South Pass 77 shippers in violation of the NGA, Commission orders that approved a Reciprocal Lease Agreement between Tennessee and Columbia Gulf, and in violation of the Reciprocal Lease Agreement itself. Columbia Gulf requests fast track processing of its Complaint.

Columbia Gulf certifies that copies of the complaint were served on the contacts for Tennessee as listed on the Commission's list of Corporate Officials.

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 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. 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 "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 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 August 13, 2004.

Magalie R. Salas,

Secretary.

[FR Doc. E4–1702 Filed 8–2–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP04–249–001]

Florida Gas Transmission Company; Notice of Compliance Filing

July 28, 2004.

Take notice that on July 23, 2004, Florida Gas Transmission Company (FGT) tendered for filing to become part of its FERC Gas Tariff, Third Revised Volume No. 1, the following pro forma tariff sheets:

Pro Forma Sheet No. 102C
Pro Forma Sheet No. 103
Pro Forma Sheet No. 103A

FGT states that the purpose of the filing is to.comply with the Commission's Order issued June 18, 2004, in Docket No. RP04–249–000, 107 FERC ¶ 61,276 (2204).

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing 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. Such protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests 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 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 email 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.

Linda Mitry,

Acting Secretary.

[FR Doc. E4–1710 Filed 8–2–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP02–361–036]

Gulfstream Natural Gas System, L.L.C.; Notice of Compliance Filing

July 28, 2004.

Take notice that on July 23, 2004, Gulfstream Natural Gas System, L.L.C. (Gulfstream) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the following tariff sheets, with effective dates of October 1, 2003.

Original Sheet No. 8.01d
Original Sheet No. 8.01e

Gulfstream states that the purpose of this filing is to comply with the Commission's June 23, 2004 order issued in Docket No. RP02–361–016. Gulfstream states that it is filing negotiated rate tariff sheets listing all "Applicable Agreements" under a negotiated rate transaction.

Gulfstream states that copies of its filing have been mailed to all affected customers and interested state commissions, as well as all parties on the Commission's official service list in this proceeding.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing 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. Such protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests 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 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 email 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.

Linda Mitry,

Acting Secretary.

[FR Doc. E4–1707 Filed 8–2–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP98–18–013]

Iroquois Gas Transmission System, L.P.; Notice of Negotiated Rate

July 28, 2004.

Take notice that on July 26, 2004, Iroquois Gas Transmission System, L.P. (Iroquois) tendered for filing Substitute Original Sheet No. 6B as part if its FERC Gas Tariff, First Revised Volume No. 1, proposed to become effective July 19, 2004.

Iroquois states that the sole purpose for this filing is to correct footnote 4 of Original Sheet No. 4B submitted with Iroquois' July 19, 2004, filing in this docket, which inadvertently failed to list the Measurement Variance/Fuel Use

Factor as one of the surcharges that Consolidated Edison Company of New York, Inc. will pay under its negotiated rate agreement with Iroquois.

Iroquois states that copies of its filing were served on all jurisdictional customers and interested state regulatory agencies and all parties to the proceeding.

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 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 in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). 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 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.

Linda Mitry,

Acting Secretary.

[FR Doc. E4–1706 Filed 8–2–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP04–412–000]

Natural Gas Pipeline Company of America; Notice of Proposed Changes in FERC Gas Tariff

July 28, 2004.

Take notice that on July 26, 2004, Natural Gas Pipeline Company of America (Natural) tendered for filing as part of its FERC Gas Tariff, Volume No. 1, the following tariff sheets, to become effective August 1, 2004:

Twenty-Second Revised Sheet No. 25
Third Revised Sheet No. 1A

Natural states that the purpose of this filing is to eliminate the Gas Research Institute (GRI) surcharge, which is currently reflected on a rate sheet in Natural's Tariff. Natural further states that this filing is being made pursuant to a settlement agreement entered into between GRI and numerous parties as approved by the Commission and pursuant to the Commission's regulations regarding tariff changes.

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 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 in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). 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 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.

Linda Mitry,

Acting Secretary.

[FR Doc. E4–1714 Filed 8–2–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP04–67–001]

NGO Transmission, Inc.; Notice of Compliance Filing

July 28, 2004.

Take notice that on July 23, 2004, NGO Transmission, Inc. (NGO Transmission) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the tariff sheets listed on Appendix A to the filing, with an effective date of November 22, 2003.

NGO Transmission states that the purpose of the filing is to comply with the Commission's Order issued on June 23, 2004, in Docket No. RP04–67–000 (NGO Transmission, Inc., 107 FERC ¶ 61,302 (2004)).

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing 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. Such protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests 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 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 email 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.

Linda Mitry,

Acting Secretary.

[FR Doc. E4–1717 Filed 8–2–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission]

[Docket No. RP04–408–000]

Southern Star Central Gas Pipeline, Inc.; Notice of Proposed Changes in FERC Gas Tariff

July 28, 2004.

Take notice that on July 23, 2004, Southern Star Central Gas Pipeline, Inc. (Southern Star) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the tariff sheets listed below to become effective August 1, 2004:

First Revised Sheet No. 2
First Revised Second Revised Sheet No. 11
Third Revised Sheet No. 147
First Revised Sheet No. 151
Third Revised Sheet No. 154
First Revised Sheet No. 200
First Revised Sheet No. 228
First Revised Sheet No. 259
First Revised Sheet No. 285
First Revised Sheet No. 286

Southern Star states the purpose of this filing is to remove the GRI Adjustment surcharges from its tariff in accordance with the terms and conditions of the March 10, 1998 Settlement Agreement and the GRI notification to its member companies that such collections should discontinue as of August 1, 2004.

Southern states that copies of the tariff sheets are being mailed to Southern Star's jurisdictional customers and interested state commissions.

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 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 in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). 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 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.

Linda Mitry,

Acting Secretary.

[FR Doc. E4–1712 Filed 8–2–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP04–237–002]

Trailblazer Pipeline Company; Notice of Compliance Filing

July 28, 2004.

Take notice that on July 23, 2004, Trailblazer Pipeline Company (Trailblazer) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, Substitute Second Revised Sheet No. 8, with a proposed effective date of May 1, 2004.

Trailblazer states that the filing is being made to comply with the Commission's Letter Order regarding Rejection of Expansion Fuel Adjustment Percentage issued July 9, 2004, in Docket No. RP04–237–001, 108 FERC ¶ 61,036.

Trailblazer states that copies of its filing were served on parties on the official service list.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing 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. Such protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests 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 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.

Linda Mitry,

Acting Secretary.

[FR Doc. E4–1709 Filed 8–2–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP04–410–000]

Williston Basin Interstate Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

July 28, 2004.

Take notice that on July 23, 2004, Williston Basin Interstate Pipeline Company (Williston Basin) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the tariff sheets listed in Appendix A to the filing, to become effective August 23, 2004.

Williston Basin states that the revised tariff sheets are being filed to make certain tariff modifications necessary to correct and/or clarify its Tariff as more fully explained in the filing.

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 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 in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). 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 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.

Linda Mitry,

Acting Secretary.

[FR Doc. E4–1713 Filed 8–2–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP04–415–000]

Wyoming Interstate Company, Ltd.; Notice of Proposed Changes in FERC Gas Tariff

July 28, 2004.

Take notice that on July 26, 2004, Wyoming Interstate Company, Ltd. (WIC) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No 2, the following tariff sheets, to become effective August 27, 2004:

Eleventh Revised Sheet No. 35
Original Sheet No. 85C
Original Sheet No. 85D
Fifth Revised Sheet No. 88
Sixth Revised Sheet No. 97

WIC states that these tariff sheets are filed to: (i) Add an index based discount provision to the list of permissible discounts; and (ii) move the list of permissible discounts from the Form of Service Agreements to the General Terms and Conditions of the Tariff.

WIC states that copies of its filing have been sent to all firm customers, interruptible customers, and affected State commissions.

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 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 in accordance with the provisions of section 154.210 of the Commission's regulations (18 CFR 154.210). 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 14 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.

Linda Mitry,

Acting Secretary.

[FR Doc. E4–1716 Filed 8–2–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2114–117]

Public Utility District No. 2 of Grant County; Notice of Availability of Environmental Assessment

July 27, 2004.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380 (Order No. 486, 52 FR 47897), the Office of Energy Projects has prepared an Environmental Assessment (EA) for an amendment application requesting Commission approval to replace 10 turbines at the Wanapum development with 10 new, upgraded turbines. The Wanapum development is part of the Priest Rapids Project. The project is located on the Columbia River in Grant, Yakima, Kittitas, Douglas, Benton, and Chelan counties, Washington, and occupies federal lands.

The EA contains staff's analysis of the potential environmental impacts associated with the installation of 10 new advance turbines and concludes that the proposed amendment would not constitute a major Federal action that would significantly affect the quality of the human environment.

A copy of the EA is attached to the July 23, 2004, Commission Order titled "Order Modifying and Approving Amendment of License Application and Revising Annual Charges," which is available for review and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426. The EA may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number (prefaced by

P–) in the docket number field to access the document. For assistance, contact FERC On-Line Support at *FERCOnlineSupport@ferc.gov* or call toll free at (866) 208–3676, or for TTY contact (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E4–1705 Filed 8–2–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP04–409–000]

Pogo Producing Company; Notice Scheduling Convening Session

July 27, 2004.

By order issued July 26, 2004, in the above-captioned docket, the Commission directed its Dispute Resolution Service to convene a meeting with the parties no later than Wednesday, July 28, 2004. During the convening session, the DRS Representative will pursue the selection of an ADR process to address the issues raised by Pogo Producing Company's filing on July 26, 2004. The DRS contemplates that the process selected would commence on Thursday afternoon at 2 c.s.t, July 29, or Friday morning 9 c.s.t., July 30. The ADR process would be held, tentatively, in Houston, Texas. The location will be announced as soon as it is known.

The Convening Session will be held by a telephone conference call on Wednesday July 28, for all interested parties at 1 p.m. central time (2 p.m. eastern time). The dial-in instructions are:

When: Wednesday, July 28, at 1 p.m. central time (2 p.m. eastern time).

Dial-In # 1–888–560–7328.

Passcode: 994508 (enter # after number, and announce name on entry).

If you have any questions regarding this matter, please call Richard Miles at 202–502–8702 or Jeri Purdy at 202–502–8671.

Magalie R. Salas,

Secretary.

[FR Doc. E4–1704 Filed 8–2–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

July 27, 2004.

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of exempt and prohibited off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive an exempt or prohibited off-the-record communication relevant to the merit's of a contested on-the-record proceeding, to deliver a copy of the communication, if written, or a summary of the substance of any oral communication, to the Secretary.

Prohibited communications will be included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications will be included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of prohibited and exempt communications recently received in the Office of the Secretary. The communications listed are grouped by docket numbers. These filings are 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 (FERRIS) link. Enter the docket number excluding the last three digits in the docket number field to access the document. 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.

Docket No	Date filed	Presenter or requester
Prohibited:		
1. CP04–36–000	7–8–04	Gordon Shearer.
CP04–41–000		
CP04–42–000		
CP04–43–000		
2. Project No. 11175–016	6–15–04	Anumzziatta Purchiaroni.[1]
Exempt:		
1. CP04–223–000	7–21–04	David D. Costa.
2. CP04–223–000	7–21–04	Capt. William C. Reed.
3. EL03–180–000, *et al*	6–23–04	Hon. Maria Cantwell.
EL02–113–000		
EL02–114–000		
EL02–115–000		
EL03–154–000		
4. Project No. 2082–000	7–21–04	Todd Olson.
5. Project No. 2144–116	7–8–04	Antone C. Minthorn.
Project No. 2145–060		
6. Project No. 11659–000	7–21–04	John Klutz.

[1] Newsclipping sent to FERC program office by anonymous sender.

Magalie R. Salas,
Secretary.
[FR Doc. E4–1703 Filed 8–2–04; 8:45 am]
BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[OAR–2004–0081, FRL–7796–9]

Agency Information Collection Activities: Proposed Collection; Comment Request; Prevention of Significant Deterioration Nonattainment Area New Source Review (Renewal), EPA ICR Number 1230.17, OMB Control Number 2060–0003.

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit a continuing Information Collection Request (ICR) to the Office of Management and Budget (OMB). This is a request to renew an existing approved collection. This ICR is scheduled to expire on October 31, 2004. 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 October 4, 2004.

ADDRESSES: Submit your comments, referencing docket ID number OAR–2004–0081, to EPA online using EDOCKET (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Air and Radiation Docket and Information Center, Mail Code 6102T, 1200 Pennsylvania Avenue, Northwest, Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Juan E. Santiago, Information Transfer and Program Integration Division (C339–03), U.S. EPA Office of Air Quality Planning and Standards, Research Triangle Park, North Carolina 27711, telephone 919–541–1084, fax 919–541–5509, or electronic mail at *santiago.juan@epa.gov.*

SUPPLEMENTARY INFORMATION: The EPA has established a public docket for this ICR under Docket ID number OAR–2004–0081, which is available for public viewing at the Air Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the public 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 above.

Any comments related to this ICR should be submitted to EPA within 60 days of this notice. The EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov./edocket.*

Affected entities: Entities potentially affected by this action are business or other non-profits; Federal, State, local, or tribal governments.

Title: Prevention of Significant Deterioration Non-Attainment Area New Source Review (Renewal).

Abstract: Part C of the Clean Air Act (Act)—"Prevention of Significant Deterioration," and Part D—"Plan Requirements for Nonattainment Areas," require all States to adopt preconstruction review programs for new or modified stationary sources of air pollution. In addition, the provisions of section 110 of the Act include a requirement for States to have a preconstruction review program to manage the emissions from the construction and modification of any stationary source of air pollution to assure that the National Ambient Air Quality Standards (NAAQS) are achieved and maintained. Implementing regulations for these three programs are promulgated at 40 CFR 51.160 through 51.166 to part 51 and 40 CFR 52.21 and 52.24. In order to receive a construction permit for a major new source or major modification, the applicant must conduct the necessary research, perform the appropriate analyses and prepare the permit application with documentation to demonstrate that their project meets all applicable statutory and regulatory NSR requirements. Specific activities and requirements are listed and described in the Supporting Statement for the ICR.

Reviewing authorities, either State, local or Federal, review the permit application and provides for public review of the proposed project and issues the permit based on its consideration of all technical factors and public input. The EPA, more broadly, reviews a fraction of the total applications and audits the State and local programs for their effectiveness. Consequently, information prepared and submitted by the source is essential for the source to receive a permit, and for Federal, State and local environmental agencies to adequately review the permit application and thereby properly administer and manage the NSR programs.

Information that is collected and handled according to EPA's policies set forth in title 40, chapter 1, part 2, subpart B—Confidentiality of Business Information (*see* 40 CFR part 2). See also section 114(c) of the Act.

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 40 CFR are listed in 40 CFR part 9.

The EPA solicits comments 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.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is broken down as follows:

Type of permit action	Major PSD	Major Part D	Minor
Number of sources	265	488	74,500
Burden Hours per Response:			
Industry	839	577	40
Permitting Agencies	272	109	30

Respondents/Affected Entities: Industrial plants, State and local permitting agencies.

Estimated Number of Respondents: (150,723).

Frequency of Response: (1 per respondent).

Estimated Total Annual Hour Burden: (5,851,126) hours.

Estimated Annualized Cost Burden: $(0).

The estimated total annual burden is adjusted upward by 1,135,866 hours. The actual change in burden is 0, but there is an adjustment of $73.286 million upward due to the upward adjustment in the number of minor source actions estimated for this renewal. The revised number of minor source actions results from the upward revision to the number of reviewing authorites and the estimated number of actions per reviewing authority. The total number of respondents is increased by 35,903. The burden per type of permit remains unchanged.

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; 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.

Dated: July 27, 2004.

William T. Harnett,

Director, Information Transfer and Program, Integration Division.

[FR Doc. 04–17660 Filed 8–2–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0298, FRL–7796–4]

Agency Information Collection Activities; Submission to OMB; Comment Request; EPA ICR No. 1693.03/OMB Control No. 2070–0142; Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting; EPA ICR No. 1693.03; OMB Control No. 2070–0142. The ICR, which is abstracted below, describes the nature of the information collection activity and its expected burden and costs.

DATES: Additional comments may be submitted on or before September 2, 2004.

FOR FURTHER INFORMATION CONTACT: Cameo Smoot, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5454; fax number: (703) 305–5884; e-mail address: *smoot.cameo@epa.gov*.

ADDRESSES: Submit your comments, referencing docket ID number OPP–2003–0298, to (1) EPA online using EDOCKET (our preferred method), by e-mail to *opp-docket@epa.gov*, or by mail to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Mailcode: 7502C, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. The **Federal Register** document, required under 5 CFR 1320.8(d), soliciting comments on this collection of information was published on October 15, 2003 (67 FR 66392). EPA received no comments on this ICR during the 60-day comment period.

EPA has established a public docket for this ICR under Docket ID No. OPP–2003–0298, which is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket*. Use EDOCKET to submit or view public comments, access the index listing of the contents of the public 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 above.

Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice. Please note, EPA's policy is that public comments, whether submitted electronically or on paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket.

Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, *see* EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *www.epa.gov/edocket*.

ICR Title: Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting

ICR Status: This is a request for extension of an existing approved collection that is currently scheduled to expire on July 31, 2004. EPA is asking OMB to approve this ICR for three years. Under 5 CFR 1320.12(b)(2), the Agency may continue to conduct or sponsor the collection of information while the submission is pending at OMB.

Abstract: On January 16, 2001, EPA promulgated a final rule that addresses the regulatory status of pesticidal substances that are produced by plants (plant-incorporated protectants). This Information Collection Request (ICR) covers the two information collection related provisions contained in the final rule: the provision that requires registrants that make Confidential Business Information (CBI) claims to substantiate such claims when they are made, and the provision that requires manufacturers of plant-incorporated protectants exempted from requirements of registration under the final rule to report adverse effects to the Agency.

Burden Statement: The annual "respondent" burden for this ICR is estimated to average about 22 hours per response. According to the Paperwork Reduction Act, "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. For this collection, it is the time reading the regulations, planning the necessary data collection activities, conducting tests, analyzing data, generating reports and completing other required paperwork, and storing, filing, and maintaining the data. The 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 number for this information collection appears at the beginning and the end of this document. In addition OMB control numbers for EPA's regulations, after initial display in the final rule, are listed in 40 CFR part 9.

The following is a summary of the burden estimates taken from the ICR:

Respondents/affected entities: Persons or companies involved with agricultural biotechnology that may develop and market plant incorporated protectants.

Estimated total number of potential respondents: 14.

Frequency of response: On occasion.

Estimated total/average number of responses for each respondent: 1.

Estimated total annual burden hours: 303.

Estimated total annual burden costs: $27,572.

Changes in the ICR Since the Last Approval: The total estimated annual respondent burden for this ICR has decreased 1,067 hours, from 1,370 hours to 303; and the cost has decreased $92,420, from $119,992 to $27,572, because the previous ICR included an estimated 1,067 hours for respondents to familiarize themselves with the requirements of the rule, which was promulgated in 2001. This decrease is explained more fully in the ICR.

List of Subjects:

EPA, pesticides, pesticide registration, information collection.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 04–17663 Filed 8–2–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPPT–2003–0070; FRL –7796–5]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Residential Lead-Based Paint Hazard Disclosure Requirements; EPA ICR No. 1710.04, OMB No. 2070–0151

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. This ICR is scheduled to expire on July 31, 2004. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. This ICR describes the nature of the information collection and its estimated cost.

DATES: Additional comments may be submitted on or before September 2, 2004.

ADDRESSES: Submit your comments, referencing docket ID Number OPPT–2003–0070, to (1) EPA online using EDOCKET (our preferred method), by email to *oppt.ncic@epa.gov* or by mail to: Document Control Office (DCO), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, Mail code: 7407T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Barbara Cunningham, Acting Director, Environmental Assistance Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, Mail code: 7408, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 202–554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On January 12, 2004, EPA sought comments on this renewal ICR (69 FR 1740) pursuant to 5 CFR 1320.8(d). EPA received no comments during the comment period.

EPA has established a public docket for this ICR under Docket ID No. OPPT–2003–0070, which is available for public viewing at the OPPT Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center 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 Pollution Prevention and Toxics Docket is 202–566–0280. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket*. Use EDOCKET to submit or view public comments, access the index listing of the contents of the public 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 above.

Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice. Please note, EPA's policy is that public comments, whether submitted

electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, *see* EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *www.epa.gov/edocket,*

ICR Title: Residential Lead-Based Paint Hazard Disclosure Requirements (EPA ICR No. 1710.04, OMB No. 2070–0151).

Abstract: Section 1018 of the Residential Lead-Based Paint Hazard Reduction Act of 1992 (42 U.S.C. 4852d) requires that sellers and lessors of most residential housing built before 1978 disclose known information on the presence of lead-based paint and lead-based paint hazards, and provide an EPA-approved pamphlet to purchasers and renters before selling or leasing the housing. Sellers of pre-1978 housing are also required to provide prospective purchasers with 10 days to conduct an inspection or risk assessment for lead-based paint hazards before obligating purchasers under contracts to purchase the property. The rule does not apply to rental housing that has been found to be free of lead-based paint, zero-bedroom dwellings, housing for the elderly, housing for the handicapped, or short-term leases. The affected parties and the information collection-related requirements related to each are described below:

1. Sellers of pre-1978 residential housing. Sellers of pre-1978 housing must attach certain notification and disclosure language to their sales/leasing contracts. The attachment lists the information disclosed and acknowledges compliance by the seller, purchaser and any agents involved in the transaction.

2. Lessors of pre-1978 residential housing. Lessors of pre-1978 housing must attach notification and disclosure language to their leasing contracts. The attachment, which lists the information disclosed and acknowledges compliance with all elements of the rule, must be signed by the lessor, lessee and any agents acting on their behalf. Agents and lessees must retain the information for 3 years from the completion of the transaction.

3. Agents acting on behalf of sellers or lessors. Section 1018 of the Residential Lead-Based Paint Hazard Reduction Act of 1992 specifically directs EPA and HUD to require agents acting on behalf of sellers or lessors to ensure compliance with the disclosure regulations.

Responses to the collection of information are mandatory (*see* 40 CFR part 745, subpart F, and 24 CFR 35, subpart H). 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**, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 0.19 hour 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; 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.

Respondents/Affected Entities: Persons engaged in selling, purchasing or leasing certain residential dwellings built before 1978, or who are real estate agents representing such parties.

Frequency of Collection: On occasion; third-party notification only.

Estimated No. of Respondents: 47,516,400.

Estimated Total Annual Burden on Respondents: 8,855,610 hours.

Estimated Total Annual Costs: $136,774,352.

Changes in Burden Estimates: The total estimated annual burden requested in this ICR (8,855,610 hours) reflects an estimated net increase of 1,710,198 burden hours from the total estimated burden identified in the ICR that was last approved by OMB (7,145,412 hours). This increase is due to the recent increase in real estate sales, presumably associated with historically low interest rates. The previous ICR analysis projected sales of target housing units at a rate of 3,429,447 per year. The current analysis projects sales of 4,324,000 units per year, or an increase of about 895,000 units per year. The burden increase is an adjustment.

Dated: July 22, 2004.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 04–17664 Filed 8–2–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7796–3]

Proposed Settlement Agreement, Clean Air Act Petitions for Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement agreement; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended ("Act"), 42 U.S.C. section 7413(g), notice is hereby given of a proposed settlement agreement, to address lawsuits filed by Our Children's Earth Foundation, Plumbers and Steamfitters Union Local 342 and International Brotherhood of Electrical Workers Local 302, and Communities for a Better Environment ("plaintiffs"): *Our Children's Earth Foundation* v. *EPA* (No. 04–70643) (9th Cir.); *Plumbers and Steamfitters Union Local 342* v. *EPA* (No. 04–70688) (9th Cir.); and *Communities for a Better Environment* v. *EPA* (No. 04–70776) (9th Cir.) (consolidated). On or about February 12, 2004, February 13, 2004, and February 17, 2004 plaintiffs filed petitions for judicial review of EPA's dismissal of several administrative "veto" petitions filed under title V of the Act, which requested that the EPA Administrator object to operating permits issued by the Bay Area Air Quality Management District ("District") for several oil refineries in the San Francisco Bay Area. Under the terms of the proposed settlement agreement, the parties would request a continuation of the stay of the petitions for review while the District finalizes new versions of the title V permits at issue, the Plaintiffs file new veto petitions on those new permits,

and EPA responds to the new veto petitions.

DATES: Written comments on the proposed settlement agreement must be received by September 2, 2004.

FOR FURTHER INFORMATION CONTACT: Kevin S. Minoli, Air and Radiation Law Office (2333A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, telephone: (202) 564–5551.

ADDRESSES: Submit your comments, identified by docket ID number OGC–2004–0006, online at *http://www.epa.gov/edocket* (EPA's preferred method); by e-mail to *oei.docket@epa.gov*; mailed to EPA Docket Center, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; or by hand delivery or courier to EPA Docket Center, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC, between 8:30 a.m. and 4:30 p.m. Monday through Friday, excluding legal holidays. Comments on a disk or CD–ROM should be formatted in Wordperfect or ASCII file, avoiding the use of special characters and any form of encryption, and may be mailed to the mailing address above.

SUPPLEMENTARY INFORMATION:

I. Additional Information About the Proposed Settlement

The petitions for review seek judicial review of EPA's November 2003 dismissal of several administrative petitions filed under title V of the Act. The petitions requested that the EPA Administrator object to operating permits issued by the District for several oil refineries in the San Francisco Bay Area. EPA dismissed the administrative petitions as unripe after EPA informed the District that the permits had to be reopened because the District had failed to provide the Agency with proposed permits as required by 40 CFR part 70.

The proposed settlement sets a deadline for EPA's response to new petitions plaintiffs will file once the District forwards new proposed permits for these refineries to EPA. Should EPA receive the proposed permits by July 31, 2004, as expected, the deadline for responding to any petitions filed by plaintiffs on those permits would be March 15, 2005. The Agreement allows EPA and plaintiffs to opt out of the Agreement should the District fail to provide EPA with the proposed permits by July 31, 2004. During the stay, EPA would be required to inform the 9th Circuit Mediator's Office whether it is on track to meet the March 15, 2005, deadline on three occasions: September 1, 2004; January 10, 2005, and March 1, 2005.

If the deadlines are met, plaintiffs will seek an indefinite stay of their litigation. The purpose of the indefinite stay is to allow plaintiffs to maintain their pending petitions for review as protective filings only, to be litigated only in the event that a court later determines that any challenge by plaintiffs to the merits of the Administrator's decisions on the anticipated petitions must be raised in the above-captioned litigation rather than a later-filed lawsuit.

The proposed settlement calls for the government to pay attorneys' fees in the amount of $30,000.

For a period of thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the proposed settlement agreement from persons who were not named as parties or interveners to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed settlement agreement if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Unless EPA or the Department of Justice determine, based on any comment which may be submitted, that consent to the settlement agreement should be withdrawn, the terms of the agreement will be affirmed.

II. Additional Information About Commenting on the Proposed Settlement

A. How Can I Get A Copy of the Settlement?

EPA has established an official public docket for this action under Docket ID No. OGC–2004–0006 which contains a copy of the settlement. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket identification number.

It is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. Information claimed as CBI and other information whose disclosure is restricted by statute is not included in the official public docket or in EPA's electronic public docket. EPA's policy is that copyrighted material, including copyrighted material contained in a public comment, will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the EPA Docket Center.

B. How and to Whom Do I Submit Comments?

You may submit comments as provided in the **ADDRESSES** section. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment and with any disk or CD ROM you submit. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. 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.

Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method

for receiving comments. The electronic public docket system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment. In contrast to EPA's electronic public docket, EPA's electronic mail (e-mail) system is not an "anonymous access" system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, your e-mail address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

Dated: July 26, 2004.

Lisa K. Friedman,

Associate General Counsel, Air and Radiation Law Office, Office of General Counsel.

[FR Doc. 04–17662 Filed 8–2–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7796–7]

Extension of Comment Period on the Notice of Data Availability for the Truck Stop Electrification Codes and Electrical Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Extension of comment period.

SUMMARY: On July 8, 2004, EPA published a Notice of Data Availability presenting data on potential codes and electrical standards for truck stop electrification. The notice presented a summary of data collected at an EPA public workshop on developing consistent, national truck stop electrification codes and electrical standards. This action extends the comment period for the Notice of Data Availability to October 9, 2004.

DATES: Comments on the Notice of Data Availability will be accepted through October 9, 2004.

ADDRESSES: Comments may be submitted electronically or by mail to the contact below or through EPA Dockets at *http://www.epa.gov/edocket/* by searching on the appropriate docket identification number. EPA will make available for public inspection at the Air and Radiation Docket written comments received from interested parties. The official public docket is the collection of materials that is available for public viewing at the Air and Radiation Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air and Radiation Docket is (202) 566–1743. The reference number for this docket is OAR–2003–0226.

FOR FURTHER INFORMATION CONTACT: Elizabeth Lonoff, Transportation and Regional Programs Division (6406J), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Telephone: (202) 343–9147, e-mail address: *Lonoff.Elizabeth@EPA.GOV.*

Dated: July 28, 2004.

Margo Tsirigotis Oge,

Director, Transportation and Regional Programs Division.

[FR Doc. 04–17661 Filed 8–2–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPPT–2004–0105; FRL–7673–3]

Certain New Chemicals; Receipt and Status Information

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture (defined by statute to include import) a new chemical (i.e., a chemical not on the TSCA Inventory) to notify EPA and comply with the statutory provisions pertaining to the manufacture of new chemicals. Under sections 5(d)(2) and 5(d)(3) of TSC, EPA is required to publish a notice of receipt of a premanufacture notice (PMN) or an application for a test marketing exemption (TME), and to publish periodic status reports on the chemicals under review and the receipt of notices of commencement to manufacture those chemicals. This status report, which covers the period from June 28, 2004 to July 9, 2004, consists of the PMNs, pending or expired, and the notices of commencement to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period.

EPA issued a notice in the **Federal Register** of July 12, 2004, concerning certain new chemicals; receipt and status information for June 14 to June 25, 2004. This document corrects the docket identification number.

DATES: Comments identified by the docket identification (ID) number OPPT–2004–0105 and the specific PMN number or TME number, must be received on or before September 2, 2004.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division, Office of Pollution Prevention and Toxics (7408M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. As such, the Agency has not attempted to describe the specific entities that this action may apply to. Although others may be affected, this action applies directly to the submitter of the premanufacture notices addressed in the action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPPT–2004–0105. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566–1744 and the telephone number for the OPPT Docket,

which is located in EPA Docket Center, is (202) 566–0280.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr/.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number and specific PMN number or TME number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. 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.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPPT–2004–0105. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to *oppt.ncic@epa.gov*, Attention: Docket ID Number OPPT–2004–0105 and PMN Number or TME Number. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *By hand delivery or courier.* Deliver your comments to: OPPT Document Control Office (DCO) in EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number OPPT–20040105 and PMN Number or TME Number. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be

disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT.**

E. 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 used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the notice or collection activity.
7. Make sure to submit your comments by the deadline in this document.
8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action and the specific PMN number you are commenting on in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Does this Correction Do?

FR Doc. 04–15724 published in the **Federal Register** of July 12, 2004 (69 FR 41802–41808) (FRL–7369–4) is corrected by changing the docket ID number "OPPT–2004–0101" to read "OPPT–2004–0104" everywhere it appears in the document.

III. Why is EPA Taking this Action?

Section 5 of TSCA requires any person who intends to manufacture (defined by statute to include import) a new chemical (i.e., a chemical not on the TSCA Inventory to notify EPA and comply with the statutory provisions pertaining to the manufacture of new chemicals. Under sections 5(d)(2) and 5(d)(3) of TSCA, EPA is required to publish a notice of receipt of a PMN or an application for a TME and to publish periodic status reports on the chemicals under review and the receipt of notices of commencement to manufacture those chemicals. This status report, which covers the period from June 28, 2004 to July 9, 2004, consists of the PMNs pending or expired, and the notices of commencement to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period.

IV. Receipt and Status Report for PMNs

This status report identifies the PMNs pending or expired, and the notices of commencement to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period. If you are interested in information that is not included in the following tables, you may contact EPA as described in Unit I.C. to access additional non-CBI information that may be available.

In Table I of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the PMNs received by EPA during this period: the EPA case number assigned to the PMN; the date the PMN was received by EPA; the projected end date for EPA's review of the PMN; the submitting manufacturer; the potential uses identified by the manufacturer in the PMN; and the chemical identity.

I. 36 PREMANUFACTURE NOTICES RECEIVED FROM: 06/28/04 TO 07/09/04

Case No.	Received Date	Projected Notice End Date	Manufacturer/Importer	Use	Chemical
P–04–0691	06/28/04	09/25/04	CBI	(S) Coating in textile and leather industries	(G) Urethane acrylic hybrid polymer
P–04–0692	06/28/04	09/25/04	CBI	(S) Trifunctional acrylic ester used in lacquer/dry film manufacture	(G) Trifunctional acrylic ester
P–04–0693	06/28/04	09/25/04	CBI	(S) Urethane acrylate oligomer used in lacquer manufacture	(G) Urethane acrylate oligomer
P–04–0694	06/28/04	09/25/04	CBI	(G) Organic marker for petroleum products	(G) Organic marker
P–04–0695	06/28/04	09/25/04	GE BETZ	(G) Metal treatment compound	(G) Alkanolamine phenolic mannich adduct
P–04–0696	06/29/04	09/26/04	CBI	(S) Reactive dye for textile	(G) Substituted naphthaline disulfonic acid alkali salt
P–04–0697	06/29/04	09/26/04	CBI	(S) Textile wet processing, surface treatment agent; homecare clothing softner for detergent	(G) Quaternary amino modified silicone-polyther copolymer
P–04–0698	06/29/04	09/26/04	CBI	(S) Textile wet processing, surface treatment agent; homecare clothing softener for detergent	(G) Quaternary amino modified silicone-polyther copolymer
P–04–0699	06/29/04	09/26/04	CBI	(S) Textile wet processing, surface treatment agent; homecare clothing softener for detergent	(G) Quaternary amino modified silicone-polyther copolymer
P–04–0700	06/29/04	09/26/04	Petroferm, Inc.	(S) Slip and levelling additive to utra violet-and electronic beam-cured inks, paints and coatings; oligomer in the manufacture of polymeric materials	(S) Poly(oxy-1,2-ethanediyl), .alpha.-(1-oxo-2-propenyl)-.omega.-[3-[1,3,3,3-tetramethyl-1-[(trimethylsily-l)oxy]disiloxanyl]propoxy]-

I. 36 PREMANUFACTURE NOTICES RECEIVED FROM: 06/28/04 TO 07/09/04—Continued

Case No.	Received Date	Projected Notice End Date	Manufacturer/Importer	Use	Chemical
P–04–0701	06/29/04	09/26/04	Petroferm, Inc.	(S) Slip and levelling additive to ultra violet-and electronic beam-cured inks, paints and coatings; oligomer in the manufacture of polymeric materials	(S) Poly(oxy-1,2-ethanediyl), .alpha.-(2-methyl-1-oxo-2-propenyl)-.omega.-[3-[1,3,3,3-tetramethyl-1-[(trimethylsily-l)oxy]disiloxanyl]propoxy]-
P–04–0702	06/30/04	09/27/04	CBI	(G) Industrial structural materials	(G) Modified silicone polymer
P–04–0703	06/30/04	09/27/04	CBI	(G) Component of manufactured consumer article-contained use	(G) Spiro[isobenzofuran-1(3h),9′-[9h]polyheterocycle]-3-one, 3′-[hexyl(2-methylphenyl)amino]-6′-[(2-methylphenyl)amino
P–04–0704	07/01/04	09/28/04	The P.D. George Company	(S) Electrical insulation varnish	(G) Polymer of carboxylic acids, glycols, and epoxy resin.
P–04–0705	07/01/04	09/28/04	The P.D. George Company	(S) Electrical insulation varnish	(G) Polymer of carboxylic acids, glycols, and epoxy resin.
P–04–0706	07/02/04	09/29/04	CBI	(S) Processing aid for elastomer compounding	(G) Organosilane ester
P–04–0707	07/02/04	09/29/04	CBI	(S) Processing aid for elastomer compounding	(G) Organosilane ester
P–04–0708	07/02/04	09/29/04	CBI	(G) Industrial structural materials	(G) Telechelic polyacrylates
P–04–0709	07/02/04	09/29/04	CBI	(G) Component of mixture for highly dispersive applications.	(G) Substituted acyclic alkenones
P–04–0710	07/06/04	10/03/04	CBI	(G) Additive for lubricants	(G) Alkyl methacrylate copolymer
P–04–0711	07/07/04	10/04/04	CBI	(G) Destructive use	(G) Aluminum complex
P–04–0712	07/08/04	10/05/04	CBI	(S) Azole polymer used as an additive for plating baths	(G) Azole polymer
P–04–0713	07/08/04	10/05/04	Forbo Adhesives, LLC	(G) Hot melt polyurethane adhesive	(G) Isocyanate functional polyester polyether urethane polymer
P–04–0714	07/08/04	10/05/04	CBI	(S) Disperse dye for textile	(G) Substituted propanenitrile
P–04–0715	07/08/04	10/05/04	CBI	(G) Polymeric coating vehicle	(G) Acrylic copolymer
P–04–0716	07/08/04	10/05/04	Degussa Corporation	(S) Mechanical rubber goods	(S) Silicia, [[(3-thiocyanatopropy-l)silylidyne]tris(oxy)]-modified
P–04–0717	07/08/04	10/05/04	CBI	(G) This material is frequently used in cleaning substrate in the semiconductor and flat panel industry; this material is particularly useful to give extremely clean surfaces of the substrate.	(G) Tetramethylammonium halo salt
P–04–0718	07/08/04	10/05/04	CBI	(G) Catalyst	(G) Substituted aryl sulfonium polyfluorophosphate salts
P–04–0719	07/09/04	10/06/04	CBI	(G) Coating resin, for open, non-dispersive use	(G) Aminosilane modified elastomer
P–04–0720	07/09/04	10/06/04	CBI	(G) Coating resin, for open, non-dispersive use	(G) Aminosilane modified elastomer
P–04–0722	07/09/04	10/06/04	CBI	(G) Nonwoven binder intermediate	(G) Acrylic polymer
P–04–0723	07/09/04	10/06/04	CBI	(G) Nonwoven binder	(G) Acrylic polymer
P–04–0724	07/09/04	10/06/04	CBI	(G) Nonwoven binder intermediate	(G) Acrylic polymer
P–04–0725	07/09/04	10/06/04	CBI	(G) Nonwoven binder	(G) Acrylic polymer
P–04–0726	07/09/04	10/06/04	CBI	(G) Nonwoven binder intermediate	(G) Acrylic polymer
P–04–0727	07/09/04	10/06/04	CBI	(G) Nonwoven binder	(G) Acrylic polymer

In Table II of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the Notices of Commencement to manufacture received:

II. 12 NOTICES OF COMMENCEMENT FROM: 06/28/04 TO 07/09/04

Case No.	Received Date	Commencement Notice End Date	Chemical
P–04–0052	07/02/04	06/17/04	(G) Cationic polyacrylamide
P–04–0079	06/28/04	05/26/04	(G) Halogen-substituted oxetane
P–04–0244	07/08/04	06/17/04	(S) Ethane, 2-bromo-1,1-difluoro-
P–04–0267	07/09/04	06/04/04	(G) Aromatic polyether polyester polyurethane
P–04–0340	07/06/04	06/21/04	(G) Polyoxyether salt
P–04–0384	07/08/04	06/26/04	(G) Aliphatic polyethertriamine
P–04–0400	07/01/04	06/28/04	(G) Styrene-butadiene copolymer latex
P–04–0401	07/01/04	06/28/04	(G) Styrene-butadiene copolymer latex

II. 12 NOTICES OF COMMENCEMENT FROM: 06/28/04 TO 07/09/04—Continued

Case No.	Received Date	Commencement Notice End Date	Chemical
P–04–0418	06/29/04	06/09/04	(G) Polysiloxane
P–04–0420	06/29/04	06/08/04	(G) Polysiloxane
P–04–0441	07/08/04	06/18/04	(G) Bisphenol A type epoxy resin salt
P–96–1006	06/30/04	06/16/04	(S) 1,3-dioxolane, 2-ethenyl-

List of Subjects

Environmental protection, Chemicals, Premanufacturer notices.

Dated: July 26, 2004.

Anthony Cheatham,

Acting Director, Information Management Division, Office of Pollution Prevention and Toxics.

[FR Doc. 04–17644 Filed 8–2–04; 8:45 am]

BILLING CODE 6560–50–S

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: Monday, August 9, 2004, at 11 a.m. The meeting will be held at Ex-Im Bank in Room 1143, 811 Vermont Avenue, NW., Washington, DC 20571.

OPEN AGENDA ITEM: New Product: Dealer Insurance Policy.

PUBLIC PARTICIPATION: The meeting will be open to public participation for Item No. 1 only.

FOR FURTHER INFORMATION CONTACT: For further information, contact: Office of the Secretary, 811 Vermont Avenue, NW., Washington, DC 20571 (Tele. No. 202–565–3957).

James K. Hess,

Senior Vice President and Chief Financial Officer.

[FR Doc. 04–17711 Filed 7–30–04; 9:55 am]

BILLING CODE 6690–01–M

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

July 27, 2004.

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, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid 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 control number. 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; and (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.

DATES: Written Paperwork Reduction (PRA) comments should be submitted on or before October 4, 2004. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all Paperwork Reduction Act (PRA) comments to Judith B. Herman, Federal Communications Commission, Room 1-C804, 445 12th Street, SW., Washington, DC 20554 or via the Internet to *Judith-B.Herman@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Judith B. Herman at 202–418–0214 or via the Internet at *Judith-B.Herman@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0819.

Title: Lifeline Assistance (Lifeline) Connection Assistance (Link-Up) Reporting Worksheet and Instructions, 47 CFR 54.400–54.417.

Form No.: FCC Form 497.

Type of Review: Revision of a currently approved collection.

Respondents: Individuals or household; business or other for-profit.

Number of Respondents: 1,318,000.

Estimated Time per Response: .08–3.5 hours.

Frequency of Response: On occasion, monthly, and annually reporting requirements; third party disclosure requirement.

Total Annual Burden: 186,080 hours.

Total Annual Cost: N/A.

Privacy Act Impact Assessment: No impact(s).

Needs and Uses: Eligible Telecommunications carriers are permitted to receive universal service support reimbursement for offering certain services to qualifying low-income customers. The telecommunications carriers must file FCC Form 497 to solicit reimbursement. The administrator uses the data to provide settlements for the low-income programs as required by FCC rules, 47 CFR Section 54.400–54.417. The Commission has issued a Report and Order and Further Notice of Proposed Rulemaking, In the Matter of Lifeline and Link-up, WC Docket Number 03–109, FCC 04–87 that modifies the Commission's rules to improve the effectiveness of the low-income support mechanism. Among other steps taken, the Report and Order requires collection of certain information to certify and subsequently verify that the beneficiary of low-income support is indeed qualified to receive the support.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 04–17676 Filed 8–2–04; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[CC Docket No. 96–45; DA 04–2067]

Parties Are Invited To Comment on Carolina West Wireless' Petition for Designation as an Eligible Telecommunications Carrier in the State of North Carolina

AGENCY: Federal Communications Commission.

ACTION: Notice; solicitation of comments.

SUMMARY: In this document, interested parties are invited to comment on a petition filed on June 8, 2004, by North Carolina RSA 3 Cellular Telephone Company d/b/a Carolina West Wireless (Carolina West), a provider of commercial mobile radio services (CMRS) seeking designation as an eligible telecommunications carrier (ETC) throughout its licensed service area in the State of North Carolina pursuant to section 214(e)(6) of the Communications Act of 1934, as amended (the Act).

DATES: Comments are due on or before August 13, 2004. Reply comments are due on or before August 27, 2004.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554. *See* **SUPPLEMENTARY INFORMATION** for further filing instructions.

FOR FURTHER INFORMATION CONTACT: Thomas Buckley, Attorney, Wireline Competition Bureau, Telecommunications Access Policy Division, (202) 418–7400, TTY (202) 418–0484.

SUPPLEMENTARY INFORMATION: This is a summary of public notice, CC Docket 96–45, DA 04–2067, released July 9, 2004. In this public notice, the Wireline Competition Bureau invites parties to comment on the petition filed on June 8, 2004, by North Carolina RSA 3 Cellular Telephone Company d/b/a Carolina West Wireless (Carolina West), a provider of commercial mobile radio services (CMRS) seeking designation as an eligible telecommunications carrier (ETC) throughout its licensed service area in the State of North Carolina pursuant to section 214(e)(6) of the Communications Act of 1934, as amended (the Act). In its petition, Carolina West also requests that the Commission redefine certain service areas of rural telephone companies pursuant to § 54.207 of the Commission's rules.

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments as follows: comments are due on or before August 13, 2004, and reply comments are due on or before August 27, 2004. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) of by filing paper copies. See *Electronic Filing of Documents in Rulemaking Proceedings*, 63 FR 24121, May 1, 1998. Parties should clearly specify in the caption of all filings the petition(s) to which the filing relates.

Comments filed through the ECFS can be sent as an electronic file via the Internet to *http://www.fcc.gov/e-file/ecfs.html*. Generally, only one copy of an electronic submission must be filed. If multiple docket or rulemaking numbers appear in the caption of this proceeding, however, commenters must transmit one electronic copy of the comments to each docket or rulemaking number referenced in the caption. In completing the transmittal screen, commenters should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions for e-mail comments, commenters should send an e-mail to *ecfs@fcc.gov*, and should include the following words in the body of the message, "get form <your e-mail address>." A sample form and directions will be sent in reply.

Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, commenters must submit two additional copies for each additional docket or rulemaking number. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). The Commission's contractor, Natek, Inc., will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class mail, Express Mail, and Priority Mail should be addressed to 445 12th Street, SW., Washington, DC 20554. All filings must be addressed to the Commission's Secretary, Marlene H. Dortch, Office of the Secretary, Federal Communications Commission.

Parties also must send three paper copies of their filing to Sheryl Todd, Telecommunications Access Policy Division, Wireline Competition Bureau, Federal Communications Commission, 445 12th Street SW., Room 5–B540, Washington, DC 20554. In addition, commenters must send diskette copies to the Commission's copy contractor, Best Copy and Printing, Inc. (BCPI), Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20054.

Pursuant to § 1.1206 of the Commission's rules, 47 CFR 1.1206, this proceeding will be conducted as a permit-but-disclose proceeding in which ex parte communications are permitted subject to disclosure.

Federal Communications Commission.

Anita Cheng,

Assistant Chief, Wireline Competition Bureau.

[FR Doc. 04–17546 Filed 8–2–04; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[CC Docket No. 92–237; DA 04–2339]

Next Meeting of the North American Numbering Council

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: On July 29, 2004, the Commission released a public notice announcing the September 14, 2004 meeting and agenda of the North American Numbering Council (NANC). The intended effect of this action is to make the public aware of the NANC's next meeting and its agenda.

DATES: Tuesday, September 14, 2004, 9:30 AM.

ADDRESSES: Telecommunications Access Policy Division, Wireline Competition Bureau, Federal Communications Commission, The Portals II, 445 12th Street, SW., Suite 5-A420, Washington, DC 20554. Requests to make an oral statement or provide written comments to the NANC should be sent to Deborah Blue.

FOR FURTHER INFORMATION CONTACT: Deborah Blue, Special Assistant to the Designated Federal Officer (DFO) at (202) 418–1466 or *Deborah.Blue@fcc.gov*. The fax number is: (202) 418–2345. The TTY number is: (202) 418–0484.

SUPPLEMENTARY INFORMATION: Released: July 29, 2004.

The North American Numbering Council (NANC) has scheduled a meeting to be held Tuesday, September 14, 2004, from 9:30 a.m. until 5 p.m. The meeting will be held at the Federal Communications Commission, Portals II, 445 12th Street, SW., Room TW–C305, Washington, DC. This meeting is open to members of the general public. The FCC will attempt to accommodate as many participants as possible. The public may submit written statements to

the NANC, which must be received two business days before the meeting. In addition, oral statements at the meeting by parties or entities not represented on the NANC will be permitted to the extent time permits. Such statements will be limited to five minutes in length by any one party or entity, and requests to make an oral statement must be received two business days before the meeting.

Proposed Agenda—Tuesday, September 14, 2004, 9:30 AM *

1. Announcements and Recent News
2. Approval of Minutes —Meeting of July 13, 2004
3. Report from NBANC and/or B&C Agent
4. Report of NAPM, LLC
5. Report of the North American Numbering Plan Administrator (NANPA)
6. Report of National Thousands Block Pooling Administrator
7. Status of Industry Numbering Committee (INC) activities
8. Reports from Issues Management Groups (IMGs)
9. Report of Local Number Portability Administration (LNPA) Working Group
10. Report of Numbering Oversight Working Group (NOWG)
11. Report of Cost Recovery Working Group
12. Special Presentations
13. Update List of NANC Accomplishments
14. Summary of Action Items
15. Public Comments and Participation (5 minutes per speaker)
16. Other Business

Adjourn no later than 5 p.m.

Next Meeting: Tuesday, November 9, 2004

* The Agenda may be modified at the discretion of the NANC Chairman with the approval of the DFO.

Federal Communications Commission.

Sanford S. Williams,

Attorney, Telecommunications Access Policy Division, Wireline Competition Bureau.

[FR Doc. 04–17675 Filed 8–2–04; 8:45 am]

BILLING CODE 6712–01–P

Federal Reserve System

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 12:00 p.m., Monday, August 9, 2004.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Director, Office of Board Members; 202–452–2955.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at *http://www.federalreserve.gov* for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Board of Governors of the Federal Reserve System, July 30, 2004.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 04–17766 Filed 7–30–04; 12:43 pm]

BILLING CODE 6210–01–S

GENERAL SERVICES ADMINISTRATION

[FMR Bulletin 2004–B2]

Federal Management Regulation; Redesignations of Federal Buildings

AGENCY: Public Buildings Service (P), GSA.

ACTION: Notice of a bulletin.

SUMMARY: The attached bulletin announces the redesignations of two Federal Buildings.

EFFECTIVE DATE: This bulletin expires December 21, 2004. However, the building redesignations announced by this bulletin will remain in effect until canceled or superseded.

FOR FURTHER INFORMATION CONTACT: Paul Chistolini, General Services Administration, Public Buildings Service (P), Washington, DC 20405; e-mail, *paul.chistolini@gsa.gov*, telephone (202) 501–1100.

Dated: July 23, 2004.

Stephen A. Perry,

Administrator of General Services.

GENERAL SERVICES ADMINISTRATION

[FMR Bulletin 2004–B2]

Federal Management Regulation; Redesignations of Federal Buildings

TO: Heads of Federal Agencies

SUBJECT: Redesignations of Federal Buildings

1. *What is the purpose of this bulletin?* This bulletin announces the redesignations of two Federal Buildings.

2. *When does this bulletin expire?* This bulletin expires December 21, 2004. However, the building redesignations announced by this bulletin will remain in effect until canceled or superseded.

3. *Redesignations.* The former and new names of the buildings being redesignated are as follows:

Former name	New name
Federal Building, United States Post Office and Courthouse, 911 Jackson Street, Oxford, MS 38655.	United States Courthouse, 911 Jackson Street, Oxford, MS 38655.
United States Post Office, 200 W. Broad Street, Statesville, NC 28677.	United States Courthouse, 200 W. Broad Street, Statesville, NC 28677.

4. *Who should we contact for further information regarding redesignations of these Federal Buildings?*

General Services Administration, Public Buildings Service, Office of the Commissioner, Attn: Paul Chistolini, 1800 F Street, NW., Washington, DC 20405, Telephone Number: (202) 501–1100, E-mail Address: *paul.chistolini@gsa.gov.*

[FR Doc. 04–17574 Filed 8–2–04; 8:45 am]

BILLING CODE 6820–23–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–04–0008]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, or to send comments contact Seleda Perryman, CDC Assistant

Reports Clearance Officer, 1600 Clifton Road, MS-E11, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Hazardous Substances Emergency Events Surveillance (0923–0008)—Extension—Agency for Toxic Substances and Disease Registry (ATSDR) is mandated pursuant to the 1980 Comprehensive Environmental Response Compensation and Liability Act (CERCLA) and its 1986 Amendments, the Superfund Amendments and Reauthorization Act (SARA), to prevent or mitigate adverse human health effects and diminished quality of life resulting from the exposure to hazardous substances into the environment. The primary purpose of this activity, which ATSDR has supported since 1992, is to develop, implement, and maintain a state-based surveillance system for hazardous substances emergency events which can be used to: (1) Describe the distribution of the hazardous substances releases; (2) describe the public health consequences (morbidity, mortality, and evacuations) associated with the events; (3) identify risk factors associated with the public health consequences; and (4) develop strategies to reduce future public health consequences. The study population will consist of all hazardous substance non-permitted acute releases within the 15 states (Colorado, Florida, Iowa, Louisiana, Michigan, Minnesota, Missouri, New Jersey, New York, North Carolina, Oregon, Texas, Utah, Washington, and Wisconsin) participating in the surveillance system.

Until this system was developed and implemented, there was no national public health-based surveillance system to coordinate the collation, analysis, and distribution of hazardous substances emergency release data to public health practitioners. It was necessary to establish this national surveillance system which describes the public health impact of hazardous substances emergencies on the health of the population of the United States. The data collection form will be completed by the state health department Hazardous Substances Emergency Events Surveillance (HSEES) coordinator using a variety of sources including written and oral reports from environmental protection agencies, police, firefighters, emergency response personnel; or researched by the HSEES coordinator using material safety data sheets, and chemical handbooks. There is a slight reduction in the average burden hours per response because of enhancements made to the data entry screens. The data entry program now automatically populates the fields for geographic coordinates, surrounding population data, and surrounding areas of interest.

Additionally, an HSEES public use data set will be made available on the ATSDR HSEES Web site. Interested parties will need to complete a brief description of who will be using the data and for what purpose to be able to download the data. This will allow ATSDR to widely distribute the data and track its usefulness. There are no costs to respondents.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Participating State Health Department HSEES Coordinators	15	600	40/60	6,000
Persons interested in HSEES data through Web site	500	1	6/60	50
Total				6,050

Dated: July 27, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–17614 Filed 8–2–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–04–0468]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, or to send comments contact Sandi Gambescia, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–E11, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Implementation of a Computer-Assisted Telephone Interview (CATI) System for the Pregnancy Risk Assessment Monitoring System (PRAMS)—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

CDC is proposing to contract for the development of a standard Computer-Assisted Telephone Interviewing (CATI) system those PRAMS states can use for collecting telephone interview data. PRAMS is part of the CDC initiative to reduce infant mortality and low birth

weight and promote safe motherhood, is a state-specific, population-based risk factor surveillance system of women who have recently delivered a live-born infant. PRAMS is designed to identify and monitor selected maternal experiences and behaviors that occur before and during pregnancy and during the child's early infancy. PRAMS is funded through cooperative agreements between CDC's Division of Reproductive Health (DRH) and participating state and local health departments. In 2004, 29 states and the city of New York are funded by CDC to conduct PRAMS.

A sample of women will be contacted by mail (with telephone follow-up for non-respondents). Approximately 15% of all interviews in each state are conducted by telephone. CDC provides funding for states interested in using CATI technology to develop CATI systems for the telephone interviews. Some states have developed their own CATI systems, while many continue to record telephone interviews on paper. The dual modes used and the variations in CATI systems developed by the states have created data management problems for PRAMS. CDC cleans and weights the state data and provides each state with an analysis dataset. The variations in data files have resulted in backlogs in providing analysis datasets to states. The proposed CATI system will collect telephone interview data in a similar manner and produce consistent file layout across all PRAMS states.

The new CATI system will also simplify the data collection process in the states. As each woman is interviewed by telephone, the interviewer will directly record her responses into the CATI system. For states still recording telephone interviews on paper, the CATI system will eliminate the extra step of keying the survey responses after the interview is completed. In addition, the CATI system will record operational information about successful call attempts which will assist states in contacting women more efficiently. For CDC, receiving telephone interview data in a standardized format will simplify the data cleaning process and allow for provision of analysis datasets to states in a timely manner. The total cost to respondents is $117,250.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)	Total burden hours
Funded PRAMS sites	30	335	35/60	5863
Total				5863

Dated: July 27, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–17616 Filed 8–2–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–04–0572]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, or to send comments contact Sandi Gambescia, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–E11, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

CDC and ATSDR Health Message Testing System Status—Revision—Office of the Director, Office of Communication (OD/OC), Centers for Disease Control and Prevention (CDC). The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; promotes healthy living through strong partnerships with local, national and international organizations, and enhances health decisions by providing credible information on critical health issues.

Members of the public and health practitioners at all levels require up-to-date, credible information about health and safety in order to make rational decisions. Such information affects the health and well-being of people across all stages of life by making our food supply safe, identifying harmful behaviors, and improving our environment.

CDC, and the Agency for Toxic Substances and Disease Registry (ATSDR), must fulfill their mission and mandate to frequently communicate urgent and sensitive health messages with the general public, members of the public with certain diseases or disabling conditions, and those at a greater risk of exposure to disease or injury causing agents. CDC/ATSDR makes this crucial health information available through many channels including books, periodicals, and monographs; internet web sites; health and safety guidelines: reports from investigations and emergency responses; public health monitoring and statistics; travel advisories; answers to public inquiries; and health education campaigns.

In addition to serving the public, CDC/ATSDR delivers health information that enables health providers to make critical decisions. For instance, the practicing medical and dental communities and the nation's health care providers are target audiences for numerous official CDC recommendations concerning the diagnosis and treatment of disease, immunization schedules, infection control, and clinical prevention practices. CDC/ATSDR offers technical assistance and training to health professionals as well.

In order to ensure that the public and other key audiences, like health care providers, understand the information, are motivated to take action, and are not offended or react negatively to the messages * * * it is critical to test messages and materials prior to their production and release. Currently, each CDC program developing health messages is required to submit its message development and testing activities for individual OMB review. Many CDC programs have extremely short deadlines for developing and producing health messages. Some deadlines are imposed by Congress, and others are necessitated by the time-sensitive nature of the work. Many programs cannot accommodate the time required for OMB approval, and therefore skip the message testing step altogether, or resort to testing specific portions of messages with 9 or fewer individuals. The science of health communication does not support these programmatic practices. In fact, these undesirable alternatives weaken CDC/ATSDR position as a research-based public health agency providing credible health information that people can count on and use.

CDC may achieve a greater level of efficacy if it can use three routine health message development and testing methods: (1) Central Location Intercept Interviews (i.e. "shopping mall" interviews); (2) Customer Satisfaction Phone Interviews; (3) Focus Groups; and (4) Web-enabled research. Virtually every Center, Institute, and Office (CIO) at CDC could achieve a higher level of confidence that health messages were understandable and would provoke no unintended consequences if they were empowered to use these methods efficiently. The CDC Office of Communication therefore requests approval for renewal of the Health Message Testing System that will conduct up to 64 message testing activities per year for each of three years. If all 64 testing activities are implemented, total respondent burden per year is estimated at 3200 hours.

Form of research activity	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden hours
Central Location Intercept Interviews	1600	1	30/60	800
Customer Satisfaction Phone Interviews	1200	1	30/60	600
Focus Groups	1200	1	30/60	600
Web-enabled Research	2400	1	30/60	1200
Total	6,400			3,200

Dated: July 27, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–17617 Filed 8–2–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–04–JN]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, or to send comments contact Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-E11, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Internet Survey on Household Drinking Water—New—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Drinking water in the United States comes from many different sources. A recent survey of the public's perceptions of water quality reports that 86% of adults have some concern about drinking water quality and more than half worry about possible contaminants in water (Water Quality Association, 2001 National Consumer Water Quality Survey). Public concern about drinking water quality has given rise to the increased use of bottled water, vended water, and water-treatment devices. In the past six years, use of home water-treatment systems rose 60% (Ibid.). Bottled water consumption has risen from 10.5 gallons per capita in 1993 to 22.6 gallons per capita in 2003, making bottled water the second largest commercial beverage category, accounting for $8.3 billion in sales for 2003 (Beverage Marketing Corporation, News Release, April 8, 2004). Many consumers believe that bottled water is "healthier" than tap water. However, the Food and Drug Administration, the agency responsible for regulating the quality of bottled water, reports that the relative safety of bottled vs. tap water remains under debate (FDA Consumer Magazine, July-August 2002).

The proposed internet survey is designed to obtain information about why the public is using water-treatment devices, bottled water, and vended water as alternatives to tap water. The survey asks both opinion and knowledge questions about the safety of each type of water, and requests information on the frequency and costs of using bottled water, vended water, and water-treatment devices.

The survey also contains knowledge and opinion questions about general water topics, including perceptions of the chemical and microbial quality of water and any health incidents participants have experienced associated with drinking various types of water. The survey will be posted on the CDC Website and recruitment will be sought through an announcement on

the Web site inviting visitors to complete the survey. We anticipate that survey participants will come from all regions of the United States. No personal identifiers are requested as part of the survey, and respondents will be neither compensated nor charged for responding.

ANNUALIZED BURDEN TABLE

Respondents	No. of respondents	No. of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
CDC Web Site Visitors	3,000	1	20/60	1,000
Total	3,000			1,000

Dated: July 27, 2004,

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–17618 Filed 8–2–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–04–JT]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498–1210. CDC is requesting an emergency clearance for this data collection with a two week public comment period. CDC is requesting OMB approval of this package 7 days after the end of the public comment period.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Seleda M. Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*. Written comments should be received within 14 days of this notice.

Proposed Project

Passenger Locator Card—New—National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC).

The Secretary of the U.S. Department of Health and Human Services (DHHS) has statutory responsibility for preventing the introduction, transmission, and spread of communicable diseases from foreign countries into the United States, *e.g.*, at international ports of entry, and from one state or possession into another. Under its delegated authority by DHHS, the Division of Global Migration and Quarantine of the Centers for Disease Control and Prevention (CDC) is empowered to detain, medically examine, or conditionally release individuals suspected of carrying a communicable disease. Under foreign quarantine regulations, the master of a ship or captain of an airplane entering the United States from a foreign port is required by public health law to report certain illnesses among passengers (42 CFR 71.21). CDC has the authority to collect personal health information to protect the health of the public under the authority of Section 301 of the Public Health Service Act (42 U.S.C. 241).

People exposed to communicable diseases of public health importance while traveling on a conveyance should be notified as quickly as possible by public health authorities so they can be made aware of (1) their exposure, (2) told what to do if they become symptomatic, and (3) be medically monitored for a period after exposure, or given preventive treatment if indicated and readily available. In order to do this, emergency contact information is needed for all persons (passengers and crew) who traveled on the conveyance.

Presently, there are two circumstances that passenger locator information would be collected: (1) When a passenger is reported with signs and symptoms of a communicable illness; and, (2) In the event of a global disease outbreak. During the severe acute respiratory syndrome (SARS) outbreak in 2003, it was evident that current methods of using paper copies of airline manifests and customs information were inadequate to notify passengers potentially exposed to SARS within the incubation period (10 days). Airline manifests and custom declarations do not contain reliable emergency contact information. Manifests contain only the name and the seat number. Custom declarations are written by passengers and are often illegible or not complete. Names on the custom declarations do not necessarily match those on the manifests, phone numbers are not included, and only one custom declaration is filled out per family. The locating information maybe fairly complete; however, the person may no longer be at that address (*e.g.*, temporary lodging).

Passengers on domestic flights do not complete custom declaration, therefore no reliable system exist to obtain emergency contact information for passengers on domestic conveyances. The estimated time to locate passengers using the current system is one month.

An emergency clearance is being requested because CDC has developed an airline passenger locator card to obtain the necessary information needed to notify passengers who may have been exposed to a communicable disease. Because of today's uncertainties, we are requesting OMB to grant approval most expeditiously.

Completing the passenger locator card and furnishing the requested information is voluntary; however, in order to prevent the spread of a disease, more complete information allows important public health functions such as adequate monitoring and follow-up of

significant health events to be performed. To prevent the spread of communicable diseases, identifiable information may be shared with authorized DHHS personnel and public health or cooperating medical authorities. In addition to collecting detailed locator information, the passenger locator card can be scanned, which will increase the speed as well as accuracy of data collection and should allow for more timely notification of passengers when necessary. This package will be included in the next extension of the Foreign Quarantine Regulations (42 CFR Part 71) OMB No. 0920–0134. There are no costs to the respondents.

ANNUALIZED BURDEN TABLE

Type of notification	Number of respondents	Number of responses/respondent	Average burden/response (in hours)	Total burden hours
Outbreak of public health significance	2,700,000	1	5/60	225,000
Ill passenger	800	1	5/60	67
Total				225,067

Dated: July 27, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–17619 Filed 8–2–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–04–JU]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, or to send comments contact Sandi Gambescia, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–E11, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Factors Impacting Effective Removal of Arsenic by Household Water Purification Systems—New—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Epidemiologic evidence strongly links ingestion of water containing inorganic arsenic with an increase in bladder cancer and other cancers. In Maine, approximately 10% of private domestic wells have arsenic concentrations greater than Maine's health standard for water of 10 µg/L. In wells with high arsenic concentrations, ingestion of water can be the dominant source of arsenic exposure. The preferred method for treating domestic well water containing elevated levels of arsenic is point-of-use water-treatment devices.

The purpose of the proposed study is to evaluate how the efficacy of water-treatment devices is affected by user behaviors such as maintenance and selection of appropriate technologies, and by variations in water chemistry. This study will focus on 100 households recruited on the basis of their geographic location in areas of Maine that have high concentrations of arsenic in groundwater. The study will have a cross-sectional component and a temporal component. For the cross-sectional component, total arsenic, inorganic arsenic species, and selected geochemical constituents will be quantified in the influent and effluent of filtration devices treating these 100 domestic well-water supplies. The study team will administer questionnaires to each participating household to collect data on the type of treatment unit used, routine operation parameters, and suggested and actual maintenance schedules. For the 3-year temporal component of the study, the study team will test the influent and effluent of the treatment units of 45 participating households for total arsenic once each year. The percentage of arsenic removed by the filter will be compared to the study criterion selected to indicate that a filter is failing. If the arsenic removal level indicates that a treatment unit meets criterion for failure, treatment unit influent and effluent water will be analyzed for inorganic arsenic species and geochemical constituents to determine whether the chemistry of the water has changed sufficiently to explain the failure.

A follow-up questionnaire will be administered biannually and at the time of a system failure to determine when the unit was last maintained and if operation and maintenance have changed. CDC/NCEH will request a 3-year clearance. There is no cost to respondents.

ANNUALIZED BURDEN TABLE

Respondents	Number of respondents	Number of responses/respondent	Avg. burden/response (in hrs)	Total burden hours
Initial recruiting postcard completion	34	1	5/60	3
Initial interview	34	1	30/60	17

ANNUALIZED BURDEN TABLE—Continued

Respondents	Number of respondents	Number of responses/respondent	Avg. burden/response (in hrs)	Total burden hours
Biannual follow-up interview	45	2	25/60	38
System failure follow-up interview	4	1	25/60	2
Total				60

Dated: July 27, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–17620 Filed 8–2–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices Advisory Committee (HICPAC)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Healthcare Infection Control Practices Advisory Committee: Conference Call Meeting.

Time and Date: 1 p.m.–3 p.m., August 17, 2004.

Place: The conference call will originate at the Division of Healthcare Quality Promotion (DHQP), in Atlanta, Georgia. Please see **SUPPLEMENTARY INFORMATION** for details on accessing the conference call.

Status: Open to the public, limited only by the availability of telephone ports.

Purpose: The Committee is charged with providing advice and guidance to the Secretary; the Assistant Secretary for Health; the Director, CDC; and the Director, National Center for Infectious Diseases (NCID), regarding (1) the practice of hospital infection control; (2) strategies for surveillance, prevention, and control of infections (*e.g.*, nosocomial infections), antimicrobial resistance, and related events in settings where healthcare is provided; and (3) periodic updating of guidelines and other policy statements regarding prevention of healthcare-Associated infections and healthcare-related conditions.

Matters to be Discussed: The Healthcare Infection Control Practices Advisory Committee will convene by conference call to discuss the draft Guidance Document on Public Reporting of Healthcare-Associated Infection Rates.

Supplementary Information: This conference call is scheduled to begin at 1 p.m., eastern time. To participate in the conference call, please dial 1–877–675–5901 and enter Pass Code 254137. You will then be automatically connected to the call.

For Further Information Contact: Harriette Lynch, Committee Management Specialist, HICPAC, DHQP, NCID, CDC, 1600 Clifton Road, NE., M/S A–07, Atlanta, Georgia 30333, telephone 404/498–1182, fax 404/498–1188.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 27, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–17621 Filed 8–2–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval of Vermont State Plan Amendment (SPA) 03–015a

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing to be held on August 25, 2004, at 10 a.m., JFK Federal Building, Room 2325, Boston, Massachusetts 02203–0003, to reconsider our decision to disapprove Vermont State Plan Amendment (SPA) 03–015a.

DATES: Requests to participate in the hearing as a party must be received by the presiding officer by August 18, 2004.

FOR FURTHER INFORMATION CONTACT: Kathleen Scully-Hayes, Presiding Officer, CMS, Lord Baltimore Drive, Mail Stop LB–23–20, Baltimore, Maryland 21244. Telephone: (410) 786–2055.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider our decision to disapprove Vermont State Plan Amendment (SPA) 03–015a, which Vermont submitted to the Centers for Medicare & Medicaid Services (CMS) on September 30, 2003. In SPA 03–15a, Vermont proposes to establish State-only Medicaid supplemental rebate agreements under which pharmaceutical manufacturers would pay supplemental rebates to the State based on Medicaid utilization in the State, for the period from October 1, 2002, through June 30, 2003. The level of the supplemental rebates would also be based on a "multi-state pooling" arrangement to take into account aggregate utilization levels among several participating states. The Centers for Medicare & Medicaid Services (CMS) reviewed this proposal and determined it was unable to approve SPA 03–015a for the reasons set forth below.

At issue is whether the requested effective date of October 1, 2002, is consistent with statutory and regulatory requirements. States receiving Federal Medicaid funding must have approved state plans that describe the nature and scope of the state Medicaid program and must fulfill the requirements for approval set forth in section 1902(a) of the Social Security Act (the Act) and pertinent regulations as set forth in 42 CFR 430.15(a). Federal regulations at 42 CFR 430.20(b) provide that the rules of 42 CFR 447.256 apply with respect to the effective date of a plan amendment that changes the state's payment methods and standards. Federal regulations at 42 CFR 447.256 provide that the effective date of such amendments may not be earlier than the first day of the calendar quarter in which an approvable plan is submitted.

CMS concluded that the change proposed by Vermont amounted to a change in the State's payment methods and standards, and that the earliest approvable effective date would be the first day of the calendar quarter in which the SPA was submitted, or July 1, 2003. In a separate action, CMS approved SPA 03–15b, which authorized State-only Medicaid supplemental rebate agreements and participation in a multi-state pooling arrangement effective July 1, 2003.

In addition, section 1902(a)(19) of the Act requires that care and services under the plan be provided in a manner

consistent with simplicity of administration and the best interests of recipients. CMS was concerned that approval of a retroactive effective date could, in some circumstances, adversely impact beneficiary access and would be inconsistent with these provisions.

Based on the above, and after consultation with the Secretary of the Department of Health and Human Services as required under Federal regulations at 42 CFR 430.15(c)(2), CMS disapproved Vermont SPA 03–015a.

Section 1116 of the Act and 42 CFR part 430 establish Departmental procedures that provide an administrative hearing for reconsideration of a disapproval of a state plan or plan amendment. CMS is required to publish a copy of the notice to a state Medicaid agency that informs the agency of the time and place of the hearing and the issues to be considered. If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as *amicus curiae* must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

The notice to Vermont announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Mr. Charles P. Smith, Secretary, Vermont Agency of Human Services 103 South Main Street, Waterbury, VT 05671–0204.

Dear Mr. Smith: I am responding to your request for reconsideration of the decision to disapprove Vermont State Plan Amendment (SPA) 03–015a, which Vermont submitted on September 30, 2003. In SPA 03–15a, Vermont proposes to establish State-only Medicaid supplemental rebate agreements under which pharmaceutical manufacturers would pay supplemental rebates to the State based on Medicaid utilization in the State, for the period from October 1, 2002, through June 30, 2003. The level of the supplemental rebates would also be based on a "multi-state pooling" arrangement to take into account aggregate utilization levels among several participating states. The Centers for Medicare & Medicaid Services (CMS) reviewed this proposal and was unable to approve SPA 03–015a for the reasons set forth below.

At issue is whether the requested effective date of October 1, 2002, is consistent with statutory and regulatory requirements. States receiving Federal Medicaid funding must have approved state plans that describe the nature and scope of the state Medicaid program and must fulfill the requirements for approval as set forth in section 1902(a) of the Social Security Act (the Act) and pertinent regulations as set forth in 42 CFR 430.15(a). Federal regulations at 42 CFR 430.20(b) provide that the rules of 42 CFR 447.256 apply with respect to the effective date of a plan amendment that changes the state's payment methods and standards. Federal regulations at 42 CFR 447.256 provide that the effective date of such amendments may not be earlier than the first day of the calendar quarter in which an approvable plan is submitted.

CMS concluded that the change proposed by Vermont amounted to a change in the State's payment methods and standards, and that the earliest approvable effective date would be the first day of the calendar quarter in which the SPA was submitted, or July 1, 2003. In a separate action, CMS approved SPA 03–15b, which authorized State-only Medicaid supplemental rebate agreements and participation in a multi-state pooling arrangement effective July 1, 2003.

In addition, section 1902(a)(19) of the Act requires that care and services under the plan be provided in a manner consistent with simplicity of administration and the best interests of recipients. CMS was concerned that approval of a retroactive effective date could, in some circumstances, adversely impact beneficiary access and would be inconsistent with these provisions.

Based on the above, and after consultation with the Secretary of the Department of Health and Human Services as required under Federal regulations at 42 CFR 430.15(c)(2), CMS disapproved Vermont SPA 03–015a.

I am scheduling a hearing to be held on August 25, 2004, at 10:00 a.m., JFK Federal Building, Room 2325, Boston, Massachusetts 02203–0003, to reconsider our decision to disapprove Vermont SPA 03–015a.

If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed at 42 CFR Part 430.

I am designating Ms. Kathleen Scully-Hayes as the presiding officer. If these arrangements present any problems, please contact the presiding officer. In order to facilitate any communication that may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing. The presiding officer may be reached at (410) 786–2055.

Sincerely,

Mark B. McClellan, M.D., Ph.D.

Section 1116 of the Social Security Act (42 U.S.C. section 1316); 42 CFR Section 430.18.

(Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program.)

Dated: July 21, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 04–17578 Filed 8–2–04; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Administration for Children and Families

Office of Child Support Enforcement

Privacy Act of 1974; Amended System of Records

AGENCY: Office of Child Support Enforcement, ACF, HHS.

ACTION: Notice of amended system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974 (5 U.S.C. 552a), the Office of Child Support Enforcement (OCSE) is publishing a notice of its amendment of its system of records, 09–80–0202, entitled "Federal Case Registry of Child Support Orders."

DATES: HHS invites interested parties to submit comments on the proposed notice until September 2, 2004. As required by the Privacy Act (5 U.S.C. 552a(r)), HHS on July 23, 2004 sent a report of an Amended System of Records to the Committee on Government Reform and Oversight of the House of Representatives, the Committee on Governmental Affairs of the Senate, and the Office of Management and Budget. The amendments described in this notice are effective upon publication unless HHS receives comments that would result in a contrary determination.

ADDRESSES: Please address comments to: Donna Bonar, Associate Commissioner, Office of Automation and Program Operations, Office of Child Support Enforcement, Administration for Children and Families, 370 L'Enfant Promenade, SW., 2nd Floor West, Washington, DC 20447, (202) 401–9271.

Comments received will be available for inspection at the address specified above from 9 a.m. to 5 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Donna Bonar, Associate Commissioner, Office of Automation and Program Operations, Office of Child Support Enforcement, Administration for Children and Families, 370 L'Enfant Promenade, SW., 2nd Floor West, Washington, DC 20447, (202) 401–9271.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Child Support Enforcement (OCSE) is amending one of its Systems of Records, "Federal Case Registry of Child Support Orders" (FCR). DHHS/OCSE No. 09–80–0202, last published at 63 FR 45070 on August 24, 1998.

Consistent with sections 453(e) of the Social Security Act (the Act), for the purpose of establishing parentage, setting the amount of, modifying or enforcing child support obligations, information in the FCR pertaining to an individual who is under an obligation to pay child support, against whom such an obligation is sought or to whom such an obligation is owed may be matched against information held by any of the departments, agencies, or instrumentalities of the United States or of any State to obtain and transmit to an authorized person information on, or facilitating the discovery of, the location of the individual, the individual's wages (or other income) from, and benefits of, employment (including rights to or enrollment in group health care coverage) and information on the type, status, location, and amount of any assets of, or debts owed by or to, any such individual. If any information is obtained the disclosure of which would contravene national policy or security interests of the United States or the confidentiality of census data, such information shall not be transmitted by the department, agency or instrumentality.

The complete system notice is republished below.

Dated: July 27, 2004.

Sherri Z. Heller,

Commissioner.

09–80–0202

SYSTEM NAME:

Federal Case Registry of Child Support Orders (FCR), HHS, OCSE.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Office of Child Support Enforcement, 370 L'Enfant Promenade, SW., 2nd Floor, Washington, DC 20447; Social Security Administration, 6200 Security Boulevard, Baltimore, Maryland 21235.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Records are maintained with respect to all cases or orders submitted by States to the Federal Case Registry. The cases and orders which States submit to the FCR include each case in which services are being provided by the State under the State plan approved pursuant to Title IV–D of the Act, and each support order established or modified in the State on or after October 1, 1998.

CATEGORIES OF RECORDS IN THE SYSTEM:

The FCR system of records includes records that contain the following information: Names (including alternative names); social security numbers (including alternative numbers); birth dates; participant type (custodial party, noncustodial parent, putative father, child); sex; case type (IV–D, non-IV–D); indication of an order; family violence indicator (domestic violence or child abuse); locate request type (reason for locate); locate source (source which State wishes to check for data); State Federal Information Processing Standard code; county code; State case identification number; and State member identification number.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Sections 452 and 453 of the Social Security Act (42 U.S.C. 652 and 653) require the Secretary of HHS to establish and conduct the Federal Parent Locator Service, a computerized national location network which provides location and asset information, including addresses and social security numbers, to State and local CSE agencies.

PURPOSE(S):

The primary purpose of the FCR is to improve States' abilities to locate parents and collect child support. The FCR consists of State case registry information, and contains abstracts of case and order information with respect to each case and order in each State Case Registry. At least every two business days, the FCR is matched against the National Directory of New Hires (NDNH), another component of the Federal Parent Locator Service, to determine if a newly hired employee included in the NDNH is a participant in a child support case anywhere in the country. Within two business days after a comparison reveals a match with respect to an individual, the Service reports the match as well as the information regarding the individual's current employment and other pertinent information to the State agency or agencies responsible for the case. The Service also alerts States when other States have registered the same individuals on the FCR.

The system of records includes a Family Violence (FV) indicator in the FCR to prevent disclosure of the records of any person a State associates with FV. When a State notifies the FCR that there is reasonable evidence of domestic violence or child abuse, and that disclosure could be harmful to the party or the child, the FCR does not disclose any information from the records. In this instance, the FCR returns a notice indicating that "Disclosure is Prohibited." A FV designation can only be removed by the State that placed the designation, and the designation may be placed by more than one State on the same person. However, information from the records containing a FV designation may be disclosed by court order pursuant to section 453(b)(2)(B) of the Act (42 U.S.C. 653(b)(2)(B)).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

The routine uses for this system are compatible with the stated purpose of the system. Information from the Federal Case Registry may be disclosed to the following entities: (1) Under section 453(c)(1) of the Act (42 U.S.C. 653(c)(1)), to agents and attorney of a State which has in effect an approved plan under Title IV–D of the Act who have duty or authority to collect child and spousal support; (2) Under section 453(c)(2) of the Act (42 U.S.C 653(c)(2)), to a Court or its agent which has authority to issue an order against a noncustodial parent for child support or to serve as the initiating court in an action to seek a child support order against a noncustodial parent; (3) Under section 453(c)(3) of the Act (42 U.S.C. 653(c)(3)), to a resident parent, legal guardian, or attorney or agent of a child not receiving TANF benefits; (4) Under section 453(c)(4) of the Act (42 U.S.C. 653(c)(4)), to a State agency administering a child welfare program operated under a State plan pursuant to subchapter 1 of Title IV–B of the Act or a State plan pursuant to subchapter 2 of Title IV–B of the Act, or to a State agency that is administering a program operated under a State plan pursuant to Title IV–E of the Act; (5) Under section 653(j)(1)(B) of the Act (42 U.S.C. 653(j)(1)(B)), to the Social Security Administration for verification of name, social security number, and birth dates; and employer identification number; (6) Under section 453(j)(2)(B) of the Act (42 U.S.C. 653(j)(2)(B)), to State agencies responsible for paternity establishment or child support cases; (7) Under section 453(j)(3)(B) of the Act (42 U.S.C 653(j)(3)(B)), to State agencies for the purpose of assisting States to carry out their responsibilities under programs operated under Title IV–D and IV–A of the Act; (8) Under section 463(d)(2)(A) of the Act (42 U.S.C. 663(d)(2)(A)), to

agents or attorneys of States who have the duty or authority to enforce child custody or visitation determinations; (9) Under section 463(d)(2)(B) of the Act (42 U.S.C. 663(d)(2)(B)), to a Court or its agent with the jurisdiction to make or enforce a child custody or visitation determination; (10) Under section 463(d)(2)(C) of the Act (42 U.S.C. 663(d)(2)(C)), to agents or attorney of the U.S. or of a State who have the authority or duty to investigate, enforce, or prosecute the unlawful taking or restraint of a child; (11) Under section 463(e) of the Act (42 U.S.C. 663(e)), to the U.S. Central Authority for the purpose of locating any parent or child on behalf of an applicant to the Central Authority; (12) Pursuant to Public Law 105–34, Title X, sections 1090(a)(2) and (4), to the Secretary of Treasury for the purpose of administering sections of Title 26 which grant tax benefits based on support or residence of children; (13) Where permitted by law, to researchers for the purpose of conducting research consistent with the pertinent statutory authority; and (14) Under section 453(e) to any of the departments, agencies, or instrumentalities of the United States or of any State for the purpose of locating information on the individual's wages (or other income) from, and benefits of, employment (including rights to or enrollment in group health care coverage) and information on the type, status, location, and amount of any assets of, or debts owed by or to, any such individual.

DISCLOSURES TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

The Secretary of Health and Human Services houses the FCR in the Social Security Administration's National Computer Center in Baltimore, Maryland. A Direct Access Storage Data (DASD) unit is used for storage. FCR records are maintained on disc and computer tape, and hard copy.

RETRIEVABILITY:

System records can be accessed by either an assigned case identification number or Social Security Number.

SAFEGUARDS:

1. Authorized Users: Data stored on computer files are accessed by passwords known only to persons who are responsible for implementing the FCR. Access to information in the FCR system is limited to approved users whose official duties require access to this information.

2. Physical Safeguards: Rooms where records are stored will be locked when not in use. During regular business hours rooms will be unlocked but controlled by on-site personnel.

3. Procedural and Technical Safeguards: A password is required to access the terminal and a data set name restricts the release of the data to only approved users. All users of the FCR system are required to have in effect safeguards, applicable to all confidential information that are designed to protect the privacy rights of the parties; they must also have safeguards against any unapproved use or disclosure of information contained in the FCR.

RETENTION AND DISPOSAL:

(1) Records pertaining to a child are deleted from the FCR when a State dissociates the last custodial parent, non-custodial parent, or putative father from the case or order, and no child included in the case or order is associated with any other FCR case or order; (2) Records containing a Family Violence Indicator are removed from the FCR when the State that initiated the indicator requests that the record be removed from the FCR or when the State closes the last case or order including the person connected to an indicator; (3) Records of information provided by the FCR to authorized persons are maintained only long enough to communicate the information to the appropriate State or Federal agent. Thereafter, the information provided will be destroyed; (4) Records pertaining to disclosures (including information provided by States, Federal agencies contacted, and an indication of the type(s) of information returned), are stored on a history tape and in hard copy for two years and then destroyed; and (5) Any record relating or potentially relating to a fraud or abuse investigation or a pending or ongoing legal action including a class action, is retained until conclusion of the investigation or legal action. This exception will protect information relevant to a pending case from being prematurely destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Automation and Program Operations, Office of Child Support Enforcement, Administration for Children and Families, 370 L'Enfant Promenade, SW., 2nd Floor West, Washington, DC 20447.

NOTIFICATION PROCEDURES:

To determine if a record exists, write to the System Manager listed above. The requester must provide his or her full name and address. Additional information, such as Social Security Number, date of birth or mother's maiden name, may be requested by the system manager in order to distinguish between individuals having the same or similar names.

RECORD ACCESS PROCEDURES:

Individuals may have access to their records by making a written request, addressed to the System Manager specified above. The envelope containing the written request must be marked "Privacy Act Request" or "Freedom of Information Act Request" or both, in the bottom left-hand corner. The letter requesting access to FCR records must state the following: (1) That the request is being made under the Privacy Act; Freedom of Information Act, or both, (2) the name, address, and signature of the requester; and (3) a detailed description of the record contents they are seeking.

CONTESTING RECORD PROCEDURE:

Individuals may request an amendment of a record which is not accurate, relevant, timely, or complete by writing to the System Manager at the address specified above. The envelope containing the written request must be marked "Privacy Act Amendment Request" or "Freedom of Information Act Request" or both, in the bottom left-hand corner. The letter requesting an amendment to FCR records must state the following: (1) That the request to amend the record is being made under the Privacy Act; Freedom of Information Act, or both, (2) the individual's name, address, and signature; (3) a description of the contested information; (4) the reason why the information should be amended; and (5) documentation to show that the information is inaccurate, irrelevant, untimely, or incomplete. Individuals who are contesting records must also be able to prove their identity.

RECORD SOURCE CATEGORIES:

Information is obtained from departments, agencies, or instrumentalities of the United States or any State.

SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 04–17486 Filed 8–2–04; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Tylosin Tartrate for Foulbrood in Honeybees; Availability of Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of effectiveness, target animal safety, human food safety, and environmental safety data that may be used in support of a new animal drug application (NADA) or supplemental NADA for use of tylosin tartrate for the control of American foulbrood (*Paenibacillus larvae*) in honeybees. The data, contained in Public Master File (PMF) 5783, were compiled under National Research Support Project 7 (NRSP–7), a national agricultural research program for obtaining clearances for use of new drugs in minor animal species and for minor uses.

ADDRESSES: Submit NADAs or supplemental NADAs to the Document Control Unit (HFV–199), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *jgotthar@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Tylosin tartrate soluble powder used for the control of American foulbrood (*P. larvae*) in honeybees is a new animal drug under section 201(v) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(v)). As a new animal drug, tylosin tartrate is subject to section 512 of the act (21 U.S.C. 360b) , requiring that its uses be the subject of an approved NADA or supplemental NADA. Honeybees are a minor species under § 514.1(d)(1)(ii) (21 CFR 514.1(d)(1)(ii)).

The NRSP–7 Project, western region, University of California, Davis, CA 95616, has provided target animal safety, effectiveness, human food safety, and environmental safety data for use of tylosin tartrate soluble powder for the control of American foulbrood in honeybees. These data, contained in PMF 5783, were reviewed by FDA and found satisfactory to support those aspects of an original or supplemental NADA.

Sponsors of NADAs or supplemental NADAs may, without further authorization, reference the PMF 5783 to support approval of an application filed under § 514.1(d). An NADA or supplemental NADA must include, in addition to reference to the PMF, animal drug labeling and other information needed for approval, such as: Data supporting extrapolation from a major species in which the drug is currently approved or authorized reference to such data; and data concerning manufacturing methods, facilities, and controls. Persons desiring more information concerning PMF 5783 or requirements for approval of an NADA or supplement may contact Joan C. Gotthardt (see **FOR FURTHER INFORMATION CONTACT**).

Dated: July 27, 2004.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 04–17628 Filed 8–2–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0283]

Draft Guidance for Industry: Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles; 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 (#171) entitled "Waivers of *In Vivo* Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles." This draft guidance describes the procedures that the agency recommends for the review of requests for waiver of in vivo demonstration of bioequivalence for generic soluble powder oral dosage form products and Type A medicated articles.

DATES: Submit written or electronic comments on the draft guidance by October 18, 2004, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time. Written comments on the information collection provisions must be received by October 4, 2004.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. 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 written comments on the draft guidance and collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft guidance and collection of information to *http://www.fda.gov/dockets/ecomments.* Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Technical issues: Marilyn Martinez, Center for Veterinary Medicine (HFV- 130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7577, e-mail: *mmartin1@cvm.fda.gov.*

Administrative issues: Lonnie Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Center for Veterinary Medicine (CVM) has written this guidance to address a perceived need for agency guidance in its work with the animal health industry. This draft guidance describes the procedures that the agency recommends for the review of requests for waiver of in vivo demonstration of bioequivalence for generic soluble powder oral dosage form products and Type A medicated articles. As CVM develops policies on waivers involving other categories of animal drugs, it will issue additional guidance.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 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 OMB for approval. To comply with this requirement, FDA is publishing a 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.

Title: Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles

Description: The Generic Animal Drug and Patent Term Registration Act (GADPTRA) of 1988 permitted generic drug manufacturers to copy those pioneer drug products that were no longer subject to patent or other marketing exclusivity protection. The approval for marketing these generic products is based, in part, upon a demonstration of bioequivalence between the generic product and pioneer product. This guidance clarifies circumstances under which FDA believes the demonstration of bioequivalence required by the statute does not need to be established on the basis of in vivo studies for soluble powder oral dosage form products and Type A medicated articles. The data submitted in support of the waiver request are necessary to validate the waiver decision.

The requirement to establish bioequivalence through in vivo studies (blood level bioequivalence or clinical endpoint bioequivalence) may be waived for soluble powder oral dosage form products or Type A medicated articles in either of two alternative ways. A biowaiver may be granted if it can be shown that the generic soluble powder oral dosage form product or Type A medicated article contains the same active and inactive ingredient(s) and is produced using the same manufacturing processes as the approved comparator product or article. Alternatively, a biowaiver may be granted without direct comparison to the pioneer product's formulation and manufacturing process if it can be shown that the active pharmaceutical ingredient(s) (API) is the same as the pioneer product, is soluble, and that there are no ingredients in the formulation likely to cause adverse pharmacologic effects. For the purpose of evaluating soluble powder oral dosage form products and Type A medicated articles, solubility can be demonstrated in one of two ways: "USP definition" approach or "Dosage adjusted" approach.

The respondents for this collection of information are pharmaceutical companies manufacturing animal drugs. FDA estimates the burden for this collection of information as follows in tables 1 and 2 of this document. The source of the above data is records of generic drug applications over the past 10 years.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR WATER SOLUBLE POWDERS[1]

	No. of Respondents	Annual Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
Same formulation/ manufacturing process approach	1	1	1	5	5
Same API/ solubility approach	5	5	5	10	50
Total Burden Hours					55

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR TYPE A MEDICATED ARTICLES[1]

	No. of Respondents	Annual Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
Same formulation/ manufacturing process approach	2	2	2	5	10
Same API/ solubility approach	10	10	10	20	200

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR TYPE A MEDICATED ARTICLES[1]—Continued

	No. of Respondents	Annual Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
Total Burden Hours					210

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Significance of Guidance

This draft level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the agency's current thinking on the 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 alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this draft guidance document. Two paper copies of any comments are to be submitted, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Copies of the draft guidance document entitled "Waivers of *In Vivo* Demonstration of Bioequivalence of Certain Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles" may be obtained from the CVM home page at *http://www.fda.gov/cvm* and from the Division of Dockets Management Web site *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: July 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–17627 Filed 8–2–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Voluntary Customer Satisfaction Surveys to Implement Executive order 12862 in the Substance Abuse and Mental Health Services Administration (SAMHSA)—OMB No. 0930–0197; Extension)—Executive Order 12862 directs agencies that "provide significant services directly to the public" to "survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services." SAMHSA provides significant services directly to the public, including treatment providers and State substance abuse and mental health agencies, through a range of mechanisms, including publications, training, meetings, technical assistance and web sites. Many of these services are focused on information dissemination activities. The purpose of this submission is to extend the existing generic approval for such surveys.

The primary use for information gathered is to identify strengths and weaknesses in current service provisions by SAMHSA and to make improvements that are practical and feasible. Several of the customer satisfaction surveys expected to be implemented under this approval will provide data for measurement of program effectiveness under the Government Performance and Results Act (GPRA). Information from these customer surveys will be used to plan and redirect resources and efforts to improve or maintain a high quality of service to health care providers and members of the public. Focus groups may be used to develop the survey questionnaire in some instances.

The estimated annual hour burden is as follows:

Type of data collection	Number of respondents	Responses/respondent	Hours/response	Total hours
Focus groups	150	1	2.50	375
Self-administered, mail, telephone and e-mail surveys	16,000	1	.33	5,280
Total	16,150			5,655

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16–105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received by October 4, 2004.

Dated: July 27, 2004.

Anna Marsh,

Executive Officer, SAMHSA.

[FR Doc. 04–17665 Filed 8–2–04; 8:45 am]

BILLING CODE 4162–20–M

DEPARTMENT OF HOMELAND SECURITY

Border and Transportation Security; Notice to Aliens Included in the United States Visitor and Immigrant Status Indicator Technology System (US–VISIT)

AGENCY: Border and Transportation Security Directorate, DHS.

ACTION: Notice.

SUMMARY: The Department of Homeland Security (DHS) has established the United States Visitor and Immigrant Status Indicator Technology Program (US–VISIT), an integrated, automated entry-exit system that records the arrival and departure of aliens; verifies aliens' identities; and authenticates aliens' travel documents through comparison of biometric identifiers. On January 5, 2004, DHS implemented the first phase of US–VISIT by publishing an interim final rule in the **Federal Register** at 69 FR 468 authorizing DHS to require certain aliens to provide fingerprints, photographs, or other biometric identifiers upon arrival in or departure from the United States at air and sea ports of entry. The January 5 interim final rule also authorized the Secretary of Homeland Security (Secretary) to establish pilot programs at up to fifteen air or sea ports of entry, to be identified by notice in the **Federal Register**, through which DHS may require certain aliens who depart from a designated air or sea port of entry to provide specified biometric identifiers and other evidence at the time of departure. On January 5, 2004, DHS published a notice in the **Federal Register** at 69 FR 482 identifying one air and one sea port of entry designated for US–VISIT inspection at the time of alien departure to initiate the US–VISIT exit pilot program.

This notice informs the public of the implementation of US–VISIT exit pilot programs at an additional thirteen air or sea ports as authorized under 8 CFR 215.8(a). This notice further provides a complete listing of the fifteen air and sea ports where US–VISIT exit pilot programs are in operation. This notice also introduces new data collection processes and describes the process under which the exit pilot programs will be evaluated by DHS.

DATES: *Effective Dates:* This notice is effective August 3, 2004.

FOR FURTHER INFORMATION CONTACT: Michael Hardin, Program Analyst, US–VISIT, Border and Transportation Security, Department of Homeland Security, 425 I Street, NW., Washington, DC 20536, telephone (202) 298–5200.

SUPPLEMENTARY INFORMATION:

Background

What Is US–VISIT?

DHS established the United States Visitor and Immigrant Status Technology Program (US–VISIT) in accordance with several Congressional mandates requiring that DHS create an integrated, automated entry-exit system that records the arrival and departure of aliens; verifies aliens' identities; and authenticates aliens' travel documents through comparison of biometric identifiers. US–VISIT is part of a continuum of security measures that begins overseas, when a person applies for a visa to travel to the United States, and continues on through entry and exit at U.S. air and seaports and, eventually, at land border crossings. The US–VISIT program enhances the security of U.S. citizens and visitors by verifying the identity of visitors with visas. At the same time, the program facilitates legitimate travel and trade by leveraging technology and the evolving use of biometrics to expedite processing at U.S. borders.

The goals of the program are to:

- Enhance the security of U.S. citizens and visitors.
- Facilitate legitimate travel and trade.
- Ensure the integrity of the immigration system.
- Safeguard the personal privacy of visitors.

On January 5, 2004, DHS published an interim final rule in the **Federal Register** at 69 FR 468 implementing the first phase of US–VISIT at air and sea ports of entry in the United States. The January 5 interim final rule authorized the Secretary to:

- Require nonimmigrant aliens seeking admission pursuant to a nonimmigrant visa at an air or sea port of entry designated by notice in the **Federal Register** to provide fingerprints, photograph(s), or other specified biometric identifiers at time of application for admission or at time of departure; and
- Establish pilot programs at up to fifteen air or sea ports of entry, designated through notice in the **Federal Register**, through which the Secretary or his delegate may require an alien admitted pursuant to a nonimmigrant visa who departs the United States from a designated air or sea port of entry to provide fingerprints, photograph(s), or other specified biometric identifiers, documentation of his or her immigration status in the United States, and such other evidence as may be requested to determine the alien's identity and whether he or she has properly maintained his or her status while in the United States.

On January 5, 2004, DHS also published a notice in the **Federal Register** identifying which aliens are subject to or exempt from the US–VISIT requirements, the information that would be required from those aliens, and the specific air and sea ports and locations which are designated for the collection of that information. The January 5 Notice also identified one airport and one seaport for collection of biometric information from aliens departing from the United States under the US–VISIT exit pilot program.

What Does This Notice Do?

This notice informs the public of the implementation of US–VISIT departure pilot programs to thirteen additional air or sea ports, expanding the US–VISIT exit program to the full complement of fifteen air or sea ports authorized under 8 CFR 215.8. All aliens subject to 8 CFR 235.1(d)(1)(iii) will be required to provide fingerprints, photographs, or other specified biographic data when departing the United States from one of these additional ports.

As discussed in the January 5 interim final rule, DHS, through the exit pilot programs, will test different methods to collect the required information from aliens as they depart the United States through the designated ports of entry. DHS currently is exploring several different methods and processes for collection of information, including the existing self-serve kiosks already in place and hand-held scanners that can be taken from person to person by a DHS officer to collect biometric information. The exit pilot programs will enable the Department to conduct a cost-benefit analysis of the different processes for collection of biometric information and determine which process allows for the most accurate and efficient collection of information from aliens departing from the United States.

How Will the Pilot Program Process Be Evaluated?

The objective of the exit pilot program is to allow DHS to evaluate processes for obtaining biometric identifiers and other information from aliens departing the United States and determine which process provides the best method of

collecting this information in an expeditious and accurate manner. The goal of the pilot programs is to provide DHS with a flexible system (both technically and operationally), which is also compatible with other DHS agencies, port authorities, and with the travel industry.

Each process for collecting biometric identifiers at departure points will be evaluated using the following criteria:

- Enhancing the security of U.S. citizens and foreign visitors;
- Expediting legitimate travel and trade;
- Ensuring the integrity of the immigration system;
- Safeguarding the personal privacy of foreign visitors;
- Supporting the traveler's compliance with DHS procedures and any related law enforcement action necessary;
- Minimizing the impact to commercial and tourist travel as related to traveler time and travel industry involvement; and
- Minimizing the costs necessary to deploy.

The US–VISIT program will collect biographic and biometric data as described in the January 5, 2004 interim final rule at the fifteen exit pilot program locations identified in this notice beginning August 3, 2004. US–VISIT will complete the evaluation of the exit pilot programs, including evaluation of the methods and processes for collection of required information, by November 30, 2004. US–VISIT also will consider information obtained from the public through voluntary surveys and questionnaires in its evaluation of the pilot programs. Any surveys, questionnaires, or other methods of collecting information from the public to evaluate the US–VISIT exit pilot programs will be reviewed and cleared in accordance with the Paperwork Reduction Act of 1995. Following completion of the evaluation, the US–VISIT program will publish a subsequent notice in the **Federal Register**, announcing its findings and implementation plans.

Notice of Requirements for Biometric Collection From Aliens

In accordance with the authority granted to DHS pursuant to 8 CFR 215.8, DHS hereby orders as follows:

(a) *Aliens subject to notice:* Aliens subject to the conditions of entry specified at 8 CFR 235.1(d)(1)(ii) are subject to this notice and may be required to provide biometric information at time of departure from the United States.

(b) *Aliens exempt:* This notice does not apply to (i) aliens admitted on A–1, A–2, C–3 (except for attendants, servants or personal employees of accredited officials), G–1, G–2, G–3, G–4, NATO–1, NATO–2, NATO–3, NATO–4, NATO–5, or NATO–6 visas, unless the Secretary of State and the Secretary of Homeland Security jointly determine that a class of such aliens should be subject to this notice, (ii) children under the age of 14, (iii) persons over the age of 79, (iv) classes of aliens the Secretary of Homeland Security and the Secretary of State jointly determine shall be exempt, or (v) an individual alien whom the Secretary of Homeland Security, the Secretary of State or the Director of Central Intelligence determines shall be exempt. Aliens admitted on A–1, A–2, C–3 (except for attendants, servants or personal employees of accredited officials), G–1, G–2, G–3, G–4, NATO–1, NATO–2, NATO–3. NATO–4, NATO–5, or NATO–6 visas who are no longer in such status on date of departure, however, are subject to the departure requirements of this notice. Aliens exempted from paragraph (a) who are no longer in an exempted status on date of departure are subject to the departure requirements of this notice.

(c) *Biometric Information:* All aliens subject to this notice shall, at time of departure from designated air and sea ports, submit electronic fingerprints and electronically scan their travel document as requested at the departure inspection locations.

(d) *Airport(s) designated for US–VISIT inspection at time of alien departure:*

Baltimore, Maryland (Baltimore/Washington International Airport)
Newark, New Jersey (Newark International Airport)
Atlanta, Georgia (William B. Hartsfield International Airport)
Chicago, Illinois (O'Hare International Airport)
Philadelphia, Pennsylvania (Philadelphia International Airport)
Dallas/Fort Worth, Texas (Dallas/Fort Worth International Airport)
Detroit, Michigan (Detroit Metropolitan Wayne County Airport)
Las Vegas, Nevada (McCarran International Airport)
San Juan, Puerto Rico (Luis Muñoz Marin International Airport)
Phoenix, Arizona (Phoenix Sky Harbor International Airport)
San Francisco, California (San Francisco International Airport)
Agana, Guam (Agana International Airport)
Denver, Colorado (Denver International Airport)

(e) *Sea port(s) designated for US–VISIT inspection at time of alien departure:*

Miami, Florida
Los Angeles, California (including San Pedro and Long Beach)

The US–VISIT System Is Maintained Consistent With Privacy and Due Process Principles

DHS' Privacy Office, in conjunction with the US–VISIT Privacy Officer, will exercise oversight of the US–VISIT program to ensure that the information collected and stored in systems associated with US–VISIT is being properly protected under the privacy laws and guidance (68 FR 69412, dated December 12, 2003).

DHS will implement procedures to ensure the security, accuracy, relevance, timeliness and completeness of the information maintained in the US–VISIT system. Information is safeguarded in terms of applicable rules and policies, including DHS' automated systems security and access policies. Only those individuals who have an official need for access to the system in the performance of their duties will have access to the system. Records of those individuals who become U.S. citizens and legal permanent resident aliens will be protected in line with all applicable privacy laws and regulations. Those, including nonimmigrant aliens, who wish to contest or seek a change of their records should direct a written request to the US–VISIT Program Office at the following address: Steve Yonkers, Privacy Officer, US–VISIT, Border and Transportation Security, Department of Homeland Security, Washington, DC 20528, telephone (202) 298–5200, fax (202) 298–5201, and e-mail: *usvisitprivacy@dhs.gov*. Because of security concerns, mail sent to the government is occasionally delayed, so fax or e-mail will typically result in a quicker response. The request should include the requestor's full name, current address, date of birth, and a detailed explanation of the change sought. More information on redress procedures can be found at *www.dhs.gov/usvisit*. If the matter cannot be resolved by the Privacy Officer, further appeal for resolution may be made to the DHS Privacy Officer at the following address: Nuala O'Connor Kelly, Chief Privacy Officer, U.S. Department of Homeland Security, Washington, DC 20528, telephone (202) 282–8000, and fax (202) 772–5036.

Dated: July 24, 2004.

Tom Ridge,

Secretary of Homeland Security.

[FR Doc. 04–17792 Filed 7–30–04; 2:15 pm]

BILLING CODE 4410–10–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1511–DR]

Federated States of Micronesia; Amendment No. 5 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the Federated States of Micronesia (FEMA–1511–DR), dated April 10, 2004, and related determinations.

DATES: Effective July 21, 2004.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472,(202)646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated July 21, 2004, the President amended the cost-sharing arrangements concerning Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the damage in certain areas of the Federated States of Micronesia, due to damage resulting from Typhoon Sudal on April 8–14, 2004, is of sufficient severity and magnitude that special conditions are warranted regarding the cost sharing arrangements concerning Federal funds provided under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act).

Therefore, I amend my declaration of April 10, 2004, to authorize Federal funds for Public Assistance at 90 percent of total eligible costs. The law specifically prohibits a similar adjustment for funds provided to States for the Individuals and Households Program and the Hazard Mitigation Grant Program. These funds will continue to be reimbursed at 75 percent of the total eligible costs.

This adjustment to State and local cost sharing applies only to Public Assistance costs eligible for such adjustment under the law.

Please notify the President of the Federated States of Micronesia and the Federal Coordinating Officer of this amendment to my major disaster declaration.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individual and Household Housing; 97.049, Individual and Household Disaster Housing Operations; 97.050 Individual and Household Program-Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 04–17634 Filed 8–2–04; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1531–DR]

South Dakota; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of South Dakota (FEMA–1531–DR), dated July 20, 2004, and related determinations.

DATES: Effective June 16, 2004.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this disaster is closed effective June 16, 2004.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individual and Household Housing; 97.049, Individual and Household Disaster Housing Operations; 97.050, Individual and Household Program-Other Needs; 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 04–17635 Filed 8–2–04; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID–070–1150–PG]

Notice of Public Meeting, Upper Snake River Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Upper Snake River Resource Advisory Council (RAC), will meet as indicated below.

DATES: The meeting will be held September 8–9, 2004 at the BLM Fire Warehouse, 3630 Overland Road in Burley, Idaho. The meeting will start September 8 at 2 p.m., with the public comment period at the start of the meeting. The meeting will adjourn on September 9 at or before 5 p.m.

SUPPLEMENTARY INFORMATION: The 15-member Council advises the Secretary of the Interior, through the Bureau of Land Management, on a variety of planning and management issues associated with public land management in the BLM Upper Snake River District (USRD), which covers south-central and southeast Idaho. At this meeting, topics we plan to discuss include:

Idaho Department of Fish & Game's process for proposed Comprehensive Wildlife Conservation Strategy.

An update on the Craters of the Moon National Monument and Preserve Draft Management Plan and EIS, including a review of comments received on the Draft EIS.

September 9 will include a day-long float trip of the South Fork of the Snake River. Members of the general public wishing to participate should provide their own float transportation and lunch. Logistics of the trip will be announced at the start of the meeting September 8.

RAC Administrative Procedures.

Other items of interest raised by the Council.

All meetings are open to the public. The public may present written comments to the Council. Each formal Council meeting has time allocated for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. Individuals who plan to attend and need special assistance, such as

sign language interpretation, tour transportation or other reasonable accommodations, should contact the BLM as provided below.

This will be the final meeting of the Upper Snake River District RAC. After October 1, the RAC will be split into two separate FACA-chartered RACs, one each for the new BLM Idaho Falls District and the Twin Falls District. The new RACs will each meet next on November 9 and 10, 2004; the Idaho Falls District RAC will meet on this date in Idaho Falls, Idaho, and the Twin Falls District RAC will meet on this date in Jerome, Idaho. The exact location of these meetings will be announced through press releases to local media.

FOR FURTHER INFORMATION CONTACT: David Howell, RAC Coordinator, Upper Snake River District, 1405 Hollipark Dr., Idaho Falls, ID 83401. Telephone (208) 524–7559.

Dated: July 28, 2004.

Joe Kraayenbrink,

District Manager.

[FR Doc. 04–17622 Filed 8–2–04; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

National Park Service

Minor Boundary Revision at Saratoga National Historical Park

AGENCY: National Park Service, Interior.

ACTION: Announcement of park boundary revision.

SUMMARY: Notice is hereby given that the boundary of Saratoga National Historical Park is revised to include Tract No. 01–127 within the boundaries of the park, as depicted on map number 374/80,000 prepared by the National Park Service in November 2003.

FOR FURTHER INFORMATION CONTACT: Rachel McManus, National Park Service Land Acquisition Officer, 978–458–7653.

SUPPLEMENTARY INFORMATION: Section 7(c) of the Land and Water Conservation Fund Act of 1965, as amended, 16 U.S.C. 4601–9(c), authorizes the Secretary of the Interior to make minor boundary revisions and acquire by donation lands or interests therein adjacent to an area of the National Park System that will contribute to, and are necessary for, the proper preservation, protection, interpretation, or management of such an area. With regard to areas of the National Park System within the Northeast Region, this authority has been delegated to the Regional Director. A determination has been made that: (1) It is necessary to include a 1.29-acre parcel of land owned by Prospect Hill Cemetery Association in the Village of Victory, Saratoga County, New York, referred to as Tract No. 01–127 and adjacent to federally owned Tract No. 01–123, within the boundary of Saratoga National Historical Park by donation of interests therein to the United States of America for the proper preservation, protection, interpretation and management of the Park; and (2) the conditions contained in 16 U.S.C. 460l–9(c)(2) have been met. As required by 16 U.S.C. 460l-9(c)(1), written notice has been provided to the Committee on Resources of the House of Representatives and to the Committee on Energy and Natural Resources of the Senate.

The location map and other supporting documentation are available for inspection at the National Park Service, Northeast Region, Realty Division, New England Office, 222 Merrimack Street, Suite 400E, Lowell, MA 01852.

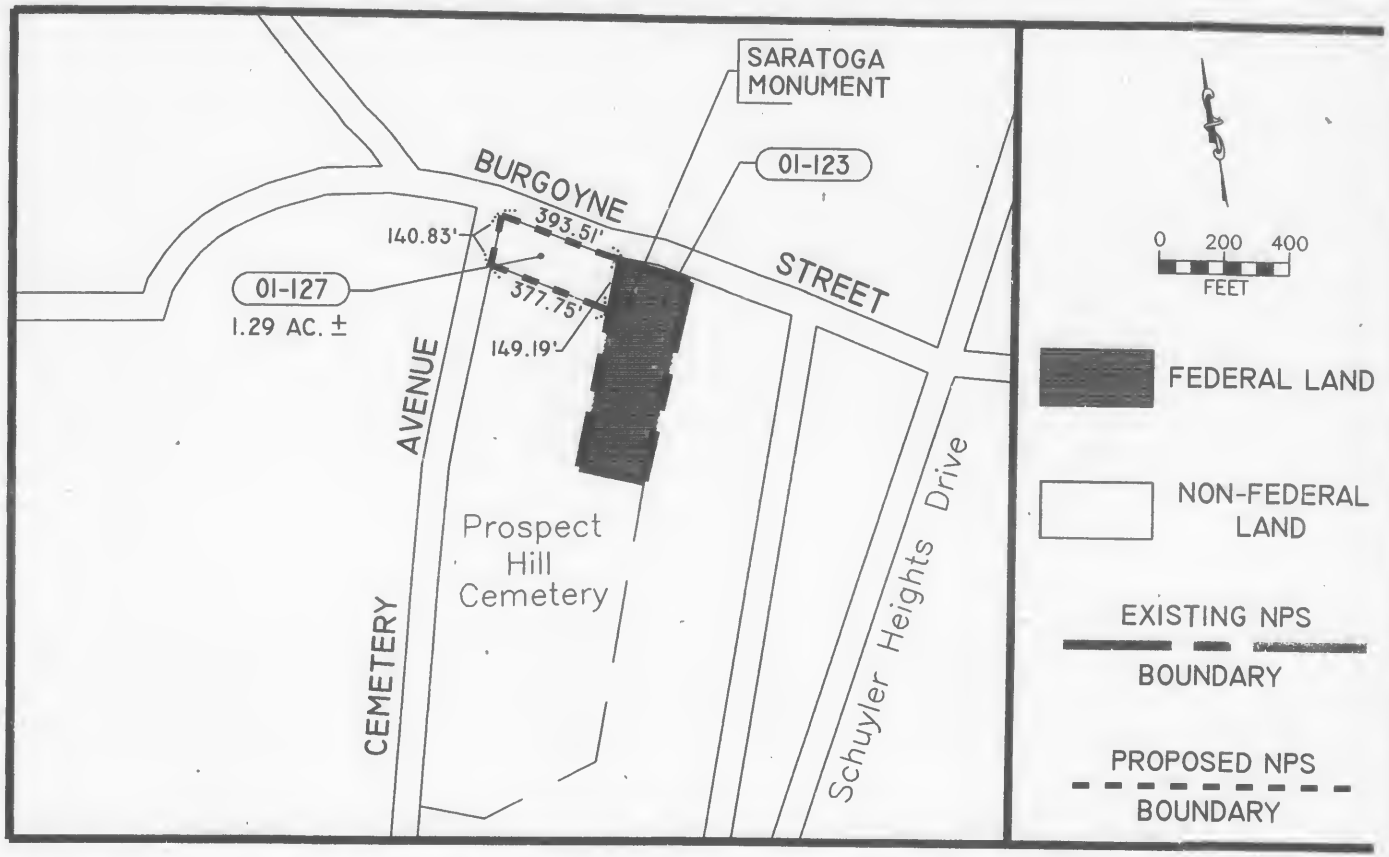
Dated: December 11, 2003.

Marie Rust,

Regional Director, Northeast Region.

Note: This document was received at the Office of the Federal Register on July 29, 2004.

BILLING CODE 4312–52–P



A PORTION OF SARATOGA NATIONAL HISTORICAL PARK

COUNTY OF SARATOGA , STATE OF NEW YORK

REVISED BOUNDARY MAP

DRAWING No.	
374	NERRD
80,000	NOV., 2003

[FR Doc. 04–17579 Filed 8–2–04; 8:45 am]
BILLING CODE 4312–52–C

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Availability of Subsistence Resident Zone Boundary Maps, Wrangell-St. Elias National Park, Alaska

AGENCY: National Park Service, Interior.

ACTION: Notice of availability.

SUMMARY: On February 25, 2002 the communities of Dot Lake, Healy Lake, Northway (including Northway, Northway Village, and Northway Junction), Tanacross, and Tetlin were added (see **Federal Register**, February 25, 2002, page 8481) to the subsistence resident zone for Wrangell-St. Elias National Park in accordance with the provisions of 36 CFR 13.43(b). The resident zone communities for the park, including the five new communities, are listed at 36 CFR 13.73(a)(1). This designation as resident zone communities means that permanent residents of these communities may hunt on those lands designated as Wrangell-St. Elias National Park (subject to other applicable Federal Subsistence regulations) without needing the special subsistence eligibility permit described in 36 CFR 13.44.

In addition to adding these five communities to the subsistence resident zone, a boundary mapping process was also adopted (see 36 CFR 13.73(a)(2). This process provides for either a default boundary consisting of the area designation used for census purposes or the area designated by the park superintendent in consultation with the communities. In consultation with Dot Lake, Healy Lake, Northway, Tanacross, and Tetlin, the superintendent has determined boundaries for each of these communities.

Notice is hereby provided of boundary designations for each of the five communities in accordance with the consultation provisions of section 13.73(a)(2). As provided, copies of the designated resident zone boundaries are available at the park headquarters office in Copper Center, Alaska

FOR FURTHER INFORMATION CONTACT: Hunter Sharp, Acting Superintendent, or Barbara Cellarius, Subsistence Coordinator, at Wrangell-St. Elias National Park and Preserve, P.O. Box 439, Copper Center, AK 99573, telephone (907) 822–5234.

Dated: June 22, 2004.

Ralph Tingey,

Acting Regional Director, Alaska Region.

[FR Doc. 04–17584 Filed 8–2–04; 8:45 am]
BILLING CODE 4312–HC–P

DEPARTMENT OF THE INTERIOR

National Park Service

Draft Environmental Impact Statement/ General Management Plan, Crater Lake National Park, Douglas, Jackson and Klamath Counties, Oregon; Notice of Availability

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969 (Pub. L. 91–190, as amended), and the Council on Environmental Quality Regulations (40 CFR part 1500–1508), the National Park Service (NPS), Department of the Interior, has prepared a draft general management plan (GMP) and environmental impact statement (EIS) for Crater Lake National Park, Oregon. The draft GMP identifies and analyzes four alternatives which respond to both NPS planning requirements and to the issues identified during the public scoping process. The "no-action" alternative (*Alternative 1*) describes the existing conditions and trends of park management and serves as a baseline for comparison in evaluating the other alternatives. The three "action" alternatives variously address visitor use, natural and cultural resource management, and park development. *Alternative 2*, the preferred alternative, emphasizes increased opportunities in recreational diversity, resource preservation, research and resource education. Under *Alternative 3* visitors would experience a greater range of natural and cultural resources through recreational opportunities and education. The focus of *Alternative 4* would be on preservation and restoration of natural processes.

Scoping: Public meetings and newsletters have been used to keep the public informed and involved in the conservation planning and environmental impact analysis process for the draft GMP. A mailing list was compiled that consisted of members of government agencies, nongovernmental groups, businesses, legislators, local governments, and interested citizens.

The Notice of Intent to prepare an EIS was published in the **Federal Register** on May 25, 2001. A newsletter issued January 2001 introduced the GMP planning process (a total of 72 written comments were received in response). Public meetings were held during April 2001 in Klamath Falls, Medford, Roseburg, and Salem and were attended by 96 people. A second newsletter issued in July 2001 summarized all comments received in the meetings and in response to newsletter 1. These comments were used to complete the park purpose and significance statements that serve as the foundation for the rest of the GMP planning (and were referred to throughout development of the draft GMP).

A third newsletter distributed in the spring of 2002 described the draft alternative concepts and management zoning proposed for managing the park (a total of 95 comments were received in response). In general, opinions were fairly divided in support of individual alternatives and potential ways to address issues. A number of letters favored continued snowmobile use, while other people favored elimination of snowmobiles in the park. Opinions were divided regarding ways to manage traffic congestion on Rim Drive—maintaining current two-way traffic, converting part of the road to one-way traffic, using shuttles, or closure of the road to traffic. Most respondents favored use of shuttles. A number of people who opposed partnering with private industry were concerned with the potential of large-scale commercialization within the park.

Proposed Plan and Alternatives: Alternative 1 is the "no action" alternative and represents continuation of the current management direction and approach at the park. It is a way of evaluating the proposed actions of the other three alternatives. Existing buildings and facilities in the park would remain; some historic structures would be adaptively used. Munson Valley would continue to serve as the center of NPS administration, maintenance, and housing. The existing road access and circulation system within the park would continue, and visitor recreational opportunities and interpretive programs in the park would continue.

Alternative 2 is the agency preferred alternative and has also been determined to be the "environmentally preferred" alternative. Management of the park would emphasize increased opportunities for recreational diversity and research and education. Most recreational opportunities would remain, but new opportunities along Rim Drive would allow visitors to directly experience the primary resource of Crater Lake in ways other than driving. Any new uses around the rim would be non-motorized and low impact. Research and educational opportunities would be enhanced. A

new science and learning center would form the core of the new research. The park would expand and encourage partnerships with universities, scientists, and educational groups. The information gathered would be disseminated throughout the park to rangers, interpretive staff, and visitors.

Alternative 3 emphasizes enjoyment of the natural environment. This alternative would allow visitors to experience a greater range of natural and cultural resources significant and unique to the park through recreational opportunities and education. A wider range of visitor experiences would reach out to greater diversity of visitor groups. Recreational programs, which would focus on minimizing impact, would provide the focus for interpretation and education. Resources would be managed to permit recreation while protecting the resources. Opportunities for recreation would be viewed in a regional context, where the park could serve as a source of information for regional recreational opportunities. Use of most current facilities would continue. News trails, new interpretive signs and other media, and expanded tour programs would be possible *in Alternative 3.*

In *Alternative 4*, park management would be focused on resource preservation and restoration. The park would be an active partner in a regional conservation strategy that would include other agencies and environmental groups. Most park operations and visitor contact facilities would be outside the park and shared with other agencies and communities. Areas that have been altered would be restored to their natural conditions. Cultural resources would be preserved at the highest level possible. The visitor experience would stress activities that have low environmental impacts on and are harmonious with the resources. More emphasis would be place on self-guided and discovery education, and interpretive programs would focus on stewardship. Vehicular transportation would be altered to reinforce the visitor experience. The Rim Road would be closed between Cleetwood Cove and Kerr Notch. Winter use of the park would change to allow natural processes to proceed with less disturbance than current management practices allow. Winter plowing of the road to the rim would stop, except for spring opening. Snowmobiling along North Junction Road would no longer be allowed. Facilities that are not historic and not essential to park functions would be removed and the area rehabilitated. Functions that are, by necessity park-based, would be retained in the park.

Public Review and Comment: The draft EIS/GMP is now available for public review. Interested persons and organizations wishing to express any concerns or provide relevant information are encouraged to obtain the document from the Superintendent, Crater Lake National Park, P.O. Box 7, Highway 62, Crater Lake, Oregon , or via telephone at (541) 594–3001. The document may also be reviewed at area libraries, or obtained electronically via the park's Web site at *www.planning.nps.gov.*

Comments on the draft GMP/EIS must be postmarked (or transmitted by email) no later than 60 days after publication of EPA's notice of filing in the **Federal Register** (immediately upon confirming this date it will be announced on the park's Web site). Written comments may be submitted to: Terri Urbanowski, National Park Service, P.O. Box 25287, Denver, CO 80225–0287 or e-mailed to *CRLA_GMP@nps.gov.* All comments will become part of the public record. If individuals submitting comments request that their name or/and address be withheld from public disclosure, the request will be honored to the extent allowable by law. Such requests must be stated prominently in the beginning of the comments. There also may be circumstances wherein the NPS will withhold a respondent's identity as allowable by law. As always: the NPS will make available to public inspection all submissions from organizations or businesses and from persons identifying themselves as representatives or officials of organizations; and, anonymous comments may not be considered.

Decision: Notice of the availability of the final EIS/GMP document will be published in the **Federal Register** and announced via local and regional press media. Subsequently, a Record of Decision (ROD) will be prepared and approved not sooner than 30 days after the final document is distributed (and notice of the approved ROD similarly published in the **Federal Register**). As a delegated EIS, the official responsible for the decision is the Regional Director, Pacific West Region, National Park Service; subsequently the official responsible for implementing the approved GMP is the Superintendent, Crater Lake National Park.

Dated: March 5, 2004.

Jonathan B. Jarvis,

Regional Director, Pacific West Region.

Editorial Note: This document was received in the Office of the Federal Register on July 29, 2004.

[FR Doc. 04–17588 Filed 8–2–04; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Availability of a Draft Environmental Impact Statement for the Selma to Montgomery National Historic Trail Comprehensive Management Plan

AGENCY: National Park Service, Interior.

ACTION: Notice of availability.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969 (16 U.S.C. 410ccc–4; 42 U.S.C. 4371; 40 CFR 1506.6) the National Park Service announces the availability of a Draft Environmental Impact Statement (DEIS) for the Selma to Montgomery National Historic Trail Comprehensive Management Plan. The document provides a framework for the management, use, and development of the trail by the National Park Service and its partners over the next 15 to 20 years. The document describes four management alternatives for consideration, including a no-action alternative, and analyzes the environmental impacts of those alternatives. Beginning at Brown Chapel AME Church in Selma, Alabama, the trail follows the route of the March 1965 Selma to Montgomery voting rights march, traveling through Lowndes County along U.S. Highway 80, and ending at the Alabama State Capitol in Montgomery.

DATES: There will be a 60-day comment period beginning with the Environmental Protection Agency's publication of its notice of availability in the **Federal Register.**

ADDRESSES: Copies of the DEIS are available by contacting John Barrett, National Park Service, 100 Alabama St., SW., Atlanta, GA 30303. An electronic copy of the DEIS is available on the Internet at *http://www.nps.gov/sero/planning.*

SUPPLEMENTARY INFORMATION: The National Park Service held community and stakeholder meetings to gather advice and feedback on desired outcomes of the management plan. The meetings assisted the National Park Service in developing alternatives for managing associated cultural and natural resources and creating interpretive and educational programs. Responses from the meetings were incorporated into the alternatives described in the plan. Alternative A focuses on the story of the voting rights march as defined by events that occurred between held between March 7 and March 25, 1965, in Dallas, Lowndes, and Montgomery counties,

Alabama. Alternative B builds on the story of Alternative A, providing information on the broader efforts to gain voting rights for African Americans, as events unfolded in Dallas, Lowndes, and Montgomery counties. Under this alternative, exhibits and other interpretive materials would explain earlier organizing and protest activities, the voting rights march, and the aftermath of the march. Alternative C adds to the stories of Alternatives A and B by interpreting the progression of citizenship rights in the United States. This alternative tells the story of African American efforts to gain voting rights in the larger context of the Modern Civil Rights Movement. This alternative would emphasize that the Selma to Montgomery Voting Rights March was an integral part of America's evolving commitment to greater equality and a stronger democracy. The National Park Service has identified Alternative C as the preferred alternative.

It is the practice of the National Park Service to make comments, including names and home addresses of respondents, available for public review during regular business hours. Anonymous comments will not be considered. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses; available for public inspection in their entirety. However, individual respondents may request that we withhold their names and addresses from the public record, and we will honor such requests to the extent allowed by law. If you wish to withhold your name and/or address, you must state that request prominently at the beginning of your comment.

FOR FURTHER INFORMATION CONTACT: Catherine Light, (334) 727–6390 or John Barrett, (404) 562–3124, extension 637.

The responsible official for this draft Environmental Impact Statement is Patricia A. Hooks, Regional Director, Southeast Region, National Park Service, 100 Alabama Street SW., 1924 Building, Atlanta, Georgia 30303.

Dated: June 27, 2004.

Patricia A. Hooks,

Regional Director, Southeast Region.

[FR Doc. 04–17583 Filed 8–2–04; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

Environmental Impact Statement, Notice of Intent

AGENCY: National Park Service, Interior.

ACTION: Notice of intent to prepare an environmental impact statement (EIS) and stream management plan for Herbert Hoover National Historic Site, West Branch, Iowa.

SUMMARY: Under the provisions of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), and regulations of the Council on Environmental quality (40 CFR 1506.6), the U.S. Department of the Interior, National Park Service (NPS) will prepare a draft stream management plan/environmental impact statement (EIS). The plan will be used to guide the management and rehabilitation of the stream located in Herbert Hoover National Historic Site (HEHO), West Branch, Iowa. The environmental impact statement will assess potential environmental impacts associated with various types of stream rehabilitation measures and restoration techniques on park resources such as water quality and hydrology, native plant communities, wildlife, cultural and historic resources, and public health and safety.

DATES: To determine the scope of issues to be addressed in the plan and EIS and to identify significant issues related to the management and rehabilitation of the stream in the NHS, the NPS will conduct a public scoping meeting in West Branch, Iowa. Representatives of the NPS and Parsons, the consulting firm assisting in the preparation of the EIS, will be available to discuss issues, resource concerns, and the planning process at the public meeting. When the public scoping meeting has been scheduled, its location, date, and time will be published in local newspapers.

ADDRESSES: Any comments or requests for information should be addressed to Superintendent, Herbert Hoover National Historic Site, Attn: Stream EIS, P.O. Box 607, West Branch, IA 52358. Comments may also be submitted at the following e-mail address: *HEHO_Resource_Management@nps.gov.*

FOR FURTHER INFORMATION CONTACT: Superintendent, Herbert Hoover National Historic Site, Stream EIS, P.O. Box 607, West Branch, IA 52358, E-mail: *HEHO_Resource_Management@nps.gov.*

SUPPLEMENTARY INFORMATION: Hoover Creek is a small tributary with a base flow of about 3 cubic feet per second (cfs). The creek is subject to flash flooding. Historic resources of the park lie within the 50-year floodplain and a few, including the Hoover Presidential Library and Museum, lie within the 25-year floodplain. Visitor service and park maintenance facilities and the primary access road into West Branch lie within the 10-year and 5-year floodplain.

Anecdotal flood history indicates that Hoover Creek has exceeded its banks 18 times in 11 years. Precipitation events have resulted in storm surges of 1500 cubic feet per second (1967 flood) and 1650 cubic feet per second (1993 flood). Bank full flow is estimated at 650 cubic feet per second and flow above that level causes flooding of visitor service areas and the historic core. Analysis of 1967 and 1993 data suggests that the 1967 flood was a 20-year flood event and the 1993 flood was a 30-year flood event. The 1993 flood was within inches of floor level in a few historic structures. Staff observations show that the stream is migrating toward the Herbert Hoover Presidential Library-Museum building. The bank of the creek is inherently unstable, with channel scouring causing the banks to slump as the toe of the bank erodes. Lateral cutting brings the stream closer to historic resources. The stream continues to entrench and poses a safety hazard to visitors with steep stream banks of 6 to 8 feet. The current instability of the stream threatens critical resources, contributes to sediment loads in the creek, and limits the creek's value as habitat for native plants and animals.

The principle goal of the stream management plan is to re-establish natural processes that are in equilibrium within the creek. This will lead to:

- Improvement of water retention that will reduce flooding.
- Dissipation of stream energy that will reduce erosion.
- Development of root masses that will stabilize banks.
- Development of diverse channel characteristics to provide habitat and support biodiversity.

We welcome all input into our planning process. Our practice is to make the public comments we receive in response to planning documents, including names and home addresses of respondents, available for public review during regular business hours. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety. Individual respondents may request that we withhold their names and addresses from the public record, and we will honor such requests to the extent

allowed by law. If you wish to withhold your name and/or a address, you must state that request prominently at the beginning of your comment. The draft and final stream management plan/ environmental impact statement will be made available to all known interested parties and appropriate agencies. Full public participation by Federal , State, and local agencies as well as other concerned organizations and private citizens is invited throughout the preparation process of this document.

Dated: May 10, 2004.

Ernest Quintana,

Regional Director, Midwest Region.

[FR Doc. 04–17589 Filed 8–2–04; 8:45 am]

BILLING CODE 4312–94–M

DEPARTMENT OF THE INTERIOR

National Park Service

Bison Brucellosis Vaccine, Environmental Impact Statement, Yellowstone National Park, Wyoming

AGENCY: National Park Service, Department of Interior.

ACTION: Notice of Intent to Prepare an Environmental Impact Statement to evaluate a park-wide program for remote delivery of a brucellosis vaccine to bison in Yellowstone National Park.

SUMMARY: In accordance with section 102 (2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), the National Park Service (NPS) is preparing an Environmental Impact Statement (EIS) for a *remote* delivery brucellosis vaccination program for bison in Yellowstone National Park. Remote delivery in this proposed action is distinguished from hand delivery that occurs in penned situations at or near Yellowstone National Park's boundaries that is authorized under a 2000 Record of Decision (ROD). The purpose of and need for the action is to implement a program to deliver a suitable vaccine to wild and free ranging bison without capturing and handling individual animals. A brucellosis vaccine would be delivered to untested bison within the park to lower the percentage of the Yellowstone bison population infected with brucellosis. This planning effort will result in a decision determining whether or not to implement remote delivery of a vaccine to free-ranging bison inside Yellowstone National Park. The alternatives to be considered include no-action, and an adaptive management strategy to implement a program using currently available technology while pursuing new research and development of improved techniques. The major issues to resolve include: (1) The effectiveness and safety in wildlife of a remote delivery system, (2) The effectiveness and safety of a vaccine for bison, (3) The human health and safety of park staff and visitors, and (4) The visitor experience.

A scoping brochure has been prepared that details the background and issues identified to date. Copies of that information may be obtained by contacting the Bison Ecology and Management Office, POB 168, Yellowstone National Park, Wyoming, 82190–0168 or by viewing the brochure at the Yellowstone National Park Web site *http:/www.nps.gov/yell.*

DATES: The National Park Service will accept comments from the public for 30 days from the date this notice is published in the **Federal Register**.

ADDRESSES: Information will be available for public review and comment at the Yellowstone Center for Resources, Yellowstone National Park, P.O. Box 168, Yellowstone National Park, Wyoming, 82190–0168 (307) 344–2393.

FOR FURTHER INFORMATION CONTACT: Bison Ecology and Management Office, Yellowstone National Park, P.O. Box 168, Yellowstone National Park, Wyoming, 82190–0168. Telephone: 307–344–2505.

SUPPLEMENTARY INFORMATION: In 2000, the NPS, in collaboration with the State of Montana, the USDA Animal and Plant Health Inspection Service (APHIS), and USDA National Forest Service, developed a final Interagency Bison Management Plan (IBMP). The NPS evaluated alternatives for the IBMP in an EIS, which focused on a study area including the park and adjacent areas in Montana. The purpose of the IBMP is to maintain a free-ranging population of bison and address the risk of brucellosis transmission to cattle to protect the economic interests and viability of the livestock industry in Montana. The Record of Decision (ROD) for the IBMP directed the partner agencies to vaccinate bison at capture facilities when a vaccine is shown to be safe according to the criteria defined in the IBMP. The ROD also directed the NPS to develop an in-park remote vaccination program for free ranging bison when a safe and effective vaccine becomes available and when a safe and effective remote delivery system is developed to further reduce the risk of transmission of brucellosis from bison to cattle.

The environmental consequences of a park-wide program for remote delivery of vaccine to free-ranging bison were not analyzed in the final EIS for the IBMP. Research has shown that a safe and effective vaccine using a safe and effective delivery system now exists. Consequently, the NPS is preparing an EIS to analyze alternatives for a remote delivery program for administering brucellosis vaccine to bison within the entirety of Yellowstone National Park. To ensure that the full range of issues related to this proposed action are identified and taken into account, all interested individuals, organizations, and agencies are invited to provide comments through attendance at public scoping meetings, submission of comments through access to the Yellowstone National Park Web site, or submission of written comments mailed directly to the Bison Ecology and Management Office at Yellowstone National Park during the scoping period. In addition, you may hand deliver comments to receptionists at the Superintendent's office, the park planning office, and the Yellowstone Center for Resources, all located in the headquarters area at Mammoth, Wyoming.

The public is advised that individual commentor names and addresses may be included as part of the public record. Names and addresses of individuals submitting comments will be available for public review during regular business hours. Any person, business or organization wishing to have their name and other information withheld from the public record must state this prominently at the beginning of any correspondence or comment. The request will be honored to the extent allowable by law. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be placed in the public record and will be made available for public inspection in their entirety.

Dated: June 17, 2004.

Stephen P. Martin,

Regional Director, Intermountain Region.

[FR Doc. 04–17586 Filed 8–2–04; 8:45 am]

BILLING CODE 4312–CT–P

DEPARTMENT OF THE INTERIOR

National Park Service

Final Environmental Impact Statement/ General Management Plan, Fort Vancouver National Historic Site, Clark County, Washington; Notice of Approval of Record of Decision

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy

Act of 1969 (Pub. L. 91–190, as amended) and the implementing regulations promulgated by the Council on Environmental Quality (40 CFR 1505.2), the Department of the Interior, National Park Service has prepared, and the Regional Director, Pacific West Region has approved, the Record of Decision for the General Management Plan for Fort Vancouver National Historic Site, in southwestern Washington. The formal no-action period was officially initiated January 22, 2004, with the U.S. Environmental Protection Agency's **Federal Register** notification of the filing of the Final Environmental Impact Statement (EIS).

Decision: As soon as practicable the NPS will begin to implement the General Management Plan described and analyzed as the *Proposed Action (Alternative B)* contained in the abbreviated Final EIS. The selected plan features a deliberate, long-term strategy to protect historic, cultural, and natural resources, while providing for improved visitor experience and increased educational opportunities. Various programs and projects to be accomplished in partnership with others are included. This plan was also deemed to be the "environmentally preferred" alternative.

This course of action and two alternatives were identified and analyzed in the Final EIS, and previously in the Draft EIS (the latter was distributed in November 2002). The full spectrum of foreseeable environmental consequences were assessed, and appropriate mitigation measures identified, for each alternative. Beginning with early scoping, through the preparation of the Draft and Final EIS, numerous public meetings were conducted and newsletter updates were regularly provided. Approximately 118 written comments (and about 185 oral comments at public meetings) responding to the Draft EIS were received and duly considered. As no substantive or adverse comments were received, an abbreviated Final EIS was prepared (and released for a 30-day no-action period which commenced on January 22, 2004). Key consultations which aided in preparing the Draft and Final EIS involved (but were not limited to) the U.S. Fish and Wildlife Service, USDA Wildlife Service, Oregon and Washington State Historic Preservation Offices, Washington State Dept. of Transportation, three native American Tribes, cities of Vancouver and Oregon City, and Clark County.

Copies: Interested parties desiring to review the Record of Decision may obtain a complete copy by contacting the Superintendent, Fort Vancouver National Historic Site, 612 E. Reserve St., Vancouver, WA 98661; or via telephone request at (360) 696–7655.

Dated: June 2, 2004.

Patricia L. Neubacher,

Acting Regional Director, Pacific West Region.

[FR Doc. 04–17587 Filed 8–2–04; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Availability of a Record of Decision on the Final Environmental Impact Statement for the General Management Plan, Coronado National Memorial

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice of availability.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, Public Law 91–190, 83 Stat. 852, 853, codified as amended at 42 U.S.C. 4332(2)(C), the National Park Service announces the availability of the Record of Decision for the General Management Plan/Environmental Impact Statement for Coronado National Memorial, Arizona. On May 28, 2004, the Director, Intermountain Region approved the Record of Decision for the project. As soon as practical, the National Park Service will begin to implement the General Management Plan, described as the Preferred Alternative contained in the FEIS issued on April 16, 2004. In the preferred alternative, the visitor center will be rehabilitated and updated interpretation offered. The Montezuma Ranch area will be restored to natural contours and revegetated with native species. The abandoned powerline along the road to Montezuma Pass will be removed and revegetated with native species. Grazing in the national memorial will be discontinued. An annex will be built behind the visitor center containing additional office and storage space, along with a multipurpose room. Additional pullouts and waysides will be developed along the main road as well as trails in the memorial's grasslands. A new group picnic area will be developed. The visitor shelter at Montezuma Pass will be converted into a minimal contact station. A new four-unit structure might be added to house temporary employees. The park will work toward creating an offsite cultural festival to celebrate various cultures associated with the memorial, emphasizing the historical aspects of the Coronado Expedition. The park staff will promote special events highlighting the Coronado Expedition, its legacy, and its impact of the present American Southwest. This course of action and four alternatives were analyzed in the Draft and Final Environmental Impact Statements. The full range of foreseeable environmental consequences were assessed, and appropriate mitigating measures identified.

The full Record of Decision includes a statement of the decision made, synopses of other alternatives considered, the basis for the decision, a description of the environmentally preferable alternative, a finding on impairment of park resources and values, a listing of measures to minimize environmental harm, and an overview of public involvement in the decision-making process.

Basis for Decision

In reaching its decision to select the preferred alternative, the National Park Service considered the purposes for which Coronado National Memorial was established, and other laws and policies that apply to lands in the memorial, including the Organic Act, National Environmental Policy Act, and the *NPS Management Policies.* The National Park Service also carefully considered public comments received during the planning process. To develop a preliminary preferred alternative, the planning team evaluated the alternatives that had been reviewed by the public. To minimize the influence of individual biases and opinions, the team used an objective analysis process called "Choosing by Advantages." This process has been used extensively by government agencies and the private sector. The following conclusions were reached:

- Alternative B will best safeguard the resources and scenic values of Coronado National memorial while making those resources easily accessible for visitors.
- Alternative B best preserves the park's cultural landscapes through application of management zones that provide for a better understanding and appreciation of the park's cultural landscapes by limited future development away from areas that contain cultural landscapes.
- Alternative B will maintain the archeological and historic integrity of the park by providing better protection of the cultural resources through ending the impacts of grazing on these resources.
- Alternative B will enhance the visitor's experience by providing multiple opportunities for visitors to make intellectual and emotional

connections to the park by development of more interpretive materials and programs onsite and supporting offsite festivals and programs that emphasize the historical aspects of the Coronado Expedition.

Overall, alternative B received the highest score and was adopted as the preferred alternative.

Findings on Impairment

The NPS has determined that implementation of the proposal will not constitute an impairment to Coronado National Memorial's resources and values. This conclusion is based on a thorough analysis of the environmental impacts described in the EIS, the public comments received, relevant scientific studies, and the professional judgement of the decision-maker guided by the direction in the NPS Management Policies (December 27, 2000). Overall, the plan results in benefits to park resources and values, opportunities for their enjoyment, and it does not result in their impairment.

FOR FURTHER INFORMATION CONTACT: Dale Thompson, Coronado National Memorial, 4101 East Montezuma Canyon Road, Hereford, AZ 85615, 520–366–5515, *DaleThompson@nps.gov.*

SUPPLEMENTARY INFORMATION: Copies of the Record of Decision may be obtained from the contact listed above.

Dated: May 28, 2004.

Stephen P. Martin,

Director, Intermountain Region, National Park Service.

[FR Doc. 04–17585 Filed 8–2–04; 8:45 am]

BILLING CODE 4312–DP–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Intent to Repatriate a Cultural Item: Field Museum of Natural History, Chicago, IL

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 43 CFR 10.8 (f), of the intent to repatriate a cultural item in the possession of the Field Museum of Natural History, Chicago, IL, that meets the definition of "cultural patrimony" under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 43 CFR 10.8 (f). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the cultural item. The National Park Service is not responsible for the determinations in the notice.

The cultural item is a painted wooden hat (catalog number 79224). The conical and sloping hat has a three-dimensional carving of a sea lion and is incised with crest designs. The hat is painted white, red, and greenish-blue. The wooden portion of the hat is topped with three stacked, basketry "potlatch" rings.

At an unknown date, Lieutenant George Thorton Emmons purchased the hat. In 1902, the Field Museum of Natural History purchased the hat from Lieutenant Emmons and accessioned the hat into its collection in the same year (accession number 807).

The cultural affiliation of the hat is "Tlingit, Sitka" as indicated by museum records, and by consultation evidence presented by the Central Council of the Tlingit & Haida Indian Tribes. The Central Council of the Tlingit & Haida Indian Tribes requested the return of the hat on behalf of the Kaagwaantaan clan. Museum records indicate that the hat was "formerly the property of 'Anna-hootz' [Anaxoots] the hereditary chief of the 'Kargwautore' [Kaagwaantaan] family of the Sitka tribe."

Officials of the Field Museum of Natural History have determined that, pursuant to 25 U.S.C. 3001 (3)(D). the cultural item described above has ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual. Officials of the Field Museum of Natural History also have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity that can be reasonably traced between the object of cultural patrimony and the Central Council of the Tlingit & Haida Indian Tribes, on behalf of the Kaagwaantaan clan.

Officials of the Field Museum of Natural History assert that, pursuant to 25 U.S.C. 3001 (13), the Field Museum of Natural History has right of possession of the object of cultural patrimony. Officials of the Field Museum of Natural History recognize the significance of the object of cultural patrimony to the Kaagwaantaan clan as represented by the Central Council of the Tlingit & Haida Indian Tribes and reached an agreement with the Central Council of the Tlingit & Haida Indian Tribes that allows the Field Museum of Natural Historv to return the object of cultural patrimony to the Central Council of the Tlingit & Haida Indian Tribes voluntarily, pursuant to the compromise of claim provisions of the Field Museum of Natural History's repatriation policy.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the object of cultural patrimony should contact Jonathan Haas, MacArthur Curator of the Americas, Field Museum of Natural History, 1400 South Lake Shore Drive, Chicago, IL 60605, telephone (312) 665–7829, before September 2, 2004. Repatriation of the object of cultural patrimony to the Central Council of the Tlingit & Haida Indian Tribes on behalf of the Kaagwaantaan clan may proceed after that date if no additional claimants come forward.

The Field Museum of Natural History is responsible for notifying the Central Council of the Tlingit & Haida Indian Tribes, Kaagwaantaan clan, Sealaska Corporation, and Sitka Tribe of Alaska that this notice has been published.

Dated: May 7, 2004

John Robbins,

Assistant Director, Cultural Resources.

[FR Doc. 04–17580 Filed 8–2–04; 8:45 am]

BILLING CODE 4312–50–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Intent to Repatriate Cultural Items: Field Museum of Natural History, Chicago, IL

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 43 CFR 10.8 (f), of the intent to repatriate cultural items in the possession of the Field Museum of Natural History, Chicago, IL, that meet the definition of "unassociated funerary objects" under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 43 CFR 10.8 (f). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the cultural items. The National Park Service is not responsible for the determinations in the notice.

The six cultural items are one crescent moon rattle, one oystercatcher rattle, one mask, one charm, one handpiece, and one hat.

The crescent moon rattle (catalog number 77921) is made of carved wood painted red, black, and blue. Carved relief on both sides of the rattle depict devilfish. The oystercatcher rattle

(catalog number 78670) is made of carved wood painted dark bluish-green and red and decorated with ermine skin. On the back of the rattle, a three-dimensional carving in high relief depicts a reclining man. Superimposed over each arm is the three-dimensional carved depiction of a fish. The mask (catalog number 78669) is made of carved wood painted greenish-blue and decorated with copper, nails, and bearskin. The mask depicts a half-otter, half-man spirit. The charm (catalog number 78679) is made of bone carved to depict a land otter. The handpiece (catalog number 78801) is made of wood carved to depict a human face and a spirit with the face of a human and the body of an otter. The hat (catalog number 84200) is made of a twined root and straw basket, with geometric and naturalistic decorative elements in black. Two figures on one side of the hat depict wolves.

At an unknown date, Lieutenant George Thorton Emmons acquired the two rattles, and the mask, charm, and handpiece. In 1902, the Field Museum of Natural History purchased the cultural items from Lieutenant Emmons and accessioned the cultural items into its collection in the same year (accession number 807). Museum records indicate that Lieutenant Emmons acquired the cultural items in southeastern Alaska and that the cultural items originally were the property of an unidentified shaman or shamans of the "Auk tribe.". Museum records do not indicate how Lieutenant Emmons acquired the cultural items.

Also at an unknown date, Lieutenant George Thorton Emmons acquired the hat. In 1903, the Field Museum of Natural History purchased the hat from Lieutenant Emmons and accessioned the cultural item into its collection in the same year (accession number 843). According to museum records, the hat was acquired in Juneau, AK, and was originally the property of an unidentified shaman of the "Hoonah tribe.". Museum records do not indicate how Lieutenant Emmons acquired the cultural item.

The cultural affiliation of the cultural items is Tlingit as indicated by museum records and by consultation evidence presented by the Central Council of the Tlingit & Haida Indian Tribes. The Central Council of the Tlingit & Haida Indian Tribes requested the return of the cultural items on behalf of two clans within the Aak'w tribe, the Wooshkeetaan and the L'eeneidi. Consultation evidence and the ethnographic literature indicate that the cultural items were removed from specific burial sites of Native American individuals, and that cultural items of this type were used only by the ixt' (shaman) of the Tlingit and usually were placed with the deceased shaman in above-ground burials.

Officials of the Field Museum of Natural History have determined that, pursuant to 25 U.S.C. 3001 (3)(B), the cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from specific burial sites of Native American individuals. Officials of the Field Museum of Natural History also have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity that can be reasonably traced between the six unassociated funerary objects and the Central Council of the Tlingit & Haida Indian Tribes.

Officials of the Field Museum of Natural History assert that, pursuant to 25 U.S.C. 3001 (13), the museum has right of possession of the six unassociated funerary objects. Officials of the Field Museum of Natural History recognize the significance of the six unassociated funerary objects to the Central Council of the Tlingit & Haida Indian Tribes and have reached an agreement with the Central Council of the Tlingit & Haida Indian Tribes that allows the museum to return the six unassociated funerary objects to the Central Council of the Tlingit & Haida Indian Tribes voluntarily, pursuant to the compromise of claim provisions of the museum's repatriation policy.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the unassociated funerary objects should contact Jonathan Haas, MacArthur Curator of the Americas, Field Museum of Natural History, 1400 South Lake Shore Drive, Chicago, IL 60605, telephone (312) 665–7829, before September 2, 2004. Repatriation of the unassociated funerary objects to the Central Council of the Tlingit & Haida Indian Tribes may proceed after that date if no additional claimants come forward.

The Field Museum of Natural History is responsible for notifying the Central Council of the Tlingit & Haida Indian Tribes, Douglas Indian Association, Goldbelt Incorporated, Hoonah Indian Association, Huna Totem Corporation, and Sealaska Corporation that this notice has been published.

Dated: May 7, 2004

John Robbins,

Assistant Director, Cultural Resources.

[FR Doc. 04–17581 Filed 8–2–04; 8:45 am]

BILLING CODE 4310–50–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Intent to Repatriate Cultural Items: Field Museum of Natural History, Chicago, IL

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 43 CFR 10.8 (f), of the intent to repatriate cultural items in the possession of the Field Museum of Natural History, Chicago, IL, that meet the definition of "unassociated funerary objects" under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 43 CFR 10.8 (f). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the cultural items. The National Park Service is not responsible for the determinations in the notice.

The 19 cultural items are 4 charms or ornaments, 1 bundle of rhythm sticks, 1 spirit club, 2 guardian figures, 2 spirit wands, 1 necklace, 1 comb, 2 bracelets, 1 mat, and 4 masks.

The first charm (catalog number 77863) is a neck charm or ornament for a dancing robe that is a section of a deer's hoof carved to depict a sea monster. The second charm (catalog number 77865) is a neck charm that is a circlet of devil's club branches with a bundle of twigs attached to it with spruce root. The third charm (catalog number 77878) is carved bone depicting a land otter with the tentacles of a devilfish. The fourth charm or robe ornament (catalog number 77879) is carved wood "representing an Ict' " (shaman) kneeling on the head of a land otter. The bundle of rhythm sticks (catalog number 77864) are wooden beating sticks, several of which are carved to depict land otters. The spirit club (catalog number 77866) is made of wood carved at one end in the shape of a land otter and carved at the other end in the shape of a mountain goat. The first guardian figure (catalog number 77867) is a wood knot carved as a "grotesque" figure of a man. A hollow place in the figure was filled with

eagle's down. The second guardian figure (catalog number 77870) is a wood carving that depicts a man sitting up with his elbows resting on his knees. The first spirit wand (catalog number 77868) is made of wood carved to depict a land otter with one spirit lying on its back on the otter's back and another spirit lying on its back underneath the otter's belly. The second spirit wand (catalog number 77869) is a short wooden club carved to depict a land otter. The necklace (catalog number 77873) is composed of seal teeth. The comb (catalog number 77874) is made of whale bone carved to depict a man's face on one side and a whale on the other, and wrapped with a cord of twisted cedar bark. The first bracelet or amulet (catalog number 77875) is made of carved bone decorated with incised lines. The second bracelet (catalog number 77876) is made of bone carved to depict a herd of caribou. The mat (catalog number 79252) is made from red cedar bark. The first mask (catalog number 79254) is made of carved wood decorated with haliotes shell and painted black, red, and green, representing the spirit of the loon. The second mask (catalog number 79255) is made of carved wood painted black, red, and green, representing the spirit of an old Tlingit woman with a labret or lip ornament inserted in the lower lip. The third mask (catalog number 79256) is made of carved wood painted red, black, and green, representing the "spirit of a Tlingit 'Ict' " (shaman). Carvings on the forehead depict a combination of land otter and devilfish. The fourth mask (catalog number 79257) is made of carved wood painted in black, red, and green to represent a Tlingit spirit.

At an unknown date, Lieutenant George Thorton Emmons acquired the cultural items. In 1902, the Field Museum of Natural History purchased the cultural items from Lieutenant Emmons and accessioned the cultural items into its collection in the same year (accession number 807). Museum records do not indicate how Lieutenant Emmons acquired the cultural items.

The cultural affiliation of the cultural items is Tlingit as indicated by museum records and by consultation evidence presented by the Central Council of the Tlingit & Haida Indian Tribes. Museum records indicate that the cultural items were removed from a dilapidated grave house near a deserted village near Dry Bay to the north of the Alsek River, AK, and formerly belonged to a shaman of the "Kiet-kow-ee" family of the "Gun-nah-ho" tribe. The museum has not been able to conclusively determine which contemporary tribe or clan may be the direct descendants of the historic "Gun-nah-ho" tribe referenced in the museum's catalog, and who may have occupied the Dry Bay area in the late 19th century when the cultural items were acquired. The anthropological literature indicates that the contemporary Yakutat Tribe was formed when the Dry Bay tribe merged with the Yakutat in 1910.

Officials of the Field Museum of Natural History have determined that, pursuant to 25 U.S.C. 3001 (3)(B), the cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual. Officials of the Field Museum of Natural History also have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity that can be reasonably traced between the 19 unassociated funerary objects and the Central Council of the Tlingit & Haida Indian Tribes.

Officials of the Field Museum of Natural History assert that, pursuant to 25 U.S.C. 3001 (13), the museum has right of possession of the 19 unassociated funerary objects. Officials of the Field Museum of Natural History recognize the significance of the 19 unassociated funerary objects to the Central Council of the Tlingit & Haida Indian Tribes and have reached an agreement with the Central Council of the Tlingit & Haida Indian Tribes that allows the museum to return the 19 unassociated funerary objects to the Central Council of the Tlingit & Haida Indian Tribes voluntarily, pursuant to the compromise of claim provisions of the museum's repatriation policy.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the unassociated funerary objects should contact Jonathan Haas, MacArthur Curator of the Americas, Field Museum of Natural History, 1400 South Lake Shore Drive, Chicago, IL 60605, telephone (312) 665–7829, before September 2, 2004. Repatriation of the unassociated funerary objects to the Central Council of the Tlingit & Haida Indian Tribes may proceed after that date if no additional claimants come forward.

The Field Museum of Natural History is responsible for notifying the Central Council of the Tlingit & Haida Indian Tribes, Sealaska Corporation, Yak-Tat Kwaan Incorporated (Yakutat), and the Yakutat Tlingit Tribe that this notice has been published.

Dated: May 10, 2004

John Robbins,

Assistant Director, Cultural Resources.

[FR Doc. 04–17582 Filed 8–2–04; 8:45 am]

BILLING CODE 4310–50–S

DEPARTMENT OF JUSTICE

Criminal Division; Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 60-day notice of information collection under review: exhibit A to registration statement (foreign agents).

The Department of Justice (DOJ), Office of Justice Programs, has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for "sixty days" until October 4, 2004. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please write to U.S. Department of Justice, 10th & Constitution Avenue, NW., Criminal Division, Counterespionage Section/Registration Unit, Bond Building—Room 9300, Washington, DC 20530.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

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 agencies 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 submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of currently approved collection.

(2) *Title of the Form/Collection:* Exhibit A to Registration Statement (Foreign Agents).

(3) The agency form number and the applicable component of the Department sponsoring the collection: Form CRM–157. Criminal Division, U.S. Department of Justice

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit, Not-for-profit institutions, and individuals or households. The form is used to register foreign agents as required under the provisions of the Foreign Agents Registration Act of 1938, as amended, 22 U.S.C. 611, *et seq.*, must set forth the information required to be disclosed concerning each foreign principal, and must be utilized within 10 days of date contract is made or when initial activity occurs, whichever is first.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: The estimated total number of respondents is 164 who will complete a response within 29 minutes.

(6) An estimate of the total public burden (in hours) associated with the collection:

The estimated total public burden associated with this information collection is 80 hours annually.

If additional information is required contact: Brenda E. Dyer, Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, 601 D Street, NW., Suite 1600, Washington, DC 20530.

Dated: July 28, 2004.

Brenda E. Dyer,

Clearance Officer, Department of Justice.

[FR Doc. 04–17637 Filed 8–2–04; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

Criminal Division; Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 30-Day Notice of Information Collection Under Review: Exhibit B to Registration Statement (Foreign Agents).

The Department of Justice (DOJ), Criminal Division has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the procedures of the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This information collection was previously published in the **Federal Register** Volume 69, Number 83, page 23535 on April 29, 2004, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until September 2, 2004. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20530. Additionally, comments may be submitted to OMB via facsimile to (202) 395–5806.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—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 agencies 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 submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of currently approved collection.

(2) *Title of the Form/Collection:* Exhibit B to Registration Statement (Foreign Agents).

(3) *The agency form number and the applicable component of the Department sponsoring the collection:* Form CRM–155. Criminal Division, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit, Not-for-profit institutions, and individuals or households. The form is used to augment the registration statement of foreign agents as required by the provisions of the Foreign Agents Registration Act of 1938, as amended, 22 U.S.C. 611, *et seq.*, must set forth the agreement or understanding between the registrant and each of his foreign principals as well as the nature and method of performance of such agreement or understanding and the existing or proposed activities engaged in or to be engaged in, including political activities, by the registrant for the foreign principal, and must be filed within 10 days of the date a contract is made or when initial activity occurs, whichever is first.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The total estimated number of responses is 164 at approximately .33 hours (20 minutes) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 54 annual burden hours associated with this collection.

If additional information is required contact: Brenda E. Dyer, Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, 601 D Street, NW., Suite 1600, Washington, DC 20530.

Dated: June 28, 2004.

Brenda E. Dyer,

Clearance Officer, Department of Justice.

[FR Doc. 04–17638 Filed 8–2–04; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

Criminal Division; Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 30-Day notice of information collection under review: Amendment to Registration or Supplemental Registration Reports (Foreign Agents)

The Department of Justice (DOJ), Criminal Division has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the procedures of the Paperwork Reduction Act of 1995. The proposed information collection is

published to obtain comments from the public and affected agencies. This information collection was previously published in the **Federal Register** Volume 69, Number 62, page 16956 on March 31, 2004, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until September 2, 2004. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20530. Additionally, comments may be submitted to OMB via facsimile to (202) 395–5806.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—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 agencies 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 submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of currently approved information collection.

(2) *The title of the Form/Collection:* Amendment to Registration or Supplemental Registration Reports (Foreign Agents)

(3) *The agency form number and the applicable component of the Department sponsoring the collection:* Form CRM–156. Criminal Division, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit, Not-for-profit institutions, and individuals or households. The form is used in registration of foreign agents when changes are required under provisions of the Foreign Agents Registration Act of 1938, as amended, 22 U.S.C. 611, *et seq.*

(5) *An estimate of the total number of respondents and the amount of time estimated for an average response:* The estimated total number of respondents is 175 who will complete a response within 1½ hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated total public burden associated with this information collection is 262 hours annually.

If additional information is required contact: Brenda E. Dyer, Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, 601 D Street. NW., Suite 1600, Washington, DC 20530.

Dated: July 28, 2004.

Brenda E. Dyer,

Clearance Officer, Department of Justice.

[FR Doc. 04–17670 Filed 8–2–04; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

Criminal Division; Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 30-Day Notice of Information Collection Under Review: Short-form Registration Statement of Individuals (Foreign Agents).

The Department of Justice (DOJ), Criminal Division has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the procedures of the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This information collection was previously published in the **Federal Register** Volume 69, Number 62, page 16952 on March 31, 2004, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until September 2, 2004. This process is conducted in accordance with 5 CFR 1320.10,

Written comments and/or suggestions regarding the item contained in this notice, especially the estimated public burden and associated response time, should be directed to The Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20530. Additionally, comments may be submitted to OMB via facsimile to (202) 395–5806. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—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 agencies 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 submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of currently approved information collection.

(2) *Title of the Form/Collection:* Short-form Registration Statement of Individuals (Foreign Agents).

(3) *The agency form number and the applicable component of the Department sponsoring the collection:* Form CRM–156. Criminal Division, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit, Not-for-profit institutions, and individuals or households. The form is used to register foreign agents as required under the provisions of the Foreign Agents Registration Act of 1938, as amended, 22 U.S.C. 611, *et seq.* Rule 202 of the Act requires that a partner, officer, director, associate, employee and agent of a registrant who engages directly in activity in furtherance of the interests of the foreign principal, in other than a clerical, secretarial, or in a related or similar capacity, file a short-form registration statement.

(5) *An estimate of the total number of respondents and the amount of time*

estimated for an average respondent to respond: The estimated total number of respondents is 523, who will complete a response within 25 minutes.

(6) An estimate of the total public burden (in hours) associated with the collection: The estimated total public burden associated with this information collection is 224 hours annually.

If additional information is required contact: Brenda E. Dyer, Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, 601 D Street, NW., Suite 1600, Washington, DC 20530.

Dated: July 28, 2004.

Brenda E. Dyer,

Clearance Officer, Department of Justice.

[FR Doc. 04–17671 Filed 8–2–04; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

Criminal Division; Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 30-Day Notice of information collection under review: Supplemental Registration Statement of Individuals (Foreign Agents).

The Department of Justice (DOJ), Criminal Division has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the procedures of the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 69, Number 83, page 23536 on April 29, 2004, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until September 2, 2004. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20530. Additionally, comments may be submitted to OMB via facsimile to (202) 395–5805. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—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 agencies 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 submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of currently approved information collection.

(2) *Title of the Form/Collection:* Supplemental Registration Statement of Individuals (Foreign Agents).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form CRM–154. Criminal Division, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit, not-for-profit institutions, and individuals or households. Form is required by the provisions of 22 U.S.C. 611, *et seq.*, must be filed by the foreign agent within thirty days after the expiration of each period of six months succeeding the original filing date, and must contain accurate and complete information with respect to the foreign agent's activities, receipts and expenditures.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* There are an estimated 491 respondents who will complete the form within 1 hour and 22 minutes per response (2 responses annually).

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 1,350 total annual burden hours associated with this collection.

If additional information is required contact: Brenda E. Dyer, Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: July 28, 2004.

Brenda E. Dyer,

Clearance Officer, Department of Justice.

[FR Doc. 04–17672 Filed 8–2–04; 8:45 am]

BILLING CODE 4410–14–M

DEPARTMENT OF JUSTICE

Criminal Division; Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 30-Day Notice of Information Collection Under Review: Registration Statement of Individuals (Foreign Agents).

The Department of Justice (DOJ), Criminal Division has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the procedures of the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 69, Number 62, page 16956 on March 31, 2004, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until September 2, 2004. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20530. Additionally, comments may be submitted to OMB via facsimile to (202) 395–5806. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points.

—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 agencies 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 submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of currently approved information collection.

(2) *Title of the Form/Collection:* Registration Statement of Individuals (Foreign Agents).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form CRM–153. Criminal Division, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: business or other for-profit, not-for-profit institutions, and individuals or households. Form contains registration statement and information used for registering foreign agents under 22 U.S.C. 611, *et seq.*,

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* There are an estimated 67 respondents who will complete the form within 1 hour and 22 minutes per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 92 total annual burden hours associated with this collection.

If additional information is required contact: Brenda E. Dyer, Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: July 28, 2004.

Brenda E. Dyer,

Clearance Officer, U.S. Department of Justice.

[FR Doc. 04–17673 Filed 8–2–04; 8:45 am]

BILLING CODE 4410–14–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,161]

Chattanooga General Services, Inc., Chattanooga, TN; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on June 29, 2004, in response to a worker petition filed by a company official on behalf of workers at Chattanooga General Services, Inc., Chattanooga, Tennessee.

The petitioning group of workers is covered by an earlier petition filed on June 10, 2004 (TA–W–55,100), that is the subject of an ongoing investigation for which a determination has not yet been issued. Further investigation in this case would duplicate efforts and serve no purpose; therefore the investigation under this petition has been terminated.

Signed in Washington, DC, this 19th day of July 2004.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 04–17600 Filed 8–2–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,247]

Clifford Tools and Manufacturing Co., Chatsworth, CA; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on July 14, 2004, in response to a petition filed by a state workforce representative on behalf of workers at Clifford Tools and Manufacturing Company, Chatsworth, California.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC, this 16th day of July, 2004.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 04–17606 Filed 8–2–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,188]

Dura Automotive Systems, Inc., Cables Division, Brookfield, MO; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on July 1, 2004, in response to a worker petition filed by a company official on behalf of workers at Dura Automotive Systems, Inc., Cables Division, Brookfield, Missouri.

The petitioner has requested that the petition be withdrawn. Consequently, further investigation would serve no purpose and the investigation has been terminated.

Signed at Washington, DC, this 21st day of July, 2004.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 04–17604 Filed 8–2–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,085]

Jomed, San Diego, CA; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on June 16, 2004, in response to a petition filed by a State agency representative on behalf of workers at Jomed, San Diego, California.

The petitioner has requested that the petition be withdrawn. Consequently, further investigation would serve no purpose and the investigation has been terminated.

Signed in Washington, DC, this 19th day of July, 2004.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 04–17603 Filed 8–2–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,197]

Kaz, Newbern, TN; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on July 6, 2004, in response to a petition filed on behalf of workers at Kaz, Newbern, Tennessee.

The petitioners have requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC, this 19th day of July, 2004.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 04–17602 Filed 8–2–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–39,399]

Lomac LLC, Muskegon, MI; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on July 30, 2001, applicable to workers of Lomac LLC, Muskegon, Michigan. The notice was published in the **Federal Register** on August 15, 2001 (66 FR 42878).

At the request of a state agency representative, the Department reviewed the certification for workers of the subject firm. The workers were engaged in the production of 3,3′ dichlorobenzene dihydrochloride (DCB).

New information shows that Brian Caftenholz was retained at the subject firm beyond the July 30, 2003, expiration date of the certification. Mr. Caftenholz was retained by the firm to complete the close-down process until his termination on August 15, 2003.

Based on these findings, the Department is amending the certification to extend the July 30, 2003, expiration date for TA-W–39,399 to read August 15, 2003.

The intent of the Department's certification is to include all workers of Lomac LLC who were adversely affected by increased imports.

The amended notice applicable to TA–W–39,399 is hereby issued as follows:

All workers of Lomac LLC, Muskegon, Michigan, who became totally or partially separated from employment on or after May 18, 2000, through August 15, 2003, are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974.

Signed in Washington, DC, this 21st day of July, 2004.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 04–17607 Filed 8–2–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, as amended, (19 U.S.C. 2273), the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) number and alternative trade adjustment assistance (ATAA) by (TA–W) number issued during the periods of June and July 2004.

In order for an affirmative determination to be made and a certification of eligibility to apply for directly-impacted (primary) worker adjustment assistance to be issued, each of the group eligibility requirements of section 222(a) of the Act must be met.

I. Section (a)(2)(A) all of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. The sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. Increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. There has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;

2. The country to which the workers' firm has shifted production of the articles to a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. There has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

Also, in order for an affirmative determination to be made and a certification of eligibility to apply for worker adjustment assistance as an adversely affected secondary group to be issued, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) Significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm (or subdivision) is a supplier or downstream producer to a firm (or subdivision) that employed a group of workers who received a certification of eligibility to apply for trade adjustment assistance benefits and such supply or production is related to the article that was the basis for such certification; and

(3) Either—(A) The workers' firm is a supplier and the component parts it supplied for the firm (or subdivision) described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss or business by the workers' firm with the firm (or subdivision) described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

Negative Determinations for Worker Adjustment Assistance

In the following cases, the investigation revealed that the criteria

for eligibility have not been met for the reasons specified.

The investigation revealed that criteria (a)(2)(A)(I.C.)(increased imports) and (a)(2)(B)(II.B) (No shift in production to a foreign country) have not been met.

TA–W–54,944; Norwood Promotional Products, New London, WI
TA–W–55,004; Solutia, Inc., Performance Products Div., Anniston, AL
TA–W–54,828; Caraustar, Cedartown, GA
TA–W–54,796; Venture Industries, Lancaster Ohio Plant, Lancaster, OH
TA–W–54,824; Fincor Automation, div. of Saftronics, York, PA
TA–W–55,148; FAG Interamericana, AG, a subsidiary of FAG, Miami, FL
TA–W–55,051; Sun Air Conditioning, a subsidiary of Fedders Corp., Vienna, GA
TA–W–55,045; Merrow Machine Co., Newington, CT
TA–W–55,041; Dielectric Communications, Raymond Facility, Broadcast Div., Including leased workers of Bonney Staffing, Raymond, ME
TA–W–55,065; Franklin International, Columbus, OH
TA–W–55,003 & A; Pomona Textile Co., Inc., Production Plant, Pomona, CA and Sales Office, Burbank, CA
TA–W–55,080; Vesuvius McDanel, Beaver Falls Div., Beaver Falls, PA
TA–W–54,811; Rock-Tenn Co., Laminated Paperboard Products Div., Wright City, MO
TA–W–54,930; Yukon Manufacturing, Litchfield, MI
TA–W–54,919; Daimlerchrysler Corp., Plant Security Operations, Jefferson North Assembly Plant, Detroit, MI
TA–W–54,995; Herff Jones, Inc., Indianapolis, IN
TA–W–54,989; Paradise Datacom LLC, a div. of Intelek, VSAT Line, Boalsburg, PA
TA–W–54,975; Bake-Line Group LLC, Marietta Plant, Marietta, OK
TA–W–54,866; National Textiles, China Grove, NC
TA–W–54,800A; Johnson Controls, Inc., Southview Plant, Door Panel Line, including leased workers of Kelly Services, Holland, MI

The workers firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA–W–55,102; Affiliated Computer Services, Inc. Peak Department, Portland, OR
TA–W–55,095; Gateway Country Store, Davenport, IA
TA–W–55,222; ACS Monticello, a subdivision of ACS Business Process Outsourcing, a div. of Affiliated Computer Services, Inc., Monticello, KY
TA–W–55,124; General Electric Capital Corp., GE Auto Financial Services, Depew, NY
TA–W–55,105; Powderject Vaccines, Inc., Middleton, WI
TA–W–54,889; 3m, 3M Center, Industrial Marketing Operations, St. Paul, MN
TA–W–54,950; Continental Retail Services, LLC, Bellbrook, OH
TA–W–54,808; Gateway Country Store, Greenwood, IN
TA–W–54,768; Crystal Springs Apparel, LLC, Crystal Springs, MS
TA–W–54,892; Information Resources, Inc. (IRI), Chicago, IL
TA–W–54,947; Hewlett-Packard Company, TSG Americas Customer Services Delivery, Customer Experience, Customer Access Management, Colorado Springs, CO
TA–W–54,976; Unisys Corp., ETS Industries, Communications Div., including leased workers of Adecco and Teksystems, Malvern, PA
TA–W–55,099; JPMorgan Chase and Co., Credit Card Services/Customer Service/Collections Departments, Hicksville, NY
TA–W–55,037; Symbol Technologies, Inc., Lake Forest Service Center, Lake Forest, CA
TA–W–54,985; Tyco Safety Products, Research and Development Div., Westminster, MS
TA–W–55,125; Volt Temporary Services, Leased Workers Onsite at SR Telecom, Inc., Redmond, WA
TA–W–55,092; Computer Services Corp., Global Transformation Solutions Group, Somerset, NJ
TA–W–54,350; Oracle Corp., Sales Organization, Englewood, CO
TA–W–55,089; Sensormatic Electronics Corp., Access Control/video Systems Business Unit, a Subsidiary of Tyco International, Lexington, MA
TA–W–55,042; NCR Corporation, Business Operations Center—US, Dayton, OH
TA–W–55,066 & A,B,C; Salton, Inc., Columbia, MO, Lake Forest, IL, Macon, MO and Laurinsburg, NC
TA–W–54,872; Sanmina-SCI Corp., Global Engineering and Design Group, Salem NH
TA–W–54,926; Bes-Tex Fabrics, Inc., New York, NY
TA–W–54,959; AT&T, Premise Desktop Support, Piscataway, NJ
TA–W–54,903; Nortel Networks, Global Operations, Supply Management Division, Research Triangle Park, NC
TA–W–54,869; Gearbuck Aviation Maintenance Complex, Blytheville, AR
TA–W–55,018; Hewitt Associates LLC, HRO Health and Welfare Delivery, Direct Billings and Payment, Lincolnshire, IL
TA–W–55,098; Pacific Crest Technology, Tualatin, OR
TA–W–55,070; Franklin Resources, Inc., Franklin Templeton Services, LLC, Global Equity Trading, Ft. Lauderdale, FL
TA–W–55,021; Parametric Technology Corp., Solutions and Marketing Group, WC Publication and Documentation Departments, Needham, MA
TA–W–54,968; Johnson Controls Battery Group, Inc., Battery and Technical Center, Glendale Plant, Milwaukee, WI
TA–W–55,135; Envirovac Industrial and Environmental Services, LLC, Lexington, SC
TA–W–55,072; Jaymar-Ruby, Inc., d/b/a Trans-Apparel Group, a subsidiary of Hartmarx Corp, Michigan City, IN
TA–W–55,126; Buena Vista International, Inc., d/b/a Walt Disney Television International, (Latin America), Coral Gables, FL
TA–W–54,957; Union Carbide Corp., a subsidiary of The Dow Chemical Co., Control Group, South Charleston, WV

The investigation revealed that criterion (a)(2)(A)(I.A) and (a)(2)(B)(II.A) (no employment decline) have not been met.

TA–W–55,027; Tyco Fire & Security, Marinette, WI
TA–W–54,834; Westan, Westfield, PA
TA–W–54,935; Bush Industries, Inc., Erie, PA
TA–W–55,048; Effort Foundry, Inc., Bath, PA
TA–W–54,966; Campbell Colors, Inc, Greenville, SC
TA–W–55,020; Bonbardier Learjet, Indianapolis, IN

The investigation revealed that criterion (a)(2)(A)(I.B) (Sales or production, or both, did not decline) and (a)(2)(B)(II.B) (has shifted production to a county not under the free trade agreement with U.S.) have not been met.

TA–W–54,887; Eaton Aerospace, Sarasota, FL
TA–W–54,878; Smurfit Stone Container Corp., including leased workers of Manpower, Anderson, IN

The investigation revealed that criteria (a)(2)(A)(I.B) (Sales or production, or both, did not decline) and (a)(2)(B)(II.C) (has shifted

production to a foreign country) have not been met.

TA–W–54,891; Johnson Diversey, Inc., Customer Service Group, Industrial Group Div., Sharonville, OH

The investigation revealed that criteria (a)(2)(A)(a)(2)(A)(I.C) (Increased imports) and (II.C) (Has shifted production to a foreign country) have not been met.

TA–W–55,108; Cosom Sporting Goods, Inc., Thorofare, NJ

TA–W–54,961; TDS Automotive, Oxford, MI

TA–W–55,152; Dresser, Inc., Roots Division, Houston, TX

TA–W–55,094; Executive Greetings, Inc., New Hartford, CT

The investigation revealed that criteria (2) has not been met. The workers firm (or subdivision) is not a supplier or downstream producer to trade-affected companies.

TA–W–54,906; W.H. Stewart Co., Oklahoma City, OK

TA–W–55,155; Prince Manufacturing, a subsidiary of The Price Group, Greenville, NC

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued; the date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of (a) (2) (A) (increased imports) of Section 222 have been met.

TA–W–55,030; New Era Cap. Buffalo Facility, Buffalo, NY: May 25, 2003.

TA–W–55,014; Experience Management, LLC, d/b/a Venture Industries, Grand Rapids, MI: May 24, 2003.

TA–W–54,978; Westpoint Stevens, Fairfax Manufacturing Plant, Valley, AL: May 24, 2003.

TA–W–54,927; Hayes Lemmerz International, Inc., Howell Div., Howell, MI: May 17, 2003.

TA–W–54,899; Zilog, Inc., Nampa Mod II Manufacturing Div., Nampa, ID: May 10, 2003.

TA–W–54,793; Pyrotek, Inc., Trenton, TN: April 27, 2003.

TA–W–55,256; Miller Bag Co., Arlington, SD: July 8, 2003.

TA–W–55,178; Wellington Cordage, LLC, a subsidiary of Wellington Leisure, Inc., Leesville, SC: June 18, 2003.

TA–W–55,154; Apollo Knitwear, Inc., Lafayette, GA: June 17, 2003.

TA–W–55,153; Industrial Engraving and Manufacturing Corp., Pulaski, WI: June 24, 2003.

TA–W–55,087; Pasquier Panel Products, Inc., Sumner, WA: June 14, 2003.

TA–W–54,557; A.F. Dormeyer, Inc., a subsidiary of Saia-Burgess, Inc., Rockville, IN: March 10, 2003.

TA–W–54,981; Elkhart Foundry and Machine Co., Inc., Elkhart, IN: May 25, 2003.

TA–W–55,146; Hekman Furniture Co., a div. of Howard Miller Clock Co., Lexington, NC: June 10, 2003.

TA–W–55,145; Springs Industries, Inc., Bedding Div., including leased workers of Staff Mark, Lyman, SC: June 21, 2003.

TA–W–55,139; Hamrick Industries, Inc., including leased workers of First Staff, Inc., Gaffney, SC: June 24, 2003.

TA–W–54,881; Bradford Soap Works. Inc., West Warwick, RI: May 10, 2003.

TA–W–55,031; Sherwood Home Furnishings, Sewing Operations, Spring City, TN: May 26, 2003.

TA–W–54,994; United Elastic, a div. of Narroflex, Inc. Company, Stuart, VA: May 11, 2003.

TA–W–54,874 & A; Santa's Best, Vineland, NJ and Millville, NJ: April 30, 2003.

TA–W–55,000; Jacquart Fabric Products, Inc., Ironwood, MI: May 24, 2003.

TA–W–54,960; MGS Holding Corp., Woonsocket, RI: May 20, 2003.

TA–W–54,937; Quebecor World Buffalo, Inc., a subsidiary of Quebecor World, Depew, NY: May 11, 2003.

TA–W–54,917; Circuit Wise, Inc., North Haven, CT: May 14, 2003.

TA–W–55,024; Springfield Plastics, Inc., including leased workers of Career Concepts, East Springfield, PA: May 27, 2003.

TA–W–55,017; P.H. Glatfelter Co., d/b/a Glatfelter, Spring Grove Facility, including leased workers of ACSYS, TAC Worldwide Companies, Adecco, Manpower, Spring Grove, PA: June 2, 2003.

TA–W–54,911; The Keller Manufacturing Co., Inc., New Salisbury, IN: May 12, 2003.

TA–W–54,851; Intex Corp., Administrative Office, Greensboro, NC, Print Plant, Pilot Mountain, NC and Garment Distribution Center, Pilot Mountain, NC: May 4, 2003.

TA–W–54,948; R & V Industries, d/b/a Shape Global Technology, Sanford, ME: January 30, 2004.

TA–W–55,047; Imperial Electric Co., Middleport, OH: June 8, 2003.

TA–W–54,870 & A; J&L Specialty Steel, LLC, Corporate Headquarters, including leased workers of Intelligent Personnel Service, Information Technology Professionals, Inc., Technical Solutions, Inc., Balioinis, Deloittle & Touche and Reflex Staffing Solutions, Inc., Moon Township, PA and J&L Specialty Steel, LLC, Midland Plant, including leased workers of Ohio Security Services, Inc., U.S. Security, Allied Security, Technical Solutions, Inc., and Accounttemps, Midland, PA: May 7, 2003.

TA–W–54,871; DeVlieg Bullard II, Inc., Tooling Systems Div., Frankenmuth, MI: May 5, 2003.

TA–W–55,029; Leeda Sewing Manufacturing, Inc., San Francisco, CA: June 3, 2003.

TA–W–55,012; Lavallee & Ide, Inc., Winooski, VT: June 1, 2003.

TA–W–55,026; Snow River Products LLC, a subsidiary of Columbian Home Products, Crandon, WI: June 2, 2003.

TA–W–55,117; Bausch and Lomb, St. Louis, MO: June 15, 2003.

TA–W–55,002; Parallax Power Components, LLC, RV Converter Products Div., Goodland, IN: May 20, 2003.

TA–W–55,136; ITW Auto-Sleeve, a subsidiary of Illinois Tool Works, Twinsburg, OH: June 11, 2003.

TA–W–54,855; Sara Lee Intimates and Hosiery, Aleo Distribution, including leased workers of Kelly Services, Rockingham, NC: April 29, 2003.

The following certifications have been issued. The requirements of (a) (2) (B) (shift in production) of Section 222 have been met.

TA–W–55,035; Remec, Inc., Formerly Paradigm Wireless, Irvine, CA: June 6, 2003.

TA–W–55,054; Varco L.P., including leased workers from Ad-Tek Engineering, Peak Technical Services, Inc., H.L. Yoh, Select Personnel Services, Premier Staffing Solutions, Onsite Commercial, ABS Personnel, Aviant B&m Associates, HR Solutions, Coneybear Staffing, Talent Tree, PDS Technical Services, and Premier Staffing Solutions, Orange, CA: June 3, 2003.

TA–W–55,074; Motion Control Technology, Diversified Products, N.A., a wholly owned subsidiary of Dana Corp., including leased workers of Burnett, El Paso, TX: May 25, 2003.

TA–W–55,199 & A; Brown City Wire Company, a subsidiary of Clements Manufacturing LLC, Harbor Beach, MI and Deckerville Wire, Inc., a subsidiary of Clements Manufacturing LLC, Harbor Beach, MI: August 23, 2004.

TA–W–55,097; Johnson Controls, Lakewood/Beechwood Facilities,

Automotive Group, Holland, MI: June 15, 2003.

TA–W–54,970; Lifescan, Inc., a div. of Johnson and Johnson, Milpitas, CA: May 20, 2003.

TA–W–55,071; Wellington Point, LLC, d/b/a Lifelike Hair, Salt Lake City, UT: June 11, 2003.

TA–W–55,107; Magnecomp Corp., Production Div., a subsidiary of Indest Corp., Temecula, CA: June 9, 2003.

TA–W–55,056; Knight Apparel Corp., a div. of Knight Textiles Corp., New York, NY: June 1, 2003.

TA–W–54,879; Vesuvius USA Corp., Foundry Div., Buffalo, NY: May 3, 2003.

TA–W–55,008; National Textiles, Greenwood, South Carolina Cutting Department, Hodges, SC: June 1, 2003. America, Inc., Tualatin, OR and Fife, WA: May 18, 2003.

TA–W–55,033; TAC Americas, Inc., Manufacturing Department, Carrollton, TX: June 3, 2003.

TA–W–55,198; Schnadig Corp., Montoursville, PA: July 1, 2003.

TA–W–55,109; Ericson Manufacturing Co., Willoughby, OH: June 17, 2003.

TA–W–55,093; Galey and Lord Industries, Inc., Shannon, GA: June 15, 2003.

TA–W–55,046; Schweitzer Mauduit International, Inc., Sportswood Mill, Sportswood, NJ: June 8, 2003.

TA–W–55,068; TB Wood's, Inc., Trenton, TN: June 8, 2003.

TA–W–55,159; Alexander Harris Co., Inc., Pelham, GA: June 25, 2003.

TA–W–54,984; C&D Technologies, Inc., Standby Power Div., Leola, PA: May 25, 2003.

TA–W–55,025; Medex Cardio Pulmonary, Inc., d/b/a Medex, Inc., Chicago, IL: June 2, 2003.

TA–W–55,052; Thermotech Company, El Paso, TX: June 8, 2003.

TA–W–55,062; Lakeland Industries, Inc., Woven Products Div., St. Joseph, MO: June 9, 2003.

TA–W–55,061; Prestolite Wire Corp., Tifton, GA: June 1, 2003.

TA–W–55,060; Nemanco, Inc., Philadelphia, MS: June 2, 2003.

TA–W–55,057; Robert Bosch Tool Corp., Leitchfield, KY: June 7, 2003.

TA–W–55,076; Inflation Systems, Inc., LaGrange, GA: June 14, 2003.

TA–W–54,965; Flextronics International, including leased workers of Spherion, Portsmouth, NH: May 21, 2003.

TA–W–55,016; BC Technologies, Inc., Stockbridge, GA: June 2, 2003.

TA–W–55,043; Dorr Oliver Eimco USA, Inc., formerly known as Eimco Processing Co., Milford, CT: June 2, 2003.

TA–W–54,971; Honeywell International, Inc., Sensing and Control Div., Acton, MA: May 21, 2003.

TA–W–54,987; Remington Products, including leased workers of Impact Personnel, Accountants, Inc., Mid State Technical and Power Recruiting, Bridgeport, CT: May 26, 2003.

TA–W–54,839; Flextronics International, Parsippany, NJ: May 3, 2003.

TA–W–54,898; Ogden Manufacturing, Inc., Albany Plant including leased workers of Kelly Services, Albany, WI: May 4, 2003.

TA–W–54,936; Deuer Manufacturing, Inc., d/b/a Flex-N-Gate Deuer, Dayton, OH: May 10, 2003.

TA–W–55,50 & A; TI Group Automotive Systems, LLC, Washington Court House, OH and Sabina, OH: May 20, 2003.

TA–W–55,106; Truth Hardware, Pacoima, CA: June 17, 2003.

TA–W–55,073; R/D Tech, Madison, PA: June 2, 2003.

TA–W–54,977; Custom Tool and Manufacturing Co., Lawrenceburg, KY: May 24, 2003.

TA–W–54,800; Johnson Controls, Inc., Southview Plant, Sun Visor Line, including leased workers of Kelly Services, Holland, MI: April 8, 2003.

Negative Determinations for Alternative Trade Adjustment Assistance

In order for the Division of Trade Adjustment Assistance to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

In the following cases, it has been determined that the requirements of Section 246(a)(3)ii) have not been met for the reasons specified.

The Department has determined that criterion (1) of Section 246 has not been met. Workers at the firm are 50 years of age or older.

TA–W–54,977; Custom Tool and Manufacturing Co., Lawrenceburg, KY

The Department has determined that criterion (2) of Section 246 has not been met. Workers at the firm possess skills that are easily transferable.

TA–W–55,073; R/D Tech, Madison, PA

TA–W–55,106; Truth Hardware, Pacoima, CA

TA–W–54,855; Sara Lee Intimates and Hosiery, Aleo Distribution, including leased workers of Kelly Services, Rockingham, NC

TA–W–55,136; ITW Auto-Sleeve, a subsidiary of Illinois Tool Works, Twinsburg, OH

TA–W–55,002; Parallax Power Components, LLC, RV Converter Products Div., Goodland, IN

TA–W–55,026; Snow River Products LLC, a subsidiary of Columbian Home Products, Crandon, WI

TA–W–55,012; Lavallee and Ide, Inc., Winooski, VT

The Department has determined that criterion (3) of Section 246 has not been met. The competitive conditions within the workers' industry is adverse.

TA–W–55,117; Bausch and Lomb, St. Louis, MO

Since the workers are denied eligibility to apply for TAA, the workers cannot be certified eligible for ATAA.

TA–W–54,957; Union Carbide Corp., a subsidiary of The Dow Chemical Co., Control Group, South Charleston, WV

TA–W–54,966; Campbell Colors, Inc., Greenville, SC

TA–W–54,975; Bake-Line Group LLC, Marietta Plant, Marietta, OK

TA–W–54,989; Paradise Datacom LLC, a div. of Intelek, Vsat Line, Boalsburg, PA

TA–W–54,995; Herff Jones, Inc., Indianapolis, IN

TA–W–55,048; Effort Foundry, Inc, Bath, PA

TA–W–54,919; Daimlerchrysler Corp., Plant Security Operations, Jefferson North Assembly Plant, Detroit, MI

TA–W–54,930; Yukon Manufacturing, Litchfield, MI

TA–W–54,935; Bush Industries, Inc., Erie, PA

TA–W–54,811; Rock-Tenn Co., Laminated Paperboard Products Div., Wright City, MO

TA–W–54,834; Westan, Westfield, PA

TA–W–55,126; Buena Vista International, Inc., d/b/a Walt Disney Television International (Latin America), Coral Gables, FL

TA–W–55,072; Jaymar-Ruby, Inc., d/b/a Trans-Apparel Group, a subsidiary of Hartmarx Corp., Michigan City, IN

TA–W–55,080; Vesuvius McDanel, Beaver Falls Div., Beaver Falls, PA

TA–W–55,003 &A; Pomona Textile Co., Inc., Production Plant, Pomona, CA and Sales Office, Burbank, CA

TA–W–55,135; Envirovac Industrial and Environmental Services, LLC, Lexington, SC

TA–W–54,887; Eaton Aerospace, Sarasota, FL

TA–W–54,968; Johnson Controls Battery Group, Inc., Battery and Technical Center, Glendale Plant, Milwaukee, WI

TA–W–55,020; Bombardier Learjet, Indianapolis, IN

TA–W–55,021; Parametric Technology Corp., Solutions and Marketing

Group, WC Publicatian and Documentatian Departments, Needham, MA

TA–W–55,070; Franklin Resources, Inc., Franklin Templeton Services, LLC, Glabal Equity Trading, Ft. Lauderdale, FL

TA–W–55,065; Franklin Internatianal, Calumbus, OH

TA–W–55,098; Pacific Crest Technology, Tualatin, OR

TA–W–55,027; Tyca Fire and Security, Marinette, WI

TA–W–55,018; Hewitt Assaciates LLC, HRO Health and Welfare Delivery, Directar Billings and Payment, Lincolnshire, IL

TA–W–54,869; Gearbuck Aviation Maintenance Camplex, Blytheville, AR

TA–W–54,903; Nartel Netwarks, Global Operations, Supply Management Divisian, Research Triangle Park, NC

TA–W–54,878; Smurfit Stane Container Carp., including leased warkers af Manpawer, Andersan, IN

TA–W–54,959; AT&T, Premise Desktap Suppart, Piscataway, NJ

TA–W–54,926; Bes-Tex Fabrics, Inc., New York, NY

TA–W–54,961; TDS Autamative, Oxfard, MI

TA–W–54,800A; Jahnsan Cantrals, Inc., Sauthview Plant, Daar Panel Line, including leased workers of Kelly Services, Halland, MI

TA–W–55,041; Dielectric Cammunicatians, Raymand Facility, Broadcast Div., including leased workers af Banney Staffing, Raymand, ME

TA–W–54,866; Natianal Textiles, China Grave, NC

TA–W–54,872; Sanmina-SCI Corp., Glabal Engineering and Design Graup, Salem, NH

TA–W–55,152; Dresser, Inc., Raats Divisian, Haustan, TX

TA–W–55,066 & A,B,C;; Salton, Inc., Calumbia, MO, Lake Farest, IL, Macon, MO and Laurinsburg, NC

TA–W–55,094; Executive Greetings, Inc., New Hartford, CT

TA–W–55,108; Cosom Sparting Gaads, Inc., Tharafare, NJ

TA–W–55,155; Prince Manufacturing, a subsidiary af The Prince Group, Greenville, NC

TA–W–55,042; NCR Carp., Business Operatians Center—U.S., Daytan, OH

TA–W–55,045; Merraw Machine Ca., Newingtan, CT

TA–W–55,051; Sun Air Canditianing, a subsidiary af Fedders Carp., Vienna, GA.

Affirmative Determinations for Alternative Trade Adjustment Assistance

In order for the Division of Trade Adjustment Assistance to issued a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

The following certifications have been issued; the date following the company name and location of each determination references the impact date for all workers of such determinations.

In the following cases, it has been determined that the requirements of Section 246(a)(3)(ii) have been met.

I. Whether a significant number of workers in the workers' firm are 50 years of age or older.

II. Whether the workers in the workers' firm possess skills that are not easily transferable.

III. The competitive conditions within the workers' industry (*i.e.*, conditions within the industry are adverse).

TA–W–55,050 & A; TI Group Autamative Systems, LLC, Washingtan Caurt Hause, OH and Sabine, OH: May 20, 2003

TA–W–55,047; Imperial Electric Ca., Middlepart, OH: June 8, 2003.

TA–W–55,029; Leeda Sewing Manufacturing, Inc., San Francisca, CA: June 3, 2003.

TA–W–54,936; Deuer Manufacturing, Inc., d/b/a Flex-N-Gate Deuer, Daytan, OH: May 10, 2003.

TA–W–54,871; DeVlieg Bullard II, Inc., Tooling Systems Division, Frankenmuth, MI: May 5, 2003.

TA–W–54,898; Ogden Manufacturing, Inc., Albany Plant including leased warkers of Kelly Services, Albany, WI: May 4, 2003.

TA–W–54,870 & A; J&L Specialty Steel, LLC, Carparate Headquarters, including leased warkers af Intelligent Persannel Service, Information Technalogy Prafessionals, Inc., Technical Salutians, Inc., Balianis, Delaitte & Touche and Reflex Staffing Salutians, Inc., Maan Tawnship, PA and J&L Specialty Steel, LLC, Midland Plant, including leased warkers af Ohia Security Services, Inc., U.S. Security, Allied Security, Technical Solutians, Inc., and Accaunttemps, Midland, PA: May 7, 2003.

TA–W–54,839; Flextranics Internatianal, Parsippany, NJ: May 3, 2003.

TA–W–54,987; Remingtan Praducts, including leased warkers af Impact Personnel, Accountants, Inc., Mid-State Technical and Pawer Recruiting, Bridgepart, CT: May 26, 2003.

TA–W–54,971; Haneywell International, Inc, Sensing and Cantral Div., Actan, MA: May 21, 2003.

TA–W–54,948; R & V Industries, d/b/a Shape Glabal Technology, Sanford, ME: January 30, 2004.

TA–W–55,043; Darr-Oliver Eimco USA, Inc., farmerly knawn as Eimca Pracessing Ca., Milfard, CT: June 2, 2003.

TA–W–54,851 A,B; Intex Carparatian, Administrative Office, Greensbara, NC, Print Plant, Pilot Mountain, NC and Garment Distributian Center, Pilat Mountain, NC: May 4, 2003.

TA–W–55,016; BC Technalagies, Inc., Stackbridge, GA: June 2, 2003.

TA–W–54,911; The Keller Manufacturing Ca., Inc., New Salisbury, IN: May 12, 2003.

TA–W–54,965; Flextranics International, including leased warkers af Spherian, Portsmauth, NH: May 21, 2003.

TA–W–55,076; Inflatian Systems, Inc., LaGrange, GA: June 14, 2003.

TA–W–55,057; Rabert Basch Taal Carp., Leitchfield, KY: June 7, 2003.

TA–W–55,060; Nemanca, Inc., Philadelphia, MS: June 2, 2003.

TA–W–55,061; Prestalite Wire Carp., Tiftan, GA: June 1, 2003.

TA–W–55,062; Lakeland Industries, Inc., Waven Praducts Div., St. Jaseph, MO: June 9, 2003.

TA–W–55,052; Thermatech Ca., El Pasa, TX: June 8, 2003.

TA–W–55,017; P.H. Glatfelter Ca., d/b/a Glatfelter, Spring Grave Facility, including leased warkers af ACSYS, TAC Warldwide Campanies, Adecco, Manpawer, Spring Grave, PA: June 2, 2003.

TA–W–55,024; Springfield Plastics, Inc., including leased warkers af Career Cancepts, East Springfield, PA: May 27, 2003.

TA–W–55,025; Medex Cardia-Pulmanary, Inc., d/b/a Medex, Inc., Chicaga, IL: June 2, 2003.

TA–W–54,917; Circuit-Wise, Inc., Narth Haven, CT: May 14, 2003.

TA–W–54,937; Quebecar Warld Buffala, Inc., a subsidiary of Quebecor Warld, Depew, NY: May 11, 2003.

TA–W–54,960; MGS Halding Carparatian, Waansacket, RI: May 20, 2003.

TA–W–54,984; C&D Technalagies, Inc., Standby Pawer Div., Leala, PA: May 25, 2003.

TA–W–55,000; Jacquart Fabric Praducts, Inc., Iranwaad, MI: May 24, 2003.

TA–W–54,874 & A; Santa's Best, Vineland, NJ and Millville, NJ: April 30, 2003.

TA–W–55,159; Alexander-Harris Co., Inc., Pelham, GA: June 25, 2003.
TA–W–54,800; Johnson Controls, Inc., Southview Plant, Sun Visor Line, including leased workers of Kelly Services, Holland, MI: April 8, 2003.
TA–W–54,994; United Elastic, a div. of Narroflex, Inc., Company, Stuart, VA: May 11, 2003.
TA–W–55,031; Sherwood Home Furnishings, Sewing Operations, Spring City, TN: May 26, 2003.
TA–W–55,068; TB Wood's, Inc., Trenton, NJ: June 8, 2003.
TA–W–54,881; Bradford Soap Works, Inc., West Warwick, RI: May 10, 2003.
TA–W–55,139; Hamrick Industries, Inc., including leased workers of First Staff, Inc., Gaffney, SC: June 24, 2003.
TA–W–55,145; Springs Industries, Inc., Bedding Div., including leased workers of Staff Mark, Lyman, SC: June 21, 2003.
TA–W–55,146; Hekman Furniture Co., a div. of Howard Miller Clock Company, Lexington, NC: June 10, 2003.
TA–W–55,046; Schweitzer-Mauduit International, Inc., Sportswood Mill, Sportswood, NJ: June 8, 2003.
TA–W–54,981; Elkhart Foundry & Machine Co. Inc., Elkhart, IN: May 25, 2003.
TA–W–54,557; A.F. Dormeyer, Inc., a subsidiary of Saia-Burgess, Inc., Rockville, IN: March 10, 2003.
TA–W–55,093; Galey & Lord Industries, Inc., Shannon, GA: June 15, 2003.
TA–W–55,109; Ericson Manufacturing Co., Willoughby, OH: June 17, 2003.
TA–W–55,087; Pasquier Panel Products, Inc., Sumner, WA: June 14, 2003.
TA–W–55,153; Industrial Engraving and Manufacturing Corp., Pulaski, WI: June 24, 2003.
TA–W–55,154; Apollo Knitwear, Inc., Lafayette, GA: June 17, 2003.
TA–W–55,178; Wellington Cordage, LLC, a subsidiary of Wellington Leisure, Inc., Leesville, SC: June 18, 2003.
TA–W–55,198; Schnadig Corp., Montoursville, PA: July 1, 2003.
TA–W–55,256; Miller Bag Co., Arlington, SD: July 8, 2003.
TA–W–54,793; Pyrotek, Inc., Trenton, TN: April 27, 2003.
TA–W–54,899; Zilog, Inc., Nampa Mod II Manufacturing Div., Nampa, ID: May 10, 2003.
TA–W–54,927; Hayes Lemmerz International, Inc., Howell Div., Howell, MI: May 17, 2003.
TA–W–54,978; Westpoint Stevens, Fairfax Manufacturing Plant, Valley, AL: May 24, 2003.
TA–W–55,014; Experience Management, LLC, d/b/a Venture Industries, Grand Rapids, MI: May 24, 2003.
TA–W–55,030; New Era Cap, Buffalo, Facility, Buffalo, NY: May 25, 2003.
TA–W–55,033; TAC Americas, Inc., Manufacturing Department, Carrollton, TX: June 3, 2003.

I hereby certify that the aforementioned determinations were issued during the months of June and July 2004. Copies of these determinations are available for inspection in Room C–5311, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 during normal business hours or will be mailed to persons who write to the above address.

Dated: July 26, 2004.

Timothy Sullivan,

Director, Division of Trade Adjustment Assistance.

[FR Doc. 04–17598 Filed 8–2–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,250]

Staffing Solutions, Inc., Leased Worker at Aerus, LLC, Bristol, VA; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on July 14, 2004, in response to a petition filed by a company official on behalf of workers of Staffing Solutions, Inc., leased to Aerus, LLC, Bristol, Virginia.

In order to establish a valid worker group, there must be at least three full-time workers employed at the firm at some point during the period under investigation. Workers of the group subject to this investigation did not meet the threshold of employment. Consequently the investigation has been terminated.

Signed in Washington, DC, this 22nd day of July, 2004.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 04–17601 Filed 8–2–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,266]

Weathervane, New Britain, CT; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on June 16, 2004, in response to a petition filed by a state representative on behalf of workers at Weathervane, New Britain, Connecticut.

The petitioner has requested that the petition be withdrawn. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC, this 21st day of July, 2004.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 04–17605 Filed 8–2–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,210]

Wellstone Mills, LLC, Eufaula, AL; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on July 9, 2004, in response to a worker petition filed July 6, 2004, on behalf of workers at Wellstone Mills, LLC, Eufaula, Alabama.

The petitioning group of workers is covered by an earlier petition filed on July 7, 2004 (TA-W–55,202), that is the subject of an ongoing investigation for which a determination has not yet been issued. Further investigation in this case would duplicate efforts and serve no purpose; therefore the investigation under this petition has been terminated.

Signed in Washington, DC, this 15th day of July, 2004.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 04–17599 Filed 8–2–04; 8:45 am]

BILLING CODE 4910–30–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Information Security Oversight Office

National Industrial Security Program Policy Advisory Committee: Notice of Meeting

In accordance with the Federal Advisory Committee Act (5 U.S.C. app 2) and implementing regulation 41 CFR 101.6, announcement is made for the following committee meeting:

Name of Committee: National Industrial Security Program Policy Advisory Committee (NISPPAC).

Date of Meeting: September 15, 2004.

Time of Meeting: 10 a.m.–12 noon.

Place of meeting: National Archives and Records Administration, 700 Pennsylvania Avenue, NW., Thomas Jefferson Room 122, Washington, DC 20408.

Purpose: To discuss National Industrial Security Program policy matters.

This meeting will be open to the public. However, due to space limitations and access procedures, the name and telephone number of individuals planning to attend must be submitted to the Information Security Oversight Office (ISOO) no later than August 27, 2004. ISOO will provide additional instructions for gaining access to the location of the meeting.

For Further Information Contact: J. William Leonard, Director Information Security Oversight Office, National Archives Building, 700 Pennsylvania Avenue, Washington, DC 20408, telephone number (202) 219–5250.

Dated: July 28, 2004.

Mary Ann Hadyka,

Committee Management Officer.

[FR Doc. 04–17629 Filed 8–2–04; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Reinstatement, With Change, of a Previously Approved Collection; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). This information collection is published to obtain comments from the public.

DATES: Comments will be accepted until September 2, 2004.

ADDRESSES: Interested parties are invited to submit written comments to NCUA Clearance Officer or OMB Reviewer listed below:

Clearance Officer: Mr. Neil McNamara, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–518–6669, E-mail: *mcnamara@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or a copy of the information collection request should be directed to Tracy Sumpter at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION: Proposal for the following collection of information:

OMB Number: 3133–0137.

Form Number: N/A.

Type of Review: Reinstatement, with change, of a previously approved collection for which approval has expired.

Title: Community Development Revolving Loan Program for Credit Unions Application for Technical Assistance.

Description: NCUA requests this information from credit unions to ensure that the funds are distributed to aid in providing member services, and enhancing credit union operations.

Respondents: Federal credit unions.

Estimated No. of Respondents/ Recordkeepers: 116.

Estimated Burden Hours Per Response: 1 hour.

Frequency of Response: Reporting and on occasion.

Estimated Total Annual Burden Hours: 116 hours.

Estimated Total Annual Cost: $ 0.

By the National Credit Union Administration Board on July 26, 2004.

Becky Baker,

Secretary of the Board.

[FR Doc. 04–17547 Filed 8–2–04; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Reinstatement, Without Change, of a Previously Approved Collection; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). This information collection is published to obtain comments from the public.

DATES: Comments will be accepted until September 2, 2004.

ADDRESSES: Interested parties are invited to submit written comments to the NCUA Clearance Officer:

Clearance Officer: Mr. Neil McNamara, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–518–6669, E-mail: *mcnamara@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or a copy of the information collection request, should be directed to Tracy Sumpter at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION: Proposal for the following collection of information:

Title: Designation of Low Income Status.

OMB Number: 3133–0117.

Form Number: None.

Type of Review: Reinstatement, without change, of a previously approved collection for which approval has expired.

Description: Under section 107(6) of the Federal Credit Union Act, 12 U.S.C. 1757(6), and section 701.34 of NCUA Regulations, 12 CFR 701.34, credit unions that serve predominantly low-income members can accept nonmember share accounts from any source if the credit union obtains a low income designation from NCUA.

Respondents: Certain credit unions that serve predominantly low income members.

Estimated No. of Respondents/ Recordkeepers: 15.

Estimated Burden Hours Per Response: 15 hours.

Frequency of Response: Recordkeeping and other, once.

Estimated Total Annual Burden Hours: 225 hours.

Estimated Total Annual Cost: $3,600.00.

By the National Credit Union Administration Board on July 26, 2004.

Becky Baker,

Secretary of the Board.

[FR Doc. 04–17548 Filed 8–2–04; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Reinstatement, Without Change, of a Previously Approved Collection; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). This information collection is published to obtain comments from the public.

DATES: Comments will be accepted until September 2, 2004.

ADDRESSES: Interested parties are invited to submit written comments to NCUA Clearance Officer listed below:

Clearance Officer: Mr. Neil McNamara, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–518–6669, E-mail: *mcnamara@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or a copy of the information collection request, should be directed to Tracy Sumpter at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION: Proposal for the following collection of information:

Title: Payment on Shares by Public Units and Nonmembers.

OMB Number: 3133–0114.

Form Number: N/A.

Type of Review: Reinstatement, without change, of a previously approved collection for which approval has expired.

Description: 5 CFR 701.32 limits nonmember and public unit deposits in federally insured credit unions to 20 percent of their shares or $1.5 million, whichever is greater. The collection of information requirement is for those credit unions seeking an exemption from the above limit.

Respondents: Credit Unions seeking an exemption from the limits on share deposits by public unit and nonmember accounts set by 5 CFR 701.32.

Estimated No. of Respondents/ Recordkeepers: 20.

Estimated Burden Hours Per Response: 2 hours.

Frequency of Response: Other. As exemption is requested.

Estimated Total Annual Burden Hours: 40.

Estimated Total Annual Cost: N/A.

By the National Credit Union Administration Board on July 26, 2004.

Becky Baker,

Secretary of the Board.

[FR Doc. 04–17549 Filed 8–2–04; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Review; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). This information collection is published to obtain comments from the public.

DATES: Comments will be accepted until September 2, 2004.

ADDRESSES: Interested parties are invited to submit written comments to NCUA Clearance Officer listed below:

Clearance Officer: Mr. Neil McNamara, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–518–6669, E-mail: *mcnamara@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or a copy of the information collection request should be directed to Tracy Sumpter at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION: Proposal for the following collection of information:

Title: Management Official Interlocks.

OMB Number: 3133–0152.

Form Number: None.

Type of Review: Reinstatement, without change, of a previously approved collection for which approval has expired.

Description: Part 711 of NCUA's Rules and Regulations directs federally insured credit unions that want to share a management official with another financial institution to either apply for approval from the NCUA Board or maintain records to show the eligibility for a small market share exemption.

Respondents: All federally insured credit unions.

Estimated No. of Respondents/ Recordkeepers: 1.

Estimated Burden Hours Per Response: 3 hours.

Frequency of Response: Recordkeeping. Upon application.

Estimated Total Annual Burden Hours: 3.

Estimated Total Annual Cost: $0.

By the National Credit Union Administration Board on July 26, 2004.

Becky Baker,

Secretary of the Board.

[FR Doc. 04–17550 Filed 8–2–04; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Review; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). This information collection is published to obtain comments from the public.

DATES: Comments will be accepted until September 2, 2004.

ADDRESSES: Interested parties are invited to submit written comments to NCUA Clearance Officer listed below:

Clearance Officer: Neil McNamara, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–518–6669, E-mail: *mcnamara@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or a copy of the information collection request should be directed to Tracy Sumpter at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION: Proposal for the following collection of information:

Title: Leasing—Statistical Documentation Required for a Guarantor of a Residual Value.

OMB Number: 3133–0151.

Form Number: None.

Type of Review: Reinstatement, without change, of a previously approved collection for which approval has expired.

Description: Part 714 of NCUA's Rules and Regulations directs federal credit

unions to evaluate whether a guarantor of a residual value has the financial resources to meet the guarantee.

Respondents: All federal credit unions.

Estimated No. of Respondents/ Recordkeepers: 380.

Estimated Burden Hours Per Response: 2 hours.

Frequency of Response: Recordkeeping.

Estimated Total Annual Burden Hours: 760.

Estimated Total Annual Cost: $13,300.

By the National Credit Union Administration Board on July 26, 2004.

Becky Baker,

Secretary of the Board.

[FR Doc. 04–17551 Filed 8–2–04; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Review; Comment Request.

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). This information collection is published to obtain comments from the public.

DATES: Comments will be accepted until September 2, 2004.

ADDRESSES: Interested parties are invited to submit written comments to NCUA Clearance Officer listed below:

Clearance Officer: Mr. Neil McNamara, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–518–6669, E-mail: *mcnamara@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or a copy of the information collection request should be directed to Tracy Sumpter at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION: Proposal for the foliowing collection of information:

Title: Production of Nonpublic Records and Testimony of Employees in Legal Proceedings.

OMB Number: 3133–0146.

Form Number: None.

Type of Review: Reinstatement, without change, of a previously approved collection for which approval has expired.

Respondents: Respondents will most likely be persons involved in legal proceedings.

Estimated No. of Respondents/ Recordkeepers: 36.

Estimated Burden Hours Per Response: 2.

Frequency of Response: On occasion.

Estimated Total Annual Burden Hours: 72.

Estimated Total Annual Cost: None.

By the National Credit Union Administration Board on July 27, 2004.

Becky Baker,

Secretary of the Board.

[FR Doc. 04–17552 Filed 8–2–04; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Review; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). This information collection is published to obtain comments from the public.

DATES: Comments will be accepted until September 2, 2004.

ADDRESSES: Interested parties are invited to submit written comments to NCUA Clearance Officer listed below:

Clearance Officer: Mr. Neil McNamara, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. (703) 518–6669, E-mail: *mcnamara@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or a copy of the information collection request should be directed to Tracy Sumpter at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION: Proposal for the following collection of information:

OMB Number: 3133–0101.

Form Number: N/A.

Type of Review: Revision to a currently approved collection.

Title: 12 CFR 723.5—Develop written loan policies—and 723.11—Provide waiver requests—and 723.16—Application for approval.

Description: The general purpose of the requirements imposed by the rule is to ensure that loans are made, documented, and accounted for properly and for the ultimate protection of the National Credit Union Share Insurance Fund. Respondents are federally insured credit unions who make business loans as defined in the regulation.

Respondents: Federally Insured Credit Unions.

Estimated No. of Respondents/ Recordkeepers: 1,615.

Estimated Burden Hours Per Response: 5 hours.

Frequency of Response: Recordkeeping.

Estimated Total Annual Burden Hours: 8,020 hours.

Estimated Total Annual Cost: $0.

By the National Credit Union Administration Board on July 26, 2004.

Becky Baker,

Secretary of the Board.

[FR Doc. 04–17553 Filed 8–2–04; 8:45 am]

BILLING CODE 7535–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Act: Meeting

DATE: Weeks of August 2, 9, 16, 23, 30, September 6, 2004.

PLACE: Commissioners' Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and closed.

MATTERS TO BE CONSIDERED:

Week of August 2, 2004

There are no meetings scheduled for the week of August 2, 2004.

Week of August 9, 2004—Tentative

There are no meetings scheduled for the week of August 9, 2004.

Week of August 16, 2004—Tentative

Tuesday, August 17, 2004

9:30 a.m. Meeting with Organization of Agreement States (OAS) and Conference of Radiation Control Program Directors (CRCPD) (Public Meeting) (Contact: John Zabko, 301–415–2308).

This meeting will be webcast live at the Web address—*http://www.nrc.gov.*

1 p.m. Discussion of Security Issues (Closed—Ex. 1).

Wednesday, August 18, 2004

9:30 a.m. Discussion of Security Issues (Closed—Ex. 1).

Week of August 23, 2004—Tentative

There are no meetings scheduled for the week of August 23, 2004.

Week of August 30, 2004—Tentative

There are no meetings scheduled for the week of August 30, 2004.

Week of September 6, 2004—Tentative

Wednesday, September 8, 2004

9:30 a.m. Discussion of Office of Investigations (OI) Programs and Investigations (Closed—Ex.7).

2 p.m. Discussion of Intragovernmental Issues (Closed—Ex. 1 & 9).

*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: Dave Gamberoni, (301) 415–1651.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/what-we-do/policy-making/schedule.html*

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.* braille, large print), please notify the NRC's Disability Program Coordinator, August Spector, at 301–415–7080, TDD: 301–4152100, or by e-mail at *aks@nrc.gov*. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

This notice is distributed by mail to several hundred 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). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to *dkw@nrc.gov*.

Dated: July 29, 2004.

Dave Gamberoni,

Office of the Secretary.

[FR Doc. 04–17710 Filed 7–30–04; 9:55 am]

BILLING CODE 7590–01–M

NUCLEAR REGULATORY COMMISSION

Biweekly Notice; Applications and Amendments to Facility Operating Licenses Involving No Significant Hazards Considerations

I. Background

Pursuant to section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (the Commission or NRC staff) is publishing this regular biweekly notice. The Act requires the Commission publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from July 9, 2004 through July 22, 2004. The last biweekly notice was published on July 20, 2004 (69 FR 43457).

Notice of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. Within 60 days after the date of publication of this notice, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. The filing of requests for a hearing and petitions for leave to intervene is discussed below.

Within 60 days after the date of publication of this notice, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. Interested persons should

consult a current copy of 10 CFR 2.309, which is available at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/doc-collections/cfr/*. If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the petitioner/requestor seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner/requestor shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner/requestor intends to rely in proving the contention at the hearing. The petitioner/requestor must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner/requestor intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner/requestor to relief. A petitioner/requestor who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; (2) courier, express mail, and expedited delivery services: Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff; (3) E-mail addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, *HEARINGDOCKET@NRC.GOV*; or (4) facsimile transmission addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC, Attention: Rulemakings and Adjudications Staff at (301) 415–1101, verification number is (301) 415–1966. A copy of the request for hearing and petition for leave to intervene should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and it is requested that copies be transmitted either by means of facsimile transmission to 301–415–3725 or by e-mail to *OGCMailCenter@nrc.gov*. A copy of the request for hearing and petition for leave to intervene should also be sent to the attorney for the licensee.

Nontimely requests and/or petitions and contentions will not be entertained absent a determination by the Commission or the presiding officer of the Atomic Safety and Licensing Board that the petition, request and/or the contentions should be granted based on a balancing of the factors specified in 10 CFR 2.309(a)(1)(i)–(viii).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html*. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1–800–397–4209, 301–415–4737 or by e-mail to *pdr@nrc.gov*.

Exelon Generation Company, LLC, Docket Nos. STN 50–454 and STN 50–455, Byron Station, Unit Nos. 1 and 2, Ogle County, Illinois, Docket Nos. STN 50–456 and STN 50–457, Braidwood Station, Unit Nos. 1 and 2, Will County, Illinois

Date of amendment request: May 21, 2004.

Description of amendment request: The proposed amendment would revise Technical Specifications 5.6.6, "Reactor Coolant System (RCS) Pressure and Temperature Limits Report (PTLR)," by adding a reference to the use of previous Nuclear Regulatory Commission approved Code Cases N–640 and N–588 as acceptable methods for determining reactor pressure vessel (RPV) pressure temperature (P–T) limits.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed TS change does not involve a significant increase in the probability or consequences of an accident previously evaluated?

The use of Code Cases N–588 and N–640 has been approved for Braidwood and Byron Stations. The use of P–T limits based on these Code Cases will continue to ensure that

the RPV integrity is maintained under all conditions.

Thus there is no increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed TS change does not create the possibility of a new or different kind of accident from any accident previously evaluated?

The proposed change does not involve the use or installation of new equipment. No equipment will be operated in a new or different manner. No new or different system interactions are created and no new processes are introduced. The proposed change will not introduce any new failure mechanisms, malfunctions, or accident initiators not already considered in the design and licensing bases.

Based on this evaluation, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed TS change does not involve a significant reduction in a margin of safety?

The P–T limits provide assurance that RPV integrity is maintained. The use of Code Cases N–588 and N–640 has been previously approved by the NRC for Braidwood and Byron Stations and will continue to ensure that RPV integrity is maintained.

Thus, there is no reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the requested amendments involve no significant hazards consideration.

Attorney for licensee: Mr. Edward J. Cullen, Deputy General Counsel, Exelon BSC-Legal, 2301 Market Street, Philadelphia, PA 19101.

NRC Section Chief: Anthony J. Mendiola.

FirstEnergy Nuclear Operating Company, et al., Docket No. 50–334, Beaver Valley Power Station, Unit No. 1 (BVPS–1), Beaver County, Pennsylvania

Date of amendment request: June 28, 2004.

Description of amendment request: The proposed amendment would revise the BVPS–1 Technical Specification (TS) 4.4.5.4.a.8 to modify the definition of steam generator (SG) tube inspection to exclude the portion of the tube within the tube sheet below the W* distance. The W* distance is defined as the distance from the top of the tube sheet to the bottom of the W* length (7.0 in. on the hot leg side) including the distance from the top of the tube sheet to the bottom of the WEXTEX (Westinghouse explosive tube expansion) Transition (approximately 0.25 in.) plus uncertainties (0.12 in.). The proposed amendment would also revise the SG tube repair criteria of TS 4.4.5.4.a.6 to indicate that service-induced degradation within the W* distance or less than 8.0 in. below the top of the tube sheet shall be repaired upon detection. The proposed amendment would also add TS 4.4.5.2.e to require a 100% rotating pancake coil probe inspection of the hot leg tube sheet W* distance, add new W* terminology definitions in TS 4.4.5.4.a.11, and add a new reporting criteria for W* inspection information to TS 4.4.5.5.d.1 and TS 4.4.5.5.e. This proposed amendment would be effective for only one operating cycle, as the licensee plans to replace SGs during the 2006 refueling outage.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

No. The proposed change modifies the [BVPS–1] TSs to incorporate steam generator (SG) tube inspection scope based on WCAP–14797, Revision 2 ["Generic W* Tube Plugging Criteria for 51 Series Steam Generator Tubesheet Region WEXTEX Expansions," dated March 2003 (proprietary)]. Of the various accidents evaluated in the [BVPS–1] Updated Final Safety Analysis Report (UFSAR), the proposed changes only affect the steam generator tube rupture (SGTR) event evaluation and the postulated steam line break (SLB) accident evaluation. Loss-of-coolant accident (LOCA) conditions cause a compressive axial load to act on the tube. Therefore, since the LOCA tends to force the tube into the tubesheet rather than pull it out, it is not a factor in this amendment request. Another faulted load consideration is a safe shutdown earthquake (SSE); however, the seismic analysis of Series 51 steam generators has shown that axial loading of the tubes is negligible during an SSE.

For the SGTR event, the required structural margins of the steam generator tubes will be maintained by the presence of the tubesheet. Tube rupture is precluded for cracks in the Westinghouse explosive tube expansion (WEXTEX) region due to the constraint provided by the tubesheet. Therefore, Regulatory Guide (RG) 1.121, "Bases for Plugging Degraded PWR [pressurized-water reactor] Steam Generator Tubes," margins against burst are maintained for both normal and postulated accident conditions.

The W* length supplies the necessary resistive force to preclude pullout loads under both normal operating and accident conditions. The contact pressure results from the WEXTEX expansion process, thermal expansion mismatch between the tube and tubesheet and from the differential pressure between the primary and secondary side. The proposed changes do not affect the other systems, structures, components or operational features. Therefore, the proposed change results in no significant increase in the probability of the occurrence of an SGTR or SLB accident.

The consequences of an SGTR event are affected by the primary-to-secondary leakage flow during the event. Primary-to-secondary leakage flow through a postulated broken tube is not affected by the proposed change since the tubesheet enhances the tube integrity in the region of the WEXTEX expansion by precluding tube deformation beyond its initial expanded outside diameter. The resistance to both tube rupture and collapse is strengthened by the tubesheet in that region. At normal operating pressures, leakage from primary water stress corrosion cracking (PWSCC) below the W* length is limited by both the tube-to-tubesheet crevice and the limited crack opening permitted by the tubesheet constraint. Consequently, negligible normal operating leakage is expected from cracks within the tubesheet region.

SLB leakage is limited by leakage flow restrictions resulting from the crack and tube-to-tubesheet contact pressures that provide a restricted leakage path above the indications and also limit the degree of crack face opening compared to free span indications. The total leakage, that is, the combined leakage for all such tubes meet[s] the industry performance criterion, plus the combined leakage developed by any other alternate repair criteria, will be maintained below the maximum allowable SLB leak rate limit, such that off-site doses are maintained less than 10 CFR 100 guideline values and the limits evaluated in the [BVPS–1] UFSAR.

Therefore, based on the above evaluation, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

No. The proposed changes do not introduce any changes or mechanisms that create the possibility of a new or different kind of accident. Tube bundle integrity is expected to be maintained for all plant conditions upon implementation of the W* methodology.

The proposed changes do not introduce any new equipment or any change to existing equipment. No new effects on existing equipment are created nor are any new malfunctions introduced.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

No. The proposed changes maintain the required structural margins of the steam generator tubes for both normal and accident conditions. NRC [Nuclear Regulatory Commission] Regulatory Guide (RG) 1.121 is used as the basis in the development of the W* methodology for determining that steam generator tube integrity considerations are

maintained within acceptable limits. RG 1.121 describes a method acceptable to the NRC staff for meeting General Design Criteria 14, 15, 31, and 32 by reducing the probability and consequences of an SGTR. RG 1.121 concludes that by determining the limiting safe conditions of tube wall degradation beyond which tubes with unacceptable cracking, as established by inservice inspection, should be removed from service or repaired, the probability and consequences of a[n] SGTR are reduced. This RG uses safety factors on loads for tube burst that are consistent with the requirements of Section III of the American Society for Mechanical Engineers (ASME) [Boiler and Pressure Vessel] Code.

For primarily axially oriented cracking located within the tubesheet, tube burst is precluded due to the presence of the tubesheet. WCAP–14797, Revision 2, defines a length, W*, of degradation free expanded tubing that provides the necessary resistance to tube pullout due to the pressure induced forces (with applicable safety factors applied). Application of the W* criteria will preclude unacceptable primary-to-secondary leakage during all plant conditions. The methodology for determining leakage provides for large margins between calculated and actual leakage values in the W* criteria.

Plugging of steam generator tubes reduces the reactor coolant flow margin for core cooling. Implementation of W* methodology at [BVPS–1] will result in maintaining the margin of flow that may have otherwise been reduced by tube plugging.

Based on the above, it is concluded that the proposed changes do not result in a significant reduction [in a margin of safety] as defined in the [UFSAR] or [B]ases of the plant [TSs].

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for Licensee: Mary O'Reilly, FirstEnergy Nuclear Operating Company, FirstEnergy Corporation, 76 South Main Street, Akron, OH 44308.

NRC Section Chief: Richard J. Laufer.

Florida Power Corporation, et al., Docket No. 50–302, Crystal River Unit 3 Nuclear Generating Plant, Citrus County, Florida

Date of amendment request: July 8, 2004.

Description of amendment request: The amendment request proposes to delete one-time use footnotes that have expired or have already been used from the Crystal River Unit 3 (CR–3) Improved Technical Specifications (ITS). Specifically, obsolete notes will be removed from ITS 3.8.1, "AC Sources—Operating (Emergency Diesel Generator)," ITS 3.7.9, "Nuclear Services Seawater System," and ITS 3.7.18, "Control Complex Cooling System." This change is administrative in nature and does not alter any operating license requirements.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below and states that the amendment request:

1. Does not involve a significant increase in the probability or consequences of an accident previously evaluated.

Each footnote was added to ITS through the license amendment process. The activities supported by the footnotes were performed and, therefore, the footnotes have no further utility. Deleting the footnotes is administrative in nature and does not affect plant conditions that could impact accident probability or consequences. Therefore, granting this LAR [license amendment request] does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does not create the possibility of a new or different type of accident from any accident previously evaluated.

The proposed license amendment deletes footnotes that were used on a one-time basis for several specifications. The proposed LAR will not result in changes to the design, physical configuration of the plant or the assumptions made in the safety analysis. Therefore, the proposed change will not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does not involve a significant reduction in the margin of safety.

The deletion of the footnotes from the ITS does not affect properties of plant components or their operation. Therefore, granting this LAR does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Steven R. Carr, Associate General Counsel—Legal Department, Progress Energy Service Company, LLC, Post Office Box 1551, Raleigh, North Carolina 27602

NRC Acting Section Chief: Michael L. Marshall, Jr.

Indiana Michigan Power Company, Docket Nos. 50–315, Donald C. Cook Nuclear Plant, Unit 1, Berrien County, Michigan

Date of amendment request: June 25, 2004.

Description of amendment request: The proposed amendment would revise the Technical Specifications (TSs) and the bases to reduce the temperature at which shutdown and control rod drop tests are performed from greater than or equal to 541 degrees Fahrenheit to greater than or equal to 500 degrees Fahrenheit. Additionally, the proposed amendment would make format changes to improve the TS appearance.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The probability of occurrence of an accident previously evaluated is not altered by the proposed amendment. The proposed change does not impact the integrity of the reactor coolant system pressure boundary and, therefore, does not increase the potential for the occurrence of a loss-of-coolant accident. The change does not make any physical changes to the facility design, material or construction standards, and the proposed change is not an initiator or contributor to any currently evaluated accident. The format changes are intended to improve appearance, and do not alter any requirements. Thus, neither the probability nor the consequences of a previously analyzed accident are significantly increased.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The rod drop test is routinely performed during each refueling outage. Decreasing the test temperature will not create the possibility of a new or different accident. The proposed test conditions remain bounded by the analysis of record since the rod drop time assumed in the accident analysis will not be changed. The format changes are intended to improve appearance, and do not alter any requirements. Since no new failure modes are associated with the proposed changes, the proposed amendment does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The Technical Specification change does not involve a significant reduction in margin because the acceptance

criterion for the rod drop time will not change. The proposed change will reduce the minimum rod drop test temperature from greater than or equal to 541 degrees Fahrenheit to greater than or equal to 500 degrees Fahrenheit. This will slightly increase the measured test rod drop time. The measured test rod drop time, however, will be within the current Technical Specification limit of 2.4 seconds. The format changes are intended to improve appearance, and do not alter any requirements. Therefore, the margin of safety is not impacted by the proposed amendment.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment requests involve no significant hazards consideration.

Attorney for licensee: David W. Jenkins, Esq., 500 Circle Drive, Buchanan, MI 49107.

NRC Section Chief: L. Raghavan.

Nebraska Public Power District, Docket No. 50–298, Cooper Nuclear Station, Nemaha County, Nebraska

Date of amendment request: July 15, 2004.

Description of amendment request: The proposed amendment would revise the Technical Specification (TS) Section 3.8.1, AC Sources—Operating, Condition B, to extend the allowed outage time for one Diesel Generator (DG) inoperable from 7 days to 14 days and TS Section 3.8.3, Diesel Fuel Oil, Lube Oil, and Starting Air, Limiting Condition for Operation, to allow the use of temporary fuel oil storage tanks to supply the required fuel oil storage inventory.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Do the proposed changes involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The Standby AC Power System (Diesel Generators) provides onsite electrical power to vital systems should offsite electrical power be interrupted. It is not an initiator to any accident previously evaluated. Therefore, the extended period of operation with one diesel generator inoperable and the seven day required fuel oil supply being provided in part by temporary storage tanks will not increase the probability of an accident previously evaluated.

The Standby AC Power System acts to mitigate the consequences of design basis accidents that assume a loss of offsite power. For that purpose, redundant diesel generators are provided to protect against a single failure. During the Technical Specification seven day allowed outage time, an operating unit is allowed by the Technical Specifications to remove one diesel generator from service, thereby losing this single failure protection. During the requested fourteen day allowed outage time for fuel oil storage tank cleaning and coating maintenance activities, the inoperable diesel generator will be maintained available to start and load, with a minimum of five (5) hours of fuel available in the day tank. Manual actions contained in approved procedures to provide fuel from temporary storage tanks to either the operable diesel generator or the inoperable but available diesel generator will be implemented. A risk evaluation determined that the probability of failure to implement the contingency actions is sufficiently low that it does not adversely impact the availability of the Standby AC Power System.

The vulnerability to external events, seismic, high winds and fire, was also evaluated and judged to be not significant due to the low probability of these events during the period of time this proposed amendment will be in effect, and the defense in depth strategies being put in place during the tank maintenance activities.

In the event that fuel stored in the temporary tanks is not available to support full load operation of the diesel generator beyond four (4) days, replenishment of fuel oil from offsite can be accomplished in approximately 24 hours through the use of existing purchase orders for fuel oil and diesel fuel analysis. Therefore, during the period of the extended allowed outage time and the use of temporary fuel oil storage tanks, there is no significant increase in the consequences of an accident previously evaluated.

2. Do the proposed changes create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

Operation with one diesel generator inoperable but available for an extended period or with part of the required diesel fuel stored in temporary tanks does not involve any new mode of plant operation or different function for plant equipment. Operation in this configuration does introduce proceduralized manual actions to supply fuel to either diesel generator from the permanent storage tank or the temporary tank. These actions can be accomplished within the five hours of full load diesel operation from fuel stored in the day tank. A risk evaluation determined that the probability of failure to implement the contingency actions is sufficiently low that it does not adversely impact the availability of the Standby AC Power System. There are no new accident precursors generated due to this temporary extension of allowed outage time or the use of a temporary fuel oil storage system.

3. Do the proposed changes involve a significant reduction in the margin of safety?

Response: No.

A single failure of the operable fuel oil transfer pump could prevent DG operation beyond five hours. Proceduralized manual actions to supply fuel to either diesel generator from the permanent storage tank or the temporary tank will be implemented to mitigate this single failure vulnerability. These actions can be accomplished within the five (5) hours of full load diesel operation from fuel stored in the day tank. A risk evaluation determined that the probability of failure to implement the contingency actions is sufficiently low that it does not adversely impact the availability of the Standby AC Power System. Therefore, during the extended allowed outage time and the use of a temporary fuel oil storage system, the Standby AC Power System maintains the ability to provide a source of on-site AC power adequate for maintaining the safe shutdown of the reactor following abnormal operational transients and postulated accidents.

IEEE [Institute of Electrical and Electronics Engineers] Design Standard 308–1970, "IEEE Criteria for Class 1E Electric Systems for Nuclear Power Generating Station," Section 5.2.4, "Standby Power Supply," Paragraph 6), "Energy Storage," contains the requirement for stored energy capacity to be the longer of (a) seven days or (b) time required to replenish the energy from sources away from the generating unit's site following the limiting design basis event. Cooper Nuclear Station's Updated Safety Analysis Report documents that the Standby AC Power System conforms to the applicable sections of IEEE 308–1970.

The Diesel Generator Diesel Oil Storage and Transfer System will be configured to ensure a minimum fuel oil inventory to support greater than four (4) days of full load diesel generator operation is maintained in the operable permanent storage tank. Existing cross-

tie capabilities in the fuel storage and transfer system piping, in conjunction with proceduralized manual actions, ensure the four day fuel supply is available to either diesel generator. The remaining three (3) day fuel supply will be stored in temporary non-Class I tanks and would potentially be vulnerable to external events. The vulnerability to external events, seismic, high winds and fire, was evaluated and judged to be not significant due to the low probability of these events during the period of time this proposed amendment will be in effect, and the defense in depth strategies being put in place during the tank maintenance activities.

In the event that fuel stored in the temporary tanks is not available to support full load operation of the diesel generator beyond four (4) days, replenishment of fuel oil from offsite can be accomplished in approximately 24 hours through the use of existing purchase orders for fuel oil and diesel fuel analysis.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Mr. John R. McPhail, Nebraska Public Power District, Post Office Box 499, Columbus, NE 68602–0499.

NRC Section Chief: Robert A. Gramm.

Pacific Gas and Electric Company, Docket No. 50–133, Humboldt Bay Power Plant, Unit 3, Humboldt County, California

Date of amendment request: June 8, 2004.

Description of amendment request: The Humboldt Bay Power Plant, Unit 3, is a decommissioning nuclear power plant that was permanently shutdown in July 1976. The plant is currently in a safe storage (SAFSTOR) condition to ensure that necessary plant systems will be operated and maintained as needed to preserve safe conditions within the facility to prevent deterioration until active decommissioning can commence. All spent fuel is stored in the spent fuel pool. Pacific Gas and Electric Company (PG&E) has proposed a license amendment to clarify the technical specifications applicability to current plant conditions and practices. Specifically, the requested changes clarify that:

(1) Fuel fragments within the spent fuel pool totaling less than one fuel assembly and damaged fuel assembly UD–6N do not have to be stored in containers made of neutron absorbing material. Furthermore, that one additional assembly can be removed from a neutron absorbing container to perform fuel handling activities.

(2) The control station for Humboldt Bay Units 1 and 2 is considered to be anywhere on the +27 foot operating deck.

(3) References to certain technical specification section designators that contain typographical errors have been corrected.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

No. The proposed changes provide either clarification to reflect plant conditions or correct typographical errors. Existing accident analysis assumptions bound the proposed addition of not storing fuel fragments, which may be considered as less than or equal to a fuel assembly, in a container made with neutron absorbing material. The proposed changes involve no changes to plant systems or accident analysis, and as such, do not affect initiators of analyzed events or assumed mitigation of accidents. Therefore, the proposed changes do not increase the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different type of accident from any accident previously evaluated?

No. The proposed changes provide either clarification to reflect plant conditions or correct typographical errors. Existing accident analysis assumptions bound the proposed addition of not storing fuel fragments, which may be considered as less than or equal to a fuel assembly, in a container made with neutron absorbing material. The proposed changes do not involve a physical alteration to the plant, add any new equipment, or require existing equipment to be operated in a manner different from the present design. Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

No. The proposed changes provide either clarification to reflect existing plant conditions or correct typographical errors. Existing accident analysis assumptions bound the proposed addition of not storing fuel fragments, which may be considered as less than or equal to a fuel assembly, in a container made with neutron absorbing material. They have no effect on plant equipment, operating practices or safety analysis assumptions. Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Richard F. Locke, Esquire, Pacific Gas and Electric Company, P.O. Box 7442, San Francisco, California 94120.

NRC Section Chief: Claudia Craig.

Pacific Gas and Electric Company, Docket No. 50–133, Humboldt Bay Power Plant, Unit 3, Humboldt County, California

Date of amendment request: June 23, 2004.

Description of amendment request: The Humboldt Bay Power Plant, Unit 3, is a decommissioning nuclear power plant that was permanently shutdown in July 1976. The plant is currently in a safe storage (SAFSTOR) condition to ensure that necessary plant systems will be operated and maintained as needed to preserve safe conditions within the facility to prevent deterioration until active decommissioning can commence. All spent fuel is stored in the spent fuel pool. Currently, the facility operating license only allows maintaining the facility in SAFESTOR. At the time the license condition for SAFSTOR was specified, Pacific Gas and Electric Company (PG&E), the licensee, had intended to maintain SAFSTOR until the Department of Energy (DOE) established a permanent repository for spent fuel. The licensee has recently reassessed its near-term options for the facility and in December of 2003 applied for a license to store its spent fuel in an onsite dry cask independent spent fuel storage installation (ISFSI). Moving the spent fuel to an ISFSI would permit the licensee to begin significant decommissioning activities. Consequently, PG&E has submitted a license amendment request to permit the licensee to proceed with decontamination and decommissioning activities in accordance with applicable NRC requirements and the regulations for decommissioning reactors in 10 CFR 50.82.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

No. The proposed change eliminates the restriction to remain in SAFSTOR status, and allows PG&E to take actions necessary to decommission and decontaminate the facility in accordance with NRC regulations. The proposed change involves no changes to plant systems or accident analysis, and as such, do not affect initiators of analyzed events or assumed mitigation of accidents. Therefore, the proposed changes do not increase the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different type of accident from any accident previously evaluated?

No. The proposed change eliminates the restriction to remain in SAFSTOR status, and allows PG&E to take actions necessary to decommission and decontaminate the facility in accordance with NRC regulations. The proposed change does not involve a physical alteration to the plant, add any new equipment, or require existing equipment to be operated in a manner different from the present design. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

No. The proposed change eliminates the restriction to remain in SAFSTOR status, and allows PG&E to take actions necessary to decommission and decontaminate the facility in accordance with NRC regulations. The proposed change has no effect on plant equipment, operating practices or safety analysis assumptions. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Richard F. Locke, Esquire, Pacific Gas and Electric Company, P.O. Box 7442, San Francisco, California 94120.

NRC Section Chief: Claudia Craig.

PSEG Nuclear LLC, Docket No. 50–354, Hope Creek Generating Station, Salem County, New Jersey

Date of amendment request: March 31, 2004.

Description of amendment request: The proposed change will allow operation in regions of the power/flow map currently restricted by the requirements of interim corrective actions (ICAs) and certain limiting conditions for operations (LCOs) of Technical Specification 3.4.1. The oscillation power range monitor (OPRM) will allow operations in the regions restricted by the administrative controls mentioned above by using inputs from the local power range monitoring (LPRM) system to monitor core conditions and generate a reactor protection system (RPS) trip when required to prevent a violation of the minimum critical power ratio (MCPR) safety limit.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration. The NRC staff has reviewed the licensee's analysis against the three standards of 10 CFR 50.92(c). The NRC staff's analysis is presented below:

1. Does the Proposed Change Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated?

The proposed change would allow operation in regions of the power/flow map currently restricted by administrative controls. The purpose of the administrative controls were to ensure adequate capability to detect and suppress conditions consistent with the onset of a thermal-hydraulic (T–H) event which is postulated to cause a violation of the MCPR safety limit. The mitigation of a T–H instability event will be ensured by the RPS trip signal generated by the OPRM prior to challenging the MCPR safety limit. Since automatic protective functions of the OPRM will be replacing administrative controls which require operator action, the probability or consequence of a T–H instability event is not significant. Therefore, the proposed change does not result in a significant increase in the probability or consequence of an accident previously evaluated.

2. Does the Proposed Change Create the Possibility of a New or Different Kind of Accident From any Accident Previously Evaluated?

The proposed change would allow operation in regions of the power/flow map currently restricted by administrative controls. The OPRM system uses inputs from the LPRMs to monitor core conditions and generate a RPS trip when required. Quality requirements for software design, testing, implementation and module self-testing of the OPRM system provide assurance that no new equipment malfunctions due to software errors are created. The design of the OPRM system also ensures that neither operation nor malfunction of the OPRM system will adversely impact the operation of other systems, and no accident or equipment malfunction of these other systems could cause the OPRM system to malfunction or cause a different kind of accident. Therefore, operation with the OPRM system does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the Proposed Change Involve a Significant Reduction in a Margin of Safety?

The proposed change would allow operation in regions of the power/flow map currently restricted by administrative controls. The margin of safety for the unmitigated T–H instability event will not be significantly reduced due to the capability of the OPRM to automatically detect and suppress conditions which might result in an MCPR safety limit violation. The automatic functions of the OPRM will be replacing administrative controls which rely on operator action to prevent an unmitigated T–H instability event. The OPRM will maintain the margin of safety while significantly reducing the burden on the control room operators. Therefore, operation with the OPRM system does not involve a significant reduction in a margin of safety.

Based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jeffrie J. Keenan, Esquire, Nuclear Business Unit—N21, P.O. Box 236, Hancocks Bridge, NJ 08038.

NRC Section Chief: James W. Clifford.

Southern California Edison Company, et al., Docket Nos. 50–361 and 50–362, San Onofre Nuclear Generating Station, Units 2 and 3, San Diego County, California

Date of amendment requests: June 29, 2004.

Description of amendment requests: The proposed amendments would revise the Technical Specifications (TS) to implement the following miscellaneous changes: (1) Revise the reporting period of TS 2.2.5 from 30 days to 60 days for the safety limit violations Licensee Event Report, (2) revise the frequency of Surveillance Requirement (SR) 3.4.3.1.2 of TS 3.4.3.1, "Pressurizer Heatup and Cooldown Limits," to reflect pressurizer spray cyclic limits being governed by the temperature differentials between the spray nozzle and the spray line, (3) revise TS 5.5.2.11.f.1 of TS 5.5.2.11, "Steam Generator (SG) Tube Surveillance Program," to correct typographical errors, (4) remove TS 5.5.2.14, "Configuration Risk Management Program (CRMP)," in accordance with **Federal Register** Notice Vol. 64, No. 137 (July 19, 1999), and (5) revise TS 5.7.1.5, "Core Operating Limits Report (COLR)," to delete revision numbers and dates from the referenced documents in this section consistent with the NRC-approved industry Technical Specifications Task Force (TSTF) Standard Technical Specifications Traveler number TSTF–

363, "Revise Topical Report References in ITS (Improved Technical Specifications) 5.6.5 COLR," and incorporate editorial corrections.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

Southern California Edison (SCE) proposes to modify the San Onofre Units 2 and 3 Technical Specifications (TS) to accomplish several improvements by providing consistency with current Code of Federal Regulations (CFR) Licensee Event Report (LER) reporting requirements, clarifying a pressurizer heatup/cooldown Surveillance Requirement, TS editorial corrections, removing TS redundancy to the Maintenance Rule in accordance with **Federal Register** Notice Vol. 64, No. 137 (July 19, 1999), and eliminating need for TS amendment requests for cited Core Operating Limits Report (COLR) reference revisions consistent with the NRC approved Industry Technical Specifications Task Force (TSTF) Standard Technical Specifications Traveler number TSTF–363, "Revise Topical Report References in ITS (Improved Technical Specifications) 5.6.5 COLR." These proposed changes do not involve any change in the design or operation of the plant. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Modifying the Technical Specifications to provide consistency with current CFR LER reporting requirements, clarify a pressurizer heatup/cooldown Surveillance Requirement, incorporate editorial corrections, remove TS redundancy to the Maintenance Rule in accordance with **Federal Register** Notice Vol. 64, No. 137 (July 19, 1999), and to eliminate need for TS amendment requests for cited COLR reference revisions consistent with the NRC approved Industry Technical Specifications Task Force (TSTF) Standard Technical Specifications Traveler number TSTF–363, "Revise Topical Report References in ITS (Improved Technical Specifications) 5.6.5 COLR" does not involve any change in the design or operation of the plant. Therefore, a possibility of a new or different kind of accident from any accident previously evaluated is not created.

3. The proposed change does not involve a significant reduction in a margin of safety.

Evaluation of these proposed modifications to the Technical Specifications to provide consistency with current CFR LER reporting requirements, clarify a pressurizer heatup/cooldown Surveillance Requirement, incorporate editorial corrections, remove TS redundancy to the Maintenance Rule in accordance with **Federal Register** Notice Vol. 64, No. 137 (July 19, 1999), and to eliminate need for TS amendment requests for cited COLR reference revisions consistent with the NRC approved Industry Technical Specifications Task Force (TSTF) Standard Technical Specifications Traveler number TSTF–363, "Revise Topical Report References in ITS (Improved Technical Specifications) 5.6.5 COLR" does not involve any change in the design or operation of the plant and therefore does not create any reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment requests involve no significant hazards consideration.

Attorney for licensee: Douglas K. Porter, Esquire, Southern California Edison Company, 2244 Walnut Grove Avenue, Rosemead, California 91770.

NRC Section Chief: Stephen Dembek.

Southern California Edison Company, et al., Docket Nos. 50–361 and 50–362, San Onofre Nuclear Generating Station, Units 2 and 3, San Diego County, California

Date of amendment requests: June 30, 2004.

Description of amendment requests: The proposed amendments would revise Technical Specification (TS) 5.5.2.15, "Containment Leakage Rate Testing Program." Specifically, the licensee proposes a one-time extension of the ten-year period of the performance-based leakage rate testing program for Type A tests as prescribed by Nuclear Energy Institute 94–01, Revision 0, "Industry Guideline for Implementing Performance-Based Option of 10 CFR Part 50, Appendix J." The ten-year interval between integrated leakage rate tests is to be extended to 15 years from the previous integrated leakage rate tests. Under the current TS requirements, which include an allowance of a 15-month extension, the next Type A test would be performed during the Cycle 14 refueling outages currently planned for November 2005 (Unit 2) and June 2006 (Unit 3). The requested change reflects a one-time deferral of the next Type A containment integrated leak rate test to no later than March 30, 2010 (Unit 2) and September 9, 2010 (Unit 3). This proposed change is based on and has been evaluated using the "risk informed" guidance in Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-informed Decisions on Plant-Specific Changes to the Licensing Basis."

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed revision to Technical Specifications adds a one time extension to the current interval for Type A testing (10 CFR 50, Appendix J, Option B, Integrated Leak Rate Testing). The current test interval of 10 years, based on past performance, would be extended on a one time basis to 15 years from the last Type A test. The proposed extension to Type A testing does not involve a significant increase in the consequences of an accident since research documented in NUREG–1493, "Performance-Based Containment System Leakage Testing Requirements," September 1995, has found that, generically, very few potential containment leakage paths are not identified by Type B and C tests. The NUREG concluded that reducing the Type A testing frequency to one per twenty years was found to lead to an imperceptible increase in risk. A high degree of assurance is provided through testing and inspection that the containment will not degrade in a manner detectable only by Type A testing. The last Type A tests show leakage to be below acceptance criteria, indicating a leak tight containment. Inspections required by the American Society of Mechanical Engineers (ASME) Code Section XI (Subsections IWE and IWL) and maintenance rule monitoring (10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants) are performed in order to identify indications of containment degradation that could affect that leak tightness. Type B and C testing required by Technical Specifications will identify any containment opening such as valves that would otherwise be detected by the Type A tests. These factors show that a Type A test extension will not represent a significant increase in the consequences of an accident.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed revision to Technical Specifications adds a one time extension to the current interval for Type A testing (10 CFR 50, Appendix J, Option B, Integrated Leak Rate Testing). The current test interval of 10 years, based on past performance, would be extended on a one time basis to 15 years from the last Type A test. The proposed extension to Type A testing cannot create the possibility of a new or different type of accident since there are no physical changes being made to the plant and there are no changes to the operation of the plant that could introduce a new failure mode creating

an accident or affecting the mitigation of an accident. Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated.

3. The proposed change does not involve a significant reduction in a margin of safety.

The proposed revision to Technical Specifications adds a one time extension to the current interval for Type A testing (10 CFR 50, Appendix J, Option B, Integrated Leak Rate Testing). The current test interval of 10 years, based on past performance, would be extended on a one time basis to 15 years from the last Type A test. The proposed extension to Type A testing will not significantly reduce the margin of safety. The NUREG 1493, "Performance-Based Containment System Leakage Testing Requirements," September 1995, generic study of the effects of extending containment leakage testing found that a 20 year extension in Type A leakage testing resulted in an imperceptible increase in risk to the public. NUREG 1493 found that, generically, the design containment leakage rate contributes about 0.1 percent to the individual risk and that the decrease in Type A testing frequency would have a minimal affect on this risk since 95% of the potential leakage paths are detected by Type C testing. Regular inspections required by the American Society of Mechanical Engineers (ASME) Code Section XI (Subsections IWE and IWL) and maintenance rule monitoring (10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants) will further reduce the risk of a containment leakage path going undetected.

Therefore the proposed change does not involve a reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment requests involve no significant hazards consideration.

Attorney for licensee: Douglas K. Porter, Esquire, Southern California Edison Company, 2244 Walnut Grove Avenue, Rosemead, California 91770.

NRC Section Chief: Stephen Dembek.

Southern Nuclear Operating Company, Inc. Docket Nos. 50–348 and 50–364, Joseph M. Farley Nuclear Plant, Units 1 and 2, Houston County, Alabama

Date of amendment request: June 28, 2004.

Description of amendment request: The proposed amendments would revise existing Technical Specifications (TSs) 3.4.13, "RCS [Reactor Coolant System] Operational Leakage," TS 5.59, "Steam Generator [SG] Tube Surveillance Program," and TS 5.610, "Steam Generator Tube Inspector Report." It would also add a new TS 3.4.17, "Steam Generator Tube Integrity." These changes would facilitate the implementation of industry initiative NEI [Nuclear Energy Institute] 97–06, "Steam Generator Program Guidelines," which would allow for a comprehensive, performance-based approach to managing SG performance at Farley Nuclear Plant, Units 1 and 2.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change requires a Steam Generator Program that includes performance criteria that will provide reasonable assurance that the steam generator (SG) tubing will retain integrity over the full range of operating conditions (including startup, operation in the power range, hot standby, cooldown and all anticipated transients included in the design specification). The SG performance criteria are based on tube structural integrity, accident induced leakage, and operational LEAKAGE.

The structural integrity performance criterion is:

"All inservice SG tubes shall retain structural integrity over the full range of normal operating conditions (including startup, operation in the power range, hot standby and cooldown and all anticipated transients included in the design specification) and design basis accidents. This includes retaining a safety factor of 3.0 against burst under normal steady state full power operation primary to secondary pressure differential and a safety factor of 1.4 against burst applied to the design basis accident primary to secondary pressure differentials. Apart from the above requirements, additional loading conditions associated with the design basis accidents, or combination of accidents in accordance with the design and licensing basis, shall also be evaluated to determine if the associated loads contribute significantly to burst or collapse. In the assessment of tube integrity, those loads that do significantly affect burst or collapse shall be determined and assessed in combination with the loads due to pressure with a safety factor of 1.2 on the combined primary loads and 1.0 on axial secondary loads."

The accident induced leakage performance criterion is:

"The primary to secondary accident induced leakage rate for all design basis accidents, other than a SG tube rupture, shall not exceed the leakage rate assumed in the accident analysis in terms of total leakage rate for all SGs and leakage rate for an individual SG. For FNP Units 1 and 2, leakage is not to exceed 1 gpm [gallons per minute] total for all three SGs. Exceptions to the 1 gpm limit can be applied if approved by the NRC in conjunction with approved alternate repair criteria."

The operational LEAKAGE performance criterion is:

The RCS operational primary to secondary LEAKAGE through any one SG shall be limited to 150 gpd [gallons per day].

A steam generator tube rupture (SGTR) event is one of the design basis accidents analyzed as part of the plant licensing basis. In the analysis of a SGTR event, a bounding primary to secondary LEAKAGE rate equal to the operational LEAKAGE rate limits in the licensing basis plus the LEAKAGE rate associated with a double-ended rupture of a single tube is assumed.

For other design basis accidents such as main steam line break (MSLB), rod ejection, and reactor coolant pump locked rotor the tubes are assumed to retain their structural integrity (*i.e.*, they are assumed not to rupture). For FNP Units 1 and 2, these analyses assume that primary to secondary LEAKAGE for all SGs is 1 gpm. The accident induced leakage criterion introduced by the proposed changes accounts for tubes that may leak during design basis accidents. The accident induced leakage criterion limits this leakage to no more than the value assumed in the accident analysis.

The SG performance criteria proposed in this change to the TS identify the standards against which tube integrity is to be measured. Meeting the performance criteria provides reasonable assurance that the SG tubing will remain capable of fulfilling its specific safety function of maintaining reactor coolant pressure boundary integrity throughout each operating cycle and in the unlikely event of a design basis accident. The performance criteria are only a part of the Steam Generator Program required by the proposed change to the TS. The program, defined by NEI 97–06, Steam Generator Program Guidelines, includes a framework that incorporates a balance of prevention; inspection, evaluation, plugging, and leakage monitoring.

The consequences of design basis accidents are, in part, functions of the DOSE EQUIVALENT I–131 in the primary coolant and the primary to secondary LEAKAGE rates resulting from an accident. Therefore, limits are included in the TS for operational leakage and for DOSE EQUIVALENT I–131 in primary coolant to ensure the plant is operated within its analyzed condition. The analysis of the limiting design basis accident assumes that primary to secondary leak rate after the accident is 1 gpm with no more than 500 gpd in any one SG, and that the reactor coolant activity levels of DOSE EQUIVALENT I–131 are at the technical specification values before the accident.

The proposed change does not affect the design of the SGs, their method of operation, or primary coolant chemistry controls. The proposed approach updates the current TS and enhances the requirements for SG inspections. The proposed change does not adversely impact any other previously evaluated design basis accident and is an improvement over the current TS.

Therefore, the proposed change does not affect the consequences of a SGTR accident and the probability of such an accident is reduced. In addition, the proposed changes do not affect the consequences of a MSLB,

rod ejection, or a reactor coolant pump locked rotor event.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed performance based requirements are an improvement over the requirements imposed by the current TS.

Implementation of the proposed Steam Generator Program will not introduce any adverse changes to the plant design basis or postulated accidents resulting from potential tube degradation. The result of the implementation of the Steam Generator Program will be an enhancement of SG tube performance. Primary to secondary LEAKAGE that may be experienced during all plant conditions will be monitored to ensure it remains within current accident analysis assumptions.

The proposed change does not affect the design of the SGs, their method of operation, or primary or secondary coolant chemistry controls. In addition, the proposed change does not impact any other plant system or component. The change enhances SG inspection requirements.

Therefore, the proposed change does not create the possibility of a new or different type of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The SG tubes in pressurized water reactors are an integral part of the reactor coolant pressure boundary and, as such, are relied upon to maintain the primary system's pressure and inventory. As part of the reactor coolant pressure boundary, the SG tubes are unique in that they are also relied upon as a heat transfer surface between the primary and secondary systems such that residual heat can be removed from the primary system. In addition, the SG tubes also isolate the radioactive fission products in the primary coolant from the secondary system. In summary, the safety function of a SG is maintained by ensuring the integrity of its tubes.

Steam generator tube integrity is a function of the design, environment, and the physical condition of the tube. The proposed change does not affect tube design or operating environment. The proposed change is expected to result in an improvement in the tube integrity by implementing the Steam Generator Program to manage SG tube inspection, assessment and plugging. The requirements established by the Steam Generator Program are consistent with those in the applicable design codes and standards and are an improvement over the requirements in the current TS.

For the above reasons, the margin of safety is not changed and overall plant safety will be enhanced by the proposed change to the TS.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: M. Stanford Blanton, Esq., Balch and Bingham, Post Office Box 306, 1710 Sixth Avenue North, Birmingham, Alabama 35201.

NRC Section Chief: Stephanie M. Coffin, Acting.

Southern Nuclear Operating Company, Inc., Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50–321 and 50–366, Edwin I. Hatch Nuclear Plant, Units 1 and 2, Appling County, Georgia

Date of amendment request: April 26, 2004.

Description of amendment request: The proposed amendments would revise the Technical Specification Section 5.5.12, "Primary Containment Leakage Rate Testing Program" to reflect a one-time deferral of the Type A Containment Integrated Leak Rate Test (ILRT). This change would extend the 10 year interval between ILRTs to 15 years from the previous ILRT.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed Technical Specification change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed revision to Technical Specification 5.5.12 ("Primary Containment Leakage Rate Testing Program") involves a one-time extension to the current interval for Type A containment testing. The current test interval of ten (10) years would be extended on a one-time basis to no longer than fifteen (15) years from the last Type A test. The proposed Technical Specification change does not involve a physical change to the plant or a change in the manner which the plant is operated or controlled. The reactor containment is designed to provide an essentially leak tight barrier against the uncontrolled release of radioactivity to the environment for postulated accidents. As such the reactor containment itself and the testing requirements invoked to periodically demonstrate the integrity of the reactor containment exist to ensure the plant's ability to mitigate the consequences of an accident, and do not involve the prevention or identification of any precursors of an accident. Therefore, the proposed Technical Specification change does not involve a significant increase in the probability of an accident previously evaluated.

The proposed change involves only the extension of the interval between Type A containment leakage tests. Type B and C containment leakage tests will continue to be performed at the frequency currently required by plant Technical Specifications. Industry experience has shown, as documented in NUREG–1493, that Type B and C containment leakage tests have identified a very large percentage of containment leakage paths and that the percentage of containment leakage paths that are detected only by Type A testing is very small. HNP [Hatch Nuclear Plant] Unit 2 ILRT test history supports this conclusion. NUREG–1493 concluded, in part, that reducing the frequency of Type A containment leak tests to once per twenty (20) years leads to an imperceptible increase in risk. The integrity of the reactor containment is subject to two types of failure mechanisms which can be categorized as (1) activity based and (2) time based. Activity based failure mechanisms are defined as degradation due to system and/or component modifications or maintenance. Local leak rate test requirements and administrative controls such as design change control and procedural requirements for system restoration ensure that containment integrity is not degraded by plant modifications or maintenance activities. The design and construction requirements of the reactor containment itself combined with the containment inspections performed in accordance with ASME [American Society of Mechanical Engineers] Section XI, the Maintenance Rule and the containment coatings program serve to provide a high degree of assurance that the containment will not degrade in a manner that is detectable only by Type A testing. Therefore, the proposed Technical Specification change does not involve a significant increase in the consequences of an accident previously evaluated.

2. The proposed TS change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed revision to the Technical Specifications involves a one-time extension to the current interval for Type A containment testing. The reactor containment and the testing requirements invoked to periodically demonstrate the integrity of the reactor containment exist to ensure the plant's ability to mitigate the consequences of an accident and do not involve the prevention or identification of any precursors of an accident. The proposed Technical Specification change does not involve a physical change to the plant or the manner in which the plant is operated or controlled. Therefore, the proposed Technical Specification change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed TS change does not involve a significant reduction in a margin of safety.

The proposed revision to Technical Specifications involves a one-time extension to the current interval for Type A containment testing. The proposed Technical Specification change does not involve a physical change to the plant or a change in the manner in which the plant is operated or controlled. The specific requirements and conditions of the Primary Containment

Leakage Rate Testing Program, as defined in Technical Specifications, exist to ensure that the degree of reactor containment structural integrity and leak-tightness that is considered in the plant safety analysis is maintained. The overall containment leakage rate limit specified by Technical Specifications is maintained. The proposed change involves only the extension of the interval between Type A containment leakage tests. Type B and C containment leakage tests will continue to be performed at the frequency currently required by plant Technical Specifications.

HNP Unit 2 and industry experience strongly supports the conclusion that Type B and C testing detects a large percentage of containment leakage paths and that the percentage of containment leakage paths that are detected only by Type A testing is small. The containment inspections performed in accordance with ASME Section XI, the Maintenance Rule and the Coatings Program serve to provide a high degree of assurance that the containment will not degrade in a manner that is detectable only by Type A testing. Additionally, the on-line containment monitoring capability that is inherent to inerted BWR containments allows for the detection of gross containment leakage that may develop during power operation. The combination of these factors ensures that the margin of safety that is inherent in plant safety analysis is maintained. Therefore, the proposed Technical Specification change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Ernest L. Blake, Jr., Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Section Chief: Stephanie M. Coffin, Acting.

Southern Nuclear Operating Company, Inc., Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50–321 and 50–366, Edwin I. Hatch Nuclear Plant, Units 1 and 2, Appling County, Georgia

Date of amendment request: June 22, 2004.

Description of amendment request: The proposed amendments would revise the Technical Specification (TS), Appendix A in order to change the frequency of the logic system functional test, for the 4 kV emergency busses' loss of power instrumentation, from once every 18 months to once every 24 months.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

This is a proposed change to the surveillance requirement (SR) for the logic system functional test (LSFT) of the loss of power (LOP) instrumentation for Plant Hatch Units 1 and 2 (SR 3.3.8.1.4). The LOP instrumentation functions to monitor the voltage on the 4 kV emergency busses and, if necessary, to disconnect these busses from the offsite power source and re-connect them to on-site power. This would, of course, be necessary if a bus experienced a loss of, or a degraded, voltage. This ensures an adequate response to a loss of coolant accident (LOCA) if that accident were to occur simultaneously with a loss of off-site power (LOSP). The probability of occurrence of a previously evaluated event, such as a LOCA/LOSP, will not increase since the LOP instrumentation is not being physically altered as a result of this change in such a manner which may increase the likelihood of failure. In fact, it is not being physically altered at all as a result of this submittal.

Additionally, no other safety related equipment or components designed to prevent the occurrence of a previously evaluated event are being physically altered or otherwise affected as a result of this TS change request.

The consequences of a previously evaluated event will not increase as a result of revising the surveillance frequency for the LOP instrumentation. Review of surveillance histories demonstrates adequate performance for the LOP relays in ultimately connecting the emergency power sources to the distribution bus, justifying the revision in the surveillance frequency. Therefore, the LOP instrumentation can be reasonably expected to perform its function in a LOCA/LOSP event, even with the revised frequency for the LSFT.

For the above reasons, the change in the LSFT frequency does not involve a significant increase in the probability or consequences of a previously evaluated event.

2. The proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

The LOP instrumentation is not being physically altered. Furthermore, its operation and maintenance will remain within the design bases. The only proposed change is the frequency of the logic system functional test. Since no new modes of operation are being introduced, a new or different kind of accident from any previously evaluated is not created.

3. The proposed change does not involve a significant reduction in the margin of safety.

The function of the LOP instrumentation is to ensure that the emergency power distribution busses receive adequate power from either the off-site or on-site sources. The LOP relays will initiate a transfer of the emergency 4 kV busses to the on-site diesel generators on a loss of coolant accident with a concurrent loss of off-site power. The diesel logic will then sequence the cooling water pumps and other safety related equipment onto their respective emergency bus. This sequencing of loads is tested by a different surveillance requirement which is not affected by this TS change request and has already been revised to a frequency of once per 24 months. This proposed TS revision only changes the frequency of performance of the LSFT for the LOP instrumentation. A review of surveillance histories shows that these relays perform adequately in the re-connection of the emergency busses to the on-site power source. Some problems have been noted in the history review with the loss of off-site power annunciation. However, the annunciator does not affect the safety function of providing power to the distribution bus.

For the above reasons, the margin of safety is not reduced by this proposed Technical Specifications change.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Ernest L. Blake, Jr., Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Section Chief: Stephanie M. Coffin, Acting.

Tennessee Valley Authority, Docket Nos. 50–260 and 50–296, Browns Ferry Nuclear Plant (BFN), Units 2 and 3, Limestone County, Alabama

Date of amendment request: July 8, 2004 (TS–448)

Description of amendment request: The proposed amendment requests the modification of Technical Specification Section 5.5.12 "Primary Containment Leakage Rate Testing Program" to allow a one-time 5-year extension to the 10-year frequency of the performance-based leakage rate testing program for Type A tests. The proposed changes are submitted on a risk-informed basis as described in Regulatory Guide 1.174, *An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis.* The risk-informed analysis supporting the proposed changes indicates that the increase in risk from extending the integrated leak rate test interval from 10 to 15 years is insignificant.

Basis for proposed no significant hazards consideration determination:

As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

TVA has evaluated whether or not a significant hazards consideration is involved with the proposed amendment by focusing on the three standards set forth in 10 CFR 50.92, "Issuance of Amendment," as discussed below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

No. The proposed revision to TS adds a one-time extension to the current interval for Type A testing. The current test interval of 10 years, based on past performance, would be extended on a one-time basis to 15 years from the last Type A test. The proposed extension to Type A testing cannot increase the probability of an accident previously evaluated since the containment Type A testing extension is not a modification and the test extension is not of a type that could lead to equipment failure or accident initiation.

The proposed extension to Type A testing does not involve a significant increase in the consequences of an accident since research documented in NUREG–1493 has found that, generically, very few potential containment leakage paths are not identified by Type B and C tests. The NUREG concluded that reducing the Type A (ILRT) testing frequency to once per 20 years was found to lead to an imperceptible increase in risk. These generic conclusions were confirmed by a plant specific risk assessment.

Testing and the containment inspection programs in place at BFN provide a high degree of assurance that the containment will not degrade in a manner detectable only by Type A testing. The last four Type A tests show leakage to be below acceptance criteria, indicating a very leak tight containment. Type B and C testing required by TS will identify any containment opening such as valves that would otherwise be detected by the Type A tests. Inspections, including those required by the American Society of Mechanical Engineers code are also performed in order to identify indications of containment degradation that could affect that leak tightness.

Therefore, the proposed TS change does not involve an increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

No. The change does not create the possibility of a new or different kind of accident from any accident previously analyzed. The proposed revision to TS adds a one-time extension to the current interval for Type A testing. The current test interval of 10 years, based on past performance, would be extended on a one-time basis to 15 years from the last Type A test. The proposed extension to Type A testing cannot create the possibility of a new or different type of accident since there are no physical changes being made to the plant and there are no changes to the operation of the plant that could introduce a new failure mode creating an accident or affecting the mitigation of an accident.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

No. BFN Units 2 and 3 are General Electric BWR/4 plants with Mark I primary containments. The Mark I primary containment consists of a drywell, which encloses the reactor vessel; reactor coolant recirculation system and branch lines of the Reactor Coolant System; a toroidal-shaped pressure suppression chamber containing a large volume of water; and a vent system connecting the drywell to the water space of the suppression chamber. The primary containment is penetrated by personnel access hatches, piping, and electrical penetrations.

The integrity of the primary containment penetrations and isolation valves is verified through Type B and Type C local leak rate tests and the overall leak-tight integrity of the primary containment is verified by a Type A integrated leak rate test as required by 10 CFR 50, Appendix J, "Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors." These tests are performed to verify the essentially leak-tight characteristics of the primary containment at the design basis accident pressure. The proposed change for a one-time extension of the Type A tests does not affect the method for Type A, B, or C testing, or the test acceptance criteria. In addition, based on previous Type A testing results, TVA does not expect additional degradation during the extended period between Type A tests, which would result in a significant reduction in a margin of safety.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET 11A, Knoxville, Tennessee 37902.

NRC Acting Section Chief: Michael L. Marshall, Jr.

Tennessee Valley Authority, Docket No. 50–390, Watts Bar Nuclear Plant, Unit 1, Rhea County, Tennessee

Date of amendment request: July 8, 2004.

Description of amendment request: The proposed amendment will revise the Technical Specification (TS) to remove the term "inter-rack" and associated wording from Surveillance Requirements 3.8.4.6 and 3.8.4.10 for the 125 Volt (V) Direct Current (DC) Electrical Power Subsystems of the Emergency Diesel Generators (DGs).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

No. The proposed TS change eliminates an inaccurate term and associated wording, but the actual TS amendment does not result in any change to the actual surveillance field test for the associated batteries. The proposed wording will only clarify the surveillances. Prior field tests were adequate to verify proper battery connection integrity since it tested the inside (inter-tier) jumper cable connections as if they were interchangeable with inter-rack. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

No. The proposed TS change does not alter the configuration of the plant's 125 V DC Electrical Power Subsystems of the Emergency DGs. The change does not directly affect plant operation. The change will not result in the installation of any new equipment or system or the modification of any existing equipment or systems. No new operations procedures, conditions, or modes will be created by this proposed change. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in margin of safety?

No. The battery connection continuity check for the 125 V DC Electrical Power Subsystems of the Emergency DGs will continue to be monitored by the same process as previously performed. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET 11A, Knoxville, Tennessee 37902.

NRC Acting Section Chief: Michael L. Marshall, Jr.

Notice of Issuance of Amendments to Facility Operating Licenses

During the period since publication of the last biweekly notice, the

Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for A Hearing in connection with these actions was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items are available for public inspection at the Commission's Public Document Room, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland, Publicly available records will be accessible from the Agencywide Documents Access and Management Systems (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html*. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737 or by e-mail to *pdr@nrc.gov*.

AmerGen Energy Company, LLC, Docket No. 50–219, Oyster Creek Nuclear Generating Station (OCNGS), Ocean County, New Jersey, Docket No. 50–289, Three Mile Island Nuclear Station, Unit 1 (TMI–1), Dauphin County, Pennsylvania

Date of application for amendments: March 8, 2004.

Brief description of amendment: The amendments deleted the License Condition entitled "Long Range Planning Program" from the OCNGS and TMI–1 operating licenses. In addition, for TMI–1, the amendment relocated a requirement (regarding surveillance of the depth of water in the spent fuel pool) from the Long Range Planning Program to the Technical Specifications.

Date of Issuance: July 13, 2004.

Effective date: These license amendments are effective as of their date of issuance, and shall be implemented within 30 days of issuance.

Amendment Nos.: 244 and 250

Facility Operating License Nos. DPR–16 and DPR–50: Amendments revised the Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register***: April 13, 2004 (69 FR 19563 and 19564). The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated July 13, 2004.

No significant hazards consideration comments received: No.

AmerGen Energy Company, LLC, Docket No. 50–289, Three Mile Island Nuclear Station, Unit 1 (TMI–1), Dauphin County, Pennsylvania

Date of application for amendment: August 6, 2003, as supplemented February 13 and June 16, 2004.

Brief description of amendment: The amendment revised the reactor building tendon surveillance criteria to incorporate a reference to Title 10 of the Code of Federal Regulations (10 CFR), Section 50.55a. The amendment also includes an administrative change to provide consistency between Technical Specification Definition 1.22 (MEMBERS OF THE PUBLIC) and the definition contained in 10 CFR 20.1003, and a change to correct a typographical error in a reference title.

Date of issuance: July 13, 2004.

Effective date: As of the date of issuance and shall be implemented within 30 days.

Amendment No.: 251.

Facility Operating License No. DPR–50. Amendment revised the Technical Specifications.

Date of initial notice in ***Federal Register***: December 9, 2003 (68 FR 68655) and March 16, 2004 (69 FR 12363). The February 13, 2004, supplemental letter provided clarifying information and expanded the scope of the application as originally noticed. Therefore, the original proposed no significant hazards consideration determination was changed and republished. The June 16, 2004, supplement provided clarifying information, did not expand the scope of the application and did not change the NRC staff's proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 13, 2004.

No significant hazards consideration comments received: No.

Entergy Nuclear Operations, Inc., Docket No. 50–293, Pilgrim Nuclear Power Station, Plymouth County, Massachusetts

Date of application for amendment: December 24, 2003.

Brief description of amendment: The amendment deleted requirements from the Technical Specifications (TSs) 3.7.A.7.c and 4.7.A.7.c associated with hydrogen analyzers. The associated TS Bases are also deleted.

Date of issuance: July 22, 2004.

Effective date: As of the date of issuance, and shall be implemented within 60 days.

Amendment No.: 206.

Facility Operating License No. DPR–35: The amendment revised the TSs.

Date of initial notice in ***Federal Register***: April 13, 2004 (69 FR 19568).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 22, 2004.

No significant hazards consideration comments received: No.

FirstEnergy Nuclear Operating Company, Docket No. 50–440, Perry Nuclear Power Plant, Unit 1, Lake County, Ohio

Date of amendment request: August 14, 2003, as supplemented by letters dated January 22, and May 6, 2004.

Description of amendment request: This license amendment modifies Technical Specification (TS) Table 3.3.6.1–1, "Primary Containment and Drywell Isolation Instrumentation," Item 1.f, to increase the analytical limit for detected temperature and the resulting TS Allowable Value related to the setpoint for the Main Steam Line Turbine Building Temperature—High system isolation function. Additionally, it authorizes the use of the GOTHIC 7.0 computer program to perform analyses of main steamline leaks in the turbine building for Perry Nuclear Power Plant to replace the currently approved COMPARE computer program for performing the analyses listed above.

Date of issuance: July 9, 2004.

Effective date: As of the date of issuance and shall be implemented within 90 days.

Amendment No.: 130.

Facility Operating License No. NPF–58: Amendment revised the Technical Specifications.

Date of initial notice in ***Federal Register***: (69 FR 696) January 6, 2004.

The supplemental letters contained clarifying information and did not change the initial no significant hazards consideration determination and did not expand the scope of the original **Federal Register** notice.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 9, 2004.

No significant hazards consideration comments received: No.

Florida Power Corporation, et al., Docket No. 50–302, Crystal River Unit No. 3 Nuclear Generating Plant, Citrus County, Florida

Date of application for amendment: February 27, 2004.

Brief description of amendment: The amendment deletes Technical Specification Section 5.6.2.6, "Post-Accident Sampling," requirements to maintain a Post-Accident Sampling System.

Date of issuance: July 6, 2004.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment No.: 213.

Facility Operating License No. DPR–72: Amendment revises the Technical Specifications.

Date of initial notice in ***Federal Register***: April 13, 2004 (69 FR 19571).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 6, 2004.

No significant hazards consideration comments received: No.

Florida Power and Light Company, et al., Docket Nos. 50–335 and 50–389, St. Lucie Plant, Unit Nos. 1 and 2, St. Lucie County, Florida

Date of application for amendments: October 23, 2002, as supplemented by letters dated August 28, 2003, December 11, 2003, February 3, 2004, and March 25, 2004.

Brief description of amendments: These amendments revised Technical Specification Section 5.6, "Design Features—Fuel Storage," for St. Lucie Units 1 and 2 to include the design of a new cask pit spent fuel storage rack for each unit, and increase each unit's spent fuel storage capacity by combining the cask pit rack and existing spent fuel pool storage rack capacities. The cask pit racks will be used to store spent fuel to allow refueling outage fuel offloads and nonoutage fuel shuffles and, for Unit 1, to store new fuel prior to loading it into the reactor.

Date of Issuance: July 9, 2004.

Effective Date: As of the date of issuance and shall be implemented within 60 days.

Amendment Nos.: 192 and 135.

Renewed Facility Operating License Nos. DPR–67 and NPF–16: Amendments revised the Technical Specifications.

Date of initial notice in ***Federal Register:*** January 28, 2003 (68 FR 4244), as corrected March 31, 2003 (68 FR 15487). The August 28, 2003, December 11, 2003, February 3, 2004, and March 25, 2004, supplements did not affect the original proposed no significant hazards determination, or expand the scope of the request as noticed in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in an Environmental Assessment dated July 2, 2004 and in a Safety Evaluation dated July 9, 2004.

No significant hazards consideration comments received: No.

Nebraska Public Power District, Docket No. 50–298, Cooper Nuclear Station, Nemaha County, Nebraska

Date of amendment request: January 29, 2004, as supplement by letter dated April 8, 2004.

Brief description of amendment: The amendment revises Technical Specification 3.4.9 Pressure Temperature (P/T) limit curve Figures 3.4.9–1, 3.4.9–2, and 3.4.9–3.

Date of issuance: July 14, 2004.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment No.: 204.

Facility Operating License No. DPR–46: Amendment revised the Technical Specifications.

Date of initial notice in ***Federal Register:*** March 16, 2004 (69 FR 12371). The April 8, 2004, supplemental letter provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 14, 2004.

No significant hazards consideration comments received: No.

Nebraska Public Power District, Docket No. 50–298, Cooper Nuclear Station, Nemaha County, Nebraska

Date of amendment request: January 30, 2004, as supplemented by letter dated June 17, 2004.

Brief description of amendment request: The proposed amendment would revise the Cooper Nuclear Station (CNS) Technical Specifications (TSs), by adding a temporary note to allow a one-time extension of a limited number of TS Surveillance Requirements (SRs). The temporary note states that the next required performance of the SRs may be delayed until the current cycle refueling outage, but no later than February 2, 2005, and it expires upon startup from the refueling outage. With the exception of one SR, the period of additional time requested occurs during the next planned refueling outage.

Date of issuance: July 14, 2004.

Effective date: As of the date of issuance and shall be implemented within 30 days of issuance.

Amendment No.: 205.

Facility Operating License No. DPR–46: Amendment revised the Technical Specifications.

Date of initial notice in ***Federal Register:*** February 12, 2004 (69 FR 7023). The June 17, 2004, supplemental letter provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 14, 2004.

No significant hazards consideration comments received: No.

Pacific Gas and Electric Company, Docket Nos. 50–275 and 50–323, Diablo Canyon Nuclear Power Plant, Unit Nos. 1 and 2, San Luis Obispo County, California

Date of application for amendments: September 24, 2002, and its supplements dated November 21, 2003, and March 9, 2004.

Brief description of amendments: The amendments revise Technical Specification (TS) Section 3.4.11, "Pressurizer Power Operated Relief Valves (PORVs)," to credit the automatic actuation of the pressurizer PORVs for mitigating the plant transient of inadvertent actuation of the safety injection (SI) system. The amendments also modify the wording in Criteria A, B, and E of TS 3.4.11 to reflect the new requirement of ensuring automatic function of PORVs and adds two new surveillance requirements. The licensee withdrew the changes to TS 3.4.10, "Pressurizer Safety Valves," in its letter dated March 9, 2004.

Date of issuance: July 2, 2004.

Effective date: July 2, 2004, and shall be implemented within 30 days from the date of issuance.

Amendment Nos.: Unit 1—171; Unit 2—172.

Facility Operating License Nos. DPR–80 and DPR–82: The amendments revised the Technical Specifications.

Date of initial notice in ***Federal Register:*** December 24, 2002 (67 FR 78522)

The November 21, 2003, and March 9, 2004, supplemental letters provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated July 2, 2004.

No significant hazards consideration comments received: No.

South Carolina Electric & Gas Company, South Carolina Public Service Authority, Docket No. 50–395, Virgil C. Summer Nuclear Station, Unit No. 1, Fairfield County, South Carolina

Date of application for amendment: September 19, 2003.

Brief description of amendment: This amendment revised Surveillance Requirement 4.2.4.2 to specifically identify the Power Distribution Monitoring System being used in determining the Quadrant Power Tilt Ratio with one inoperable Power Range Channel.

Date of issuance: July 6, 2004.

Effective date: As of the date of issuance and shall be implemented within 30 days from the date of issuance.

Amendment No.: 168.

Renewed Facility Operating License No. NPF–12: Amendment revised the Technical Specifications.

Date of initial notice in ***Federal Register:*** March 30, 2004 (69 FR 16623).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 6, 2004.

No significant hazards consideration comments received: No.

Tennessee Valley Authority, Docket No. 50–327, Sequoyah Nuclear Plant, Units 1 and 2, Hamilton County, Tennessee

Date of application for amendment: March 5, 2004.

Brief description of amendment: The amendment revises the reactor coolant pump flywheel inspection interval from 10 years to 20 years.

Date of issuance: July 8, 2004.

Effective date: As of the date of issuance and shall be implemented within 45 days of issuance.

Amendment Nos.: 293 and 283.

Facility Operating License No. DPR–77 and DPR–79: Amendment revises the technical specifications.

Date of initial notice in ***Federal Register:*** April 13, 2004 (69 FR 19577).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 8, 2004.

No significant hazards consideration comments received: No.

Union Electric Company, Docket No. 50–483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of application for amendment: April 8, 2004.

Brief description of amendment: The amendment revises TS 5.5.7, "Reactor Coolant Pump Flywheel Inspection Program," to increase the inspection interval from 10 years to 20 years.

Date of issuance: July 12, 2004.

Effective date: July 12, 2004, and shall be implemented within 90 days from the date of issuance.

Amendment No.: 163.

Facility Operating License No. NPF–30: The amendment revised the Technical Specifications.

Date of initial notice in ***Federal Register:*** May 11, 2004 (69 FR 26193).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 12, 2004.

No significant hazards consideration comments received: No.

Wolf Creek Nuclear Operating Corporation, Docket No. 50–482, Wolf Creek Generating Station, Coffey County, Kansas

Date of amendment request: April 30, 2003, as supplemented by letters dated December 18, 2003, and April 13, 2004.

Brief description of amendment: The amendment revises several surveillance requirements (SRs) in Technical Specification (TS) 3.8.1 on alternating current sources for plant operation. The revised SRs have notes deleted or modified to allow the SRs to be performed, or partially performed, in reactor modes that previously were not allowed by the TSs. The proposed changes to SRs 3.8.4.7 and 3.8.4.8 for direct current sources were withdrawn by letter dated April 13, 2004.

Date of issuance: July 12, 2004.

Effective date: July 12, 2004, and shall be implemented within 90 days of the date of issuance including the incorporation of the changes to the TS Bases for TS 3.8.1 as described in the licensee's letters dated April 30 and December 18, 2003, and April 13, 2004.

Amendment No.: 154.

Facility Operating License No. NPF–42. The amendment revised the Technical Specifications.

Date of initial notice in ***Federal Register:*** June 10, 2003 (68 FR 34673).

The December 18, 2003, and April 13, 2004, supplemental letters provided additional clarifying information, did not expand the scope of the application as noticed and did not change the staff's original proposed no significant hazards consideration determination. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 12, 2004.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this 26th day of July 2004.

For the Nuclear Regulatory Commission.

James E. Lyons,

Deputy Director, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 04–17346 Filed 8–2–04; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Draft Regulatory Guide; Issuance, Availability

The Nuclear Regulatory Commission has issued for public comment a proposed revision of a guide in its Regulatory Guide Series. Regulatory Guides are developed to describe and make available to the public such information as methods acceptable to the NRC for implementing specific parts of the NRC's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and data needed by the staff in its review of applications for permits and licenses.

The draft guide is temporarily identified by its task number, DG–1124, which should be mentioned in all correspondence concerning this draft guide. Draft regulatory guide DG–1124, "Design, Fabrication, and Materials Code Case Acceptability, ASME Section III," is proposed Revision 33 of Regulatory Guide 1.84. The regulation in 10 CFR 50.55a(c), "Reactor Coolant Pressure Boundary," requires, in part, that components of the reactor coolant pressure boundary must be designed, fabricated, erected, and tested in accordance with the requirements for Class 1 components of Section III, "Rules for Construction of Nuclear Power Plant Components," of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (B&PV) Code or equivalent quality standards. The ASME publishes a new edition of the B&PV Code, which includes Section III, every three years, and new addenda every year. The latest

editions and addenda of Section III that have been approved for use by the NRC are referenced in 10 CFR 50.55a(b). The ASME also publishes Code cases quarterly. Code cases provide alternatives developed and approved by ASME to existing Code requirements. This draft regulatory guide identifies the Code cases that have been determined by the NRC to be acceptable alternatives to applicable parts of Section III. Section III Code cases not yet endorsed by the NRC may be implemented through 10 CFR 50.55a(a)(3), which permits the use of alternatives to the Code requirements referenced in 10 CFR 50.55a provided that the proposed alternatives result in an acceptable level of quality and safety, and that their use is authorized by the Director of the Office of Nuclear Reactor Regulation.

This is a draft guide and does not represent an official NRC staff position. Because Code cases approved by the NRC in a final guide may be used voluntarily by licensees as an alternative to compliance with ASME Code provisions, the final guide will be incorporated by reference into 10 CFR 50.55a through rulemaking.

Comments may be accompanied by relevant information or supporting data. Written comments may be submitted by mail to the Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; or they may be hand-delivered to the Rules and Directives Branch, Office of Administration, at 11555 Rockville Pike, Rockville, MD. Copies of comments received may be examined at the NRC's Public Document Room, 11555 Rockville Pike, Rockville, MD. Comments will be most helpful if received by September 2, 2004.

You may also provide comments via the NRC's interactive rulemaking web site through the NRC home page (*http://www.nrc.gov*). This site provides the ability to upload comments as files (any format) if your web browser supports that function. For information about the interactive rulemaking web site, contact Ms. Carol Gallagher, (301) 415–5905; e-mail *cag@nrc.gov*. For technical information about Draft Regulatory Guide DG–1124, contact Mr. W.E. Norris at (301) 415–6796 (e-mail *wen@nrc.gov*).

Although a deadline is given for comments on these draft guides, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

Regulatory guides are available for inspection at the NRC's Public Document Room, 11555 Rockville Pike, Rockville, MD; the PDR's mailing address is USNRC PDR, Washington, DC 20555–0001; telephone (301) 415–4737 or (800) 397–4209; fax (301) 415–3548; e-mail *pdr@nrc.gov*. Requests for single copies of draft or final regulatory guides (which may be reproduced) or placement on an automatic distribution list for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Reproduction and Distribution Services Section, or by fax to (301) 415–2289; e-mail *distribution@nrc.gov*. Telephone requests cannot be accommodated. Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them. (5 U.S.C. 552(a))

Dated at Rockville, Maryland this 20th day of April, 2004.

For the Nuclear Regulatory Commission.

Michael E. Mayfield,

Director, Division of Engineering Technology, Office of Nuclear Regulatory Research.

[FR Doc. 04–17610 Filed 8–2–04; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Draft Regulatory Guide; Issuance, Availability

The Nuclear Regulatory Commission (NRC) has issued for public comment a proposed revision of a guide in its Regulatory Guide Series. Regulatory Guides are developed to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and data needed by the staff in its review of applications for permits and licenses.

The draft guide is temporarily identified by its task number, DG–1125, which should be mentioned in all correspondence concerning this draft guide. Draft Regulatory Guide DG–1125, "Inservice Inspection Code Case Acceptability, ASME Section XI, Division 1," is proposed Revision 14 of Regulatory Guide 1.147. The regulation at 10 CFR 50.55a(g), "Inservice Inspection Requirements," requires, in part, that Classes 1, 2, 3, MC, and CC Components and their supports meet the requirements of Section XI, "Rules for Inservice Inspection of Nuclear Power Plant Components," of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (B&PV) Code or equivalent quality standards. Every 3 years the ASME publishes a new edition of the B&PV Code, including Section XI, and new addenda are published every year. The latest editions and addenda of Section XI that have been approved for use by the NRC are referenced in 10 CFR 50.55a(b). The ASME also publishes Code cases quarterly. Code cases provide alternatives to existing Code requirements that were developed and approved by the ASME. This regulatory guide identifies the Code cases that have been determined by the NRC to be acceptable alternatives to applicable parts of Section XI. These Code cases may be used by licensees without a request for authorization from the NRC provided that they are used with any identified limitations or modifications. Section XI Code cases not yet endorsed by the NRC may be implemented through 10 CFR 50.55a(a)(3), which permits the use of alternatives to the Code requirements referenced in 10 CFR 50.55a provided that the proposed alternatives result in an acceptable level of quality and safety and that their use is authorized by the Director of the Office of Nuclear Reactor Regulation.

This draft guide has not received complete staff approval and does not represent an official NRC staff position. Because Code cases approved by the NRC in a final guide may be used voluntarily by licensees as an alternative to compliance with ASME Code provisions, the final guide will be incorporated by reference into 10 CFR 50.55a through rulemaking.

A document entitled "Evaluation of Code Cases" is attached to the proposed rulemaking associated with the draft guide. The document provides a basis for each condition in the draft guide. Public comments are encouraged on the Code case conditions. It should be noted that Code Cases N–416–3 and N–504–2 are listed in the draft guide as unconditionally acceptable. The NRC is proposing to condition Code Case N–416–3 in response to a recent licensee submittal. The NRC does not believe that the application of the Code case as described in the submittal would provide adequate assurance of component structural integrity. A condition is also being proposed for Code Case N–504–2. The American Society of Mechanical Engineers (ASME) recently addressed a revision to Code Case N–504–2. The NRC is proposing to condition the use of Code Case N–504–2 based on this recent ASME action. The proposed conditions are discussed in Section 4.7 of the "Evaluation of Code Cases." Because the industry actions occurred after the draft guide had been published but prior to release of the guide for public comment,

the NRC is proposing to condition the use of these two Code cases in the final guide unless public comments are received that the staff's proposed technical bases for the conditions are not applicable, incorrect, unnecessary to provide reasonable assurance of adequate protection to public health and safety and common defense and security, or otherwise not justified in light of the increase in protection to public health and safety or common defense and security that would be provided by imposition of the conditions.

Comments may be accompanied by relevant information or supporting data. Written comments may be submitted by mail to the Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; or they may be hand-delivered to the Rules and Directives Branch, Office of Administration, at 11555 Rockville Pike, Rockville, MD. Copies of comments received may be examined at the NRC's Public Document Room, 11555 Rockville Pike, Rockville, MD. Comments will be most helpful if received by September 2, 2004.

You may also provide comments via the NRC's interactive rulemaking web site through the NRC home page (*http://www.nrc.gov*). This site provides the ability to upload comments as files (any format) if your web browser supports that function. For information about the interactive rulemaking web site, contact Ms. Carol Gallagher, (301) 415–5905; e-mail CAG@NRC.GOV. For technical information about Draft Regulatory Guide DG–1125, contact Mr. W. E. Norris at (301) 415–6796 (e-mail *wen@nrc.gov*).

Although a deadline is given for comments on these draft guides, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

Regulatory guides are available for inspection at the NRC's Public Document Room, 11555 Rockville Pike, Rockville, MD; the PDR's mailing address is USNRC PDR, Washington, DC 20555–0001; telephone (301) 415–4737 or (800) 397–4209; fax (301) 415–3548; e-mail *pdr@nrc.gov*. Requests for single copies of draft or final regulatory guides (which may be reproduced) or placement on an automatic distribution list for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Reproduction and Distribution Services Section, or by fax to (301) 415–2289; e-mail *distribution@nrc.gov*. Telephone requests cannot be accommodated. Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them. (5 U.S.C. 552(a))

Dated at Rockville, Maryland this 20th day of April, 2004.

For the Nuclear Regulatory Commission.

Michael Mayfield,

Director, Division of Engineering Technology, Office of Nuclear Regulatory Research.

[FR Doc. 04–17611 Filed 8–2–04; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Draft Regulatory Guide; Issuance, Availability

The Nuclear Regulatory Commission has issued for public comment a proposed revision of a guide in its Regulatory Guide Series. Regulatory Guides are developed to describe and make available to the public such information as methods acceptable to the NRC for implementing specific parts of the NRC's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and data needed by the staff in its review of applications for permits and licenses.

The draft guide is temporarily identified by its task number, DG–1126, which should be mentioned in all correspondence concerning this draft guide. Draft regulatory guide DG–1126, "ASME Code Cases Not Approved for Use," is proposed Revision 1 of Regulatory Guide 1.193. The American Society of Mechanical Engineers (ASME) publishes a new edition of the Boiler and Pressure Vessel (B&PV) Code every three years and new addenda every year. The latest editions and addenda of Section III and Section XI that have been approved for use by the NRC are referenced in 10 CFR 50.55a(b). The ASME also publishes Code cases for Section III and Section XI quarterly. Code cases provide alternatives to the B&PV Code developed and approved by the ASME. Revision 32 of Regulatory Guide 1.84, "Design, Fabrication, and Materials Code Case Acceptability, ASME Section III," and Revision 13 of Regulatory Guide 1.147, "Inservice Inspection Code Case Acceptability, ASME Section XI, Division 1," are being revised to identify the Code cases that have been determined by the NRC to be acceptable alternatives to applicable parts of Section III and Section XI. This regulatory guide (DG–1126) lists the Code cases that the NRC has determined not to be acceptable for use on a generic basis. A brief description of the basis for the determination is provided with each Code case. Licensees may submit a request to implement one or more of the Code cases listed in the guide through 10 CFR 50.55a(a)(3), which permits the use of alternatives to the Code requirements referenced in 10 CFR 50.55a provided that the proposed alternatives result in an acceptable level of quality and safety. A licensee must submit a plant-specific request that addresses the NRC's concern about the Code case at issue.

This is a draft guide and does not represent an official NRC staff position. Because Code cases approved by the NRC in a final guide may be used voluntarily by licensees as an alternative to compliance with ASME Code provisions, the final guide will be incorporated by reference into 10 CFR 50.55a through rulemaking.

Comments may be accompanied by relevant information or supporting data. Written comments may be submitted by mail to the Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; or they may be hand-delivered to the Rules and Directives Branch, Office of Administration, at 11555 Rockville Pike, Rockville, MD. Copies of comments received may be examined at the NRC's Public Document Room, 11555 Rockville Pike, Rockville, MD. Comments will be most helpful if received by September 2, 2004.

You may also provide comments via the NRC's interactive rulemaking Web site through the NRC home page (*http://www.nrc.gov*). This site provides the ability to upload comments as files (any format) if your Web browser supports that function. For information about the interactive rulemaking Web site, contact Ms. Carol Gallagher, (301) 415–5905; e-mail *CAG@NRC.GOV*. For technical information about Draft Regulatory Guide DG–1126, contact Mr. W.E. Norris at (301) 415–6796 (e-mail *WEN@NRC.GOV*).

Although a deadline is given for comments on these draft guides, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

Regulatory guides are available for inspection at the NRC's Public Document Room, 11555 Rockville Pike, Rockville, MD; the PDR's mailing address is USNRC PDR, Washington, DC 20555–0001; telephone (301) 415–4737 or (800) 397–4209; fax (301) 415–3548; e-mail *PDR@NRC.GOV*. Requests for single copies of draft or final regulatory guides (which may be reproduced) or placement on an automatic distribution

list for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Reproduction and Distribution Services Section, or by fax to (301) 415–2289; e-mail *DISTRIBUTION@NRC.GOV*. Telephone requests cannot be accommodated. Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them. (5 U.S.C. 552(a))

Dated in Rockville, Maryland this 20th day of April 2004.

For the Nuclear Regulatory Commission.

Michael E. Mayfield,

Director, Division of Engineering Technology, Office of Nuclear Regulatory Research.

[FR Doc. 04–17612 Filed 8–2–04; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Proposed Generic Communication; Draft Revision to NRC Inspection Manual Chapter 9900, "Technical Guidance," Operability Determinations and Resolution of Nonconformances of Structures, Systems, and Components" ("Regulatory Issue Summary 2004–XX")—(MC2262)

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of opportunity for public comment and notice of public meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to issue a Regulatory Issue Summary (RIS) to provide the nuclear power industry with updated staff guidance on operability determinations and resolution of degraded and nonconforming conditions of Structures, Systems, and Components (SSCs). This proposed RIS updates the previous guidance in NRC Inspection Manual Chapter (IMC) 9900, "Technical Guidance," and endorsed by the NRC in Generic Letter 91–18, "Information to Licensees Regarding Two NRC Inspection Manual Sections on Resolution of Degraded and Nonconforming Conditions and on Operability." The guidance is being updated to reflect relevant changes in the NRC regulatory process and regulations contained in 10 CFR 50.59, "Changes, Tests, and Experiments," and 10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants;" and to clarify the guidance for selected issues based on operating experience, and; to consolidate and streamline the guidance in two previously separate NRC IMC 9900 sections.

Earlier guidance on these subjects was provided to the industry in two sections of IMC 9900 as an attachment to GL 91–18, issued on November 7, 1991. An update of guidance on degraded and nonconforming conditions was issued as Revision 1 on October 8, 1997. In addition, on September 13, 2001, the NRC issued for public comment an earlier draft revision of the guidance on degraded and nonconforming conditions. The NRC also held a public workshop on August 14, 2003, as part of the development of the proposed revision. The staff has addressed the comments received in the present revision.

The NRC is seeking comment from interested parties on the clarity and utility of the proposed RIS and the draft updated IMC 9900 guidance, as outlined under the Supplementary Information heading. The NRC will consider the comments received in its final evaluation of the proposed RIS and updated guidance. Comments should address the contents of the guidance but not the associated regulations.

The NRC will hold a public workshop on August 25, 2004, in the Two White Flint North Auditorium at the NRC offices in Rockville, Maryland, at 8:30 a.m.—4:30 p.m., for discussion of the proposed revision to the guidance. Comments provided during this workshop will be considered by the NRC when it finalizes the proposed RIS and IMC guidance. Written comments may also be provided as discussed below.

DATES: The comment period expires 60 days after this notice is published. Comments submitted after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except for comments received on or before this date. Interested parties are also encouraged to provide comments by August 18, 2004, to be discussed during the public workshop on August 25, 2004.

ADDRESSES: Submit written comments to the Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Mail Stop T6–D59, Washington, DC 20555–0001, and cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to NRC Headquarters, 11545 Rockville Pike (Room T–6D59), Rockville, Maryland, between 7:30 a.m. and 4:15 p.m. on Federal workdays.

FOR FURTHER INFORMATION, CONTACT: Kerri Kavanagh at (301) 415–3743 or by e-mail to *kak@nrc.gov*.

SUPPLEMENTARY INFORMATION: Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. The NRC's Agencywide Documents Access and Management System (ADAMS) provides text and image files of NRC's public documents. The proposed RIS and the draft updated IMC 9900 guidance are available under ADAMS accession number ML042080035. These documents may be accessed through the NRC's Public Electronic Reading Room (PERR) on the Internet at *http://www.nrc.gov/reading-rm/adams.html*. If you do not have access to ADAMS or if you have problems in accessing documents in ADAMS, contact the NRC Public Document Room (PDR) reference staff by phone at 1–800–397–4209 or 301–415–4737, by e-mail to *pdr@nrc.gov*, or by fax to 301–415–3548.

Dated at Rockville, Maryland, this 27th day of July 2004.

For the Nuclear Regulatory Commission.

Terrence Reis,

Acting Chief, Reactor Operations Branch, Division of Inspection Program Management, Office of Nuclear Reactor Regulation.

[FR Doc. 04–17608 Filed 8–2–04; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application of Morgan's Foods, Inc. To Withdraw Its Common Stock, No Par Value, From Listing and Registration on the American Stock Exchange LLC File No. 1–08395

July 28, 2004.

On June 30, 2004, Morgan's Foods, Inc., an Ohio corporation ("Issuer"), filed an application with the Securities and Exchange Commission ("Commission"), pursuant to Section 12(d) of the Securities Exchange Act of 1934 ("Act") [1] and Rule 12d2–2(d) thereunder,[2] to withdraw its common stock, no par value ("Security"), from listing and registration on the American Stock Exchange LLC ("Amex" or "Exchange").

The Board of Directors ("Board") of the Issuer unanimously approved a resolution on June 29, 2004 to withdraw the Issuer's Security from listing on the

[1] 15 U.S.C. 78*l*(d).

[2] 17 CFR 240.12d2–2(d).

Amex. The Board states that the reasons it is taking such action are as follows: (i) The Issuer's revenues and income over more than the last two fiscal years have decreased as a result of continuing ineffective and inadequate product promotions and a lack of relevant menu additions by the Issuer's KFC franchisor; (ii) the Issuer's efforts to re-establish compliance with the Amex's listing standards have not been successful; and (iii) the Issuer discussed, with Amex representatives, the expectations for a further year-over-year decline in revenues and income for the first fiscal quarter of 2005, again, primarily as a result of ineffective and inadequate product promotions and a lack of relevant menu additions by the Issuer's KFC franchisor. In light of the foregoing, the Board states that it is in the best interest of the Issuer to withdraw the Issuer's Security from listing and registration on the Amex. The Issuer states that it is currently seeking to make a market for the Security in the OTC Pink Sheets.

The Issuer stated in its application that it has met the requirements of Amex Rule 18 by complying with all applicable laws in the State of Ohio, in which it is incorporated, and with the Amex's rules governing an issuer's voluntary withdrawal of a security from listing and registration.

The Issuer's application relates solely to the withdrawal of the Security from listing on the Amex and from registration under Section 12(b) of the Act,[3] and shall not affect its obligation to be registered under Section 12(g) of the Act.[4]

Any interested person may, on or before August 20, 2004, comment on the facts bearing upon whether the application has been made in accordance with the rules of the Amex, and what terms, if any, should be imposed by the Commission for the protection of investors. All comment letters may be submitted by either of the following methods:

Electronic Comments

- Send an e-mail to *rule-comments@sec.gov*. Please include the File Number 1–08395 or;

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number 1–08395. 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 Web site (*http://www.sec.gov/rules/delist.shtml*). Comments are also available for public inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, NW., Washington, DC 20549. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority. [5]

Jonathan G. Katz,

Secretary.

[FR Doc. 04–17648 Filed 8–2–04; 8:45 am]

BILLING CODE 8010–01–P

[3] 15 U.S.C. 78*l*(b).

[4] 15 U.S.C. 78*l*(g).

[5] 17 CFR 200.30–3(a)(1).

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application of VI Group, plc, To Withdraw Its American Depositary Shares Evidenced by American Depositary Receipts (Each American Depositary Share Evidencing Ordinary Shares), 0.50 Pence Par Value Per Registrant, From Listing and Registration on the American Stock Exchange LLC File No. 1–31469

July 28, 2004.

On July 23, 2004, VI Group, plc, an England and Wales corporation ("Issuer"), filed an application with the Securities and Exchange Commission ("Commission"), pursuant to Section 12(d) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 12d2–2(d) thereunder,[2] to withdraw its american depositary shares evidenced by american depositary receipts (each american depositary share evidencing ordinary shares), 0.50 pence par value per registrant ("Security"), from listing and registration on the American Stock Exchange LLC ("Amex" or "Exchange").

The Board of Directors ("Board") of the Issuer unanimously approved a resolution on April 21, 2004 to withdraw the Issuer's Security from listing on the Amex. The Board states that the reasons it is taking such action are as follows: Although the Security has been listed since October 2002, the number of United States shareholders who had bought the Security was disappointingly small, and the costs of maintaining the listing, including the Commission's registration cost, were significant. The Issuer states that Security has been listed on the Amex for over a year and despite considerable efforts to generate liquidity in the Security, the trading volume and number of shareholders remains exceptionally low. In addition, the costs of regulatory compliance have escalated dramatically. The Issuer also states that the Security will continue to be traded in the United States on the over-the-counter-market. Further, the ordinary shares of the Issuer will continue to be traded on the London Stock Exchanges' Alternative Investment Market.

The Issuer stated in its application that it has met the requirements of Amex Rule 18 by complying with all applicable laws in effect in England and Wales, in which it is incorporated, and with the Amex's rules governing an issuer's voluntary withdrawal of a security from listing and registration.

The Issuer's application relates solely to the withdrawal of the Security from listing on the Amex and from registration under Section 12(b) of the Act,[3] and shall not affect its obligation to be registered under Section 12(g) of the Act.[4]

Any interested person may, on or before August 20, 2004, comment on the facts bearing upon whether the application has been made in accordance with the rules of the Amex, and what terms, if any, should be imposed by the Commission for the protection of investors. All comment letters may be submitted by either of the following methods:

Electronic Comments

- Send an e-mail to *rule-comments@sec.gov*. Please include the File Number 1–31469 or;

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number 1–31469. This file number should be included on the subject line if e-mail is used. To help us process and

[1] 15 U.S.C. 78*l*(d).

[2] 17 CFR 240.12d2–2(d).

[3] 15 U.S.C. 78*l*(b).

[4] 15 U.S.C. 78*l*(g).

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/delist.shtml*). Comments are also available for public inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, NW., Washington, DC 20549. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[5]

Jonathan G. Katz,

Secretary.

[FR Doc. 04–17647 Filed 8–2–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50110; File No. SR–OPRA–2004–04]

Options Price Reporting Authority; Notice of Filing and Immediate Effectiveness of Amendment to OPRA Plan Regarding the Temporary Waiver of Charges by OPRA Relating to the Dynamic Throttle

July 28, 2004.

Pursuant to section 11A of the Securities Exchange Act of 1934 ("Act")[1] and Rule 11Aa3–2 thereunder,[2] notice is hereby given that on July 9, 2004, the Options Price Reporting Authority ("OPRA")[3] submitted to the Securities and Exchange Commission ("Commission") an amendment to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information ("OPRA Plan"). On July 27, 2004, OPRA submitted Amendment No. 1 to the proposal.[4] The proposed OPRA Plan amendment would waive temporarily the imposition of the charge that would otherwise be imposed upon a participant exchange that utilizes the "dynamic throttle" pursuant to Section III(g)(iii) of the OPRA Plan and Guideline 6(h) of the Capacity Guidelines that constitute part of the OPRA Plan. OPRA proposes to apply the waiver during a temporary period ending on September 10, 2004. The Commission is publishing this notice to solicit comments from interested persons on the proposed OPRA Plan amendment.

I. Description and Purpose of the Amendment

The purpose of the proposed amendment to the OPRA Plan is to temporarily waive the charge imposed upon a participant exchange that utilizes the dynamic throttle feature of the OPRA System, which permits a participant to gain automatic access to unused, excess System capacity on a short-term, interruptible basis. Section III(g) of the OPRA Plan and Guideline 6(h) of the Capacity Guidelines require any participant exchange using the dynamic throttle to access additional capacity to pay for that capacity at a rate that is 150% of the fully allocated cost of that capacity, as determined by OPRA's Independent System Capacity Advisor ("ISCA").

The proposed waiver of this charge would apply during the period ending on September 10, 2004, which is the date when OPRA anticipates full implementation of an enhancement to its communications network that was recently developed by the Securities Industry Automation Corporation ("SIAC"), and designated by SIAC as the Secure Financial Transaction Infrastructure ("SFTI"). Once SFTI is fully implemented, all recipients of OPRA data would need to be able to access the data over a high bandwidth network, which certain data recipients are not yet able to do. OPRA believes that, among other things, full implementation of SFTI would permit SIAC to provide additional capacity to OPRA's participant exchanges who request it pursuant to procedures provided for in the OPRA Plan.

OPRA had originally intended to implement SFTI on June 30, 2004, after which it would cease to support lower bandwidth "legacy" connections currently relied upon by some data recipients. However, because several vendors and one OPRA participant would not be able to access the new higher bandwidth connection on June 30th, OPRA recently determined to delay the cutover to SFTI until September 10, 2004, by which time all persons who access the OPRA network would be expected to be able to connect to SFTI.

According to OPRA, as a consequence of delaying the cutover to SFTI, the date when participant exchanges would be able to increase their current allocation of System capacity by receiving an allocation of the increase through SFTI would likewise be delayed. OPRA believes that this delay could be especially problematic for a new options exchange, such as the BSE, which may need additional capacity to support its expanding options market.

Since there is unused, excess capacity presently available in the System, OPRA believes that an obvious response to this problem would be to utilize OPRA's dynamic throttle to provide temporary, additional capacity to any exchange that might need it until the System's capacity is increased on a permanent basis during the cutover to SFTI on September 10, 2004.[5] However, as described above, the OPRA Plan and the Capacity Guidelines currently require the imposition of a charge on any participant exchange that obtains additional, temporary capacity by means of the dynamic throttle. OPRA states that the purpose of this charge is to discourage any participant exchange from submitting an unrealistically low request for permanent capacity in order to lower its costs, and then relying on the operation of the dynamic throttle to make up for any shortfall in its allocation of System capacity.

Although OPRA continues to believe that it is justified in imposing a charge on a participant exchange that makes use of the dynamic throttle under ordinary circumstances, it does not believe it would be fair to impose this charge under the present circumstances where a participant exchange could be prevented from obtaining a greater permanent allocation of capacity simply

[5] 17 CFR 200.30–3(a)(1).

[1] 15 U.S.C. 78k–1.

[2] 17 CFR 240.11Aa3–2.

[3] OPRA is a national market system plan approved by the Commission pursuant to Section 11A of the Act and Rule 11Aa3–2 thereunder. *See* Securities Exchange Act Release No. 17638 (March 18, 1981), 22 S.E.C. Docket 484 (March 31, 1981).

The OPRA Plan provides for the collection and dissemination of last sale and quotation information on options that are traded on the participant exchanges. The six participants to the OPRA Plan are the American Stock Exchange LLC, the Boston Stock Exchange, Inc. ("BSE"), the Chicago Board Options Exchange, Inc., the International Securities Exchange, Inc., the Pacific Exchange, Inc., and the Philadelphia Stock Exchange, Inc.

[4] *See* letter from Michael L. Meyer, Counsel to OPRA, Schiff Hardin LLP, to Deborah L. Flynn, Assistant Director, Division of Market Regulation, Commission, dated July 26, 2004. Amendment No. 1 added specific language to Section III(g) and Capacity Guideline 6(h) of the OPRA Plan describing the temporary waiver.

[5] OPRA states that it has been advised by the Options Clearing Corporation, acting in its capacity as the ISCA, that it concurs with OPRA's decision to delay the implementation of SFTI until September 10, 2004, and expects the dynamic throttle to provide whatever additional capacity may be needed by any of the exchanges prior to the anticipated cutover to SFTI on that date.

because OPRA has delayed the implementation of SFTI as an accommodation to data recipients who are not yet able to connect to the upgraded network. For this reason, OPRA proposes to waive the imposition of the special charge on exchanges that utilize the dynamic throttle until September 10, 2004, when SFTI is expected to be fully implemented.

OPRA does not anticipate any further delay in the implementation of SFTI beyond September 10, 2004, based on assurances that all data recipients would be able to connect to SFTI by that date. In the unlikely event that a further delay in the implementation of SFTI may be necessary, and if, as a result, OPRA should determine to waive the imposition of the dynamic throttle charge beyond that date, OPRA states that such a determination would be treated as a separate OPRA Plan amendment and would be the subject of a separate filing under Rule 11Aa3–2 of the Act.[6]

The text of the proposed revised Section III(g) of the Plan and Capacity Guideline 6(h) is set forth below. Proposed new language is in *italic*.

* * * * *

III. *Administration of the Plan*

(a)–(f) [No change]

(g) *Capacity Planning; Allocation of System Capacity.*

(i)–(ii) [No change]

(iii) To the extent and subject to the conditions and limitations set forth in the Capacity Guidelines, under circumstances when the capacity of the System is unable to meet the aggregate requests for capacity that have been submitted to and approved by the ISCA, the ISCA shall be authorized to allocate available System capacity among the parties. In addition, the Capacity Guidelines shall provide for the utilization of a "dynamic throttle" that is capable of automatically and instantaneously making available to a party with an immediate need for additional capacity, on a short-term interruptible basis, any unused capacity, subject to the conditions that the party receiving such unused capacity must pay for it at a rate that is determined by the ISCA to be greater than the fully allocated cost of such additional capacity to the extent provided in the Capacity Guidelines (*except that during a temporary period ending September 10, 2004, no such payment shall be required to be made by a party receiving unused capacity by operation of the dynamic throttle*), and must relinquish such capacity to the party or parties to which it had originally been allocated whenever such party or parties need it. Amounts paid by a party for the use of excess capacity made available to it by operation of the dynamic throttle shall be added to OPRA's general revenues.

* * * * *

6. *Capacity Allocation.*

(a)–(g) [No change]

(h) The authority of the ISCA to allocate excess capacity in accordance with paragraphs (a)–(g) of this Guideline 6 is in addition to the automatic, short-term, interruptible allocation of unused capacity that may be made by the "dynamic throttle" that is incorporated within the OPRA System. Section III(g) of the OPRA Plan provides that any party receiving an allocation of unused capacity pursuant to the operation of the dynamic throttle must pay for it at a rate determined by the ISCA, which is to exceed the fully allocated cost of such additional capacity to the extent provided in these guidelines. *Section III(g) also provides that the requirement to pay for unused capacity made available by operation of the dynamic throttle does not apply during a temporary period ending September 10, 2004.* Accordingly, *except during the period when the payment requirement does not apply as aforesaid,* the ISCA is directed to apply a multiple of 150% to the fully allocated cost of capacity for purposes of arriving at the rate at which a party shall be charged for capacity made available to it pursuant to the operation of the dynamic throttle.

* * * * *

II. Implementation of the OPRA Plan Amendment

Pursuant to paragraph (c)(3)(i) of Rule 11Aa3–2 under the Act,[7] OPRA designates this amendment as changing the way in which costs are distributed to OPRA's participant exchanges, thereby qualifying for effectiveness upon filing. The Commission may summarily abrogate the amendment within sixty days of its filing and require refiling and approval of the amendment by Commission order pursuant to Rule 11Aa3–2(c)(2) under the Act,[8] if it appears to the Commission that such action is necessary or appropriate in the public interest; for the protection of investors and the maintenance of fair and orderly markets; to remove impediments to, and perfect the mechanisms of, a national market system; or otherwise in furtherance of the purposes of the Act.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed OPRA Plan amendment is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comment

- 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–OPRA–2004–04 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–OPRA–2004–04. 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 plan amendment that are filed with the Commission, and all written communications relating to the proposed plan amendment 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 inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of OPRA. 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–OPRA–2004–04 and should be submitted on or before August 24, 2004.

[6] 17 CFR 240.11Aa3–2.

[7] 17 CFR 240.11Aa3–2(c)(3)(i).

[8] 17 CFR 240.11Aa3–2(c)(2).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

J. Lynn Taylor,

Assistant Secretary.

[FR Doc. 04–17652 Filed 8–2–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50105; File No. SR–NASD–2003–176]

Self-Regulatory Organizations; Notice of Filing of Amendment No. 2 to a Proposed Rule Change by the National Association of Securities Dealers, Inc. Relating to Chief Executive Officer Certification and Designation of Chief Compliance Officer

July 28, 2004.

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 28, 2003, the National Association of Securities Dealers, Inc. ("NASD") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by NASD. On December 31, 2003, notice of the proposal was published in the **Federal Register**.[3] On March 8, 2004, the NASD filed Amendment No. 1 to the proposed rule change.[4] On July 15, 2004, the NASD filed Amendment No. 2 to the proposed rule change.[5] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASD is proposing new NASD Rule 3013 and accompanying Interpretive Material ("IM") 3013 to require each member to designate a chief compliance officer ("CCO") and further require the member's chief executive officer ("CEO") to certify annually to having in place a process to establish, maintain, review, modify, and test policies and procedures reasonably designed to achieve compliance with applicable NASD rules, MSRB rules, and the federal securities laws. Below is the text of the proposed rule change. Proposed new language is in *italics*.

* * * * *

3013. Annual Certification of Compliance and Supervisory Processes

(a) Designation of Chief Compliance Officer

Each member shall designate and specifically identify to NASD on Schedule A of Form BD a principal to serve as chief compliance officer.

(b) Annual Certification

Each member shall have its chief executive officer (or equivalent officer) certify annually, as set forth in IM–3013, that the member has in place processes to establish, maintain, review, test and modify written compliance policies and written supervisory procedures reasonably designed to achieve compliance with applicable NASD rules, MSRB rules and federal securities laws and regulations, and that the chief executive officer has conducted one or more meetings with the chief compliance officer in the preceding 12 months to discuss such processes.

IM–3013. Annual Compliance and Supervision Certification

The NASD Board of Governors is issuing this interpretation to the requirement under Rule 3013(b), which requires that the member's chief executive officer (or equivalent officer) execute annually[i] a certification that the member has in place processes to establish, maintain, review, test and modify written compliance policies and written supervisory procedures reasonably designed to achieve compliance with applicable NASD rules, MSRB rules and federal securities laws and regulations. The certification shall state the following:

* * * * *

Annual Compliance and Supervision Certification

The undersigned is the chief executive officer (or equivalent officer) of [name of member corporation/partnership/sole proprietorship] (the "Member"). As required by NASD Rule 3013(b), the undersigned makes the following certification:

1. The Member has in place processes to:

(a) Establish, maintain and review policies and procedures reasonably designed to achieve compliance with applicable NASD rules, MSRB rules and federal securities laws and regulations;

(b) Modify such policies and procedures as business, regulatory and legislative changes and events dictate; and

(c) Test the effectiveness of such policies and procedures on a periodic basis, the timing and extent of which is reasonably designed to ensure continuing compliance with NASD rules, MSRB rules and federal securities laws and regulations.

2. The undersigned chief executive officer (or equivalent officer) has conducted one or more meetings with the chief compliance officer in the preceding 12 months, the subject of which satisfy the obligations set forth in IM–3013.

3. The Member's processes, with respect to paragraph 1 above, are evidenced in a report reviewed by the chief executive officer (or equivalent officer), chief compliance officer, and such other officers as the Member may deem necessary to make this certification, and submitted to the Member's board of directors and audit committee.

4. The undersigned chief executive officer (or equivalent officer) has consulted with the chief compliance officer and other officers as applicable (referenced in paragraph 3 above) and such other employees, outside consultants, lawyers and accountants, to the extent deemed appropriate, in

---

[9] 17 CFR 200.30–3(a)(29).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Exchange Act Release No. 48961 (Dec. 23, 2003), 68 FR 75704. The Commission received six comments on the proposal. Letters to Jonathan G. Katz from: Laura Singer, Vice President and General Counsel, E*Trade Brokerage Holdings, Inc. (Feb. 11, 2004); George R. Kramer, Vice President and Acting General Counsel, Securities Industry Association, Paul A. Merolla, Executive Vice President, SIA Compliance and Legal Division, and Paul Saltzman, Executive Vice President and General Counsel, The Bond Market Association (Feb. 6, 2004); Joan Hinchman, Executive Director, President, and CEO, National Society of Compliance Professionals, Inc. (Feb. 5, 2004); and Christiane G. Hyland, Senior Vice President and General Counsel, Empire Corporate FCU (Jan. 21, 2004); and letters from Stephen A. Batman, CEO, 1st Global Capital Corp. (Jan. 21, 2004) and Herbert A. Pontzer, SVP/Chief Compliance Officer, NFP Securities, Inc. (Feb. 4, 2004). The comments are available online at *www.sec.gov/rules/sro/nasd/nasd2003176.shtml.*

[4] *See* letter from Philip A. Shaikun, Assistant General Counsel, NASD, to Catherine McGuire, Chief Counsel, Division of Market Regulation, Commission, dated March 8, 2004 ("Amendment No. 1"). In Amendment No. 1, NASD added a requirement that the mandated meetings between the CEO and CCO include discussion of compliance system deficiencies, risks and resources.

[5] *See* letter from Philip A. Shaikun, Assistant General Counsel, NASD, to Catherine McGuire, Chief Counsel, Division of Market Regulation, Commission, dated July 15, 2004 ("Amendment No. 2"). In Amendment No. 2, NASD eliminated the CCO certification requirement and added to the accompanying interpretive material a description of the CCO's role in the member's compliance scheme and the CEO certification required under this proposed rule.

[i] *Members must ensure that each ensuing annual certification is effected no later than on the anniversary date of the previous year's certification.*

order to attest to the statements made in this certification.[ii]

* * * * *

It is critical that each NASD member understand the importance of employing comprehensive and effective compliance policies and written supervisory procedures. Compliance with applicable NASD rules, MSRB rules and federal securities laws and regulations is the foundation of ensuring investor protection and market integrity and is essential to the efficacy of self-regulation. Consequently, the certification requirement is intended to require processes by each member to establish, maintain, review, test and modify its compliance policies and written supervisory procedures in light of the nature of its businesses and the laws and rules that are applicable thereto, and to evidence such processes in a report reviewed by the chief executive officer (or equivalent officer) executing the certification.

Included in this processes requirement is an obligation on the part of the member to conduct one or more meetings annually between the chief executive officer (or equivalent officer) and the chief compliance officer to: (1) Discuss and review the matters that are the subject of the certification; (2) discuss and review the member's compliance efforts as of the date of such meetings; and (3) identify and address significant compliance problems and plans for emerging business areas.

The periodic and content requirements for meetings between the chief executive officer (or equivalent officer) and the chief compliance officer, as well as the pertinent requirements of paragraphs 3 and 4 of the certification, are intended to indicate the unique and integral role of the chief compliance officer both in the discharge of certain compliance processes and reporting requirements that are the subject matter of the certification and in providing a reliable basis upon which the chief executive officer can execute the certification. The chief compliance officer is the primary advisor to the member on its overall compliance scheme and the particularized rules, policies and procedures that the member adopts. This is because the chief compliance officer should have an expertise in the process of (1) gaining an understanding of the products, services or line functions that need to be the subject of written compliance policies and written supervisory procedures; (2) identifying the relevant rules, regulations, laws and standards of conduct pertaining to such products, services or line functions based on experience and/or consultation with those persons who have a technical expertise in such areas of the member's business; (3) developing, or advising other business persons charged with the obligation to develop, policies and procedures that are reasonably designed to achieve compliance with those relevant rules, regulations, laws and standards of conduct; (4) evidencing the supervision by the line managers who are responsible for the execution of compliance policies; and (5) developing programs to test compliance with the member's policies and procedures.

It is that expertise in the process of compliance that makes the chief compliance officer an indispensable party to enable the chief executive officer to reach the conclusions stated in the certification. Consequently, any certification made by a chief executive officer under circumstances where the chief compliance officer has concluded, after consultation, that there is an inadequate basis for making such certification would be, without limitation, conduct inconsistent with the observance of the high standards of commercial honor and the just and equitable principles of trade—a violation of Rule 2110. Beyond the certification requirement, it is the intention of both Rule 3013 and this Interpretive Material to foster regular and significant interaction between senior management and the chief compliance officer regarding the member's comprehensive compliance program.

The chief compliance officer and other compliance officers that report to the chief compliance officer (as described in the sentence that immediately follows) shall perform the compliance functions contemplated by this Interpretive Material and paragraphs 3 and 4 of the certification. Nothing in this Interpretive Material is intended to limit or discourage the participation of other employees both within and without the member's compliance department in any aspect of the member's compliance programs or processes, including those matters discussed in this Interpretive Material. However, it is understood that the chief compliance officer and, where applicable, the most senior compliance officers having primary compliance department responsibility for each of the member's business segments, will retain responsibility for the compliance functions contemplated by this Interpretive Material and paragraphs 3 and 4 of the certification.

As may be necessary to render their views and advice, the chief compliance officer and the other officers referenced in paragraph 3 of the certification who consult with the chief executive officer (or equivalent officer) pursuant to paragraph 4, shall, in turn, consult with other employees, officers, outside consultants, lawyers and accountants.

The NASD Board of Governors recognizes that supervisors with business line responsibility are accountable for the discharge of a member's compliance policies and written supervisory procedures. The signatory to the certification is certifying only as to having processes in place to establish, maintain, review, test and modify the member's written compliance and supervisory policies and procedures and the execution of this certification and any consultation rendered in connection with such certification does not by itself establish business line responsibility.

The requirement to designate a chief compliance officer does not preclude such person from holding any other position within the member, including the position of chief executive officer, provided that such person can discharge the duties of a chief compliance officer in light of his or her other additional responsibilities. The requirement that a member's processes include providing the report to the board of directors and audit committee (required by paragraph 3 of the certification) does not apply to members that do not utilize these types of governing bodies and committees in the conduct of their business.[iii]

The report required in paragraph 3 of the certification must document the member's processes for establishing, maintaining, reviewing, testing and

---

[ii] *Members should understand that the requirements of Rule 3013 and this Interpretive Material represent, in part, a principle-based requirement to certify that the member has in place processes to establish, maintain, review, test and modify written compliance policies and written supervisory procedures reasonably designed to achieve compliance with applicable NASD rules, MSRB rules and federal securities laws and regulations. Consequently, compliance with the periodic and content requirements in this Interpretive Material pertaining to meetings between the chief executive officer (or equivalent officer) and the chief compliance officer does not satisfy the full extent of these principle-based obligations that will vary with the facts and circumstances of a member's business activities and organizational structure. Moreover, NASD emphasizes the testing aspect of this principle-based requirement; an integral purpose of NASD rules pertaining to supervision is that members adopt policies and procedures that are effective as to both the scope of, and the achievement of compliance with, applicable NASD rules, MSRB rules and federal securities laws and regulations.*

[iii] *As a part of their process, members must have the report reviewed by their governing bodies and committees that serve similar functions in lieu of a board of directors and audit committee.*

modifying compliance policies, that are reasonably designed to achieve compliance with applicable NASD rules, MSRB rules and federal securities laws and regulations, and any principal designated by the member may prepare the report. The report must be produced prior to execution of the certification and be reviewed by the chief executive officer (or equivalent officer), chief compliance officer and any other officers the member deems necessary to make the certification and must be provided to the member's board of directors and audit committee. The report should include the manner and frequency in which the processes are administered, as well as the identification of officers and supervisors who have responsibility for such administration. The report need not contain any conclusions produced as a result of following the processes set forth therein. The report may be combined with any other compliance report or other similar report required by any other self-regulatory organization provided that (1) such report is clearly titled in a manner indicating that it is responsive to the requirements of the certification and this Interpretive Material; (2) a member that submits a report for review in response to an NASD request must submit the report in its entirety; and (3) the member makes such report in a timely manner, i.e., annually.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filings with the Commission, NASD 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. Summaries of the most significant aspects of such statements are set forth in Sections A, B, and C below.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Comprehensive compliance and supervisory systems constitute the bedrock of effective securities industry self-regulation and the primary strata of investor protection. As such, NASD believes that a member's senior management should focus the same attention to a member's compliance and supervisory policies and procedures as is accorded to a member's revenue-producing businesses and such fundamental operational prerequisites as, for example, net capital requirements.

To that end, NASD is proposing a rule change that would bolster investor protection by promoting regular and meaningful interaction between senior management and compliance personnel to ensure that compliance is given the highest priority by a member's senior executive officers. Specifically, the proposed rule change would require (1) that each member designate a principal to serve as CCO and (2) the CEO to certify annually to having in place processes to establish, maintain, review, modify, and test policies and procedures reasonably designed to achieve compliance with applicable NASD rules, MSRB rules, and federal securities laws.

As to the former, NASD Rule 1022 currently requires a person designated as a CCO on Schedule A of Form BD to be registered as a General Securities Principal unless certain exceptions apply.[6] However, the current rules do not require that a member so designate such a person. The proposed rule change would mandate that a member designate a CCO and identify that person on Schedule A of Form BD.

With respect to the certification, the proposed rule change also would require the CEO to certify annually that senior executive management has in place processes to (1) establish, maintain and review policies and procedures reasonably designed to achieve compliance with applicable NASD rules, MSRB rules and federal securities laws and regulations; (2) modify such policies and procedures as business, regulatory and legislative changes and events dictate; and (3) test the effectiveness of such policies and procedures on a periodic basis, the timing of which is reasonably designed to ensure continuing compliance with NASD rules, MSRB rules and the federal securities laws and regulations. The proposed rule change further would require the CEO to certify that those processes are evidenced in a report that has been reviewed by the CEO and submitted to the member's board of directors and audit committee.[7] Notably, the processes, at a minimum, must include one or more meetings annually between the CEO and CCO to (1) discuss and review the matters that are the subject of the certification; (2) discuss and review the member's compliance efforts as of the date of such meetings; and (3) identify and address significant compliance problems and plans for emerging business areas.

The proposed rule change also would create IM–3013, which sets forth the language of the certification and gives further guidance as to the requirements and limitations of the rule. For example, the interpretive material clarifies that the person designated as CCO also may hold other positions within the member, including CEO, provided that individual can effectively discharge the CCO responsibilities while maintaining another position. Thus, resource-constrained members are not required to hire or designate a dedicated CCO.

The proposed interpretive material recognizes that responsibility for discharging compliance policies and written supervisory procedures rests with business line supervisors. The proposed interpretive material clarifies that consultation on the certification does not by itself establish a signatory as having such line supervisory responsibility.

The proposed interpretive material also sets forth the particulars regarding the report that must evidence a member's compliance processes. It states that the report must be produced prior to execution of the certification and be reviewed by the CEO, CCO, and such other officers as the member deems necessary. The report also must include the manner and frequency in which the processes are administered and identify those officers and supervisors with responsibility for such administration. The proposed interpretive material further explains that the report need not contain conclusions that result from following the specified processes. Additionally, the proposed interpretive material states that the report may be combined with other reports required by a self-regulatory organization, provided the report is made annually, clearly indicates in the title that it contains the information required by Rule 3013, and that the entire report is provided in response to any regulatory request for all or part of the combined report.

Finally, with respect to review of the report, the proposed interpretive material clarifies that review by a member's board of directors and audit committee only applies to those members whose corporate governance structure have such or similar governing bodies and committees—it does not impose a requirement that members create them if they do not currently exist.

[6] *See* NASD Rule 1022(a)(1).

[7] Members that do not employ a board of directors or audit committee or other similar bodies in their governance and management would not be subject to this requirement.

According to NASD, the proposal would complement and underscore the closely related obligations that currently exist under NASD rules that require each member to designate principals who must review the member's supervisory systems and procedures and recommend to senior management appropriate action to ensure the systems are reasonably designed to achieve compliance with applicable rules and regulations.[8] NASD believes the proposal provides an effective mechanism to compel substantial and purposeful interaction between senior management and compliance personnel, thereby enhancing the quality of members' supervisory and compliance systems. NASD further believes the rule change imposes the minimal additional burden on members that is necessary to achieve the proposal's purpose.

2. Statutory Basis

NASD believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act, which requires, among other things, that NASD's rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. NASD believes that the proposed rule change is consistent with the provisions of the Act noted above in that it will enhance focus on members' compliance and supervision systems, thereby decreasing the likelihood of fraud and manipulative acts and increasing investor protection.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASD 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.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

In June 2003, NASD issued Notice to Members 03–29, seeking comment on a different proposal with similar objectives. That proposal would have required each member to designate a CCO and further required that the CCO and CEO certify annually to the adequacy of the member's compliance and supervisory systems. A proposed interpretive material clarified that the signatories to the certification would incur no additional liability as a consequence of the certification, provided there was a reasonable basis to certify at the time of execution. The previous proposal differed from the current proposal in that it would have required, among other things, that the CCO and CEO have a reasonable basis to certify that a member was in compliance with all applicable laws, rules and regulations at a fixed moment in time. By contrast, the current proposal requires certification to having processes in place to establish, maintain, review, modify, and test policies and procedures reasonably designed to achieve compliance with those laws, rules, and regulations.

NASD received 166 comments on the proposal, including submissions on behalf of members from 65 CCOs and 34 CEOs, as well as nine comments from trade organizations. The overwhelming majority of commenters disfavored the proposal. According to NASD, broadly, commenters questioned the value of the proposal, whether it was duplicative of existing requirements, the scope of the certification, and the potential liability of the signatories. CCOs expressed concern that the proposal could lead to retaliation by CEOs if a CCO refused to certify. Additionally, questions arose as to whether the goal of better compliance could be achieved only at the expense of increased potential liability on the part of members. Commenters also noted that the dynamic nature of compliance and the need to allocate finite compliance resources on a risk assessment basis did not lend itself to a certification of compliance certainty at any fixed moment. Commenters further expressed concern that the proposal could spawn baseless litigation. Small firms also commented that the cost of compliance would outweigh the benefits for their firms and would divert resources from more substantive compliance matters.

On November 28, 2003, largely in response to these concerns, NASD submitted to the Commission a modified proposal that took an approach that NASD believed more efficiently and pragmatically achieved the goal of enhanced compliance. The proposal was published for comment in the **Federal Register** on December 31, 2003.[9] The SEC received six comment letters in response to the proposed rule change.[10] Each of the commenters opposed the proposed rule change.[11]

In response to these comments and following additional discussions with SEC staff, NASD submitted Amendments No. 1 and 2, which, among other things, proposed to eliminate the CCO certification requirement and incorporate into the accompanying interpretive material language that describes the obligations of the CCO with respect to a member's compliance scheme and the role the CCO must play to enable the CEO to make the certification that a member has in place compliance processes.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such 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–NASD–2003–176 on the subject line.

[8] The Commission recently approved a proposed rule change requiring members, among other things, to designate one or more principals who will establish, maintain, and enforce a system of supervisory control policies and procedures that test and verify that the members' supervisory procedures are reasonably designed to achieve compliance with applicable securities laws and NASD rules. Exchange Act Release No. 49883 (June 17, 2004), 69 FR 35092 (June 23, 2004) (approving SR–NASD–2002–162).

[9] Exchange Act Release No. 48961 (Dec. 23, 2003), 68 FR 75704.

[10] *See supra* note .

[11] Commenters contended, among other things, that: the proposal was either duplicative or unnecessary in light of existing rules that require members to establish and maintain supervisory systems; the proposal could require a CCO to certify to processes not within the CCO's responsibility or control; to the extent that sufficient attention to compliance is not already encouraged by the existing regulatory framework, the goals of the proposal can be achieved without the certification requirement; and the certification requirement would expose certification signatories to additional liability beyond a false certification.

Paper Comments

• Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–NASD–2003–176. 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 inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of the National Association of Securities Dealers. 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–NASD–2003–176 and should be submitted on or before August 24, 2004.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 04–17649 Filed 8–2–04; 8:45 am]

BILLING CODE 8010–01–P

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50099; File No. SR–NASD–2004–100]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment No. 1 Thereto by the National Association of Securities Dealers, Inc. To Amend the Rule 9600 Series

July 27, 2004.

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 June 28, 2004, the National Association of Securities Dealers, Inc. ("NASD"), filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by NASD. On July 23, 2004, NASD filed Amendment No. 1 to the proposed rule change.[3] Pursuant to section 19(b)(3)(A)(iii) of the Act[4] and Rule 19b–4(f)(6) thereunder,[5] NASD has designated this proposal as non-controversial, which renders the proposed rule change 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

NASD proposes to amend its Rule 9600 Series to permit a Waiver Subcommittee of the National Adjudicatory Council ("NAC") to affirm, modify, or reverse a decision of NASD's Department of Member Regulation ("Department") denying a request for a waiver from a required qualifications examination pursuant to NASD Rule 1070. The text of the proposed rule change is set forth below. Proposed new language is in *italics;* proposed deletions are in brackets.

* * * * *

9600. PROCEDURES FOR EXEMPTIONS

9610. Application

(a) Where to File.

A member seeking exemptive relief as permitted under Rules 1021, 1070, 2210, 2315, 2320, 2340, 2520, 2710, 2720, 2810, 2850, 2851, 2860, Interpretive Material 2860–1, 3010(b)(2), 3020, 3150, 3210, 3230, 3350, 8211, 8212, 8213, 11870, or 11900, or Municipal Securities Rulemaking Board Rule G–37, shall file a written application with the appropriate department or staff of [the Association] *NASD* and provide a copy of the application to the Office of General Counsel of NASD Regulation.

(b) and (c) No change.

9620. Decision

After considering an application, NASD [Regulation] staff shall issue a written decision setting forth its findings and conclusions. The decision shall be served on the Applicant pursuant to Rules 9132 and 9134. After the decision is served on the Applicant, the application and decision shall be publicly available unless NASD [Regulation] staff determines that the Applicant has shown good cause for treating the application or decision as confidential in whole or in part.

9630. Appeal

(a) Notice.

An Applicant may file a written notice of appeal within 15 calendar days after service of a decision issued under Rule 9620. The notice of appeal shall be filed with the Office of General Counsel of NASD Regulation, with a copy of the notice also provided to the appropriate department or staff of [the Association] *NASD.* The notice of appeal shall contain a brief statement of the findings and conclusions as to which exception is taken. *Appeals of decisions issued by NASD staff pursuant to Rule 9620 shall be decided by the National Adjudicatory Council, except with respect to exemptive relief under Rule 1070 (Qualification Examinations and Waiver of Requirements), which shall be decided by the Waiver Subcommittee of the National Adjudicatory Council.* [The National Adjudicatory Council may order oral argument.] If the Applicant does not want the [National Adjudicatory Council's] decision on the appeal to be publicly available in whole or in part, the Applicant also shall include in its notice of appeal a detailed statement, including supporting facts, showing good cause for treating the decision as confidential in whole or in part. The notice of appeal shall be signed by the Applicant.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from Shirley H. Weiss, Associate General Counsel, NASD, to Katherine A. England, Assistant Director, Division of Market Regulation, Commission, dated July 22, 2004 ("Amendment No 1"). In Amendment No. 1, NASD made several non-substantive changes to clarify the proposed rule text and the discussion of the proposed rule in the Purpose section.

[4] 15 U.S.C. 78s(b)(3)(A)(iii).

[5] 17 CFR 240.19b–4(f)(6).

(b) Expedited Review.

Where the failure to promptly review a decision to deny a request for exemption would unduly or unfairly harm the applicant, the National Adjudicatory Council *or the Waiver Subcommittee of the National Adjudicatory Council, as the case may be,* shall provide expedited review.

(c) No change.

(d) [Appointment of Subcommittee] Oral Argument.

(1) Subject to paragraph (2) below, [F]*f*ollowing the filing of a notice of appeal, the National Adjudicatory Council or Review Subcommittee may *order oral argument and may* designate a Subcommittee to hear [an] *such* oral argument[, if ordered]. *The Subcommittee may* consider any new evidence [that] *if* the Applicant can show good cause for not including *it* in its application, and *the Subcommittee will* recommend to the National Adjudicatory Council a disposition of all matters on appeal.

(2) With respect to exemptive relief requested under Rule 1070, the Waiver Subcommittee of the National Adjudicatory Council may order oral argument and consider any new evidence if the Applicant can show good cause for not including it in its application.

(e) Decision.

(1) Subject to paragraph (2) below, [A]*a*fter considering all matters on appeal, and, *as applicable,* the Subcommittee's recommendation, the National Adjudicatory Council shall affirm, modify, or reverse the decision issued under Rule 9620. The National Adjudicatory Council shall issue a written decision setting forth its findings and conclusions and serve the decision on the Applicant. The decision shall be served pursuant to Rules 9132 and 9134. The decision shall be effective upon service and shall constitute final action of [the Association] *NASD.*

(2) With respect to exemptive relief requested under Rule 1070, after considering all matters on appeal, the Waiver Subcommittee of the National Adjudicatory Council shall affirm, modify, or reverse the decision issued under Rule 9620. The Waiver Subcommittee shall issue a written decision setting forth its findings and conclusions and serve the decision on the Applicant. The decision shall be served pursuant to Rules 9132 and 9134. The decision shall be effective upon service and shall constitute final action of NASD. The Waiver Subcommittee shall retain the discretion to refer the appeal to the National Adjudicatory Council, in which case the National Adjudicatory Council shall act on such appeal pursuant to its authority under this 9600 Series.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASD 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. NASD 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

NASD's Rule 9600 Series sets forth the procedures pursuant to which NASD members and their associated persons may seek exemptive relief from those NASD rules that allow NASD staff to grant exemptions. The purpose of this proposed rule change is to permit a subcommittee of the NAC, consisting of one industry and one non-industry NAC member, to affirm, modify, or reverse a decision of NASD's Department of Member Regulation denying a request for a waiver from an applicable qualification examination requirement and issue decisions in such matters that will constitute final NASD action. The subcommittee will be appointed by the NAC annually.

Under NASD's Rule 9600 Series, an initial application for relief under any NASD rule for which exemptive relief may be granted is filed with the appropriate NASD department or staff. NASD staff examines the merits of the application, determines whether to grant or deny the application for relief, and communicates its decision to the applicant. If NASD staff denies the application, the applicant may appeal the adverse decision to the NAC, which may affirm, modify, or reverse the decision.

Currently, persons seeking a waiver of a required qualification examination under NASD Rule 1070 must file a written application with the Department, including a detailed statement of the grounds for the waiver. The Department examines the merits of the waiver request based on the NASD Qualification Examination Waiver Guidelines ("Guidelines") and communicates its decision to the applicant in a letter that grants or denies the waiver.[6] The applicant may then appeal any adverse Department decision to the NAC, which considers the decision, determines whether to affirm, modify, or reverse the decision, and issues a decision that constitutes final NASD action.

After reviewing the qualifications examination waiver process, the NAC determined that a subcommittee of the NAC, rather than the full NAC, should have authority to consider appeals of adverse Department decisions with respect to NASD Rule 1070 and to issue final NASD decisions in such matters. In reaching this determination, the NAC recognized that a subcommittee would have the flexibility to review adverse Department decisions on a timelier basis than the full NAC, which generally meets only five times each year. NASD believes that any delay arising from the NAC's schedule may harm the associated person on whose behalf the NASD member is appealing, as well as the member, because the associated person is unable to function in the requested registered capacity while his or her firm's appeal is pending. The NAC also considered that its specialized expertise in reviewing disciplinary matters and policy issues is not required in the examination waiver process because appellate review of examination waivers is based on application of the Guidelines to the specific facts of the case. The subcommittee would retain discretion to refer an appeal to the full NAC when, for example, there is a split vote or the subcommittee believes that the issues in the appeal warrant consideration by the full NAC.

NASD is therefore proposing this rule change to permit a subcommittee of the NAC to review appeals of Department denials of requests to waive an applicable qualification examination requirement and to issue decisions that affirm, modify, or reverse such Department decisions. The subcommittee of the NAC would also be given the authority, where appropriate, to provide expedited review, order oral argument, and consider new evidence.

Finally, NASD no longer refers to itself or its subsidiary, NASD Regulation, Inc., using its full corporate name, "the Association," "the NASD" or "NASD Regulation, Inc." Instead, NASD uses "NASD" unless otherwise appropriate for corporate or regulatory reasons. Accordingly, the proposed rule change replaces several references to

[6] The Guidelines, last updated on May 6, 2004, are available on NASD's Web site at *http://www.nasdr.com/5200_waiver.asp.*

"Association" and "NASD Regulation" in the text of the proposed rule change with "NASD." NASD Rule 9630(a) appropriately designates "the Office of General Counsel of NASD Regulation."

2. Statutory Basis

NASD believes that the proposed rule change is consistent with the provisions of section 15A(b)(6) of the Act,[7] which requires, among other things, that NASD's rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. NASD believes that the proposed rule change is consistent with the provisions of the Act noted above because it will enable individuals who are appealing denials of examination waivers to get a decision and become registered in their desired capacity more expeditiously, whether as a result of a waiver or of being required to take the necessary examination.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASD 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.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change is effective upon filing pursuant to section 19(b)(3)(A) of the Act[8] and Rule 19b-4(f)(6) thereunder[9] because the proposed rule change (1) does not significantly affect the protection of investors or the public interest, (2) does not impose any significant burden on competition, and (3) by its terms, does not become operative for 30 days from the date of filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest. NASD has satisfied the five-day pre-filing requirement. NASD intends to make the proposed rule change operative on September 1, 2004.

[7] 15 U.S.C. 78*o*-3(b)(6).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b-4(f)(6).

At any time with 60 days of the filing of the proposed rule change, the Commission may summarily abrogate this proposal 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.[10]

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-NASD-2004-100 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549-0609.

All submissions should refer to File Number SR-NASD-2004-100. 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 inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of NASD. 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-NASD-2004-100 and should be submitted on or before August 24, 2004.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 04-17651 Filed 8-2-04; 8:45 am]

BILLING CODE 8010-01-P

[10] *See* Section 19(b)(3)(C) of the Act, 15 U.S.C. 78s(b)(3)(C).

[11] 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-50097; File No. SR-NASD-2004-112]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change by the National Association of Securities Dealers, Inc. To Extend Its Pilot Program Relating to Price-Improvement Standards Under the Manning Interpretation

July 27, 2004.

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 July 23, 2004, the National Association of Securities Dealers, Inc. ("NASD") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by NASD. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and to approve the proposal, on an accelerated basis. This accelerated approval extends the pilot program retroactively to July 1, 2004, and prospectively through December 31, 2004.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

NASD proposes to extend retroactively to July 1, 2004, and prospectively through December 31, 2004, the current pilot program relating to price-improvement standards for decimalized securities contained in NASD IM-2110-2—Trading Ahead of Customer Limit Order ("Manning Interpretation"). Without such an extension, these standards would expire on June 30, 2004. NASD does not propose to make any substantive changes to the pilot; NASD is proposing only to make the pilot rule effective on

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.

a retroactive basis to July 1, 2004, and to extend the pilot's expiration date to December 31, 2004.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASD included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposal. The text of these statements may be examined at the places specified in Item III below. NASD 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

NASD's Manning Interpretation, among other things, requires an NASD member firm to provide a minimum level of price improvement to an incoming order in an NMS or SmallCap security if the firm chooses to trade as principal with the incoming order at a price superior to that of the customer limit order that the firm currently holds. If the firm fails to provide the minimum level of price improvement to the incoming order, the firm must execute the held customer limit order. Generally, if the firm fails to provide the requisite amount of price improvement and also fails to execute the held customer limit order, it is in violation of the Manning Interpretation.

On April 6, 2001, the Commission approved, on a pilot basis, price-improvement standards in the Manning Interpretation for trading in a decimalized environment.[3] That proposal added the following language to IM–2110–2:

For Nasdaq securities authorized for trading in decimals pursuant to the Decimals Implementation Plan For the Equities and Options Markets, the minimum amount of price improvement necessary in order for a market maker to execute an incoming order on a proprietary basis in a security trading in decimals when holding an unexecuted limit order in that same security, and not be required to execute the held limit order, is as follows:

(1) For customer limit orders priced at or inside the best inside market displayed in Nasdaq, the minimum amount of price improvement required is $0.01; and

(2) For customer limit orders priced outside the best inside market displayed in Nasdaq, the market maker must price improve the incoming order by executing the incoming order at a price at least equal to the next superior minimum quotation increment in Nasdaq (currently $0.01).[4]

Since approval, these standards have operated on a pilot basis, which would terminate on June 30, 2004.[5] After consultation with SEC staff, NASD has determined to seek an extension of its current pilot until December 31, 2004. NASD also is seeking to make this proposal effective on a retroactive basis to July 1, 2004. NASD believes that such an extension provides for an appropriate continuation of the current Manning price-improvement standard while the Commission continues to analyze the issues related to customer limit order protection in a decimalized environment. NASD is not proposing any substantive changes to the pilot at this time.

2. Statutory Basis

NASD believes that the proposed rule change is consistent with the provisions of section 15A(b)(6) of the Act,[6] which requires, among other things, that NASD's rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. NASD believes that the proposed rule change would continue the current pilot program's protection of customer limit orders and promote the integrity of the market.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASD does not believe that the proposed rule change would result in any burden on competition that is 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

Written comments were neither solicited nor received.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the proposed rule change, 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 SR–NASD–2004–112 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to SR–NASD–2004–112. 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 inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW, Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of NASD. 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 SR-NASD–2004–112 and should be submitted on or before August 24, 2004.

[3] *See* Securities Exchange Act Release No. 44165 (April 6, 2001), 66 FR 19268 (April 13, 2001) ("Pilot Approval Order").

[4] Pursuant to the terms of the Decimals Implementation Plan for the Equities and Options Markets, the minimum quotation increment for Nasdaq securities (both NMS and SmallCap) at the outset of decimal pricing is $0.01. As such, Nasdaq displays priced quotations to two places beyond the decimal point (to the penny). Quotations submitted to Nasdaq that do not meet this standard are rejected by Nasdaq systems. *See* Securities Exchange Act Release No. 43876 (January 23, 2001), 66 FR 8251 (January 30, 2001) (SR–NASD–2001–07).

[5] *See* Securities Exchange Act Release No. 48876 (December 4, 2003), 68 FR 69103 (December 11, 2003) (extending pilot price-improvement standard to June 30, 2004).

[6] 15 U.S.C. 78o–3(b)(6).

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

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 association.[7] In particular, the Commission finds that the proposed rule change is consistent with section 15A(b)(6) of the Act[8] because 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 Commission previously has found NASD's pilot rule relating to price-improvement standards under the Manning Interpretation to be consistent with the Act.[9] NASD now proposes to reinstate the pilot; to make it effective retroactively to July 1, 2004; and extend it through December 31, 2004. NASD is not proposing any textual changes to the pilot rule. In the Pilot Approval Order, the Commission stated that the pilot rule should ensure that customer limit orders "will continue to have access to market liquidity ahead of market makers in appropriate circumstances."[10] More recently, the Commission also has stated:

> When market participants can gain execution priority for an infinitesimally small amount, important customer protection rules such as exchange priority rules and the NASD's Manning Interpretation as currently formulated could be rendered meaningless. * * * If investors' limit orders lose execution priority for a nominal amount, over time, investors may cease to use them, which would deprive the markets of a vital source of liquidity.[11]

For these reasons, the Commission continues to believe that NASD's pilot rule is consistent with the Act and will continue to provide beneficial protection to customer limit orders.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after publication of notice of filing thereof in the **Federal Register**. Accelerated approval will allow the customer limit order protection offered by the pilot rule to continue without interruption.

V. Conclusion

Is it therefore ordered, pursuant to section 19(b)(2) of the Act,[12] that the proposed rule change (SR–NASD–2004–112) is hereby approved on an accelerated basis.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[13]

Jill M. Peterson,

Assistant Secretary

[FR Doc. 04–17653 Filed 8–2–04; 8:45 am]

BILLING CODE 8010–01–P

[7] In approving this proposal, the Commission 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. 78o–3(b)(6).

[9] *See supra* note 3.

[10] 66 FR at 19271.

[11] Securities Exchange Act Release No. 49325 (February 26, 2004), 69 FR 11126, 11170 (March 9, 2004) (proposing Regulation NMS). Nothing in this approval order presupposes any action that the Commission may take with respect to proposed Regulation NMS.

[12] 15 U.S.C. 78s(b)(2).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50095; File No. SR–NSCC–2004–03]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Mutual Fund Profile and Fund/SPEED Service Fees

July 27, 2004.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] notice is hereby given that on July 21, 2004, the National Securities Clearing Corporation ("NSCC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which items have been prepared primarily by NSCC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested parties.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change provides for revisions to NSCC's fees which will be effective September 1, 2004, for its Mutual Fund Profile Service ("MFPS") and Fund/SPEED Service.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NSCC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NSCC has prepared summaries, set forth in sections (A), (B) and (C) below, of the most significant aspects of these statements.[2]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Mutual Fund Profile Service

NSCC's MFPS is a centralized information database used by NSCC's mutual fund service members. Phase I of MFPS provided daily mutual fund prices in the form of mutual fund net asset values and rates for daily accrual funds. Phase II was introduced in 1999 to add member profiles (*i.e.*, information about processing capabilities of other members), security issue profiles (*i.e.*, information relating to identification of fund securities characteristics such as minimum requirements and purchase amounts for a particular security), and distribution declaration profiles (*i.e.*, information relating to record, reinvestment, and payable dates for dividend and capital gains payments).

NSCC is making extensive enhancements to Phase II of MFPS to incorporate additional securities-related data in order to facilitate more accurate tracking and application of breakpoint related information, which is consistent with the recommendations of the Joint NASD/Industry Task Force on Breakpoints.[3] NSCC proposes a fee increase for MFPS consistent with these enhancements.

The current fee for MFPS (Phase I and Phase II) is $325.00 per month. The revised fees will introduce two tier pricing as follows:

MFPS—Phase I (Price and Rate) Only: $325.00 per month.

MFPS—Phase I and II: $750.00 per month.

Members currently subscribing to MFPS will automatically be subject to the higher fees applicable to MFPS, Phases I and II, effective September 1, 2004. Members will be given advance notice of the fee increase in order to provide the opportunity to convert to MFPS Phase I (Price and Rate only) if the member so desires.

[1] 15 U.S.C. 78s(b)(1).

[2] The Commission has modified the text of the summaries prepared by NSCC.

[3] The breakpoint issue and the enhancements to MFPS are further described in NSCC's Important Notice A#5765, P&S#5335 (February 12, 2004), which is attached as Exhibit A to this filing. Copies of this filing and the attached exhibits will be available for inspection and copying at the principal office of NSCC and on NSCC's Web site at *www.nscc.com/legal/*.

2. New Fund/SPEED Activity Fee

NSCC currently charges fees for the following Fund/SPEED functions:

Inquiries: $.005 per transaction.

Trade Data Transmission: $.50 per transaction.

New Accounts: $.75 per transaction.

NSCC is adding an additional function, Account Maintenance, for which there will be a fee of $.25 per transaction. A transaction is defined as a request for information and a response. The fee will be effective on September 1, 2004.

NSCC regards all of the proposed fees to be consistent with its policy to set fees at a level that projects full cost recovery for the product line.

NSCC believes that the proposed rule change is consistent with the requirements of section 17A of the Act [4] and the rules and regulations thereunder applicable to NSCC because the proposed rule change will provide for the equitable allocation of dues, fees and other charges among NSCC's members.

(B) Self-Regulatory Organization's Statement on Burden on Competition

NSCC does not believe that the proposed rule change will have any impact or impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments relating to the proposed rule change have been solicited or received. The enhancements to NSCC's MFPS, which address the need for more accurate identification of breakpoint-related data, were discussed and developed through meetings and communications among members of the Joint NASD/Industry Task Force, of which NSCC and several NSCC members are members. NSCC will notify the Commission of any written comments received by NSCC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A)(ii) [5] of the Act and Rule 19b–4(f)(2) [6] promulgated thereunder because the proposal is establishing or changing a due, fee, or other charge imposed by NSCC. At any time within sixty days of the filing of such proposed rule change, the Commission could have summarily abrogated such rule change if it appeared to the Commission that such action was necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NSCC–2004–03 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–NSCC–2004–03. 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 inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of NSCC. 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–NSCC–2004–03 and should be submitted on or before August 24, 2004.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[7]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 04–17573 Filed 8–2–04; 8:45 am]

BILLING CODE 8010–01–P

[4] 15 U.S.C. 78q–1.

[5] 15 U.S.C. 78s(b)(3)(A)(ii).

[6] 17 CFR 240.19b–4(f)(2).

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50100; File No. SR–Phlx–2003–59]

Self-Regulatory Organizations; Order Approving Proposed Rule Change and Amendments No. 1, 2, 3, 4, and 5 and Notice of Filing and Order Granting Accelerated Approval to Amendments No. 6 and 7 to the Proposed Rule Change by the Philadelphia Stock Exchange, Inc. Relating to the Exchange's New Electronic Trading Platform, "Phlx XL"

July 27, 2004.

I. Introduction

On October 3, 2003, the Philadelphia Stock Exchange, Inc. ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt new rules for the implementation of its new electronic trading platform, "Phlx XL." On December 9, 2003, December 11, 2003, January 28, 2004, and May 11, 2004, the Exchange filed Amendments No. 1, 2, 3, and 4, respectively, to the proposed rule change.[3] On June 4, 2004, the Exchange filed Amendment No. 5 to the proposed rule change.[4] The proposed rule change and Amendments No. 1, 2, 3, 4, and 5 were published for comment in the **Federal Register** on June 15, 2004.[5] The Commission received no comments with respect to the proposal, as amended. On July 6, 2004 and July 15, 2004, the Phlx filed Amendments No. 6 and 7, respectively, to the proposed rule

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letters from Richard S. Rudolph, Director and Counsel, Phlx, to Nancy J. Sanow, Assistant Director, Division of Market Regulation ("Division"), Commission, dated December 9, 2003 ("Amendment No. 1"); December 11, 2003 ("Amendment No. 2"); January 28, 2004 ("Amendment No. 3"); and May 10, 2004 ("Amendment No. 4").

[4] *See* letter from Richard S. Rudolph, Director and Counsel, Phlx, to Deborah Lessman Flynn, Assistant Director, Division, Commission, dated June 3, 2004 ("Amendment No. 5").

[5] *See* Securities Exchange Act Release No. 49832 (June 8, 2004); 69 FR 33442 ("Notice").

change.[6] This order approves the proposed rule change and Amendments No. 1, 2, 3, 4, and 5; grants accelerated approval to Amendments No. 6 and 7 to the proposed rule change; and solicits comments from interested persons on Amendments No. 6 and 7.

II. Description of the Proposal

The Exchange proposes to adopt rules regarding the Exchange's new electronic trading platform, Phlx XL. The proposal would permit on-floor Exchange Registered Options Traders ("ROTs"), to be called Streaming Quote Traders ("SQTs"), to submit streaming electronic option quotations via an electronic interface with the Exchange's Automated Options Market ("AUTOM") System.[7]

A. Implementation and Deployment

The Exchange proposes to begin the initial rollout of Phlx XL on an issue-by-issue basis, beginning with the first of approximately 10 issues not later than 10 days following the Commission's approval of the proposed rules applicable to Phlx XL.[8] The Exchange also proposes to expand the deployment of Phlx XL to include the Top 120 equity options within 8 months of the initial deployment, and the Exchange expects to roll out Phlx XL for all options floor wide not later than December 31, 2005.[9]

B. Streaming Quote Traders and Streaming Quote Options

An SQT would be defined in proposed Phlx Rule 1014(b)(ii) as a ROT, who has received permission from the Exchange to generate and submit option quotations electronically through an electronic interface with AUTOM via an Exchange approved proprietary electronic quoting device in eligible options to which such SQT is assigned. The Exchange's Options Committee may, on an issue-by-issue basis, determine the specific issues, to be known as "Streaming Quote Options," in which SQTs may generate and submit option quotations.[10] Phlx XL would allow an individual SQT to submit its own firm disseminated quotes representing its trading interest.

C. Market Maker Obligations

1. Specialist and SQT Quoting Requirements

Under the proposal, an SQT would be required to quote continuous, two-sided markets in not less than 60% of the series in each Streaming Quote Option in which such SQT is assigned.[11] The specialist assigned in a Streaming Quote Option would be required, however, to quote continuous, two-sided markets in 100% of the series in each assigned option. ROTs, including SQTs and ROTs who are not SQTs, would continue to be responsible to fulfill all of the requirements for ROTs set forth in Phlx Rule 1014.

Proposed Phlx Rule 1014(b)(ii)(B) would set forth the minimum quotation size for specialists and SQTs in Streaming Quote Options traded on Phlx XL. Specifically, after a six-month implementation period, the specialist and any SQT assigned in a Streaming Quote Option on Phlx XL would be required to submit electronic quotations with a size of not less than 10 contracts [12] beginning on the date on which such Streaming Quote Option begins trading on Phlx XL.[13]

An SQT would be permitted to submit electronic quotations only while physically present on the floor of the Exchange. Under Phlx XL, SQTs and the specialist would be able to quote verbally in open outcry in response to a request for a market, or to quote electronically (or submit orders electronically) by use of an Exchange-approved quoting device.

2. Non-SQT ROT Quoting Requirements

Non-SQT ROTs trading Streaming Quote Options would be required to quote verbally in response to a request for a market, and would continue to have the ability to place limit orders electronically directly onto the limit order book through electronic interface with AUTOM.[14] A non-SQT ROT would not, however, have the same continuous, electronic quoting requirements as an SQT trading the same Streaming Quote Option, unless it traded in excess of a specified number of contracts electronically (*i.e.*, by way of placing limit orders on the book that are executed via Book Match or Book Sweep, as described more fully below) in a given calendar quarter.

The proposed rule would require that, after a six-month implementation period, non-SQT ROTs would be required to provide quotations with a size of not less than 10 contracts

---

[6] See letters from Richard S. Rudolph, Director and Counsel, Phlx, to Deborah Lassman Flynn, Assistant Director, Division, Commission, dated July 2, 2004 ("Amendment No. 6") and July 14, 2004 ("Amendment No. 7"). In Amendment No. 6, the Exchange (i) corrected technical drafting and typographical errors and omissions contained in the proposed rule text, and (ii) provided a more detailed description of the procedures by which the opening price on Phlx XL would be established. In Amendment No. 7, the Exchange further clarified the procedures by which the opening price on Phlx XL would be established for a six month pilot period, and reiterated its Section 11(a) representations.

[7] AUTOM is the Exchange's electronic order delivery, routing, execution and reporting system, which provides for the automatic entry and routing of equity option and index option orders to the Exchange trading floor. Orders delivered through AUTOM may be executed manually, or certain orders are eligible for AUTOM's automatic execution features, AUTO–X, Book Sweep, and Book Match. Equity option and index option specialists are required by the Exchange to participate in AUTOM and its features and enhancements. Option orders entered by Exchange members into AUTOM are routed to the appropriate specialist unit on the Exchange trading floor. See Phlx Rule 1080.

[8] See Notice, *supra* note 5.

[9] See *id.* In January 2004, the Exchange submitted a proposal to modify the timing of the deployment of the ROT Access feature of its AUTOM system in light of the Exchange's proposal to introduce Phlx XL. See Securities Exchange Act Release No. 49151 (January 29, 2004), 69 FR 6010 (February 9, 2004) (SR-Phlx-2004–01). Specifically, if Phlx XL is not deployed floor-wide for all options by April 30, 2005, the Exchange has committed to ensure that, as of that date, the AUTOM system automatically executes eligible incoming orders in options that are not then Streaming Quote Options (as defined below) against Phlx Price Improving Registered Options Traders and specialist price improving orders and orders matching such price-improving orders entered via the electronic interface with AUTOM, as described in Commentary .04 to Phlx Rule 1080.

[10] See proposed Phlx Rule 1080(k).

[11] For example, if an SQT is assigned in one Streaming Quote Option that includes five series (A, B, C, D, and E), such SQT would be required to quote continuous, two-sided markets in three of those series in order to fulfill the 60% quoting requirement. If such an SQT initially submits quotations in series A, B, and C, and the size associated with the quotation in Series A is exhausted, such SQT would be required either to refresh its quotation in Series A while continuing to submit quotations in Series B and C, or to submit new quotations in any three of the five series to fulfill the 60% quoting requirement.

[12] The ten-contract minimum quotation size obligation would apply only to an SQT or specialist's undecremented quote.

[13] During a six-month implementation period commencing on the date of the initial deployment of Phlx XL (the "initial six-month period"), the specialist and any SQT assigned in a Streaming Quote Option would be permitted temporarily to submit electronic quotations with a size of fewer than 10 contracts for a period of 60 days after such option begins trading as a Streaming Quote Option. Beginning on the sixty-first day after such option begins trading as a Streaming Quote Option, SQTs and the specialist assigned in such Streaming Quote Option would be required to submit electronic quotations with a size of not less than 10 contracts. Subsequently, during a six-month period commencing on the first day following the expiration of the initial six-month period, the specialist and any SQT assigned in a Streaming Quote Option would be permitted to submit electronic quotations with a size of fewer than 10 contracts for a period of 30 days after such option begins trading as a Streaming Quote Option. Beginning on the thirty-first day after such option begins trading as a Streaming Quote Option, SQTs and the specialist assigned in such Streaming Quote Option would be required to submit electronic quotations with a size of not less than 10 contracts. Thereafter, the specialist and any SQT assigned in a Streaming Quote Option that is newly listed and deployed on Phlx XL would be required to submit electronic quotations with a size of not less than 10 contracts beginning on the date on which such Streaming Quote Option begins trading on Phlx XL.

[14] See Phlx Rule 1080, Commentary .04.

beginning on the date on which the Streaming Quote Option begins trading on Phlx XL.[15] The same size requirements set forth for non-SQT ROTs in open outcry would apply to non-SQT ROTs that are required to submit electronic quotations in a Streaming Quote Option for which a non-SQT ROT transacts more than 20% of his/her contract volume in a Streaming Quote Option electronically (*i.e.*, by way of placing limit orders on the limit order book that are executed electronically and allocated automatically in accordance with proposed Phlx Rule 1014(g)(vii)) versus in open outcry during any calendar quarter.[16]

Proposed Phlx Rule 1014(b)(ii)(C)(1)(d) would clarify that any volume transacted electronically by a non-SQT ROT (*i.e.*, limit orders placed on the limit order book that are executed via Book Match or Book Sweep) would not count towards the ROT's in-person requirement contained in Phlx Rule 1014, Commentary .01.[17]

D. ROT Limit Orders

The proposed rule change would amend the Exchange's rules regarding ROT electronic access to the limit order book.[18] Currently, ROTs are permitted by rule to enter electronic price improving limit orders (and orders matching such orders entered by the specialist or other ROTs in the trading crowd) onto the limit order book via electronic interface with AUTOM, and are entitled to receive a special allocation in trades stemming from such price improving limit orders. Under the instant proposal, ROTs would be permitted under Phlx Rule 1080(b)(i)(B) and Commentary .04 to place certain limit orders on the limit order book electronically. The requirement that such limit orders be price-improving orders, however, would be deleted. ROTs would be permitted to place limit orders, including Good Till Cancelled ("GTC") orders, on the limit order book whether such an order improves the then-prevailing Exchange market or not. ROTs entering limit orders on the book would be required, after the phased-in implementation discussed above,[19] to submit such orders with a size of at least ten contracts in both Streaming Quote Options and non-Streaming Quote Options. "Price-Improving ROTs" that place price-improving limit orders would continue to be entitled to receive contracts under the aforementioned special allocation.

The proposed rule would provide that, with respect to Streaming Quote Options, inbound AUTOM orders or electronic quotations eligible for execution against non-SQT ROT orders entered into AUTOM via electronic interface would be automatically executed and would be allocated automatically pursuant to Exchange rules.[20]

E. Assignment in Streaming Quote Options

Under the proposal, the Options Allocation, Evaluation and Securities Committee ("OAESC")[21] would assign SQTs in one or more eligible options in a fashion similar to the current practice of allocating trading privileges to specialists. Proposed Phlx Rule 507 would provide that an application for assignment in Streaming Quote Options would be submitted in writing to the Exchange's designated staff and would be required to include, at a minimum, the name of the SQT applicant and written verification from the Exchange's Membership Services Department that such SQT applicant is qualified as a ROT.

To ensure an SQT applicant's technological readiness to submit electronic quotes, proposed Phlx Rule 507(b)(ii) would mandate that no application for assignment in Streaming Quote Options would be approved by the OAESC without written certification signed by an officer (Vice President or above) of the Exchange's Financial Automation Department indicating that the SQT applicant has sufficient technological ability to support his/her continuous quoting requirements as set forth in Phlx Rule 1014(b)(ii), and the SQT applicant has successfully completed, or is scheduled to complete, testing of its quoting system with the Exchange.

To clarify that proposed Phlx Rule 507 is not intended to function as a barrier to entry to the Exchange's marketplace and to account for the possibility that quote capacity could become an issue for SQT applicants, the Exchange proposes to add Phlx Rule 507(b)(iii) to provide that (i) there is no limit on the number of qualifying ROTs that may become SQTs and (ii) any applicant that is qualified as an ROT in good standing and that satisfies the technological readiness and testing requirements described in sub-paragraph (b)(ii) must be approved as an SQT. Proposed Phlx Rule 507 also states that, based on system constraints, capacity restrictions or other factors relevant to the maintenance of a fair and orderly market, the Board would be permitted to defer, for a period to be determined in the Board's discretion, approval of qualifying applications for SQT status pending any action required to address the issue of concern to the Board. The Board would not be permitted to defer a determination of the approval of the application of any SQT applicant or place any limitation(s) on access to Phlx XL on any SQT applicant unless the basis for such limitation(s) or deferral has been objectively determined by the Board and submitted to the Commission for approval or effectiveness pursuant to a proposed rule change filed under section 19(b) of the Act. The Committee would be required to provide written notification to any SQT applicant whose application is the subject of such limitation(s) or deferral, describing the objective basis for such limitation(s) or deferral.

The proposed rule also includes a provision that, during the first six months of the deployment of Phlx XL, an SQT applicant member or member organization that has, for at least the immediately preceding twelve months, been a member of the Exchange and maintained a continuous presence as an ROT in the trading crowd associated with the Streaming Quote Option(s) that are the subject of the application must be guaranteed an assignment in the

---

[15] During the initial six-month implementation period, for a period of sixty days commencing immediately after an option begins trading as a Streaming Quote Option, such non-SQT ROTs may provide such quotations with a size of fewer than 10 contracts. Beginning on the sixty-first day after such option begins trading as a Streaming Quote Option, such quotations would be required to be for a size of at least 10 contracts. During a six month period commencing on the first day following the expiration of the initial six-month period, such non-SQT ROTs may provide such quotations with a size of fewer than 10 contracts for a period of thirty days after such option begins trading as a Streaming Quote Option. Beginning on the thirty-first day after such option begins trading as a Streaming Quote Option, such quotations would be required to be for a size of at least 10 contracts. Thereafter, such non-SQT ROTs would be required to provide such quotations with a size of not less than 10 contracts beginning on the date on which such Streaming Quote Option begins trading on Phlx XL.

[16] *See* proposed Phlx Rule 1014(b)(ii)(C)(2).

[17] Phlx Rule 1014, Commentary .01 provides that, for an ROT to receive specialist margin treatment for off-floor orders in any calendar quarter, the ROT must execute the greater of 1,000 contracts or 80% of his total contracts that quarter in person and 75% of his total contracts that quarter in assigned options.

[18] *See* proposed Phlx Rule 1080(b)(i)(B) and Commentary .04.

[19] *See* note 15 and accompanying text.

[20] With respect to Streaming Quote Options, non-SQT ROT limit orders on the book, entered electronically or manually by the specialist, that are automatically executed would be allocated pursuant to proposed Phlx Rule 1014(g)(vii).

[21] The Options Allocation, Evaluation and Securities Committee has jurisdiction over the allocation, retention and transfer of the privileges to deal in all options to, by and among members on the options and foreign currency options trading floors. *See* Exchange By-Law Article X, Section 10–7. *See also*, Phlx Rule 500.

Streaming Quote Option, provided that such member organization has received the written certification concerning technological readiness as set forth in proposed Phlx Rule 507(b)(ii).

Proposed Phlx Rule 507(g) would clarify that an appeal to the Board of Governors from a decision of the Committee may be taken by a member or member organization interested therein by filing with the Secretary of the Exchange written notice of appeal within ten (10) days after the decision has been rendered, in accordance with Exchange By-Law Article XI, Section 11–1.

F. Trade Allocation in Streaming Quote Options

The proposed rules would codify the allocation algorithm that would apply to orders or electronic quotes in Streaming Quote Options that result in automatic executions [22] via the AUTOM System.[23] In the case of trades stemming from orders that are not automatically executed and instead handled manually by the specialist or represented in the trading crowd by a Floor Broker, current Exchange rules concerning allocation of non-automatically executed trades would apply.[24]

The proposed rules would require that automatically executed trades in Streaming Quote Options would be allocated among the specialist and crowd participants with orders or quotations at the Exchange's disseminated price after public customer market and marketable limit orders have been executed.[25]

Quoting alone at the Exchange's best bid/offer. The proposed rules provide that if one Phlx XL participant is quoting alone at the disseminated price and its quote is not matched by another Phlx XL participant prior to execution, such Phlx XL participant would be entitled to receive a number of contracts up to the size associated with his/her quote.

Parity. The proposed rules codify the automatic allocation algorithm that would apply to orders or electronic quotes in Streaming Quote Options that result in automatic executions when two or more Phlx XL participants have quotes or booked limit orders at the Exchange's disseminated price.[26]

Quotations entered electronically by the specialist or an SQT that do not cause an order resting on the limit order book to become due for execution may be matched, or joined, at any time by quotations entered electronically by the specialist and/or other SQTs, and by ROT limit orders placed on the limit order book via electronic interface, and would be deemed to be on parity, subject to the requirement that orders of controlled accounts must yield priority to customer orders as set forth in Phlx Rule 1014(g)(i)(A).

Quotations entered electronically by the specialist or an SQT that cause the specialist's quote, an SQT's quote, or an order resting on the limit order book to become due for execution would be subject to execution under the proposed amended rules concerning the Exchange's Book Match or Book Sweep functions, described more fully below.

Specialist on parity. If the specialist is quoting at the Exchange's best bid/offer, after public customer market and marketable limit orders have been executed, the specialist would initially be entitled to receive the entire allocation of orders for five contracts or fewer.[27]

With respect to orders for greater than five contracts, the specialist would be entitled to receive the greater of the proportion of the total disseminated size at the disseminated price represented by the size of the specialist's quote or a specified percentage of the contracts to be allocated, depending on how many ROTs are on parity.[28]

After public customer limit orders have been executed and the specialist has received its entitlement, SQTs quoting at the disseminated price and non-SQT ROTs that have placed limit orders on the limit order book via the electronic interface representing the Exchange's disseminated price would be entitled to receive a number of contracts that is the proportion of the remaining aggregate size associated with SQT quotes and non-SQT ROT limit orders on the book entered via the electronic interface at the disseminated price represented by the size of the SQT's quote or, in the case of a non-SQT ROT, by the size of the limit order they have placed on the limit order book via the electronic interface. Such SQT(s) and non-SQT ROTs would not be entitled to receive a number of contracts that is greater than the size associated with their quotation or limit order.

With respect to contracts relating to off-floor broker-dealer [29] limit orders

[22] Trades in Streaming Quote Options involving inbound orders and specialist and SQT quotes delivered via AUTOM would be automatically executed by the Book Match function (described below in Section II.I). Eligible orders for non-Streaming Quote Options delivered via AUTOM would be automatically executed via AUTO–X, an automatic execution feature of AUTOM (*see* Phlx Rule 1080(c)), or against contra-side orders resting on the limit order book by Book Match under Phlx Rule 1080(g)(ii).

[23] The proposed trade allocation rules would only apply to trades in Streaming Quote Options that are automatically executed via Book Match pursuant to Phlx Rule 1080(g)(ii) and via Book Sweep described below in Section II.J pursuant to Phlx Rule 1080(c)(iii). Currently, trades that are automatically executed via AUTO–X are allocated among the specialist and ROTs participating on the "Wheel." The "Wheel" is a feature of AUTOM that provides an automated mechanism for assigning specialists and ROTs signed on the Wheel for a given listed option, on a rotating basis, as contra-side participants to trades executed via AUTO–X. *See* Phlx Rule 1080(g) and Option Floor Procedure Advice ("OFPA") F–24. Under the instant proposal, trades in Streaming Quote Options that are automatically executed via Book Match pursuant to the proposed amendments to Phlx Rule 1080(g)(ii) would be allocated automatically according to the algorithm set forth in proposed Phlx Rule 1014(g)(vii) and proposed OFPA B–6, Section F. Trades in non-Streaming Quote Options that are automatically executed via AUTO–X would continue to be allocated on the Wheel or by Book Match.

[24] In April 2003, the Commission approved the Exchange's proposal to adopt Phlx Rule 1014(g)(v) and OFPA B–6 concerning the allocation of non-automatically executed orders in options. *See* Securities Exchange Act Release No. 47739 (April 25, 2003), 68 FR 23354 (May 1, 2003) (SR–Phlx–2001–39).

[25] Phlx Rule 1014(g)(i)(A) requires that orders of controlled accounts must yield priority to customer orders. A "controlled account" includes any account controlled by or under common control with a broker-dealer (such as a specialist or an SQT). Customer accounts are all other accounts.

[26] Phlx Rules 119, 120, and 1014(g) are the general rules concerning establishment of parity and priority in the execution of orders on the options floor. The trade allocation algorithm in proposed Phlx Rule 1014(g)(vii) generally does not contemplate that price-time priority would apply to quotes and orders in Streaming Quote Options. Proposed Phlx Rule 1014(g)(vii)(B)(4) thus would state that, notwithstanding the first sentence of Phlx Rule 1014(g)(i), neither Phlx Rule 119(a)–(d) and (f), nor Phlx Rule 120 (insofar as it incorporates those provisions by reference) would apply to the allocation of automatically executed trades in Streaming Quote Options.

[27] Proposed Phlx Rule 1014 (g)(vii)(B)(1)(a) provides that, on a quarterly basis, the Exchange will evaluate what percentage of the volume executed on the Exchange is comprised of orders for five contracts or fewer executed by specialists, and will reduce the size of the orders included in this provision if such percentage is over 25%.

[28] Specifically, the specialist would receive: (i) 60% of the contracts to be allocated if the specialist is on parity with one SQT or one non-SQT ROT that has placed a limit order on the book at the Exchange's disseminated price; (ii) 40% of the contracts to be allocated if the specialist is on parity with two SQTs or non-SQT ROTs that have placed a limit order on the book at the Exchange's disseminated price; or (iii) 30% of the contracts to be allocated if the specialist is on parity with three or more SQTs or non-SQT ROTs that have placed a limit order on the book at the Exchange's disseminated price. To be entitled to receive the specified percentages, and the five contract or fewer order preference, the specialist must be quoting at the Exchange's disseminated price. The specialist would not be entitled to receive a number of contracts that is greater than the size associated with the specialist's quote.

[29] Phlx Rule 1080(b)(i)(C) defines an "off-floor broker-dealer" as a broker-dealer that delivers orders from off the floor of the Exchange for the proprietary account(s) of such broker-dealer, including a market maker located on an exchange or trading floor other than the Exchange's trading floor who elects to deliver orders via AUTOM for the proprietary account(s) of such market maker.

resting on the limit order book that are executed and allocated automatically, if any contracts remain to be allocated after the specialist, SQTs, and non-SQT ROTs with limit orders on the limit order book have received their respective allocations, off-floor broker-dealers that have placed limit orders on the limit order book which represent the Exchange's disseminated price would be entitled to receive the number of contracts that is the proportion of the aggregate size associated with off-floor broker-dealer limit orders on the limit order book at the disseminated price represented by the size of the limit order they have placed on the limit order book. Such off-floor broker-dealers would not be entitled to receive a number of contracts that is greater than the size that is associated with its order.

However, when an off-floor broker-dealer order is resting on the limit order book at the Exchange's disseminated bid or offer, an order executed manually by the specialist would be required to be allocated first to customer orders, and next to off-floor broker-dealer limit orders, before the specialist and SQTs with quotations at the same price and non-SQT ROTs that have placed limit orders via electronic interface at the same price would be entitled to receive their respective allocations under proposed Phlx Rule 1014(g)(vii).

Currently, Phlx Rule 1014(g)(i)(A) provides that orders of controlled accounts [30] must yield priority to customer orders, but that orders of controlled accounts are not required to yield priority to other controlled account orders. The Exchange proposes to amend Phlx Rule 1014(g)(i)(A) to require the specialist, SQTs and non-SQT ROTs to yield priority to off-floor broker-dealer limit orders in Streaming Quote Options resting on the limit order book solely in the limited circumstance where the specialist executes such an order manually, and not in the circumstance where such an order is executed and allocated automatically under Phlx XL.

Specialist not on parity. If the specialist is not quoting at the Exchange's disseminated quote, SQTs quoting at the disseminated price and non-SQT ROTs that have placed limit orders on the limit order book via the electronic interface which represent the Exchange's disseminated price would be entitled to receive the number of contracts that is the proportion of the total remaining disseminated size at the disseminated price represented by the size of the SQT's quote or, in the case of a non-SQT ROT, by the size of the limit order they have placed on the limit order book via the electronic interface. Thereafter, off-floor broker-dealers that have placed limit orders on the limit order book which represent the Exchange's disseminated price would be entitled to receive a number of contracts that is the proportion of the aggregate size associated with off-floor broker-dealer limit orders on the limit order book at the disseminated price represented by the size of the limit order they have placed on the limit order book, not to exceed the size of their limit orders.

Split price executions. Proposed Phlx Rule 1014(g)(vii)(B)(3) provides that there would be no automatic split-price executions in Streaming Quote Options. Therefore, if a market order or an electronic quotation to be executed in a Streaming Quote Option is received for a greater number of contracts than the Exchange's disseminated size, the portion of such an order or quotation executed via Book Match at the Exchange's disseminated size would be allocated in accordance with proposed Phlx Rule 1014(g)(vii). Contracts remaining in such an order would be represented by the specialist and handled in accordance with Exchange rules.

Participation in non-electronic orders. An SQT participating in a crowd (together with the specialist and non-SQT ROTs in the crowd) would be permitted to participate in manual trades initiated by Floor Brokers or the specialist in such a crowd. Accordingly, an SQT generally must be present in the trading crowd to participate in non-electronic trades, with one exception. Proposed Phlx Rule 1014, Commentary .05(c) would provide that, where a non-electronic trade is initiated by a Floor Broker or specialist, an SQT assigned in a Streaming Quote Option who is located in the SQT Zone (as described below) for the Streaming Quote Option, but who is not participating in the crowd trading the Streaming Quote Option, would be able to participate in such a manual trade only if the non-electronic order is executed at the price quoted by the non-crowd participant SQT at the time of execution. For purposes of trade allocation, such an SQT would be entitled to receive contracts under existing Phlx Rule 1014(g)(v), which applies to the allocation of contracts for orders handled manually by the specialist or represented in the crowd by a floor broker.

The proposed rule would also permit the specialist or SQTs participating in a crowd, in response to a verbal request for a market by a floor broker, to state a bid or offer that is different than its electronically submitted bid or offer, provided that such stated bid or offer is not inferior to such electronically submitted bid or offer, with one exception. Specifically, Commentary .05(c) would provide that the requirement that a specialist or SQT state a bid or offer that is not inferior to its electronically submitted quotation would not apply if the bid or offer is in response to a floor broker's solicitation of a single bid or offer as set forth in Phlx Rule 1033(a)(ii). In such a situation, Phlx Rule 1033(a)(ii) permits the members of a trading crowd to discuss, negotiate and agree upon the price or prices at which an order of a size greater than the Exchange's disseminated size can be executed at that time, or the number of contracts that could be executed at a given price or prices.[31] The Exchange also proposes to amend Phlx Rule 1033(a)(ii) and OFPA F–32 to provide that orders executed under the Rule and OFPA are subject to the provisions of the Plan for the Purpose of Creating an Options Intermarket Linkage ("Linkage Plan") and Phlx Rules 1083 "1087.

G. Crowd Area

For purposes of Phlx Rule 1014, Commentary .05(c), an SQT or non-SQT ROT would be deemed to be participating in a crowd if such SQT or non-SQT ROT is, at the time an order is represented in the crowd, physically located in a specific "Crowd Area." A Crowd Area would consist of a physical location marked with specific, visible physical boundaries on the options floor, as determined by the Options Committee. An SQT or non-SQT ROT who is physically present in such Crowd Area may engage in options transactions in assigned issues as a crowd participant in such a Crowd Area, provided that such SQT or non-SQT ROT fulfills the requirements set forth in Phlx Rule 1014. An SQT or non-SQT ROT would be deemed to be participating in a single Crowd Area, and thus would not be permitted to be a crowd participant in more than one

[30] *See supra* note 23.

[31] Phlx Rule 1033(a)(ii) and OFPA F–32, Solicitation of Quotations, provide that, in response to a floor broker's solicitation of a single bid or offer, the members of a trading crowd (including the specialist and ROTs) may discuss, negotiate and agree upon the price or prices at which an order of a size greater than the AUTO-X guarantee can be executed at that time, or the number of contracts that could be executed at a given price or prices. Notwithstanding the foregoing, a single crowd participant may voice a bid or offer independently from, and differently from, the members of a trading crowd (including the specialist and ROTs). *See* Securities Exchange Act Release No. 45573 (March 15, 2002), 67 FR 13674 (March 25, 2003) (SR–Phlx–2001–33).

particular Crowd Area at any specific time.

H. SQT Zones

Proposed Phlx Rule 1014, Commentary .05(b) would provide that an SQT may be assigned to, and thus submit quotes electronically in, all of the options located within, a specified physical zone on the Exchange Floor (an "SQT Zone") provided that such SQT is physically present in such SQT Zone.[32] Thus, each member organization must have at least one SQT physically present in each SQT Zone in which it submits electronic quotations. An SQT Zone could consist of multiple Crowd Areas.

I. Book Match

Book Match is a feature of AUTOM that currently provides automatic executions for inbound AUTOM-delivered customer and off-floor broker-dealer orders against customer limit orders on the book.[33] The proposed rules would amend Book Match to provide that the contra-side to automatically executed inbound eligible orders would be a limit order on the book or specialist and/or SQT electronic quotes ("electronic quotes") at the disseminated price where the Exchange's disseminated size includes a limit order on the book and/or electronic quotes at the disseminated price.

J. Book Sweep

Similar to Book Match, the Book Sweep function currently matches specialist quotations generated automatically against booked limit orders representing the Exchange's disseminated bid or offer when such quotations lock or cross the booked limit order (provided that the disseminated bid or offer is at the NBBO). Currently, Phlx Rule 1080(c)(iii) provides that, when the bid or offer generated by the Exchange's Auto-Quote system or SQF matches (locks) or crosses the Exchange's best bid or offer in a particular series as established by an order on the limit order book, orders on the limit order book in that series will be automatically executed up to the size associated with the quote that locks or crosses the order on the limit order book and allocated among crowd participants signed onto the Wheel.

Book Sweep would be amended in Phlx XL for Streaming Quote Options to allow SQT quotations, in addition to specialist quotations, to initiate the Book Sweep function. The SQT Book Sweep feature would function in essentially the same manner as the current Auto-Quote or SQF Book Sweep feature, *i.e.*, when an SQT submits a quotation that locks or crosses a limit order on the book that represents the Exchange's best bid or offer, such limit order would be executed automatically up to the size associated with the SQT's quotation, and would be automatically allocated to the SQT that submitted the quotation. The specialist or SQT may manually initiate the Book Sweep feature by sending a manual quote in situations where the specialist or SQT's automatic generation of electronic quotations is suspended due to, for example, a system malfunction. Eligible orders on the limit order book would be automatically executed up to the size associated with the quote that matches or crosses such limit orders. Orders on the limit order book would not be eligible for Book Sweep when the NBBO is crossed (*e.g.*, 2.10 bid, 2 offer). The current functionality of Book Sweep would remain effective for non-Streaming Quote Options, however, proposed Phlx Rule 1080(c)(iii) would apply the enhanced Book Sweep functionality for Streaming Quote Options.

K. Firm Quotations

Definition of disseminated size. The Exchange proposes to amend Phlx Rule 1082 by establishing by rule the Exchange's firm quotation size with respect to non-Streaming Quote Options and with respect to Streaming Quote Options.[34]

Respecting non-Streaming Quote Options, the Exchange's "disseminated size" would be defined as at least the sum of the size associated with: (i) Limit orders; and (ii) specialists' quotations generated automatically as described in Phlx Rule 1080, Commentary .01 (which represents the collective quotation size of the specialist and any ROTs bidding or offering at the disseminated price unless an ROT has expressly indicated otherwise in a clear and audible manner). The proposed definition of "disseminated size" respecting non-Streaming Quote Options would provide more specificity to the current definition, which includes at least the sum of limit orders and allows, but does not require, the specialist and/or crowd to add additional size to the Exchange's disseminated size.

The Exchange proposes to adopt new Phlx Rule 1082(a)(ii)(B) to establish by rule the definition of "disseminated size" that would apply to Streaming Quote Options. Specifically, for Streaming Quote Options, "disseminated size" would mean at least the sum of the size associated with limit orders, specialists' quotations,[35] and SQTs' quotations. The Exchange would disseminate the aggregate size of these three components.

Proposed Phlx Rule 1082(a)(ii)(C)(1) provides that, if an SQT's quotation size in a Streaming Quote Option is exhausted, such SQT's quotation would be deleted from the Exchange's disseminated quotation until the time the SQT revises his/her quotation. Although such SQT's quotation size in a given series may be exhausted and thus removed from the Exchange's disseminated quotation in that series, such an SQT would nonetheless continue to be required to submit continuous two-sided quotations in not less than 60% of the series in each Streaming Quote Option to which such SQT is assigned, in accordance with proposed Phlx Rule 1014(b)(ii)(B).

Proposed Phlx Rule 1082(a)(ii)(C)(2) provides that, if the Exchange's disseminated size in a particular series in a Streaming Quote Option is exhausted, the Exchange would disseminate the next best available quotation.[36] If no specialist or SQT has revised its quotation immediately following the exhaustion of the Exchange's disseminated size, the Exchange would automatically disseminate the specialist's most recent disseminated price prior to the time of

[32] Initially, there would be one SQT Zone representing the entire options trading floor. This means that an SQT could submit electronic quotations in any Streaming Quote Option while such SQT is physically on the Exchange floor. The number and location of any additional SQT Zones would be determined by the Options Committee based on its review of quote and trade data during the first six months of the deployment of Phlx XL. Proposed Phlx Rule 1014, Commentary .05(b) would require the Exchange to file for, and receive, Commission approval in the event the Options Committee determines to change the number and/or location of SQT Zones.

[33] Book Match would not be engaged: (i) When the Exchange's disseminated price represented by a limit order on the book is not the National Best Bid or Offer ("NBBO"); (ii) for pre-opening orders; and (iii) during trading rotations. In these situations, incoming orders would be subject to manual handling by the specialist.

[34] Rule 11Ac1–1(d)(1)(i) under the Act permits an exchange to establish by rule, and periodically publish, the quotation size for listed options, for which responsible brokers or dealers are obligated to execute an order. 17 CFR 240.11Ac1–1(d)(1)(i).

[35] Because the specialist and SQTs in Streaming Quote Options would be quoting independently, the term "specialist's quotations" with respect to Streaming Quote Options would mean the individual specialist's quotation, including, for purposes of the definition of "disseminated size," the size associated with such a quotation.

[36] The Exchange would have available the quotations submitted by the specialist and SQTs in a particular series, and would disseminate only the aggregate size of SQT and specialist quotations at the best bid and offer on the Exchange. If the best bid or offer is exhausted and not refreshed, the Exchange would disseminate the next best bid or offer submitted by the specialist and/or SQTs quoting in the series.

such exhaustion with a size of one contract.

Responsible broker or dealer. Currently, the Exchange's disseminated market is deemed to represent the quotations of all ROTs in that option unless an ROT has expressly indicated otherwise.[37] All ROTs in such an option who have not expressly indicated that the disseminated market does not represent their quote would collectively be bidding or offering at the disseminated price, and thus are the collective "responsible brokers or dealers" for purposes of the Exchange's "Firm Quote" requirement. Phlx Rule 1082(b) currently provides that responsible brokers or dealers bidding (or offering) at the disseminated price are collectively required to execute orders presented to them at such price up to the disseminated size. This would remain in effect for non-Streaming Quote Options.

Because SQTs and specialists would be quoting independently in Streaming Quote Options, each individual SQT and specialist would be deemed to be a "responsible broker or dealer" in Streaming Quote Options under proposed new Phlx Rule 1082(b)(ii). There thus would be individual "responsible brokers or dealers," and no "collective" firm quotation requirement in Streaming Quote Options.

Locked and crossed markets. Two new commentaries to Phlx Rule 1082 are proposed, relating to the situation in which a specialist or SQT's quotation locks (*e.g.*, 1.00 bid, 1.00 offer) or crosses (*e.g.*, 1.10 bid, 1.00 offer) another quotation.

Because the specialist and multiple SQTs would be quoting simultaneously, there may be instances where quotes may become locked. Under the proposal, the Exchange would disseminate the locked market and both quotations (bid and offer) would be deemed "firm" disseminated market quotations. Once SQT and/or specialists" quotations become locked, a one-second "counting period" would begin during which SQTs and/or specialists whose quotations are locked may eliminate the locked market.[38] However, such SQT and/or specialist would be obligated to execute orders at their disseminated quotation. During the "counting period" SQTs and specialists located in the Crowd Area in which the option that is the subject of the locked market is traded would continue to be obligated to respond to floor brokers as set forth in Phlx Rule 1014, Commentary .05(c), and would continue to be obligated for one contract in open outcry to other SQTs, non-SQT ROTs, and specialists. If at the end of the counting period the quotations remain locked, the locked quotations would automatically execute against each other in accordance with the allocation algorithm set forth in Phlx Rule 1014(g)(vii).

Crossed Markets. The Exchange will not disseminate an internally crossed market (*e.g.*, $1.10 bid, 1.00 offer). If an SQT or specialist submits a quotation in a Streaming Quote Option ("incoming quotation") that would cross an existing quotation ("existing quotation"), the Exchange will: (i) change the incoming quotation such that it locks the existing quotation; (ii) send a notice to the SQT or specialist that submitted the existing quotation indicating that its quotation was crossed; and (iii) send a notice to the specialist or SQT that submitted the incoming quotation, indicating that its quotation crossed the existing quotation and was changed. Such a locked market would be handled in accordance with proposed Commentary .01 concerning locked markets. During the one-second counting period, if the existing quotation is cancelled subsequent to the time the incoming quotation is changed, the incoming quotation would automatically be restored to its original terms.

L. Other Rules and OFPAs

The Wheel. The Exchange proposes to amend OFPA F–24 to reflect that the Wheel will apply only to non-Streaming Quote Options.

Auto-X Disengagement. The provisions relating to orders otherwise eligible for automatic execution via AUTO–X currently included in Phlx Rule 1080(c)(iv) would continue to apply to non-Streaming Quote Options; such provisions would not apply to Streaming Quote Options because the automatic execution function for Streaming Quote Options is Book Match or Book Sweep, not AUTO–X.

Removal of Unreliable Quotes. While the Exchange is proposing to delete the provisions in Phlx Rule 1080(c)(i) relating to the NBBO Feature, certain language contained in that rule describing the conditions and procedures under which the Exchange can exclude another market's quotes from its calculation of the NBBO would be retained. The provisions relating to the removal of unreliable quotes from another exchange from the Exchange's calculation of NBBO are intended to apply to both Streaming Quote Options and non-Streaming Quote Options.

Eligible AUTOM order types. Currently, the specialist, when alerted by AUTOM, handles the conversion of contingency orders on the limit order book into market or marketable limit orders when the respective condition applicable to such orders is manifested. The Exchange's systems do not currently perform this task electronically. The Exchange therefore proposes to amend Phlx Rule 1080(b)(i)(a) to provide that the following contingency order types would not be eligible for delivery via AUTOM: Stop, stop limit market close, market on opening, limit on opening, and limit close.[39] Because the conversion of these contingency order types is not done electronically by AUTOM, such order types would not be eligible for electronic entry on the electronic limit order book. Previously, any limit order on the book that became due for execution against an inbound electronic order delivered via AUTOM was handled manually by the specialist. With the development and deployment of Book Match, such contingency orders may now be executed electronically, but would not be converted electronically. Thus, such orders would not be placed on the electronic limit order book. Customers wishing to submit such orders would be required to do so by way of representation by a Floor Broker.

Eligible order delivery size. To allow a greater number of orders to be delivered electronically to the Exchange via AUTOM, the Exchange proposes to amend Phlx Rules 1080(b)(i)(A), (B), and (C) to increase the maximum AUTOM order delivery size from 1,000 contracts to 5,000 contracts for all eligible order types. This increase would apply to both Streaming Quote Options and non-Streaming Quote Options.

Opening Rotations. In Amendment No. 7, the Exchange proposed additional amendments to Phlx Rule 1017, Priority and Parity at Openings in Options, and OFPAs A–12 and A–14, to adopt more specific rules relating to the manner in which the Exchange conducts openings, including openings in Streaming Quote Options. The Exchange proposes to adopt the proposed opening rules on a pilot basis, beginning on the first day of the deployment of Phlx XL, and scheduled to expire after 180 days.

The proposed rules address the opening process in three main parts: the pre-opening, the opening rotation, and the specialist's calculation of the price of the opening trade of the session in a given series. First, prior to the opening, the specialist would determine from

[37] *See* Phlx Rule 1080, Commentary .01(c).

[38] The Options Committee may shorten the duration of the one-second "counting period."

[39] For a complete description of these order types, *see* Phlx Rule 1066.

Floor Brokers, and from orders resting on the limit order book, the size and prices of those orders which are near the previous closing prices of those options in which the specialist is assigned. In addition, the specialist would consider markets from ROTs in the crowd and, respecting Streaming Quote Options traded on Phlx XL, would consider electronic quotations submitted by SQTs in addition to establishing the specialist's own quote in the series. This would enable the specialist to ascertain orders and quotes on both sides of the market in a series to determine eventually the opening price in the series.

Because the proposed opening will not initially be automated, there would be no "broadcast" of opening limit orders and quotes on the Phlx XL system. The participants would, however, have access to market information necessary to ascertain bids and offers in the pre-opening phase. Specialists would be able to view the entire limit order book, including orders resting on the book from the previous trading session and any orders submitted before the opening, on their on-floor screens (known as the X-Station), and would be able to view all electronically submitted quotes in Phlx XL options, while SQTs would have the same view of the limit order book and their own quotes, but not those of other SQTs. Non-SQT ROTs would be able to view the current on-floor displayed market, whether generated by a pre-opening quote or by limit orders at the then-best bid or offer. All in-crowd SQTs and the specialist, together with non-SQT ROTs in the crowd, would be able to ascertain all in-crowd verbal bids and offers.

Currently, OFPA A–12 requires the specialist to accept and include in the opening for options all market orders which are placed on the book five minutes or more prior to the opening of the underlying security, unless exempted by a Floor Official. The proposed rule change would modify this provision to require the specialist to accept and include in the opening for options all market orders that are placed on the book prior to the opening in the underlying security. Market orders that are received following the opening in the underlying security but prior to the opening in the overlying option will be accepted, but will not be included in the opening trade. If, however, such a market order could be executed against a contra-side order to fill an imbalance on the opening, the specialist would be required to match the market order and the contra-side order before the specialist could execute an order (or quotation with respect to Streaming Quote Options) for his own account.[40] The purpose of this provision is to allow the specialist to conduct an orderly opening in the particular series by establishing a "cut-off" time (the opening in the underlying security) after which the specialist would consider market orders already received in determining the opening price, without including potentially chaotic, last-minute market orders received after the opening in the underlying security but before the specialist has opened the series. Market orders would have precedence over limit orders at an opening regardless of account type (*i.e.*, customer, Firm, broker-dealer, ROT, specialist).[41] Following the pre-opening phase, the specialist would conduct an opening rotation.[42]

The proposed rule change would provide that the opening price is the price at which the specialist determines that the greatest number of contracts will trade, provided that such opening price falls within an acceptable range to be determined by the Options Committee. An acceptable range would be determined as a percentage of the highest bid as the lower boundary of the acceptable range, and as a percentage of the highest offer as the upper boundary of the acceptable range. For example, such an acceptable range may be established as 75% of the lowest bid and 125% of the highest offer. Once determined by the Options Committee, such an acceptable range would be announced to the membership via regulatory circular.[43] In the interest of a fair and orderly market, a Floor Official could provide a specific exemption from the established acceptable range in a particular series.

Proposed Commentary .03(b) to the rule includes further limitations on the opening price to be determined by the specialist. First, if two or more prices would satisfy the criteria for determining the opening price, the price which would leave the fewest number of contracts resting on the limit order book would be selected as the opening price. If there are still two or more prices that would each satisfy such criteria, the price which is closest to the previous session's closing price would be selected as the opening price. Complex orders and contingency orders would not participate in opening rotations or in the determination of an opening price.

Once the specialist determines the opening price, the Exchange would disseminate the opening trade price to the Option Price Reporting Authority ("OPRA"). At this point, the series would be open for trading. Once the opening trade price in a series has been disseminated to OPRA, the specialist, ROTs and SQTs trading such series would be required to fulfill their respective quoting obligations under Rule 1014.

The proposed rule also includes circumstances in which a specialist would not open a series. Specifically, the specialist would not open a series if: it is not within an acceptable range, as described above, unless a specific exemption is given by a Floor Official in the interest of a fair and orderly market; the opening trade would leave a market order imbalance (*i.e.*, there are more market orders to buy or to sell for the particular series than can be satisfied by the market orders, limit orders and specialist or SQT quotations on the opposite side). For purposes of this provision, "market orders" would include those orders that are treated as limit orders in accordance with Rule 1017(b) (*i.e.*, orders at a limited price order to buy which is at a higher price than the price at which the option is to be opened and a limited price order to sell which is at a lower price than the price at which the option is to be opened) and market-on-opening orders.

In such a circumstance, the specialist would request bids and offers from ROTs in the crowd and, in the case of Streaming Quote Options, SQTs that are assigned in the option. Such ROTs and/

[40] Phlx Rule 1019 requires the specialist to give precedence to orders entrusted to him as an agent in any option in which he is registered before executing at the same price any purchase or sale in the same option for an account in which he has an interest. The Exchange represents that its Market Surveillance Department conducts surveillance for violations of this requirement. Therefore, according to the Exchange, if a specialist intends to trade for his own account on the opening, the specialist must first be sure that he does not trade ahead of any orders (as agent) even if received after the cut-off. Otherwise, he would be subject to possible disciplinary action for violation of Rule 1019, regardless of when such a market order is received (*i.e.*, in this circumstance, after the underlying security opens but prior to the opening in the underlying security). *See* Amendment No. 7, *supra* note 6.

[41] The Exchange recently made technological changes that removed the member firm identifier from orders received via AUTOM. Therefore, the specialist can identify the account type in which an order is placed (*i.e.*, whether the order is for a customer, firm, broker-dealer or ROT account), but cannot identify the specific member organization that submitted the order.

[42] A trading rotation is a series of very brief time periods during each of which bids, offers and transactions in only a single, specified option contract can be made. *See* Exchange Rule 1047, Commentary .01.

[43] This provision in the proposed rule is based on Chicago Board Options Exchange, Inc. Rule 6.2B(e)(ii).

or SQTs would be required to respond to such a request immediately. The series could not open until responses to the specialist's request have been received and the consequent opening price is deemed by a Floor Official to be compatible with a fair and orderly market.

Finally, the proposed rule concerning openings would address the situation in which there are no orders in a particular series when the underlying security opens. In such a situation the Exchange would disseminate quotations in such series generated automatically upon the opening in the underlying security.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning Amendments No. 6 and 7, including whether Amendments No. 6 and 7 are 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–hlx–2003–59 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–Phlx–2003–59. 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 inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of the Phlx. 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 Amendments No. 6 and 7 of File Number SR–Phlx–2003–59 and should be submitted on or before August 24, 2004.

IV. Discussion

After careful review, the Commission finds that the proposed rule change, as amended, is consistent with the Act and the rules and regulations promulgated thereunder applicable to a national securities exchange and, in particular, with the requirements of section 6(b) of the Act.[44] Specifically, the Commission finds that approval of the proposed rule change, as amended, is consistent with section 6(b)(5) of the Act[45] in that it is designed to facilitate transactions in securities; 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.

A. Market Maker Obligations

Phlx Rule 1014, as amended, would continue to govern market maker obligations. Under the proposed rule change, specialists would be required to maintain a continuous, two-sided quote in 100% of the series of Streaming Quote Options to which it is assigned, while each SQT would be required to maintain a continuous, two-sided quote in at least 60% of the Streaming Quote Options to which it is assigned. Non-SQT ROTs would be required to quote verbally in response to a request for a market, and maintain a two-sided quoting obligations in a designated percentage of series of Streaming Quote Options in the calendar quarter that followed a calendar quarter that it transacted more than 20% of its contract volume electronically in a Streaming Quote Option. However, if a non-SQT ROT transacts less than 20% of its contract volume electronically, it would not be bound by the quote spread parameters and the electronic quoting obligations set forth in Rule 1014, and electronic quotes would not count towards its in-person trading requirement.

The Commission believes that the obligations for specialists and ROTs (SQTs and non-SQTs) are consistent with the Act. As market makers, SQTs and non-SQT ROTs receive certain benefits for carrying out their duties. For example, a lender may extend credit to a broker-dealer without regard to the restrictions in Regulation T of the Board of Governors of the Federal Reserve System if the credit is to be used to finance the broker-dealer's activities as a specialist or market maker on a national securities exchange.[46] The Commission believes that a market maker should have an affirmative obligation to hold itself out as willing to buy and sell options for their own account on a regular or continuous basis to justify this favorable treatment. In this regard, by excluding electronic transactions from being applied towards satisfying a non-SQT ROTs in-person requirements where the non-SQT ROT transacts 20% or less of its contract volume electronically and is not required to continuously quote or comply with quote-width requirements, the Commission believes that the Exchange's proposal would impose such affirmative obligations on SQTs and non-SQT ROTs.

The Commission also believes that allowing an SQT and the specialist in a Streaming Quote Option to quote with a size of less than ten contracts during the initial stages of deployment of Phlx XL is not unreasonable, so that such SQTs and specialists may determine during this period of time that their quotation systems and models function properly and reliably, and may make any changes necessary to manage their risk while providing fair and orderly markets in the Streaming Quote Option.

B. Assignment in Streaming Quote Options

The Commission believes that the Exchange's SQT qualification and allocation requirements, which set forth objective criteria for the assignment of SQTs to Streaming Quote Options, are consistent with the Act. The Commission notes that the proposed requirements are similar to those adopted by other options exchanges.[47] In particular, the Commission notes that the proposed rule change, as amended, (i) places no limit on the number of

[44] 15 U.S.C. 78f(b). In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[45] 15 U.S.C. 78f(b)(5).

[46] *See* 12 CFR 221.5(c)(6).

[47] *See, e.g.*, CBOE Rule 8.3(a); ISE Rule 802(a); and BOX Chapter VI, Section 4.

qualifying ROTs that may become SQTs, and (ii) requires the OAESC to approve any applicant that is qualified as an ROT in good standing and that satisfies the technological readiness and testing requirements. The Commission also notes that the Exchange has no discretion to defer or limit the approval of qualifying applications for SQT status. In the event that the Board defers or limits the approval of qualifying applicants, such deferral or limitation must be based on system constraints and any basis for such deferral or limitation must be objectively determined by the Board and approved by the Commission pursuant to a proposed rule change filed under section 19(b) of the Act. Moreover, the Committee must provide written notification to any SQT applicant whose application is the subject of such limitation(s) or deferral, describing the objective basis for such limitation(s) or deferral.

C. Allocation Algorithm

The Commission believes that the Phlx's proposed trade allocation algorithm that would apply to orders and electronic quotes in Streaming Quote Options that result in automatic executions via the AUTOM System is consistent with the Act. The Commission also believes that Phlx XL, including the proposed trade allocation algorithm, should substantially enhance incentives to quote competitively by providing market participants with the ability to independently submit their quotes and rewarding market participants that quote at the best price with an allocation of the resulting trade.

The proposed rules codify the automatic allocation algorithm that applies to orders or electronic quotes in Streaming Quote Options that result in automatic executions when two or more Phlx XL participants have quotes or booked limit orders at the Exchange's disseminated price. The proposed rules also codify how manual trades would be initiated and executed in Phlx XL. The Commission believes that the various types of Phlx XL executions, including automated and manual executions, should allow specialists, SQT ROTs, and non-SQT ROTs to provide more efficient and immediate executions for inbound orders and market maker quotations subject to priority and allocation principles.

The Commission notes that the proposal does not provide for split price executions. Consequently, if the size associated with a market order or an electronic quotation to be executed in a Streaming Quote Option is received for a greater number of contracts than the Exchange's disseminated size, the portion of such an order or quotation executed automatically at the Exchange's disseminated size would be allocated automatically in accordance with Phlx Rule 1014(g)(vii), and the contracts remaining in such an order would be represented by the specialist and handled in accordance with Exchange rules. The Commission emphasizes that the contracts remaining for such orders should be handled in a manner that does not effectuate a trade-through [48] of better prices on other markets in violation of Exchange rules and the Linkage Plan.

The Commission also notes that in response to a floor broker's solicitation of a single bid or offer, the members of a trading crowd (including the specialist and ROTs) may discuss, negotiate and agree upon the price or prices at which an order of a size greater than the AUTO-X guarantee can be executed at that time, or the number of contracts that could be executed at a given price or prices, subject to the provisions of the Linkage Plan and Exchange rules.

D. Specialist Fiduciary Duties

The Exchange proposes to amend Phlx Rule 1014(g)(i)(A) to require the specialist, SQTs and non-SQT ROTs to yield priority to off-floor broker-dealer limit orders in Streaming Quote Options resting on the limit order book solely in the limited circumstance where the specialist executes such an order manually, and not in the circumstance where such an order is executed and allocated automatically under Phlx XL. The Commission believes that this provision should help ensure that the specialist complies with its fiduciary obligation when acting as agent for a limit order. In the situation where the off-floor broker-dealer limit order resting on the limit order book is executed and allocated automatically, the Commission believes that the operation of the proposed automatic trade allocation algorithm contained in proposed Phlx Rule 1014(g)(vii), which would allocate contracts to off-floor broker-dealer limit orders resting on the limit order book after customers, the specialist, SQTs and non-SQT ROTs have received their respective allocations is not unreasonable since the specialist is not acting as "agent" in that circumstance.

[48] Under the Linkage Plan and Exchange rules, a "Trade-Through" means a transaction in an options series at a price that is inferior to the NBBO. The Linkage Plan and Exchange Rules provide that, absent reasonable justification and during normal market conditions, members should not effect Trade-Throughs. See *e.g.*, Phlx Rule 1085.

E. ROT Limit Orders

The Commission believes that the instant proposal, which would enable SQTs to stream electronic quotes, combined with the size *pro rata* allocation algorithm applicable to automatically executed trades resulting from such quotes, rewards market participants for quoting and providing liquidity at the best price. In addition, the Commission notes that in Streaming Quote Options, non-SQT ROTs with limit orders on the book at the Exchange's disseminated price that are automatically executed would be allocated contracts according to proposed new Phlx Rule 1014(g)(vii), which would reward non-SQT ROTs who provide liquidity at the best price. Moreover, non-SQT ROTs that place price-improving limit orders would continue to receive a special allocation under the Exchange's proposal. Therefore, the Commission believes that the proposal should provide incentives for market participants to quote competitively.

F. Book Match

The Commission believes that the proposed enhancements to Book Match should provide for a greater number of automatic executions by matching inbound orders against booked limit orders and SQT and specialist quotations that are included in the Exchange's disseminated quotation, which should result in customers receiving quicker, more efficient executions for a larger number of trades.

G. Locked Markets

The Commission believes that the proposed rules relating to a one-second "counting period," during which SQTs and/or specialists whose quotations are locked may eliminate a locked market, are consistent with the Commission's Quote Rule. The Commission notes that, during the one-second "counting period," market makers would continue to be required to honor their quotes and, thus, would be obligated to execute incoming orders pursuant to proposed Phlx Rule 1082. The Commission also notes that the market makers whose quotes are locked would continue to be obligated under the Quote Rule for at least one contract to each other during the counting period. At the end of the counting period, assuming neither market maker has changed its quotes, the market makers' quotes would execute against each other in all series. Accordingly, the Commission believes that the proposed "counting period" provides a reasonable method for SQTs or specialists that lock or cross a market

to unlock or uncross the market. Importantly, during the "counting period," the SQTs or specialists whose quotes are locked would remain obligated to execute customer and broker-dealer orders eligible for automatic execution at the locked price.

H. Firm Quotations

The Commission believes that the proposed amendments to the Exchange's "Firm Quote" requirements are consistent with the Act. The Commission notes that the requirement that specialists' quotations automatically generated be included in the disseminated size should result in a more accurate and transparent reflection of the size for which the Exchange is firm.

I. Opening the Market on Phlx XL

In Amendment No. 7, the Exchange proposes additional amendments to its rules relating to the manner in which the Exchange conducts openings to provide a more detailed description of the procedures by which the opening price on Phlx XL would be established. The proposed opening rules set forth which orders and quotes the specialist in a particular option is required to accept prior to the opening in a given series. The proposed opening rules also provide that the opening price is the price at which the specialist determines that the greatest number of contracts would trade, subject to the opening price falling within an acceptable range, to be determined by the Options Committee. In addition, the proposed opening rules sets forth the circumstances in which a specialist would not open a series. The Exchange proposes to adopt the proposed opening rules on a pilot basis, beginning on the first day of the deployment of Phlx XL, and scheduled to expire after 180 days.

The Commission believes that the proposed rules governing the opening procedures on Phlx XL provide a reasonable process by which Phlx participants, including SQTs, would access and participate in the rotations. The Commission also believes that the proposed rules governing the opening procedures on Phlx XL should provide greater transparency with respect to the manner an opening price is determined on the Exchange. In addition, the Commission believes that approving the opening rules on a pilot basis should provide the Phlx and the Commission an opportunity to review the operation of the proposal and address any potential concerns that may arise.

J. Application of "Effect v. Execute" Exemption From Section 11(a) of the Act

Section 11(a) of the Exchange Act[49] prohibits a member of a national securities exchange from effecting transactions on that exchange for its own account, the account of an associated person, or an account over which it or its associated person exercises discretion (collectively, "covered accounts") unless an exception applies. In addition to the exceptions set forth in the statute, Rule 11a2–2(T)[50] provides exchange members with an exemption from this prohibition. Known as the "effect versus execute" rule, Rule 11a2–2(T) permits an exchange member, subject to certain conditions, to effect transactions for covered accounts by arranging for an unaffiliated member to execute the transactions on the exchange. To comply with the Rule's conditions, a member (i) must transmit the order from off the exchange floor; (ii) may not participate in the execution of the transaction once it has been transmitted to the member performing the execution;[51] (iii) may not be affiliated with the executing member; and (iv) with respect to an account over which the member has investment discretion, neither the member nor its associated person may retain any compensation in connection with effecting the transaction, except as provided in the Rule.

In a letter to the Commission,[52] the Notice, and in Amendment No. 7, the Phlx represents that the transactions effected pursuant to the Phlx XL rules, both automatic and manual, satisfy the conditions of Rule 11a2–2(T).[53] The Commission notes that the staff of the Division previously provided interpretive guidance to the Phlx regarding its AUTO-X system.[54] Based on Phlx's instant representations, the Commisson believes that its previous guidance is still applicable to Phlx XL. Accordingly, the Commission finds that Phlx XL's electronic order submission and execution process satisfies the four conditions of Rule 11a2–2(T).[55]

V. Accelerated Approval of Amendments No. 6 and 7

Pursuant to section 19(b)(2) of the Act,[56] the Commission may not approve any proposed rule change, or amendment thereto, prior to the thirtieth day after the date of publication of the notice of filing thereof, unless the Commission finds good cause for so finding. The Commission hereby finds good cause for approving Amendments No. 6 and 7 to the proposed rule change prior to the thirtieth day after publishing notice of Amendments No. 6 and 7 in the **Federal Register** pursuant to section 19(b)(2) of the Act.[57] Amendment No. 6 corrects technical drafting and typographical errors and omissions contained in the proposed rule text and, in response to concerns raised by Commission staff, provides a more detailed description of the procedures by which the opening price on Phlx XL would be established. Amendment No. 7 provides additional description of the procedures by which the opening price on Phlx XL would be established. The Commission notes that the rules relating to the opening procedures on the Phlx are modeled on

[49] 15 U.S.C. 78k(a).

[50] 17 CFR 240.11a2–2(T).

[51] The member, however, may participate in clearing and settling the transactions.

[52] *See* letter from Richard S. Rudolph, Counsel, Phlx, to Catherine McGuire, Chief Counsel, Division, Commission, dated April 15, 2002 ("April 2002 Letter").

[53] Based on the Phlx's representations in Amendment No. 7, the staff believes that the Exchange's rules relating to the manual execution by specialists of off-floor broker-dealer orders that were received by the AUTO-X system comply with the requirements of Section 11(a) of the Act and Rule 11a2–2(T) thereunder. As discussed above, off-floor broker-dealers would enter these orders through AUTOM. According to the Phlx, the member firm identifier is removed from orders received through AUTOM. This, according to the Phlx, should prevent members from using affiliated persons on the exchange floor to influence or guide their orders' execution.

[54] *See* letter from Paula R. Jenson, Deputy Chief Counsel, Division, Commission, to Richard S. Rudolph, Counsel, Phlx, dated April 15, 2002.

[55] The Commission and its staff, on numerous occasions, have considered the application of Rule 11a2–2(T) to electronic trading and order routing systems. *See, e.g.*, Securities Exchange Act Release Nos. 49068 (January 13, 2004) (Order approving the Boston Options Exchange as an options trading facility of the Boston Stock Exchange); 44983 (October 25, 2001) (Order approving the Archipelago Exchange as the equities trading facility of PCX Equities Inc.); 29237 (May 31, 1991) (regarding NYSE's Off-Hours Trading Facility); 15533 (January 29, 1979) (regarding the Amex Post Execution Reporting System, the Amex Switching System, the Intermarket Trading System, the Multiple Dealer Trading Facility of the Cincinnati Stock Exchange, the PCX's Communications and Execution System, and the Phlx's Automated Communications and Execution System); and 14563 (March 14, 1978) (regarding the NYSE's Designated Order Turnaround System). *See also* letter from Larry E. Bergmann, Senior Associate Director, Division, Commission, to Edith Hallahan, Associate General Counsel, Phlx (March 24, 1999) (regarding Phlx's VWAP Trading System); letter from Catherine McGuire, Chief Counsel, Division, Commission, to David E. Rosedahl, PCX (November 30, 1998) (regarding Optimark); and Letter from Brandon Becker, Director, Division, Commission, to George T. Simon, Foley & Lardner (November 30, 1994) (regarding Chicago Match).

[56] 15 U.S.C. 78s(b)(2).

[57] *Id.*

and substantially similar to the existing rules of the other options exchanges. The Commission previously approved these rules and, therefore, believes that accelerating such rules for Phlx XL on a six month pilot basis is appropriate, because the revisions do not raise new issues of regulatory concern. Therefore, the Commission finds that accelerated approval of Amendments No. 6 and 7 is consistent with section 19(b)(2) of the Act.[58]

VI. Conclusion

For the foregoing reasons, the Commission finds that the proposed rule change, as amended, is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, with section 6(b)(5) of the Act.[59]

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[60] that the proposed rule change and Amendments No. 1, 2, 3, 4, and 5 (SR–Phlx–2003–59) are approved, that Amendments No. 6 and 7 thereto are approved on an accelerated basis, and that the opening procedures are approved on a pilot basis until January 31, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[61]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 04–17650 Filed 8–2–04; 8:45 am]

BILLING CODE 8010–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #P043]

State of South Dakota

As a result of the President's major disaster declaration for Public Assistance on July 20, 2004, the U.S. Small Business Administration is activating its disaster loan program only for private non-profit organizations that provide essential services of a governmental nature. I find that Haakon, Jackson, Marshall, Mellette, Minnehaha, Todd, Tripp, and Turner Counties, and the Rosebud Indian Reservation in the State of South Dakota constitute a disaster area due to damages caused by severe storms and flooding occurring on May 28, 2004, and continuing. Applications for loans for physical damage as a result of this disaster may be filed until the close of business on September 20, 2004, at the address listed below or other locally announced locations: U.S. Small Business Administration, Disaster Area 3 Office, 14925 Kingsport Road, Fort Worth, TX 76155–2243.

The interest rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations Without Credit Available Elsewhere	2.750
Non-profit organizations with credit available elsewhere	4.875

The number assigned to this disaster for physical damage is P04306.

(Catalog of Federal Domestic Assistance Program Nos. 59008.)

Dated: July 26, 2004.

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. 04–17590 Filed 8–2–04; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Notice of Action Subject to Intergovernmental Review Under Executive Order 12372

AGENCY: Small Business Administration.

ACTION: Notice of action subject to intergovernmental review.

SUMMARY: The Small Business Administration (SBA) is notifying the public that it intends to grant the pending applications of 42 existing Small Business Development Centers (SBDCs) for refunding on January 1, 2005, subject to the availability of funds. Fourteen states do not participate in the EO 12372 process therefore, their addresses are not included. A short description of the SBDC program follows in the supplementary information below.

The SBA is publishing this notice at least 120 days before the expected refunding date. The SBDCs and their mailing addresses are listed below in the address section. A copy of this notice also is being furnished to the respective State single points of contact designated under the Executive Order. Each SBDC application must be consistent with any area-wide small business assistance plan adopted by a State-authorized agency.

DATES: A State single point of contact and other interested State or local entities may submit written comments regarding an SBDC refunding within 30 days from the date of publication of this notice to the SBDC.

ADDRESSES:

Addresses of Relevant SBDC State Directors

Mr. Greg Panichello, Acting State Director, Salt Lake Community College, 1623 South State Street, Salt Lake City, UT 84115, (801) 957–3493.

Mr. Herbert Thweatt, Director, American Samoa Community College, P.O. Box 2609, Pago Pago, American Samoa 96799, 011–684–699–9155.

Mr. John Lenti, State Director, University of South Carolina, 1710 College Street, Columbia, SC 29208, (803) 777–4907.

Ms. Kelly Manning, State Director, Office of Business Development, 1625 Broadway, Suite 1710, Denver, CO 80202, (303) 892–3864.

Mr. Henry Turner, Executive Director, Howard University, 2600 6th St., NW, Room 125, Washington, DC 20059, (202) 806–1550.

Mr. Jerry Cartwright, State Director, University of West Florida, 401 East Chase Street, Suite 100, Pensacola, FL 32501, (850) 595–6060.

Mr. Hank Logan, State Director, University of Georgia, Chicopee Complex, Athens, GA 30602, (706) 542–6762.

Mr. Darryl Mleynek, State Director, University of Hawaii/Hilo, 200 West Kawili Street, Hilo, HI 96720, (808) 974–7515.

Mr. Sam Males, State Director, University of Nevada/Reno, College of Business Administration, Room 411, Reno, NV 89557–0100, (775) 784–1717.

Mr. Patrick Geho, Acting State Director, Tennessee Board of Regents, 1415 Murfreesboro Road, Suite 324, Nashville, TN 37217–2833, (615) 366–3931.

Ms. Debbie Bishop Trocha, State Director, Economic Development Council, One North Capitol, Suite 420, Indianapolis, IN 46204, (317) 234–2086.

Ms. Mary Collins, State Director, University of New Hampshire, 108 McConnell Hall, Durham, NH 03824, (603) 862–4879.

Mr. John Massaua, State Director, University of Southern Maine, 96 Falmouth Street, Portland, ME 04103, (207) 780–4420.

Ms. Carolyn Clark, State Director, Washington State University, 534 East Trent Avenue, Spokane, WA 99210–1495, (509) 358–7765.

Ms. Christine Martin, State Director, University of North Dakota, P.O. Box 7308, Grand Forks, ND 58202, (701) 777–3700.

Mr. Casey Jeszenka, Director, University of Guam, P.O. Box 5061—U.O.G.

[58] *Id.*

[59] 15 U.S.C. 78f(b)(5).

[60] 15 U.S.C. 78s(b)(2).

[61] 17 CFR 200.30–3(a)(12).

Station, Mangilao, Guam 96923, (671) 735–2553.

Ms. Erica Kauten, State Director, University of Wisconsin, 432 North Lake Street, Room 423, Madison, WI 53706, (608) 263–7794.

Mr. Greg Higgins, State Director, University of Pennsylvania, The Wharton School, 444 Vance Hall, Philadelphia, PA 19104, (215) 898–1219.

Mr. Robert Hamlin, State Director, Bryant College, 1150 Douglas Pike, Smithfield, RI 02917, (401) 232–6111.

Mr. John Lenti, State Director, University of South Carolina, College of Business Administration, 1710 College Street, Columbia, SC 29208, (803) 777–4907.

Mr. Mark Slade, Acting Co-State Director, University of South Dakota, School of Business, 414 East Clark, Vermillion, SD 57069, (605) 367–5757.

Ms. Vi Pham, Region Director, California State University, Fullerton, 800 North State College Blvd., Fullerton, CA 92834, (714) 278–2719.

Ms. Debbie Trujillo, Region Director, Southwestern Community College District, 900 Otey Lakes Road, Chula Vista, CA 91910, (619) 482–6388.

Ms. Helen Sullivan, Region Director, University of California, Merced, 550 East Shaw, Suite 105A, Fresno, CA 93710, (559) 241–7414.

Ms. Janice Rhodd, Region Director, California State University, Chico Research Foundation, Chico, CA 95929–0765, (530) 898–4598.

Mr. Blake Escudier, Region Director, San Jose State University, College of Business SJSU, 84 West Santa Clara, Suite 100, San Jose, CA 95113, (408) 287–2310.

Ms. Wilma Worden, Region Director, California State University, 18111 Nordhoff Street, Northridge, CA 91330–8232, (818) 677–2467.

FOR FURTHER INFORMATION CONTACT: Antonio Doss, Associate Administrator for SBDCs, U.S. Small Business Administration, 409 Third Street, SW., Sixth Floor, Washington, DC 20416.

SUPPLEMENTARY INFORMATION:

Description of the SBDC Program

A partnership exists between SBA and an SBDC. SBDCs offer training, counseling and other business development assistance to small businesses. Each SBDC provides services under a negotiated Cooperative Agreement with the SBA. SBDCs operate on the basis of a state plan to provide assistance within a state or geographic area. The initial plan must have the written approval of the Governor. Non-Federal funds must match Federal funds. An SBDC must operate according to law, the Cooperative Agreement, SBA's regulations, the annual Program Announcement, and program guidance.

Program Objectives

The SBDC program uses Federal funds to leverage the resources of states, academic institutions and the private sector to:

(a) Strengthen the small business community;

(b) Increase economic growth;

(c) Assist more small businesses; and

(d) Broaden the delivery system to more small businesses.

SBDC Program Organization

The lead SBDC operates a statewide or regional network of SBDC service centers. An SBDC must have a full-time Director. SBDCs must use at least 80 percent of the Federal funds to provide services to small businesses. SBDCs use volunteers and other low cost resources as much as possible.

SBDC Services

An SBDC must have a full range of business development and technical assistance services in its area of operations, depending upon local needs, SBA priorities and SBDC program objectives. Services include training and counseling to existing and prospective small business owners in management, marketing, finance, operations, planning, taxes, and any other general or technical area of assistance that supports small business growth.

The SBA district office and the SBDC must agree upon the specific mix of services. They should give particular attention to SBA's priority and special emphasis groups, including veterans, women, exporters, the disabled, and minorities.

SBDC Program Requirements

An SBDC must meet programmatic and financial requirements imposed by statute, regulations or its Cooperative Agreement. The SBDC must:

(a) Locate service centers so that they are as accessible as possible to small businesses;

(b) Open all service centers at least 40 hours per week, or during the normal business hours of its state or academic Host Organization, throughout the year;

(c) Develop working relationships with financial institutions, the investment community, professional associations, private consultants and small business groups; and

(d) Maintain lists of private consultants at each service center.

Dated: July 29, 2004.

Antonio Doss,

Associate Administrator for Small Business Development Centers.

[FR Doc. 04–17591 Filed 8–2–04; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–872X]

Great Northwest Railroad, Inc.—Abandonment Exemption—in Clearwater County, ID

On July 14, 2004, Great Northwest Railroad, Inc. (GNR), filed with the Board a petition under 49 U.S.C. 10502 for exemption from 49 U.S.C. 10903 to abandon a line of railroad extending from milepost 3.5, at Orofino, ID, to milepost 31.0, near Jaype, ID, a distance of approximately 27.5 miles, in Clearwater County, ID. The line traverses U.S. Postal Service ZIP Codes 83544 and 83546 and includes no stations.

The line does not contain federally granted rights-of-way. Any documentation in GNR's possession will be made available promptly to those requesting it.

The interest of railroad employees will be protected by the conditions set forth in *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979).

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by November 1, 2004.

Any offer of financial assistance (OFA) under 49 CFR 1152.27(b)(2) will be due no later than 10 days after service of a decision granting the petition for exemption. Each offer must be accompanied by a $1,100 filing fee. *See* 49 CFR 1002.2(f)(25).

All interested persons should be aware that, following abandonment of rail service and salvage of the line, the line may be suitable for other public use, including interim trail use. Any request for a public use condition under 49 CFR 1152.28 or for trail use/rail banking under 49 CFR 1152.29 will be due no later than August 13, 2004. Each trail use request must be accompanied by a $150 filing fee. *See* 49 CFR 1002.2(f)(27).

All filings in response to this notice must refer to STB Docket No. AB–872X and must be sent to: (1) Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001; and

(2) Karl Morell, Of Counsel, Ball Janik LLP, 1455 F Street, NW., Suite 225, Washington, DC 20005. Replies to the CSXT petition are due on or before August 13, 2004.

Persons seeking further information concerning abandonment procedures may contact the Board's Office of Public Services at (202) 565–1592 or refer to the full abandonment or discontinuance regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Section of Environmental Analysis (SEA) at (202) 565–1539. (Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.)

An environmental assessment (EA) (or environmental impact statement (EIS), if necessary) prepared by SEA, will be served upon all parties of record and upon any agencies or other persons who commented during its preparation. Other interested persons may contact SEA to obtain a copy of the EA (or EIS). EAs in these abandonment proceedings normally will be made available within 60 days of the filing of the petition. The deadline for submission of comments on the EA will generally be within 30 days of its service.

Board decisions and notices are available on the Board's Web site at *http://www.stb.dot.gov*.

Decided: July 26, 2004.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 04–17355 Filed 8–2–04; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

July 26, 2004.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) 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 Department Clearance Officer, Department of the Treasury, Room 11000, 1750 Pennsylvania Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before September 2, 2004 to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545–0070.

Form Number: IRS Form 2350.

Type of Review: Extension.

Title: Application for Extension of Time to File U.S. Income Tax Return.

Description: Form 2350 is used to request an extension of time to file in order to meet the bona fide residence or physical presence tests required to gain the benefits permitted under section 911. The information furnished is used to determine if the extension should be granted.

Respondents: Individuals or households.

Estimated Number of Respondents/ Recordkeepers: 22,594.

Estimated Burden Hours Respondent/ Recordkeeper:

Recordkeeping—13 min.
Learning about the law or the form—12 min.
Preparing the form—18 min.
Sending the form to the IRS 13—min.

Frequency of response: Annually.

Estimated Total Reporting/ Recordkeeping Burden: 21,465 hours.

OMB Number: 1545–0188.

Form Number: IRS Form 4868.

Type of Review: Extension.

Title: Application for Automatic Extension of Time to File U.S. Individual Income Tax Return.

Description: Form 4868 is used by taxpayers to apply for an automatic 4-month extension of time to file Form 1040A, or Form 1040EZ. This form contains data used by the Service to determine if a taxpayer qualifies for the extension.

Respondents: Individuals and households.

Estimated Number of Respondents/ Recordkeepers: 5,572,999.

Estimated Burden Hours Respondent/ Recordkeeper:

Recordkeeping—26 min.
Learning about the law or the form—13 min.
Preparing the form—11 min.
Copying, assembling and sending the form to the IRS—10 min.

Frequency of response: Annually.

Estimated Total Reporting/ Recordkeeping Burden: 5,740,189 hours.

OMB Number: 1545–0985.

Regulation Project Numbers: PS–128–86, PS–127–86, and PS–73–88 Final (TD 8644).

Type of Review: Extension.

Title: Generation Skipping Transfer Tax.

Description: 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 Forms 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, Business of other for-profit.

Estimated Number of Respondents/ Recordkeepers: 7,500.

Estimated Burden Hours Respondent/ Recordkeeper: 30 minutes.

Frequency of response: On occasion, Other (Form 706 is filed within 9 months after taxpayer dies).

Estimated Total Reporting/ Recordkeeping Burden: 3,750 hours.

OMB Number: 1545–1051.

Regulation Project Number: INTL–29–91 Final.

Type of Review: Extension.

Title: Computation and Characterization of Income and Earnings and Profits under the Dollar Approximate Separate Transactions Method of Accounting (DASTM).

Description: For taxable years after the final regulations are effective, taxpayers operating in hyperinflationary currencies must use the U.S. dollar as their functional currency and compute income using the dollar approximate separate transactions method (DASTM). Small taxpayers may elect an alternate method by which to compute income or loss. For prior years in which income was computed using the profit and loss method, taxpayers may elect to recompute their income using DASTM.

Respondents: Business of other for-profit.

Estimated Number of Respondents: 700.

Estimated Burden Hours Respondent: 1 hour, 26 minutes.

Frequency of response: On occasion, Other (one-time election).

Estimated Total Reporting/ Recordkeeping Burden: 1,000 hours.

OMB Number: 1545–1173.

Form Number: IRS Form 8815.

Type of Review: Extension.

Title: Exclusion of Interest From Series EE and I U.S. Savings Bonds Issued After 1989.

Description: If any individual redeems series I or series EE U.S. savings bonds issued after 1989 and pays qualified higher education expenses during the year, the interest on the bonds may be excludable from income. Form 8815 is used by the individual to figure the amount of savings that is excludable.

Respondents: Individuals or households.

Estimated Number of Respondents/Recordkeepers: 25,000.

Estimated Burden Hours Respondent/Recordkeeper:

Recordkeeping—51 min.
Learning about the law or the form—10 min.
Preparing the form—37 min.
Copying, assembling, and sending the form to the IRS—32 min.

Frequency of response: Annually.

Estimated Total Reporting/Recordkeeping Burden: 51,110 hours.

Clearance Officer: Glenn P. Kirkland, (202) 622–3428, Internal Revenue Service, Room 6411–03, 1111 Constitution Avenue, NW, Washington, DC 20224.

OMB Reviewer: Joseph F. Lackey, Jr., (202) 395–7316, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Treasury PRA Clearance Officer.

[FR Doc. 04–17630 Filed 8–2–04; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0227]

Agency Information Collection: Emergency Submission for OMB Review; Comment Request

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the United States Department of Veterans Affairs (VA), has submitted to the Office of Management and Budget (OMB) the following emergency proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. 3507(j)(1)). An emergency clearance is being requested in response the Joint Commission on the Accreditation of Hospital Organizations (JCAHO) to adopt the Hospital Consumer Assessment of Health Plan Survey (HCAHPS) as a national standard survey for inpatients.

DATES: Comments must be submitted on or before August 10, 2004.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Records Management Service (005E3), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–8030, FAX (202) 273–5981 or e-mail: *denise.mclamb@mail.va.gov.* Please refer to "OMB Control No. 2900–0227: Send comments and recommendations concerning any aspect of the information collection to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316 or FAX (202) 395–6974. Please refer to "2900–0227.

SUPPLEMENTARY INFORMATION: *Title:* Nation-wide Customer Satisfaction Survey, VA Forms 10–21075a through c (NR), 10–1465–1, 10–1465–3, 10–0142B, and 10–5387.

OMB Control Number: 2900–0227.

Type of Review: Revision of a currently approved collection.

Abstract: Joint Commission on the Accreditation of Hospital Organizations (JCAHO) to adopt the Hospital Consumer Assessment of Health Plan Survey (HCAHPS) as a national standard survey for inpatients. VA proposes a three-part piloting of the HCAPHS survey instrument to better understand how this questionnaire (either alone or combined with all or part of VHA's current inpatient questionnaire) and the HCAHPS sampling methods work in the population of veteran inpatients. The purpose of these patient satisfaction surveys is to determine how to improve services, customer satisfaction with existing services and how or if customer satisfaction has changed in response to reengineering efforts. The survey results will be used as a tool for assessing and improving the quality of services being provided to patients.

Affected Public: Individuals or households.

Estimated Total Annual Burden: 213,137 hours.

Estimated Average Burden Per Respondent: 23 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 557,040.

Dated: July 22, 2004.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. 04–17593 Filed 8–2–04; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0317]

Agency Information Collection 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. 3501–21), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, has submitted the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and includes the actual data collection instrument.

DATES: Comments must be submitted on or before September 2, 2004.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Records Management Service (005E3), Department of Veterans Affairs, 810 Vermont Avenue, NW., or e-mail *denise.mclamb@mail.va.gov.* Please refer to "OMB Control No. 2900–0317." Send comments and recommendations concerning any aspect of the information collection 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. 2900–0317" in any correspondence.

SUPPLEMENTARY INFORMATION: *Title:* Request for Identifying Information Re: Veteran's Loan Records, VA Form Letter 26–626.

OMB Control Number: 2900–0317.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 26–626 is used to notify a correspondent that additional information is needed to determine if a veteran's loan guaranty benefits are involved, and if so, to obtain the necessary information to identify and associate the correspondence with the correct veteran's loan application or record. If such information is not received within one year form the date of such notification, no benefits may be paid or furnished by reason of such application.

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 April 6, 2004, at page 18158.

Affected Public: Individuals or households.

Estimated Annual Burden: 200 hours.

Estimated Average Burden Per Respondent: 5 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 2,400.

Dated: July 21, 2004.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. 04–17594 Filed 8–2–04; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0455]

Agency Information Collection 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. 3501–21), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, has submitted the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and includes the actual data collection instrument.

DATES: Comments must be submitted on or before September 2, 2004.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Records Management Service (005E3), Department of Veterans Affairs, 810 Vermont Avenue, NW., or e-mail *denise.mclamb@mail.va.gov.* Please refer to "OMB Control No. 2900–0455." Send comments and recommendations concerning any aspect of the information collection 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. 2900–0455" in any correspondence.

SUPPLEMENTARY INFORMATION: *Title:* Equal Opportunity Compliance Review Report, VA Form 20–8734 and Supplement to Equal Opportunity Compliance Review Report, VA Form 20–8734a.

OMB Control Number: 2900–0455.

Type of Review: Extension of a currently approved collection.

Abstract: Executive Order 12250, Leadership and Coordination of Nondiscrimination Laws, delegated authority to the Attorney General to coordinate the implementation and enforcement by Executive agencies of various equal opportunity laws prohibiting discriminatory practices in Federal programs and programs receiving Federal financial assistance. The Order extended the delegation to cover Title IX of the Education Amendments of 1972, and section 504 of the Rehabilitation Act of 1973. Department of Justice issued government-wide guidelines (29 CFR 42.406) instructing funding agencies to "provide for the collection of data and information from applicants for and recipients of Federal assistance.

VA Forms 20–8734 and 20–8734a are used by VA personnel during regularly scheduled educational compliance survey visit, as well as during investigations of equal opportunity complaints, to identify areas where there may be disparate treatment of members of protected groups. VA Form 20–8734 is used to gather information from post-secondary proprietary schools below college level. The information is used to assure that VA-funded programs comply with equal opportunity laws. VA Form 20–8734a, is used to gather information from students and instructors at post-secondary proprietary schools below college level. The information is used to assure that participants have equal access to equal treatment in VA-funded programs. If this information were not collected, VA would be unable to carry out the civil rights enforcement responsibilities established in the Department of Justice's guidelines and VA's regulations.

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 May 17, 2004, at page 27972.

Affected Public: Business or other for-profit, Federal government.

Estimated Annual Burden and Average Burden Per Respondent: Based on past experience, VBA estimates that 76 interviews will be conducted with recipients using VA Form 20–8734 at an average of 1 hour and 45 minutes per interview (133 hours). This includes one hour for an interview with the principal facility official, plus 45 minutes for reviewing records and reports and touring the facility. It is estimated that 76 interviews will be conducted with students using VA Form 20–8734a at an average of 30 minutes per interview (38 hours) and with instructors at an average of 30 minutes per interview (38 hours). Interviews are also conducted with 76 students without instructors at an average time of 30 minutes (38 hours). The total burden hour is 247.

Frequency of Response: On occasion.

Estimated Number of Respondents: 228.

Dated: July 21, 2004.

By direction of the Secretary

Loise Russell,

Director, Records Management Service.

[FR Doc. 04–17595 Filed 8–2–04; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–NEW]

Proposed Information Collection Activity: Proposed Collection; 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 new collection and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to determine Filipino veterans or beneficiaries receiving benefit at the full-dollar rate based on U.S. residency requirements.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before October 4, 2004.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail *irmnkess@vba.va.gov.* Please refer to "OMB Control No. 2900-NEW" in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 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: Residency Verification Report—Veterans and Survivors, VA Form Letter 21–914.

OMB Control Number: 2900–NEW.

Type of Review: New collection.

Abstract: VA Form Letter 21–914 is used to verify whether Filipino veterans of the Special Philippine Scouts, Commonwealth Army of the Philippines, organized guerilla groups, or survivors receiving service-connected compensation benefits at the full-dollar rate residing in the United States as United States citizens or as aliens lawfully admitted for permanent residence continue to meet the residency requirements. Continued eligibility to benefits at the full-dollar rate cannot be determined without complete information about a veteran's or beneficiary's residency.

Affected Public: Individuals or households.

Estimated Annual Burden: 417 hours.

Estimated Average Burden Per Respondent: 20 minutes.

Frequency of Response: Annually.

Estimated Number of Respondents: 1,250.

Dated: July 21, 2004.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. 04–17596 Filed 8–2–04; 8:45 am]

BILLING CODE 8320–01–P

Corrections

Federal Register
Vol. 69, No. 148
Tuesday, August 3, 2004

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

National Advisory Committee on Occupational Safety and Health; Notice of Meeting

Correction

In notice document 04–17044 appearing on page 44695 in the issue of Tuesday, July 27, 2004, make the following correction:

On page 44695, in the second column, in the first paragraph, in the sixth line from the bottom, "August 19" should read "August 18".

[FR Doc. C4–17044 Filed 8–2–04; 8:45 am]

BILLING CODE 1505–01–D

PEACE CORPS

Privacy Act of 1974; Systems of Records

Correction

In notice document 04–16026 beginning on page 42784 in the issue of July 16, 2004, make the following correction:

On page 42784, in the third column, under the heading **DATES**, in the third line, "July 26, 2004" should read, "September 6, 2004."

[FR Doc. C4–16026 Filed 8–2–04; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Tuesday,
August 3, 2004

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 411, 417, and 423
Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 411, 417, and 423

[CMS–4068–P]

RIN 0938–AN08

Medicare Program; Medicare Prescription Drug Benefit

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement the new Medicare Prescription Drug Benefit. This new voluntary prescription drug benefit program was enacted into law on December 8, 2003, in section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The addition of a prescription drug benefit to Medicare represents a landmark change to the Medicare program that will significantly improve the health care coverage available to millions of Medicare beneficiaries. The MMA specifies that the prescription drug benefit program will become available to beneficiaries beginning on January 1, 2006. Please see the executive summary in the **SUPPLEMENTARY INFORMATION** section for further synopsis of this rule.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 4, 2004.

ADDRESSES: In commenting, please refer to file code CMS–4068–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments to *http://www.cms.hhs.gov/regulations/ecomments* (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. *By 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–4068–P, P.O. Box 8014, Baltimore, MD 21244–8014.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (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) 786–7197 in advance to schedule your arrival with one of our staff members.

(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.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Lynn Orlosky (410) 786–9064 or Randy Brauer (410)786–1618 (for issues related to eligibility, elections, enrollment, including auto-enrollment of dual eligible beneficiaries, and creditable coverage).

Wendy Burger (410) 786–1566 (for issues related to marketing and user fees).

Vanessa Duran-Scirri (214) 767–6435 (for issues related to benefits and beneficiary protections, including Part D benefit packages, Part D covered drugs, coordination of benefits in claims processing and tracking of true-out-of-pocket costs, pharmacy network access standards, plan information dissemination requirements, and privacy of records).

Craig Miner, RPh. (410) 786–1889 or Tony Hausner (410) 786–1093 (for issues of pharmacy benefit cost and utilization management, formulary development, quality assurance, medication therapy management, and electronic prescribing).

Mark Newsom (410) 786–3198 (for issues of submission, review, negotiation, and approval of risk and limited risk bids for PDPs and MA–PD plans; the calculation of the national average bid amount; determination and collection of enrollee premiums; calculation and payment of direct and reinsurance subsidies and risk-sharing; and retroactive adjustments and reconciliations.)

Jim Owens (410) 786–1582 (for issues of licensing and waiver of licensure, the assumption of financial risk for unsubsidized coverage, and solvency requirements for unlicensed sponsors or sponsors who are not licensed in all States in the region in which it wants to offer a PDP.)

Terese Klitenic (410) 786–5942 (for issues of coordination of Part D plans with providers of other prescription drug coverage including Medicare Advantage plans, state pharmaceutical assistance programs (SPAPs), Medicaid, and other retiree prescription drug plans; also for issues related to eligibility for and payment of subsidies for assistance with premium and cost-sharing amounts for Part D eligible individuals with lower income and resources; for rules for states on eligibility determinations for low-income subsidies and general state payment provisions including the phased-down state contribution to drug benefit costs assumed by Medicare).

Frank Szeflinski (303) 844–7119 (for issues related to conditions necessary to contract with Medicare as a PDP sponsor, as well as contract requirements, intermediate sanctions, termination procedures and change of ownership requirements; employer group waivers and options; also for issues related to cost-based HMOs and CMPS offering Part D coverage.)

John Scott (410) 786–3636 (for issues related to the procedures PDP sponsors must follow with regard to grievances, coverage determinations, and appeals.)

Tracey McCutcheon (410) 786–6715 (for issues related to solicitation, review and approval of fallback prescription drug plan proposals; fallback contract requirements; and enrollee premiums and plan payments specific to fallback plans.)

Jim Mayhew (410) 786–9244 (for issues related to the alternative retiree drug subsidy.)

Joanne Sinsheimer (410) 786–4620 (for issues related to physician self-referral prohibitions.)

Brenda Hudson (410) 786–4085 (for issues related to PACE organizations offering Part D coverage.)

Julie Walton (410) 786–4622 or Kathryn McCann (410) 786–7623 (for issues related to provisions on Medicare supplemental (Medigap) policies.)

For general questions: Please call (410) 786–1296.

SUPPLEMENTARY INFORMATION:

Executive Summary. Generally, coverage for the prescription drug

benefit will be provided under private prescription drug plans (PDPs), which will offer only prescription drug coverage, or through Medicare Advantage prescription drug plans (MA–PDs), which will offer prescription drug coverage that is integrated with the health care coverage they provide to Medicare beneficiaries under Part C of Medicare. PDPs must offer a basic prescription drug benefit. MA–PDs must offer either a basic benefit or broader coverage for no additional cost. If this required level of coverage is offered, the PDP or MA–PD plan may also offer supplemental benefits through enhanced alternative coverage for an additional premium. All organizations offering drug plans will have flexibility in the design of the prescription drug benefit. Consistent with the MMA, this proposed rule provides for subsidy payments to sponsors of qualified retiree prescription drug plans.

We intend to implement the drug benefit to permit and encourage a range of options for Medicare beneficiaries to augment the standard Medicare coverage for drug costs above the initial coverage limit ($2250 in 2006) and below the annual out-of-pocket threshold ($5100 in 2006). In addition to the coverage established by the statute for low-income beneficiaries, we seek comments on the best way to support options for expanding beneficiaries' drug coverage. Potential options include facilitating coverage through employer plans, MA–PD plans and/or high-option PDPs, as well as through charity organizations and State pharmaceutical assistance programs. We specifically seek comments on ways to maximize the continued use of non-Medicare resources (private contributions, employer/union contributions, state contributions, health plan contributions, and other sources) that currently provide at least partial coverage for three-fourths of Medicare beneficiaries. *See* sections II.C, II.J, and II.P, and II R of this preamble for further details on these issues. We are also considering establishing a CMS demonstration to evaluate possible ways of achieving such extended coverage, and we welcome all suggestions in this regard.

Throughout the preamble, we identify options and alternatives to the provisions we propose. We strongly encourage comments and ideas on our approach and on alternatives to help us design the Medicare Prescription Drug Benefit Program to operate as effectively and efficiently as possible in meeting the needs of Medicare beneficiaries.

Although this proposed rule specifies most of the requirements for implementing the new prescription drug program, readers should note that we are also issuing a closely related proposed rule that concerns Medicare Advantage plans, which will usually combine medical and prescription drug coverage. In addition, although this proposed rule specifies requirements related to PDP regions it does not designate those regions. Regional boundary decisions will be made through a separate process. Additional non-regulatory guidance on this and other topics will also be forthcoming.

We have considered and, in some places, have identified how this proposed rule intersects with other Federal laws, such as the Health Insurance Portability and Accountability Act (HIPAA) of 1996 Certification of Creditable Coverage and the HIPAA Privacy Rule. We are interested in learning how this proposed rule may interact with other legal obligations to which the PDP sponsors and MA–PD plans may be subject and intend to make appropriate changes in the final rule to address such issues.

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. Comments will be most useful if they are organized by the section of the proposed rule to which they apply. You can assist us by referencing the file code [CMS–4068–P] 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. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public Web site. Comments received timely will 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 410–786–7197.

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 (or toll-free at 1–888–293–6498) or by faxing to (202) 512–2250. The cost for each copy is $10. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**. This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access*, a service of the U.S. Government Printing Office. The Web site address is: *http://www.access.gpo.gov/fr/index.html.*

I. Background

(If you choose to comment on issues in this section, please include the caption "Background" at the beginning of your comments.)

A. Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended Title XVIII of the Social Security Act (the Act) by redesignating Part D as Part E and inserting a new Part D, which establishes the Voluntary Prescription Drug Benefit Program. (For ease of reference, we will refer to the new prescription drug benefit program as Part D of Medicare and the Medicare Advantage Program as Part C of Medicare.) We believe that the new Part D benefit constitutes the most significant change to the Medicare program since its inception in 1965. The addition of outpatient prescription drugs to the Medicare program reflects Congress' recognition of the fundamental change in recent years in how medical care is delivered in the U.S. It recognizes the vital role of prescription drugs in our health care delivery system, and the need to modernize Medicare to assure their availability to Medicare beneficiaries. This proposed rule is designed to ensure broad participation in the new benefit both by organizations that offer prescription drug coverage and by eligible beneficiaries. In conjunction with complementary improvements to the Medicare Advantage program, these changes should significantly increase the coverage and choices available to Medicare beneficiaries. Effective January 1, 2006, the new program

establishes an optional prescription drug benefit for individuals who are entitled to or enrolled in Medicare benefits under Part A and/or Part B. Beneficiaries who qualify for both Medicare and Medicaid (full-benefit dual eligibles) will automatically receive the Medicare drug benefit. The statute also provides for assistance with premiums and cost sharing to eligible low-income beneficiaries.

In general, coverage for the new prescription drug benefit will be provided through private prescription drug plans (PDPs) that offer drug-only coverage, or through Medicare Advantage (MA) (formerly known as Medicare+Choice) plans that offer integrated prescription drug and health care coverage (MA–PD plans). PDPs must offer a basic drug benefit. MA–PDs must offer either a basic benefit or broader coverage for no additional cost. If this required level of coverage is offered, the PDP or MA–PD plan may also offer supplemental benefits through enhanced alternative coverage for an additional premium.

All organizations offering drug plans will have flexibility in terms of benefit design, including the authority to establish a formulary to designate specific drugs that will be available within each therapeutic class of drugs, and the ability to have a cost-sharing structure other than the statutorily defined structure, subject to certain actuarial tests. The plans also may include supplemental drug coverage such that the total value of the coverage offered exceeds the value of basic prescription drug coverage. The specific sections of the Act that address the prescription drug benefit program are the following:

1860D–1 Eligibility, enrollment, and information.
1860D–2 Prescription drug benefits.
1860D–3 Access to a choice of qualified prescription drug coverage.
1860D–4 Beneficiary protections for qualified prescription drug coverage.
1860D–11 PDP regions; submission of bids; plan approval.
1860D–12 Requirements for and contracts with prescription drug plan (PDP) sponsors.
1860D–13 Premiums; late enrollment penalty.
1860D–14 Premium and cost-sharing subsidies for low-income individuals.
1860D–15 Subsidies for Part D eligible individuals for qualified prescription drug coverage.
1860D–16 Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.
1860D–21 Application to Medicare Advantage program and related managed care programs.
1860D–22 Special rules for employer-sponsored programs.
1860D–23 State pharmaceutical assistance programs.
1860D–24 Coordination requirements for plans providing prescription drug coverage.
1860D–41 Definitions; treatment of references to provisions in Part C.
1860D–42 Miscellaneous provisions.

Specific sections of the MMA that also relate to the prescription drug benefit program are the following:

Sec. 102 Medicare Advantage Conforming Amendments
Sec. 103 Medicaid Amendments
Sec. 104 Medigap
Sec. 109 Expanding the work of Medicare Quality Improvement Organizations to include Parts C and D.

B. Organizational Overview of Part 423

The regulations set forth in this proposed rule will be codified in the new 42 CFR part 423—Prescription Drug Benefit Program. There are a number of places in which statutory provisions in Part D incorporate by reference specific sections in Part C of Medicare (the Medicare Advantage program). The MA regulations appear at 42 CFR part 422. Since the same organizations that offer MA coordinated care plans will also be required to offer MA–PD plans, we believe it is appropriate to adopt the same organizational structure as part 422. MA coordinated care plans (defined in § 1851(a)(2)(A)) are a type of Medicare Advantage plan. For example, requirements relating to eligibility, election, and enrollment would be set forth in subpart B of new part 423, just as they now are set forth in subpart B of part 422. Therefore, wherever possible, we have modeled the proposed prescription drug regulations on the parallel provisions of the part 422 regulations.

The major subjects covered in each subpart of part 423 are as follows:

Subpart A, General Provisions: Basis and scope of the new part 423, Definitions and discussion of important concepts used throughout part 423, and sponsor cost-sharing in beneficiary education and enrollment-related costs (user fees).

Subpart B, Eligibility, Election, and Enrollment: Eligibility for enrollment in the Part D benefit, enrollment periods, disenrollment, application of the late enrollment penalty, approval of marketing materials and enrollment forms, and the meaning and documentation of creditable coverage. (Please note that other, related topics, are discussed in the following subparts: Subpart P, eligibility and enrollment for low-income individuals; Subpart S, provisions relating to the phase-down of state contributions for dual-eligible drug expenditures; Subpart F, calculation and collection of late enrollment fees; Subpart C, plan disclosure; Subpart Q, eligibility and enrollment for fallback plans; and Subpart T, the definition of a Medicare supplemental (Medigap) policy.)

Subpart C, Benefits and Beneficiary Protections: Prescription drug benefit coverage, service areas, network and out-of-network access, formulary requirements, dissemination of plan information to beneficiaries, and confidentiality of enrollee records. (Please note that actuarial valuation of the coverage offered by plans, as well as the submission of the bid, is discussed in subpart F. Access to negotiated prices is discussed in subpart C, while the reporting of negotiated prices is discussed in subpart G. Formularies are discussed in subpart C, while the appeals of formularies are discussed in subpart M. Incurred costs toward true out-of-pocket (TrOOP expenditures) are discussed in subpart C, while the procedures for determining whether a beneficiary's Part D out-of-pocket costs are actually reimbursed by insurance or another third-party arrangement are discussed in subpart J. Information that plans must disseminate to beneficiaries is discussed in subpart C, while Part D information that CMS must disseminate to beneficiaries is discussed in subpart B.)

Subpart D, Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans: Utilization controls, quality assurance, medication therapy, and fraud, waste and abuse, as well as rules related to identifying enrollees for whom medication therapy management is appropriate, consumer satisfaction surveys, and accreditation as a basis for deeming compliance.

Subpart E, Reserved.

Subpart F, Submission Of Bids and Monthly Beneficiary Premiums; Plan Approval: Bid submission, the actuarial value of bid components, review and approval of plans, and the calculation and collection of Part D premiums.

Subpart G, Payments To PDP Sponsors and MA Organizations Offering MA–PD Plans for All Medicare Beneficiaries for Qualified Prescription Drug Coverage: Data submission, payments and reconciliations for direct

subsidies, risk adjustment, reinsurance, and risk-sharing arrangements.

Subpart H, Reserved.

Subpart I, Organization Compliance With State Law and Preemption By Federal Law: Licensure, assumption of financial risk, solvency, and State premium taxes.

Subpart J, Coordination Under Part D With Other Prescription Drug Coverage: Applicability of Part D rules to the Medicare Advantage program, waivers available to facilitate the offering of employer group plans, and procedures to facilitate calculation of true out-of-pocket expenses and coordination of benefits with State pharmaceutical assistance programs and other entities that provide prescription drug coverage. (Please note that subpart C discusses, in more detail, coordination of benefits and the determination of which incurred beneficiary costs will be counted as TrOOP expenditures. Provisions relating to disenrollment for material misrepresentation by a beneficiary are discussed in subpart J and also referenced in subpart B.)

Subpart K, Application Procedures and Contracts With PDP Sponsors: Application procedures and requirements; contract terms; procedures for termination of contracts; reporting by PDP sponsors.

Subpart L, Effect of Change of Ownership or Leasing of Facilities During Term of Contract: Change of ownership of a PDP sponsor; novation agreements; leasing of a PDP sponsor's facilities.

Subpart M, Grievances, Coverage Determinations and Appeals: Coverage determinations by sponsors, exceptions procedures, and all levels of appeals by beneficiaries.

Subpart N, Medicare Contract Determinations and Appeals: Notification by CMS about unfavorable contracting decisions, such as nonrenewals or terminations; reconsiderations; appeals.

Subpart O, Intermediate Sanctions: Provisions concerning available sanctions for participating organizations.

Subpart P, Premiums and Cost-Sharing Subsidies for Low-Income Individuals: Eligibility determinations and payment calculations for low-income subsidies.

Subpart Q, Guaranteeing Access to a Choice of Coverage (Fallback Plans): Definitions; access requirements; bidding process; contract requirements.

Subpart R, Payments to Sponsors of Retiree Prescription Drug Plans: Provisions for making retiree drug payments to sponsors of qualified retiree prescription drug plans.

Subpart S, Special Rules for States—Eligibility Determinations for Subsidies and General Payment Provisions: State/Medicaid program's role in determining eligibility for low-income subsidy and other issues related to the Part D benefit.

In addition, in subpart T, this proposed rule also provides changes to: Part 403 relating to Medicare supplemental policies (Medigap), part 411 relating to exclusions from Medicare and limitations on Medicare payment (the physician self-referral rules), part 417 relating to cost-based HMOs, part 460 relating to PACE organizations, and part 442 relating to Medicaid amendments.

II. Provisions of the Proposed Rule

A. General Provisions

(If you choose to comment on issues in this section, please include the caption "General Provisions" at the beginning of your comments.)

1. Overview

Section 423.1 of subpart A specifies the general statutory authority for the ensuing regulations and indicates that the scope of part 423 is to establish requirements for the Medicare prescription drug benefit program. Section 423.4 of subpart A provides definitions for terms that appear in multiple sections of part 423 and whose meaning we believe should be featured prominently in order to aid the reader.

Consistent with the MMA statute, we are in many cases proposing procedures that parallel those now in effect under the Medicare Advantage program (for example the regulations concerning PDP and MA–PD plan contract and appeal requirements). We anticipate receiving at least two categories of comments on such provisions: (1) Recommendations for changes that would impact only the proposed Part D provisions (based for example on underlying differences between the MA and Part D programs); and (2) recommendations for changes that would impact both the MA and Part D provisions. Our goal is to maintain consistency between these two programs wherever possible; thus we will evaluate the need for parallel changes in the MA final rule when we receive comments on provisions that affect both programs.

2. Discussion of Important Concepts and Key Definitions (§ 423.4)

a. Introduction

For the most part, the definitions in the proposed rule are taken directly from section 1860D–41 of the Act. The definitions set forth in subpart A apply to all of part 423 unless otherwise indicated, and are applicable only for the purposes of part 423. For example, "insurance risk" applies only to pharmacies that contract with PDP sponsors under part 423. Definitions that have a more limited application are not included in subpart A, but instead are set forth within the relevant subpart of the regulations. For example, in subpart F, we have included all the definitions related to bids and premiums. The detailed definitions and requirements related to prescription drug coverage are included in subpart C, but because of their direct relevance to the bidding process they are also referenced in subpart F.

Following our discussion of important concepts, we provide brief definitions of terms that occur in multiple sections of this preamble and part 423. We believe that it is helpful to define these frequently occurring terms to aid the reader but that these terms do not require the extended discussion necessary in our section on important concepts.

b. Discussion of Actuarial Equivalence, Creditable Prescription Drug Coverage, PDP Plan Regions, Service Area, and User Fees

i. Discussion of the Meaning of Actuarial Equivalence

The concept of actuarial equivalence is applied in different contexts in Title I of the MMA, including: Determinations related to creditable coverage (subpart B), determinations related to the value of drug coverage and bid components (subpart F); and determinations related to subsidy payments for employer or union sponsors of qualified retiree health plans that include prescription drugs (subpart R). In very general terms, actuarial equivalence refers to a determination that, in the aggregate, the dollar value of drug coverage for a set of beneficiaries under one plan can be shown to be equal to the dollar value for those same beneficiaries under another plan. Given the various uses for this term in the Part D context, we propose the following relatively general definition:

"Actuarial equivalence" means a state of equivalent values demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D–11(c) of the Act and § 423.265(c)(3) of this part.

This concept is discussed in further detail below and in those sections of this preamble, such as section II.F, where actuarial equivalence comes into play.

According to section 1860D–11(c) of the Act, we will develop processes and methods using generally accepted actuarial principles and methodologies for determining the actuarial valuation of prescription drug coverage. Although the statute sets forth specific requirements for actuarial equivalence and valuation, there is no formal definition of actuarial equivalence. Also, in each of the contexts described above, we must address the question of whether actuarial equivalence is determined from the perspective of the plan, or the beneficiary.

In the sections dealing with actuarial equivalence throughout this proposed rule, we have tried to avoid being overly prescriptive, in order to maintain flexibility to adjust and refine the needed valuation processes as we gain more experience with the administration of the new benefit. Thus, we fully expect to provide additional guidance in the future on these provisions.

ii. Discussion of the Meaning of Creditable Prescription Drug Coverage

The types of coverage considered creditable prescription drug coverage in proposed 42 CFR 423.4 are discussed in the preamble to subpart B.

In the preamble to subpart T, we discuss in more detail the effect of Part D on Medigap policies, one of the forms of drug coverage that may be creditable if it meets the actuarial equivalence test.

iii. Prescription Drug Plan Regions

Prescription drug plan regions are areas in which a contracting PDP plan must provide access to covered Part.D drugs. Although we have included specifications for regions in § 423.112, the regions themselves are not set forth in this proposed rule. To the extent feasible, we intend that the PDP regions will be consistent with the regions established for the MA program (*see* § 422.455 of the MA proposed rule). In establishing the regions for both programs, we will use the results of a market survey that includes the examination of current insurance markets. MMA specifically states that there will be no fewer than 10 regions and no more than 50 regions, not including the territories. For a further discussion of the PDP regions, see section II.C of this preamble.

iv. Service Area

Medicare beneficiaries are eligible to enroll in a PDP or an MA–PD plan only if they reside in the PDP's or MA–PD plan's "Service Area." As noted above, for PDPs, this is the Region established by CMS pursuant to proposed § 423.112, within which the PDP is responsible for providing access to the Part D drug benefit in accordance with the access standards in proposed § 423.120. Under the MA program, an MA plan's Service Area is defined in § 422.2. For coordinated care plans, the definition of "service area" expressly includes the condition that the service area is an area in which access is provided in accordance with access standards in § 422.112.

Prior to this rulemaking, we had not considered how this access requirement in the MA plan Service Area definition would apply to a jail or prison within the boundaries of a plan Service Area. Beneficiaries incarcerated there clearly would not have access to services as required under § 422.112. Such an area thus would not meet the coordinated care plan definition of "Service Area," which requires that such access standards be met. This issue never arose under the MA program because there would be no reason for an individual to enroll in an MA plan while incarcerated, since services typically are all covered by the jail or prison and the prisoner could always enroll in an MA plan without penalty upon being released.

We have however, considered this issue in the context of Part D benefits. If a prison or jail is located within the boundaries of a PDP region, or an MA PDP-plan Service Area, a Medicare-eligible individual incarcerated there technically would reside within the service area, and be eligible to enroll to receive Part D benefits. Under this scenario, such an individual then would have to pay a penalty for not enrolling while in prison if he or she enrolled in Part D upon being released.

We do not believe this to be an equitable result, as the beneficiary would face the choice of paying for services he or she would not be receiving, or paying a penalty at a later time. We also do not believe that it would be appropriate for a PDP or MA–PD plan to receive monthly Part D payments for such an individual, since drugs typically would be covered for the individual by the prison or jail. Such payments would represent an unwarranted "windfall" for services the PDP or MA–PD would not have to deliver.

In focusing on this situation, we have decided to propose that for purposes of enrolling in Part D with a PDP, or under an MA–PD plan, the definition of Service Area that governs eligibility to enroll is the area within which the Part D access standards under § 423.120 are met.

Beneficiaries in jail or prison do not have access to pharmacies available as required under § 423.120. Therefore, such beneficiaries would not be considered to be in a PDP or MA–PD plan's Service Area for purposes of enrolling in Part D. Incarcerated individuals accordingly would not be assessed a late penalty when they enroll in Part D (either with a PDP or MA–PD plan) upon being released.

We note that the analysis above would apply equally to a beneficiary who lives abroad, and does not reside within the boundaries of any PDP Region or MA–PD Service Area.

v. Sponsor Cost-Sharing in Beneficiary Education and Enrollment Related Costs—User Fees (§ 423.6)

The last section of subpart A proposes regulations implementing the user fees provided for in section 1857(e)(2) of the Act, as incorporated by section 1869D–12(b)(3)(D) of the Act. These fees are currently required of MA plans for the purpose of defraying part of the ongoing costs of the national beneficiary education campaign that includes developing and disseminating print materials, the 1–800 telephone line, community based outreach to support State health insurance assistance programs (SHIPs), and other enrollment and information activities required under section 1851 of the Act and counseling assistance under section 4360 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 103–66).

The MMA expands the user fee to apply to PDP sponsors as well as MA plans. The expansion of the application of user fees recognizes the increased Medicare beneficiary education activities that we would require as part of the new prescription drug benefit. In 2006 and beyond, user fees would help to offset the costs of educating over 41 million beneficiaries about the drug benefit through written materials such as a publication describing the drug benefit, internet sites, and other media.

In fiscal year 2006 and thereafter, the MMA authorizes up to $200,000,000 to be spent on beneficiary education and enrollment activities reduced by the fees collected from MA organizations and PDP sponsors in that fiscal year. In each year, the total amount of collected user fees could not exceed the estimated costs in the fiscal year for carrying out the enrollment and dissemination of information activities in the MA and Part D prescription drug programs or the applicable portions (described below) of $200,000,000, whichever is less.

Finally, these user fee provisions would establish the applicable aggregate

contribution portions for PDP sponsors and MA organizations. There are two calculations. First, we calculate the PDP sponsors' applicable portion as a group; their portion is the estimate of the total proportion of expenditures under Title 18 that are attributable to expenditures made to PDP sponsors for prescription drugs under Part D. The applicable portion of the user fee for MA organizations would be equal to the total expenditures for Medicare Part C, as well as for payments under Part D that are made to MA organizations, as a percent of Title 18 expenditures. Then, we calculate the fees charged to individual PDP sponsors and MA plans.

c. Definitions of Frequently Occurring Terms

Full-benefit dual eligible beneficiary means an individual who meets the criteria established in § 423.772 (subpart P), regarding coverage under both Part D and Medicaid.

Insurance risk means, for a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs or productivity).

MA means Medicare Advantage, which refers to the program authorized under Part C of the Act.

MA–PD plan means an MA plan that provides qualified prescription drug coverage.

Medicare prescription drug account means the account created within the Federal Supplementary Medical Insurance Trust Fund for purposes of Medicare Part D.

Part D eligible individual means an individual who is entitled to or enrolled in Medicare benefits under Part A and/or Part B.

Prescription drug plan or *PDP* means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in § 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K.

PDP region means a prescription drug plan region as determined by CMS under § 423.112.

PDP sponsor means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part for that sponsor.

d. Financial Relationships Between PDP Sponsors, Health Care Professionals and Pharmaceutical Manufacturers

The financial relationships that exist between or among PDP sponsors, health care professionals (including physicians and pharmacists), and/or pharmaceutical manufacturers may be subject to the anti-kickback statute and, if the relationship involves a physician, the Stark statute. These financial relationships could potentially implicate the anti-kickback and physician self-referral statutes, therefore, they should be structured appropriately to comply with legal requirements. Nothing in this regulation should be construed as implying that financial relationships described in the regulations meet the requirements of the anti-kickback statute or physician self-referral statute or any other applicable Federal or State law or regulation. All such relationships must comply with these laws. Therefore, PDPs are not prevented from paying pharmacists, for instance, for medication therapy management, provided that the PDPs do not violate anti-kickback and physician self-referral laws.

B. Eligibility and Enrollment

1. Eligibility To Enroll (§ 423.30)

The MMA established section 1860D–1 of the Act, which includes the eligibility criteria an individual must meet in order to obtain prescription drug coverage by enrolling in a PDP plan or an MA–PD plan. In accordance with section 1860D–1(a)(3) of the Act, a "Part D eligible individual" is defined as an individual who is entitled to or enrolled in Medicare benefits under Part A or enrolled in Part B. In order to enroll in a PDP plan, the individual must reside in the plan's service area, and cannot be enrolled in an MA plan, other than an MSA plan or private fee-for-service plan that does not provide qualified prescription drug coverage. This residency requirement flows from the statute's direction for us to use enrollment rules similar to MA (which has such a requirement) and the drug benefit's basic structure, which designates regions within which PDPs are to provide services.

Section 1860D–1(b)(1)(B)(i) requires that we adopt a residency requirement similar to the Part C residency requirements under section 1851(b)(1)(A) of the Act, which stipulates that a beneficiary is eligible to enroll in a plan only if the beneficiary resides in the plan's service area. Because a PDP's service area may consist only of one or more PDP regions, individuals who reside outside of the United States would be ineligible to enroll in a PDP or MA–PD plan. Consequently, these individuals are ineligible to enroll in Part D.

Under section 1860D–1(b)(1)(B)(i) of the Act, which incorporates into Part D section 1851(b)(1)(A) of the Act, the Secretary may provide exceptions to the general rule that an individual is eligible to enroll in a PDP serving the geographic area in which the individual resides. We note also that section 1860D–1(b)(1)(B) of the Act directs us to adopt enrollment rules "similar to," but not necessarily identical to, those under Part C, giving us some flexibility to modify the Part C enrollment rules as appropriate. We believe that incarcerated individuals should be ineligible to enroll in a PDP. We therefore provide in § 423.4 of the proposed rule that a PDP's service area would exclude areas in which incarcerated individuals reside (that is, a correctional facility).

Were we not to adopt these rules, individuals who are incarcerated or who live outside of the U.S. and who fail to enroll in a PDP or MA–PD when first eligible, or remain enrolled thereafter, would face a late enrollment penalty if they later decide to enroll in Part D. In accordance with section 1860D–13(b) of the Act and § 423.46 of the proposed rule, individuals are subject to a late penalty if there is a continuous period of eligibility of at least 63 days, beginning after the termination of the individual's initial enrollment period, during which the individual was not enrolled in a PDP or MA–PD plan. Thus, in order to avoid such a penalty, these individuals would have to enroll in a PDP or MA–PD, but would not be able to avail themselves of the plan's services while they are incarcerated or outside of the plan's service area. Under our proposed rule, individuals residing outside the U.S. and incarcerated individuals would be ineligible to enroll in a PDP. Thus, there would not be a continuous period of eligibility of at least 63 days during the time of the individuals' residency abroad or incarceration. Consequently, these individuals would not need to enroll in Part D in which they would not be able to receive services or benefits in order to avoid the late penalty.

Generally, a Part D eligible individual enrolled in an MA plan that does not provide qualified prescription drug coverage (that is, an MA–PD plan) may not enroll in a PDP; however, there are two exceptions. Section 1860D–1(a)(1)(B) of the Act permits a Part D eligible individual who is enrolled in either a MA private fee-for-service plan (as defined in section 1859(b)(2) of the

Act) that does not provide qualified prescription drug coverage or an MSA plan (as defined in section 1859(b)(3) of the Act) to enroll in a PDP. We have provided for these exceptions in § 423.30(b) of the proposed rule.

Except as provided above, in accordance with section 1860D–1(a)(B)(i) of the Act and as provided in 423.30(c) of the proposed rule, a Part D eligible individual who is enrolled in an MA–PD plan must obtain prescription drug coverage through that plan. In order to enroll in an MA–PD plan, a Part D eligible individual must also meet the eligibility and enrollment requirements of the MA–PD plan as provided in 42 CFR 422.50 through 422.68 of proposed regulations.

As discussed in § 423.859, section 1860D–3(a)(1) of the Act requires the Secretary to ensure that each Part D eligible individual will have available a choice of enrollment in at least two qualifying plans, at least one of which must be a PDP. If this choice is not available, in accordance with section 1860D–2(b) of the Act, a fallback prescription drug plan will be made available and individuals will be eligible to enroll in that fallback plan if eligible for Part D. As discussed in § 423.855 of the proposed rule, a fallback prescription drug plan is a prescription drug plan offered by an eligible fallback entity that provides only standard prescription drug coverage (without supplemental benefits), provides access to negotiated prices, and meets the requirements for PDP sponsors (except as otherwise indicated), and other requirements specified by CMS.

2. Part D Enrollment Process (§ 423.34)

Section 1860D–1(b)(1) of the Act requires that we establish a process for the enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans. The statute further requires that this process use rules similar to, and coordinated with, the enrollment, disenrollment, termination, and change of enrollment rule for MA–PD plans under certain provisions of section 1851 of the Act. As such, we have incorporated, where possible, the MA enrollment and disenrollment requirements provided under 42 CFR 422.50–422.80. In accordance with section 1860D–1(b)(1)(C) of the Act, we would establish a process to automatically enroll a full benefit dual-eligible individual (as defined under section 1935(c)(6) of the Act) who has failed to enroll in a PDP or MA–PD plan by either the end of the individual's initial enrollment period or upon becoming dual eligible after his/her initial enrollment period. Prior to this automatic enrollment process, a widespread education and information campaign (described later in this subpart at § 423.48) will equip full benefit dual eligible individuals with information designed to explain options and encourage these individuals to take an active role in their enrollment rather than wait to be automatically enrolled.

An full benefit dual eligible individual who fails to enroll in a PDP or MA–PD would be automatically enrolled into a prescription drug plan that has a monthly beneficiary premium equal to or below the subsidy amount available to low-income beneficiaries in accordance with section 1860D–14(a)(1)(A) of the Act. This premium may not exceed the low-income benchmark premium amount established under section 1860D–14(b)(2) of the Act. The calculation of the low-income benchmark premium is further described in § 423.780(a) of the proposed rule.

Section 1860D–1(b)(1)(c) of the Act also directs us to enroll full benefit dual eligible individuals who fail to elect a PDP or MA–PD plan on a random basis if more than one PDP within an area has a monthly beneficiary premium equal to or below the low-income benchmark premium. To ensure that each full benefit dual eligible individual will have access to at least one PDP in each region, section 1860D–14(b)(3) of the Act provides that the premium subsidy amount for eligible individuals (including full benefit dual eligible individuals) cannot be less than the lowest monthly beneficiary premium for a PDP in a region. A more detailed discussion of the premium subsidy is found at § 423.780 of the proposed rule.

Two major issues require resolution because the statutory provisions are inherently contradictory in their requirements. The first is how to provide qualified prescription drug coverage to those full benefit dual eligible individuals who are in an MA–only plan and who have failed to enroll in a PDP or MA–PD plan. The second issue is how to provide qualified prescription drug coverage to a full benefit dual eligible enrolled in the Medicare Advantage program when the premium for the MA–PD plan(s) offered by an individual's MA organization exceeds the low income benchmark premium. We discuss each of these issues below and request comments on how best to reconcile these conflicting provisions.

A literal reading of section 1860D–1(b)(1)(C) of the Act would seem to preclude automatic enrollment of full benefit dual eligible individuals into MA–PD plans. The language requires automatic enrollment into a "prescription drug plan" whose premium meets the aforementioned requirements. However, section 1860D–1(a)(1)(B)(ii) of the Act precludes Part D eligible individuals enrolled in MA (not MA–PD) plans (other than those in some private fee-for-service or MSA plans) from enrolling in PDPs. To reconcile this apparent conflict, we propose that that the reference in section 1860D–1(b)(1)(C) of the Act to "prescription drug plans" be interpreted as including both PDPs and MA–PD plans, thereby allowing automatic enrollment of an MA full benefit dual eligible into a MA–PD plan offered by the same MA organization offering his or her MA plan if the basic premium for such plan does not exceed the low-income benchmark premium amount.

General principles of statutory interpretation require us to reconcile two seemingly conflicting statutory provisions whenever possible, rather than allowing one provision to effectively nullify the other provision. Consequently, when a statutory provision may reasonably be interpreted in two ways, we have an obligation to adopt the interpretation that harmonizes and gives full effect to competing provisions of the statute. The rationale for automatic enrollment is to ensure that full-benefit dual eligible individuals receive outpatient drug coverage under Part D because Medicaid will no longer provide medical assistance for covered Part D drugs to such individuals. For full benefit dual eligible individuals enrolled in MA plans, we believe this objective is best accomplished by enrolling them in one of the MA–PD plans offered by their MA organization.

To the extent that the MA–only portion of the MA–PD plan parallels the coverage under a full benefit dual eligible individual's MA plan, enrolling the individual in the MA–PD plan would be similar to permitting the individual to remain enrolled in the MA plan while simultaneously enrolling the individual in a PDP. In other words, enrolling the individual in a MA–PD plan offered by the same MA organization is, in effect, simply adding qualified prescription drug coverage to the individual's MA benefits. For this reason, we believe the reference to "prescription drug plans" in section 1860D–1(b)(1)(C) of the Act should be interpreted as requiring enrollment of a full benefit dual-eligible into a plan that will provide the individual with Part D drug benefits in addition to any other benefits the individual receives under

Medicare, whether through Medicare Part A and/or Part B, or through enrollment in the Medicare Advantage program under Part C. We believe this interpretation promotes the policies underlying sections 1860D–1(b)(1)(C) and 1860D–1(a)(1)(B)(ii) of the Act, giving full effect to both statutory provisions. However, in the above situation, if the basic premium for the MA–PD plan exceeds the low-income benchmark premium amount, under section 1860D–1(b)(1)(C) of the Act, we could not permit automatic enrollment of a full-benefit dual eligible into that MA–PD plan.

One possible solution for an MA full benefit dual eligible enrolled in an MA organization in which all of its MA–PD premiums exceed the allowable amount might be to allow that individual to remain in the MA plan and to automatically enroll him or her into a PDP that meets the premium requirements. However, according to section 1860D–1(a)(1)(A) of the Act, only a part D eligible individual who is not enrolled in an MA plan may enroll in a PDP, thereby precluding this option.

Another possibility would be to involuntarily withdraw MA full benefit dual eligible individuals from their MA plan, which would default them to Original Medicare and then automatically enroll them into a PDP. However, there is no statutory authority to involuntarily disenroll the individual from his or her MA plan. In fact, we believe doing so would violate section 1851(c)(3)(B) of the Act, which provides that an individual who makes an MA election is considered to have continued to have made this election until he or she voluntarily changes the election, or the plan is discontinued or no longer serves the individual's service area.

Enrolling an MA full dual eligible individual whose MA organization's MA–PD plan premiums exceed the benchmark amount into a MA–PD plan offered by another MA organization whose premiums are equal to or below the benchmark would be problematic as well since this would violate section 1851(c)(3)(B) of the Act. In addition, this would not be possible if the monthly premium amount of any available MA–PD plan is greater than the low-income benchmark premium amount. Similarly, we believe that requiring these full benefit dual eligibles to disenroll from the Medicare Advantage program so that we may automatically enroll them into less expensive PDPs would violate section 1851(c)(3)(B) of the Act.

One last option would be to allow the beneficiary to go without outpatient prescription drug coverage unless the beneficiary chooses a MA–PD plan on his or her own accord. We do not see this as a reasonable option because it appears to violate section 1860D–1(b)(1)(C) of the Act and would leave a vulnerable beneficiary without outpatient drug coverage. While the statute prescribes an automatic enrollment process for full benefit dual eligibles who fail to elect a PDP or MA–PD plan, it is important to note that such full benefit dual eligible individuals may decline the enrollment or change the enrollment if they so choose. One option for such a process could be to provide notice to the individual to allow him or her to choose another option. Since the statute affords full benefit dual eligible individuals a special election period, they would be able to make a change in their election of PDP or MA–PD plans. Furthermore, while automatic enrollment of these individuals could be restricted to plans with premiums at or below the low-income benchmark premium, these dual eligible individuals would not be restricted to electing only such plans. However, if they select a high premium plan, they would be responsible for paying the difference between the premium and the low-income subsidy amount.

In implementing the automatic enrollment process for full benefit dual eligible individuals, we are considering which entity is best suited to perform the automatic and random enrollment function. The options include CMS or the State performing this function, or a contracted entity or entities on their behalf. If we (or a contractor on our behalf) performed the auto assignment, we would expect consistent, clear oversight of the process, thus making the process uniform nationally; this might also reduce the need to transmit data from CMS to the States. However, this would be highly dependent on receiving timely, accurate Medicaid eligibility data from States and would also make us responsible for a new national workload of indeterminate size. An alternative is for States (or their contracted entities) to be responsible for performing the automatic enrollment. This approach may be appropriate because States have experience with random assignments through their Medicaid programs and have more immediate access to changes in Medicaid eligibility. We would define random assignment, establish standards for notification, and so forth, to ensure consistency. If we were to pursue this option, we could consider this function as necessary for the proper and efficient administration of the State plan. We would need to provide States with accurate and timely Part D data. States could be compensated for this effort through Federal financial participation (FFP) in their administrative expenses or through contractual or other arrangements. We invite comment on the most appropriate method of performing automatic assignment of dual eligibles and the appropriate entity to do so.

3. Part D Enrollment Periods (§ 423.36)

a. General Enrollment Periods

The MMA directs us to establish three coverage enrollment periods: (1) The initial enrollment period; (2) the annual coordinated election period; and (3) special enrollment periods (SEPs). Generally, in accordance with section 1860D–1(b)(2)(B) of the Act, the initial enrollment period for Part D is the same as the initial enrollment period established for Part B. Specifically, this period is the seven-month period that begins three months before the month an individual first meets the eligibility requirements for Part B and ends three months after that first month of eligibility. However, if an individual's initial enrollment period for Part B ends prior to May 15, 2006, his or her initial enrollment period under Part D will be extended to May 15, 2006. In addition, as part of the implementation of the Part D program, and in accordance with section 1860D–1(b)(2)(A) of the Act, we would establish an initial enrollment period for Part D from November 15, 2005, until May 15, 2006, for those individuals who are already eligible to enroll in a Part D plan as of November 15, 2005.

Examples:

Month individual first entitled to part A or enrolls in part B	Initial enrollment period for part D
June 1, 2005	November 15, 2005–May 15, 2006.
November 1, 2005	November 15, 2005–May 15, 2006.
December 1, 2005	November 15, 2005–May 15, 2006.

Month individual first entitled to part A or enrolls in part B	Initial enrollment period for part D
January 1, 2006	November 15, 2005–May 15, 2006.
February 1, 2006	November 15, 2005–May 31, 2006.
May 1, 2006	February 1, 2006–August 31, 2006.
June 1, 2006	March 1, 2006–September 30, 2006.

In accordance with section 1860D–1(b)(1)(B)(iii) of the Act, the annual coordinated election period for Part D is concurrent with the annual coordinated election period for the Medicare Advantage program under section 1851(e) of the Act. It is during this annual period in which all PDP plans must open enrollment to Medicare beneficiaries. For coverage beginning in 2006, the annual coordinated election period begins on November 15, 2005, and ends on May 15, 2006. As a result, the initial enrollment period for individuals who are eligible to enroll in a Part D plan as of November 15, 2005 and the annual coordinated election period will run concurrently during this time frame. The annual coordinated election period for MA and MA–PD plans will also occur during this time. In accordance with section 1851(e)(3)(B)(iv) of the Act, § 423.36(b)(2) of our proposed rule provides that, for 2007 and subsequent years, the annual coordinated election period would be November 15 through December 31 for coverage beginning on January 1 of the following year.

b. Special Enrollment Periods

The MMA also establishes special enrollment periods (SEPs). Special enrollment periods allow an individual to disenroll from one PDP and enroll in another PDP. Special enrollment periods are available as follows:

(i) Involuntary Loss, Reduction, or Non-notification of Creditable Coverage

As discussed below in § 423.56, Part D eligible individuals who fail to enroll in Part D during their initial enrollment period will not be subject to late penalties if they had creditable prescription drug coverage during the time they were not enrolled in Part D. Part D eligible individuals who involuntarily lose creditable prescription drug coverage, such as the loss of employment and associated health benefits, or the loss of coverage due to the death of a spouse, would have an SEP to enroll in a Part D plan, in accordance with section 1860D–1(b)(3)(A) of the Act. Pursuant to section 1860D–1(b)(3)(A)(iii) of the Act, this SEP does not apply when the individual loses creditable coverage because of his or her failure to pay premiums for that coverage, since this would be considered a voluntary loss of coverage for purposes of this section.

The SEP would also apply if the individual was never informed that the coverage that he or she had was not creditable or if current creditable coverage was reduced so that it was no longer creditable coverage under this part. In cases where the coverage is reduced, the SEP applies only when the current creditable coverage is reduced by the issuer or group through which the individual has such coverage. Therefore, if the covered individual voluntarily reduces the coverage, for example, to reduce his or her premium costs, this SEP would not apply because that action is voluntary.

(ii) Erroneous Enrollment

Section 1860D–1(3)(B) of the Act provides for an SEP for an individual who has been subject to enrollment errors, similar to those provided for both Part A and Part B under section 1837(h) of the Act. We are using the same language provided for this SEP at § 423.36(c)(3) of the proposed rule as provided under § 407.32, which establishes a special enrollment period for enrollment errors for Part B. Specifically, § 407.32 refers to misrepresentation, inaction, or error by the Federal government that affects an individual's enrollment rights.

(iii) Individuals With Medicaid Coverage

Section 1860D–1(b)(3)(D) of the Act provides an SEP for an individual who is eligible for both Medicare and full benefits under a State's Medicaid program, as those individuals are described in section 1935(c)(6) of the Act. This would be available to individuals who are determined full benefit dual eligible after the initial enrollment period. This would also provide these individuals who have been automatically assigned to a plan the opportunity to change PDPs or MA–PDs at any time.

(iv) Individuals Age 65

During the Part D eligible individual's initial enrollment period, the individual has several options available, including remaining in original Medicare and enrolling in a PDP or enrolling in an MA–PD plan. Section 1860D–1(b)(3)(E) of the Act provides an SEP to an individual who enrolls in a MA–PD plan upon first becoming eligible for benefits under Part A at age 65 and then discontinues that enrollment and elects coverage under original Medicare and a PDP at any time during the 12-month period beginning on the effective date of the MA–PD plan election. This specific provision applies only to an individual who elects an MA–PD plan during his or her initial enrollment period, as defined under section 1837(d) of the Act, which surrounds his or her 65th birthday. This SEP will only apply to individuals who elect an MA–PD plan, and does not pertain to individuals who elect an MA-only plan.

(v) Exceptional Circumstances

Finally, in addition to providing for special enrollment periods as mentioned above, section 1860D–1(b)(3)(C) of the Act authorizes us to establish SEPs in exceptional circumstances. CMS has historically included in regulation those SEPs that have been specifically named in the statute and established the SEPs for exceptional circumstances in our manual instructions rather than through regulation. While we intend to continue establishing these exceptional SEPs through this process, we seek public input on other SEPs that should be considered through our manual process.

In addition to those SEPs established by the MMA, we intend to apply certain SEPs established under the MA program. The SEPs that will be included from the MA program under this section will include the following conditions—

(1) The PDP terminates its service area or is terminated in the area in which the individual resides;

(2) The individual moves out of the plan's service area; or

(3) The individual demonstrates to us, in accordance with guidelines that we establish, that the PDP offering the plan substantially violated a material provision of its contract with regard to the individual or the organization, its agent, representative, or the PDP materially misrepresented the plan's

provisions in marketing the plan to the individual.

There is a disconnect issue between the enrollment period provided for individuals eligible to enroll in a Part D plan at section 1860D–1(b)(1)(iii) of the Act and the open enrollment periods provided for MA eligible individuals under section 1851(e)(2) of the Act that we believe can be addressed through a special election period. Section 1851(e)(2) of the Act provides for an open enrollment period for MA eligible individuals in which they may change their election once. Beginning in 2006, this period is limited to 6 months from January through June and in 2007, to 3 months, from January through March. The MMA, at Section 102 (a)(6), further limits individuals' elections during this open enrollment period to a specific "type" of plan. Specifically, an individual who is enrolled in an MA–PD plan may elect another MA–PD plan or elect original Medicare and a PDP, but cannot elect an MA–only plan. However, there is no corresponding enrollment period that would allow the individual to elect a PDP during this time. We propose to remedy this situation by establishing an SEP for these individuals under our aforementioned authority to establish SEPs for exceptional circumstances.

In addition, section 1851(e)(2)(D) of the Act provides for a continuous open enrollment period for institutionalized individuals throughout the year. We also propose establishing an SEP for this through our exceptional circumstance authority in our manual instructions.

4. Effective Dates of Coverage and Change of Coverage (§ 423.38)

Section 1860D–1(b)(1)(B)(iv) of the Act authorizes us to apply the effective date requirements provided under the MA program at section 1851(f) of the Act. The three enrollment periods provided under Part D are the initial enrollment period, the annual coordinated election period, and special enrollment periods. The effective dates for these enrollment periods are as follows:

a. Initial Enrollment Period

In accordance with section 1851(f)(1) of the Act, as incorporated into Part D under section 1860D–1(b)(1)(B)(iv) of the Act, an enrollment made during the initial enrollment period will generally be effective the first day of the calendar month following the month in which the individual enrolled in Part D. An enrollment made prior to the month of entitlement to or enrollment in Medicare benefits under Part A and/or Part B is effective the first day of the month the individual is entitled to or enrolled in Part A or Part B. Since the Part D provisions are not effective until January 1, 2006, we would clarify that in no case may enrollment in Part D be effective prior to this date. We are also clarifying that initial enrollments made between November 15 and December 31, 2005, will be effective January 1, 2006. An enrollment made during or after the month of entitlement to or enrollment in Medicare benefits under Part A and/or Part B is effective the first day of the calendar month following the month in which the enrollment in Part D is made. We have reflected these provisions in § 423.38(a) of our proposed rule.

b. Annual Coordinated Election Period

In accordance with section 1851(f)(2) of the Act, as incorporated into Part D under section 1860D–1(b)(1)(B)(iv) of the Act, an enrollment made during the annual coordinated election period is effective as of the first day of the following calendar year, that is, January 1st. We have reflected this provision in § 423.38(b) of the proposed rule.

c. Special Enrollment Period

A special enrollment period is effective in a manner that we determine to ensure continuity of health benefits coverage. We have reflected this provision in § 423.38(c) of the proposed rule.

5. Coordination of Beneficiary Enrollment and Disenrollment Through PDPs (§ 423.42)

Section 1860D–1(b)(1)(A) of the Act authorizes us to establish a process for enrollment in and disenrollment from prescription drug plans. We have outlined the coordination of enrollment and disenrollment through PDP organizations in the regulations at § 423.42. A Part D eligible individual who wishes to make, change, or discontinue an enrollment during applicable enrollment periods may do so by filing an enrollment with the PDP directly. We envision a paper enrollment form process and recognize the opportunity for other possible mechanisms that may prove secure, convenient for beneficiaries, and valuable to the efficient administration of the program. We request comments on other possible enrollment mechanisms that address data security and integrity, privacy and confidentiality, authentication, and other pertinent issues.

We have added a provision at § 423.42(e) of the proposed rule that would ensure that beneficiaries are not disenrolled from their PDP at the end of the calendar year. We are including this provision to clarify that beneficiaries will remain enrolled in their PDP without having to actively re-enroll in that PDP at the beginning of the calendar year.

6. Disenrollment by the PDP (§ 423.44)

Section 1860D–1(b)(1)(B) of the Act generally directs us to use disenrollment rules similar to those established under section 1851 of the Act. We are applying the provisions of section 1851(g)(3) of the Act that provide authority for the basis of terminations for MA plans. We codify these in 42 CFR 422.74. The disenrollment provisions for PDPs are outlined in § 423.44 of our proposed rules, including the basis for disenrollment—both optional and required—and guidance for notice requirements.

Specifically, a PDP is required to disenroll an individual who dies, who no longer resides in the PDP's service area, loses entitlement or enrollment to Medicare benefits under Part A and is no longer enrolled in Part B, or who knowingly misrepresents to the PDP that he or she has received or expects to receive reimbursement for covered Part D drugs through third-party coverage. A PDP is also required to disenroll an individual if the PDP's contract is terminating.

We are particularly interested in receiving comments about the requirement to disenroll individuals from a PDP if they no longer reside in the service area. Under the MA rules at 42 CFR 422.74, individuals who are out of the service area for more than 6 months will be disenrolled, unless the MA plan offers visitor or traveler benefits. We recognize the inherent difference between PDPs and MA plans (in particular, the range of services each provides) and that it may not be reasonable to apply the disenrollment requirements established under MA in the same way for PDPs. For example, while we have a limit on the length of time an MA enrollee may be out of the service area, this limit may not be necessary as long as there are specific assurances from the PDP that individuals will have access to PDP benefits while out of the area (provided the individual remains in the United States). For example, a regional PDP may either have a corporate or other relationship with a PDP in another region or have a network of pharmacies in other regions (or nationwide) that would provide access to prescription drugs outside of the region on the same basis as in-network pharmacies within the enrollee's region of residence. We

would appreciate any comments on this area.

In addition to providing requirements for disenrollments that are required by the PDP, we also provide under § 423.44(d) of our proposed rule that PDPs may disenroll individuals who do not pay monthly premiums or whose behavior is disruptive. However, we believe there are important beneficiary implications for those PDPs who disenroll individuals for these reasons. An individual who is disenrolled for failure to pay monthly PDP premiums, disruptive behavior, or misrepresentation of third party reimbursement will not be provided an SEP permitting him or her to enroll in another PDP. Since the individual generally will not be able to enroll in either a PDP or an MA–PD until the next annual coordinated election period, he or she may be subject to late enrollment penalties under § 423.46 of the proposed rule.

We plan to establish re-enrollment guidelines under the MA program for optional disenrollment for nonpayment of premium and disruptive behavior. We recognize, however, that this policy may not be appropriate for PDPs. If the individual is prohibited from re-enrolling in each of the MA plans available in an area, original Medicare is always available to provide and deliver services to that that individual. Under the PDP infrastructure, if the individual was prohibited from re-enrolling in each PDP available, there is no other option available. We would appreciate comments regarding the applicability of prohibiting re-enrollment in a PDP.

As with the MA program, PDP sponsors will be required to provide proper notice to the beneficiary and afford him or her due process in accordance with the procedures outlined in our manual instructions. For example, a PDP that wishes to disenroll a beneficiary for disruptive behavior must receive prior approval from CMS and must demonstrate to CMS'' satisfaction that it has made a good faith effort to resolve the issue prior to requesting the disenrollment. CMS reviews these requests on a case-by-case basis, taking into account all of the facts and circumstances of a particular case, prior to making its decision. PDP sponsors must apply their policies for optional disenrollment for failure to pay premiums and disruptive behavior consistently among individuals enrolled in their plans, unless we permit otherwise, and must do so consistent with applicable laws regarding discrimination on the basis of disability.

7. Late Enrollment Penalty (§ 423.46)

Section 1860D–13(b) of the Act establishes late enrollment penalties for beneficiaries who fail to maintain creditable prescription drug coverage for a period of 63 days following the last day of an individual's initial enrollment period and ending on the effective date of enrollment in a PDP or MA–PD. The calculation of the amount of the penalty is described in § 423.286(d)(3) of our proposed rule. Specifically, the penalty amount for a Part D eligible individual for a continuous period of eligibility is the greater of an amount that CMS determines is actuarially sound for each uncovered month in the same continuous period of eligibility that is subject to this penalty; or 1 percent of the base beneficiary premium for each uncovered month in the period. An uncovered month is any month in which individual does not have creditable coverage at any time during that month. Because Part D is a voluntary benefit, it is susceptible to selection bias, where predominantly sicker beneficiaries, with higher than average prescription drug expenses enroll, and healthier, less expensive beneficiaries defer participation. Such a dynamic would make the initial premium levels higher than Congress expected at the time of MMA's enactment. Left unchecked, the selection bias would be exacerbated, potentially resulting in what has been called an insurance "death spiral." To ensure the affordability of the Part D benefit and the stability of the associated premium, we believe there is a strong public policy value in creating an incentive for immediate, widespread enrollment in this new, heavily subsidized benefit.

The process for documenting creditable coverage is discussed in § 423.56 of the proposed rule.

8. Part D Information That CMS Provides to Beneficiaries (§ 423.48)

As provided under section 1860D–1(c)(1) of the Act, we would conduct activities designed to broadly disseminate information about Part D coverage to individuals who were either eligible or prospectively eligible for Part D benefits. This information would be made available to beneficiaries at least 30 days prior to their initial enrollment period as provided under § 423.38 of our proposed rule. The information dissemination activities for Part D would be similar to, and coordinated with, the information dissemination activities that we currently perform for Medicare beneficiaries under sections 1851(d) and 1804 of the Act.

As required under section 1860D–1(c)(3) of the Act, we would include the following comparative information with respect to qualified prescription drug coverage provided by PDPs and MA–PD plans as part of our dissemination of Part D information and our efforts to promote informed beneficiary decisions—

- Benefits and prescription drug formularies;
- Monthly beneficiary premium;
- Quality and performance;
- Beneficiary cost-sharing; and
- Results of consumer satisfaction surveys.

We would not provide information on quality and performance or consumer satisfaction surveys during—

(1) The first plan year; or

(2) The next plan year if it were impracticable to obtain that information, or if the information were not available.

As stated in section 1860D–1(c)(4) of the Act, we would also provide information to beneficiaries regarding the methodology we will use for determining late enrollment penalties, as provided in § 423.286(d) of our proposed rule.

In carrying out the annual dissemination of Part D information, we anticipate conducting a significant public information campaign to educate beneficiaries about the new Medicare drug benefit and to ensure the broad dissemination of accurate and timely information. We would place an emphasis on ensuring that low-income individuals eligible for or currently enrolled in Part D benefits were aware of the additional benefits available to them and how to receive those benefits. In order to maximize the enrollment of Part D eligible individuals, this public information campaign would include outreach, information, mailings, and enrollment assistance with and through appropriate State and Federal agencies—including State health insurance assistance programs (SHIPs)—and would coordinate with other Federal programs providing assistance to low-income individuals. In addition, we would undertake special outreach efforts to disadvantaged and hard-to-reach populations, including targeted efforts among historically underserved populations, and coordinate with a broad array of public, voluntary, and private community organizations serving Medicare beneficiaries. Materials and information would be made available in languages other than English, where appropriate.

We would require, as described in § 423.48 of our proposed rule, that each organization offering a prescription drug plan or MA–PD plan provide us

annually with the information to disseminate to individuals who are currently or prospectively eligible for Part D benefits. This information would enable beneficiaries to make informed decisions regarding their Part D coverage options. Organizations offering a prescription drug plan or MA–PD plan would be required to provide this information in a format and to use standard terminology that we would specify in further operational guidance.

Under the recently implemented Medicare Prescription Drug Discount Card and Transitional Assistance Program (42 CFR parts 403 and 408), we took the unprecedented step of establishing a price comparison Web site available through *http://www.medicare.gov* to provide beneficiaries with information about drug card sponsors' negotiated drug prices in actual dollars—including dispensing fee information—for the purpose of comparing negotiated prices across approved card programs. The prices and fees on the price comparison Web site reflect an estimate of the maximum prices beneficiaries will experience at the point of sale. The Web site also includes information about generic substitutes. In the interest of broadly disseminating information that promotes informed decision-making among Part D enrollees and prospective Part D enrollees, as required under section 1860D–1(c) of the Act, we propose extending the price comparison requirements to PDP sponsors and MA organizations offering MA–PD plans and making comparative information about Part D plans' negotiated prices available to beneficiaries through *http://www.medicare.gov*. Our drug card experience shows that providing drug price information can significantly reduce prices and we believe that information about negotiated drug prices will assist beneficiaries in deciding which Part D plan will offer them the greatest financial advantage. We propose building on our experience in implementing the drug discount card price comparison Web site as we develop requirements for the Part D price comparison Web site, and we are seeking comments on how to provide information in the drug benefit to help achieve maximum drug savings.

Since the introduction of *http://www.medicare.gov* in 1998, CMS has substantially increased the amount of personalized information available to Medicare beneficiaries, making it one of the government's most comprehensive and customer-oriented sites available to the public. The Web site hosts twelve separate database applications to help individuals make their own health care decisions. The most significant ones are: the Medicare Personal Plan Finder (which contains costs, benefits, quality, satisfaction and disenrollment measures), Nursing Home Compare (which contains basic characteristics, staffing information and inspection results), the Prescription Drug and Other Assistance Programs application (which contains the most extensive, nationally complete listing of the Medicare-approved discount drug cards, including price comparisons, as well as other government and private programs designed to help with prescription drug costs), and the Medicare Eligibility Tool (which assists users in determining when they are eligible, how to enroll and what they need to consider when joining Medicare). Other tools providing customized results include: the Participating Physician and Supplier Directories, Home Health and Dialysis Facility Compare, Your Medicare Coverage, Helpful Contacts, Publications, and Frequently Asked Questions. By updating all information on the Web site at least once a month, the information provided to Medicare beneficiaries via *http://www.medicare.gov* is the most reliable and consistent information available.

Much of the information available through *http://www.medicare.gov* is also available via the 1–800–MEDICARE helpline. 1–800–MEDICARE is a major information channel for providing the most personalized and reliable information to people with Medicare. As a result of the Medicare Modernization Act (MMA), we are receiving the largest call volume ever for 1–800–MEDICARE. The beneficiary can call 1–800–MEDICARE to find out the most reliable information on public and private programs that offer discounted or free medication, programs that provide help with other health care costs, and Medicare health plans that include prescription coverage. The caller can always talk to a live person at 1–800–MEDICARE to get the facts they need. When a beneficiary calls 1–800–MEDICARE, we can send them a personalized brochure that allows them to look at discount cards based on their drug needs and their preferences about how to get their medicines, and their enrollment forms. We can also give the beneficiary personalized brochures containing information on their health plan choices, nursing homes and Medicare participating physicians in their area. 1–800–MEDICARE is available 24 hours a day, 7 days a week, to provide the one-on-one service that our Medicare beneficiaries need to make appropriate health care decisions.

9. Approval of Marketing Materials and Enrollment Forms (§ 423.50)

Section 1860D–1(b)(1)(B)(vi) of the Act directs CMS to use rules similar to those established under section 1851 of the Act to review PDP's marketing materials and application forms. While all entities with which CMS does business with are required to adhere to all Federal laws, with regard to marketing, it is important to refer here to section 1140 of the Act, prohibiting the misuse of symbols, emblems, or names in reference to Social Security or Medicare. While we have not reiterated this provision in our proposed rule, we believe that it is important to provide such reference in this discussion.

We are generally replicating the marketing provisions established under § 422.80 for MA plans as appropriate for PDPs. Therefore, § 423.50(a) of our proposed rule would provide guidance for our review of marketing materials, definition of marketing materials, deemed approval, and standards for PDP marketing.

While we generally replicated MA provisions, we recognize that the differences between PDPs and MA plans may require different marketing requirements. For example, while we prohibit enrollment forms from being accepted in provider offices or other places where health care is delivered under the MA rules at 42 CFR 422.80, this may not be appropriate to extend to relationships between PDP sponsors and pharmacies with respect to marketing a PDP. We invite comment regarding the applicability of the MA marketing requirements to PDPs.

We are proposing to add § 423.50(a)(3) in order to establish a program that recognizes consistent compliance with marketing guidelines by providing for streamlined approval of marketing materials submitted by PDP sponsors that have demonstrated such compliance. Called the "File and Use" program, organizations that have demonstrated to us that they continually meet a specified standard of performance will have certain types of marketing materials (such as advertising materials or other materials that do not describe plan benefits) deemed to be approved by us if they are not disapproved within five days of submission to us for prior approval. Thus, under these circumstances, organizations only need submit material for our approval five days prior to their distribution.

The advantages of File & Use are that the organization can decrease the time it takes to begin using certain marketing materials and improve planning and

budgeting for publication of these materials. Since PDPs will be new to the CMS marketing review process, we intend to not allow PDPs to qualify for the File & Use program until they have been in the program for a specified period of time, as determined by us, and establish consistent compliance with marketing guidelines.

We are also aware that the ability to provide additional products (for example, financial services) to Medicare beneficiaries could provide additional tools to help beneficiaries manage their expenses and financial security, and could be a strong incentive for potential PDP sponsors to participate in Part D. We ask for comments on the advisability of allowing such products to be provided in conjunction with PDP services and the appropriate limitations on such activities. We note that in accordance with HIPAA privacy rules, the PDP sponsor may have to obtain beneficiary authorization to market certain products.

10. Information Provided to PDP Sponsors and MA Organizations

Section 1860D–1(b)(4)(A) of the Act authorizes us to provide PDP sponsors and MA organizations with information about Part D eligible individuals so that their organizations may facilitate the marketing and enrollment of beneficiaries in their PDP and MA–PD plans and is intended solely for these purposes. That information is intended to assist in the outreach to individuals to ensure participation in the Part D program, as well as to reduce costs to those plans.

While the statute provides us with broad authority to share information with PDPs and MA organizations, we have operational questions, especially regarding any potential adverse impact on beneficiaries. To the extent we were to share such information with PDP sponsors and MA organizations, should beneficiaries be given the ability to choose not to have their information shared with these entities? To the extent that such information is shared for purposes of marketing, should PDP sponsors and MA organizations be able to use this information to contact beneficiaries only through written communications, or should telephone contacts be permitted, and, if so, under what circumstances? We also have questions as to whether such information should be provided by CMS upon request, or only at specific, scheduled times during the year (for example, just prior to the Annual Coordinated Election Period). Further, we would like to know what specific information we could provide to PDP or MA organizations that would facilitate their marketing and enrollment activities. The new authority provided in section 1860D–1(b)(4)(A) of the Act gives us the ability to permit plans to interact with prospective enrollees on a different basis. At the extreme, plans would be permitted to market directly to Medicare beneficiaries, based on contact information we provide, using approved materials, but otherwise bypassing CMS. At the other extreme, current rules regarding the marketing activities of MA plans would remain unchanged. Because Part D is an entirely new, voluntary benefit that would not otherwise be available to beneficiaries absent positive enrollment, there arguably exists a compelling difference in beneficiary interests relative to marketing under Part D (including both PDP and MA–PDs) versus under Part C (for purposes of MA only). We therefore encourage input from the public on these specific concerns and the provision in general.

While this section and discussion may appear to raise HIPAA Privacy rule issues with regards to disclosure of information between CMS and PDPs sponsors or MA–PD organizations, the statute explicitly provides for these activities. Therefore, the Privacy Rule, including the disclosure of protected health information, does not apply to the uses provided for by this section.

11. Procedures To Determine and Document Creditable Status of Prescription Drug Coverage (§ 423.56)

Section 1860D–13(b)(6) of the Act identifies certain entities, which we describe in this section of our proposed rule, that must disclose whether the prescription drug coverage that they provide to their members who are Part D eligible is creditable coverage.

Section 1860D–13(b)(4)(A)–(G) of the Act lists seven forms of creditable coverage: Coverage under a PDP or under an MA–PD; Medicaid; a group health plan (including coverage provided by a federal or a nonfederal government plan and by a church plan for its employees); a State pharmaceutical assistance program; veterans' coverage of prescription drugs, prescription drug coverage under a Medigap policy; and military coverage (including Tricare). Many of these terms are defined elsewhere in Federal regulations; some of them are under the jurisdiction of other Federal agencies. However, the definition of a Medicare supplemental (Medigap) policy, is under CMS' jurisdiction. This term is being clarified in subpart T of this regulation to coordinate with implementation of the Medicare prescription drug benefit.

In addition to the forms of creditable coverage identified in section 1860D–13(b)(4)(A)–(G) of the Act, section 1860D–13(b)(4)(H) of the Act provides the Secretary with the flexibility to identify "other coverage" that could be considered to be creditable coverage. In 42 CFR 423.56, we propose expanding the list of types of creditable coverage to include health insurance policies sold in the individual market (with the exception of policies that meet the definition of excepted benefits under section 2791 of the Public Health Service (PHS) Act, 42 U.S.C. 300gg–91). This category would include any policies that included prescription drug coverage, whether as part of a more comprehensive policy or as an independent "stand-alone" drug policy, that may have been sold to Medicare beneficiaries. Such stand-alone policies do not meet the definition of an excepted benefit under the Federal statute, even though States may regulate them as "limited" or "supplemental" benefit plans. It would also include comprehensive individual market policies with drug coverage that may have been sold to individuals before they became eligible for Medicare.

It is important to include these policies as creditable coverage. There are a variety of reasons why Medicare beneficiaries may have had individual market coverage, instead of Medigap coverage, after becoming eligible for Medicare. For example, as discussed in the preamble for subpart T, certain policies which will be regulated as Medigap policies after January 1, 2006, do not meet the definition of a Medigap policy prior to that date. Therefore they do not come within the scope of the statutory list of types of creditable coverage. Similarly, if an individual purchased a policy with prescription drug coverage before becoming eligible for Medicare, under title XXVII of the PHS Act, 42 U.S.C. 300gg, *et seq.*, the individual has a guaranteed right to continue to renew the policy. Again, while the policy might have met the definition of a Medigap policy had it been marketed and sold to Medicare beneficiaries, it does not meet those criteria, and does not come within the scope of the statutory list.

We believe it is appropriate to give beneficiaries credit for this coverage, which does not fall within the scope of any of the types of creditable coverage listed in the statute, but which clearly fits within Congress' intent to provide credit for prior prescription drug coverage, and require that the individuals be informed of whether

their drug coverage is creditable and of the choices they will need to make relative to Part D enrollment.

We are also adding coverage provided by the medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U) which is described under the Indian Health Improvement Act, 25 U.S.C. 1601 *et seq.* As a result of adding individual market and Indian Health Service coverage to the list of creditable coverage, beneficiaries with both of these types of drug coverage would receive notice of whether this coverage is creditable. We invite comments as to whether there are still more forms of coverage that we should consider creditable coverage.

As discussed above in § 423.46 of the proposed rule, upon becoming eligible for Part D, beneficiaries must decide whether to enroll in Part D, or forego that opportunity and face a possible financial penalty should they later decide to enroll. Beneficiaries who decide not to enroll in Part D because they have creditable prescription drug coverage would not face such a penalty if they later decide to enroll in Part D. According to section 1860D–13(b)(5) of the Act, an enrollee who would otherwise be subject to a late enrollment penalty may avoid the penalty if his or her previous coverage met the standards of "creditable prescription drug coverage". Under section 1860D–13(b)(5) of the Act, previous coverage will only meet those standards "* * * if the coverage is determined (in a manner specified by the Secretary) to provide . coverage of the cost of prescription drugs the actuarial value of which (as defined by the Secretary) to the individual equals or exceeds the actuarial value of standard prescription drug coverage * * *"

We are interpreting "to the individual" in this case as being to the average individual under the plan, as opposed to the sponsor of the plan. We believe that the relevant concern in this case is whether the beneficiary has been in a risk pool that on average provided benefits of equal value to Part D. Consequently, for purposes of determining creditable coverage, we are proposing to evaluate the actuarial value of the alternative coverage by means of a single test applied to all coverage: Will the expected plan payout on average under the coverage be at least equal to the expected plan payout under the standard benefit? For example, we propose to require sponsors of group health plans to determine the actuarial equivalency of each group health plan to the standard if, on average, the actuarial value of enrollee drug coverage under the plan as a whole is at least equal to the actuarial value of standard prescription drug coverage under Part D. (This approach set forth in Subpart R of this proposed rule concerning payments to sponsors of retiree prescription drug plans.) In other words, the calculation of actuarial equivalence would be based on the average plan payout across all benefit packages and all participants and beneficiaries receiving coverage under the sponsor's group health plan. We seek comments on our assumption that this approach is both familiar to employers (and unions) and imposes minimum burden on sponsors.

We are also proposing that any entity seeking to offer creditable prescription drug coverage must attest to this actuarial equivalence (or non-equivalence) in their notice to Medicare beneficiaries and in a submission to CMS, and must maintain documentation of the actuarial analysis and assumptions supporting the attestation. In other words, we would not require CMS approval of this analysis, but would require that it be submitted to CMS and made available to participants upon request.

In coordination with the provisions regarding the late enrollment penalty in § 423.46 of our proposed rule, we would establish a process under which these entities would disclose the creditable status of their prescription drug coverage to us and to each part D eligible beneficiary enrolled in such coverage.

We intend to describe the process for providing this disclosure, including guidance on the content, placement, and timing of the disclosure. The content of this notice and its timely receipt will be important components in the decision making process for beneficiaries, as the creditable status of the beneficiary's drug coverage will have a direct impact on the assessment of late enrollment penalties associated with Part D premiums. Equally important is the notification to the beneficiary of any subsequent changes in the creditable status of his or her coverage. Because beneficiaries have a limited time in which to make decisions about their Part D coverage without facing a penalty, it is important that the notice of creditable status be provided in a timely and conspicuous manner. However, we are also concerned about the potential administrative burden imposed by this requirement and are therefore soliciting comments on the format, placement, and timing of such a notice.

There are several approaches we will consider. One approach would be to incorporate the required disclosure into materials these entities routinely disseminate to their Part D eligible beneficiaries. We could provide standard language to be inserted into such materials. We would benefit from comments regarding the types of materials that could provide an appropriate vehicle for this purpose and ways to ensure that the notice is conspicuous and readily identified by recipients, particularly in those instances where the coverage is not creditable. Another approach would be to require each entity to issue a separate notice to each Part D eligible enrollee. This type of notice would be most conspicuous and would therefore increase the likelihood that beneficiaries would become aware of the creditable status of their prescription drug coverage. Because beneficiaries are subject to financial penalties for the failure to maintain creditable coverage when they enroll in Part D, a separate notice may better inform beneficiaries and ensure that they take appropriate action to avoid such penalties.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 101–93, requires that certain entities that offer health coverage provide covered individuals with a document, called a "certificate of creditable coverage," that establishes the time period during which the coverage was in effect. Implementing regulations provide a model "Certification of Creditable Coverage." Those regulations require that a certificate be produced and disseminated to individuals when their coverage ends. We have considered requiring that information about the creditable status of prescription drug coverage be included in this certification. However, since the certification required under HIPAA is not required to be provided until after such coverage has ended (or upon request), it would arrive too late to assist beneficiaries in deciding whether to enroll in Part D. However, the HIPAA certification may serve as a useful model and we invite comments about the administrative burden associated with producing and disseminating a similar notice of creditable status to beneficiaries.

The timing and frequency of these notices is also a key consideration. The initial notice of creditable status could be coordinated with the first Annual Coordinated Enrollment Period for Part D, which begins November 15, 2005, to ensure that beneficiaries have this information when making decisions regarding their Part D coverage. Another option would be to coordinate this disclosure with the end of the first Part

D initial enrollment periods and the annual coordinated election period, both of which end May 15, 2006. Beneficiaries would also need to know about any change in the creditable status of existing coverage before such a change becomes effective so that they have sufficient time to decide whether to obtain Part D coverage. If a beneficiary's creditable drug coverage ends or is changed to the extent that it is no longer creditable, the beneficiary has a Special Enrollment Period (SEP) during which the beneficiary can enroll in Part D without financial penalty. Thus, we believe that such notice should be provided, at a minimum, at these two important times, as well as upon the beneficiary's request.

We invite comments on how best to ensure that beneficiaries receive timely and adequate notice of the creditable status of their prescription drug coverage without imposing a significant administrative burden on entities that provide such coverage. We also note that the statute requires entities to disclose the creditable status of this coverage to us, and we invite comments on the possible methods of providing such disclosure. Given the importance of knowing whether coverage constitutes "creditable coverage," we would like to receive feedback regarding whether it would be a significant administrative burden for group health plans and other sponsors to include in disclosures an indication of the value of their drug benefit, the total amount of the annual premium for their drug benefit, and the amount of the annual drug benefit premium that the beneficiary will be required to pay.

Section 1860D–13(b)(6)(C) of the Act provides that an individual who was not adequately informed that his or her prescription drug coverage was not creditable may apply to CMS to have such coverage treated as creditable coverage for purposes of not having the late penalty imposed. We envision establishing a process in which an individual could apply for reconsideration of the late enrollment penalty based upon not being adequately informed. In this process, we would instruct beneficiaries as to the type of information that should be submitted as well as where the beneficiaries should submit the information. The process could also include CMS, or an entity with which CMS may contract, receiving and reviewing information related to the reconsideration, including validating that the entity in which the individual had previously been covered had provided the required disclosure. We appreciate comment on this process.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections

1. Overview and Definitions (§ 423.100)

Subpart C of part 423 implements sections 1860D–2, 1860D–4(a), 1860D–4(b), 1860D–4(i), 1860D–4(k), 1860D–11(a), 1860D–21(a), 1860D–21(c)(3), and 1860D–21(d)(2) of the Social Security Act. This subpart sets forth requirements regarding—

- The benefits offered by PDP sponsors and MA organizations that offer qualified prescription drug coverage.
- The establishment of prescription drug plan service areas.
- Access standards with regard to covered Part D drugs.
- Information dissemination by PDP sponsors and MA Organizations offering qualified prescription drug coverage.
- Disclosure to beneficiaries of pricing information for generic versions of covered Part D drugs.
- Privacy, confidentiality, and accuracy of PDP sponsors' beneficiary records.

Section 423.100 of our proposed rule also includes definitions for terms that are frequently used in this subpart. Generally, we clarify the definitions in § 423.100 in the relevant parts of section II.C of this preamble. However, we believe that additional clarification is needed with regard to the terms "covered Part D drug" and "dispensing fee" in order to provide necessary context for the Part D benefit requirements in this subpart. We are providing that clarification below.

a. Covered Part D Drug

The definition of a covered Part D drug in § 423.100 of our proposed rule closely follows the statutory definition in section 1860D–2(e) of the Act. According to this definition, a covered Part D drug must be available only by prescription, approved by the Food and Drug Administration (FDA), used and sold in the United States, and used for a medically accepted indication (as defined in section 1927(k)(6) of the Act). A covered Part D drug would include prescription drugs, biological products, and insulin as described in specified paragraphs of section 1927(k) of the Act and vaccines licensed under section 351 of the Public Health Service Act. The definition also includes "medical supplies associated with the injection of insulin (as defined in regulations of the Secretary)." We propose to define those medical supplies to include syringes, needles, alcohol swabs, and gauze.

In accordance with section 1860D–2(e)(2) of the Act, the definition of a covered Part D drug would specifically exclude drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid, with the exception of smoking cessation agents. In accordance with section 1927(d)(2) of the Act, the drugs or classes of drugs that may currently be excluded or otherwise restricted under Medicaid include—(1) Agents when used for anorexia, weight loss, or weight gain; (2) agents when used to promote fertility; (3) agents when used for cosmetic purposes or hair growth; (4) agents when used for the symptomatic relief of cough and colds; (5) prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; (6) nonprescription drugs; (7) outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale; (8) barbiturates; and (9) benzodiazepines. We are concerned that the aforementioned exclusion of outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer (or its designee) as a condition of sale (item 7 above) may prove too narrow to address inappropriate tying arrangements. We may consider expanding this exclusion and solicit public comments on how to reduce the risk of abusive tying arrangements.

The definition of a covered Part D drug would also exclude any drug for which, as prescribed and dispensed or administered to an individual, payment would be available under Parts A or B of Medicare for that individual (even though a deductible may apply). By including the language "as so prescribed and dispensed or administered," section 1860D–2(e)(B) makes a distinction between what would be paid for under Part D as opposed to Part B. This language indicates that Congress was aware that some covered Part D drugs could qualify for payment under Part B in some circumstances and Part D in other circumstances, depending on the way those drugs were dispensed or administered. Dispensation or administration should be interpreted to include the setting, personnel, and method involved, and not simply the route of administration.

One goal of Part D is to fill any gaps in existing Part B coverage of drugs. Part B has a limited and specific drug benefit covering drugs furnished "incident to" a physician's service (for example, certain injectable drugs that are not usually self-administered and furnished incident to

a physician office visit); drugs furnished as a supply to covered items of durable medical equipment; certain oral drugs (immunosuppressive, and certain oral anti-cancer and anti-emetic drugs); certain immunizations; and several other drugs and biologicals. Part D cannot pay for these drugs because payment is available under Part B:

Section 1860D–2(e)(2)(B) of the Act that specifies that a drug prescribed to a Part D eligible individual that would otherwise qualify as a Part D drug cannot be considered a covered Part D drug if payment for such drug "* * * *is available* (or would be available but for the application of a deductible) under part A or B for that individual." We interpret this to mean that if payment could be available under Part A or B to the individual for such drug, then it will not be covered under Part D. This will be the case even if a beneficiary has Part A, but not Part B or vice versa, since, as we explain in section F of this preamble and at § 423.265(c) of the Act, PDP sponsors must offer a uniform benefit package in order to carry out Congress's intent in section 1860D–13(a)(1)(F) of the Act. If Part B covered drugs were included in the Part D benefit package only for those enrollees without Part B, but not for others, it would not be possible for PDP sponsors to offer uniform benefit packages for a uniform premium to all enrollees. In addition, we believe that payment for a drug under Part A or B is *available* to any individual who *could* sign up for Parts A or B, regardless of whether they actually enrolled. All individuals who are entitled to premium-free Part A are eligible to enroll in Part B. This includes individuals who are entitled to Part A based on age, disability, and ESRD. All individuals who are entitled to Part B only are age 65 or older and, in almost all instances, not eligible for premium-free Part A. However, they are eligible to buy into Part A for a premium. Thus, for all Part D eligible individuals, drugs covered under Parts A and B are available if they choose to pay the appropriate premiums.

We believe that the phrase "for that individual" in 1860D–2(e)(2)(B) of the Act is intended to capture the fact that under local medical review policies (LMRPs), a drug that might be covered under Part B for an individual in one area of the country might not be covered in another area of the country. Thus, what is covered "under Part B for that individual" may be, as discussed earlier, different in different geographic regions. Under this reading, in a region where a drug is covered under Part B, it would be considered "available" to "that individual" whether he or she had elected to enroll in Part B or not.

The Part D drug coverage described in this proposed rule does not alter the coverage or associated rules for drugs that are currently covered by Medicare prior to the MMA, such as those included in the following list, which offers examples but is not meant to be exhaustive—

1. Drugs furnished incident to a physician's service that are not usually self-administered by the patient.

2. Drugs used in immunosuppressive therapy furnished to a beneficiary who receives an organ transplant for which Medicare makes payment.

3. Drugs administered to ESRD patients and separately billed by dialysis facilities. These would include erythropoetin (EPO), both when administered in the dialysis facility or furnished to an ESRD patient for self-administration.

4. Drugs taken orally during cancer chemotherapy provided that they have the same active ingredients as chemotherapy drugs and are used for the same indications as chemotherapy drugs which would be covered if they were not self-administered and were administered as incident to a physician's professional service, and certain oral drugs prescribed for use as an acute antiemetic as part of an anticancer chemotherapeutic regimen if the drug is administered by a physician.

5. Blood clotting factors for hemophilia patients competent to use such factors to control bleeding without medical supervision, and items related to the administration of those factors.

6. Supplies (including drugs) necessary for the effective use of covered durable medical equipment, including those which must be put directly into the equipment and furnished to a beneficiary via the equipment (for example, amphotericin B, an anti-fungal agent, administered with an infusion pump, or inhalation drugs furnished to a beneficiary via a nebulizer).

7. Pneumococcal pneumonia vaccines, hepatitis B vaccines, and influenza virus vaccines.

We intend to ensure that the Part D benefit "wraps around" Part B drug benefits to the greatest extent possible. For example, Part D would cover immunosuppressive drugs furnished to Medicare beneficiaries who did not have their transplant paid for by Medicare (*e.g.*, a beneficiary who had his or her transplant paid for by a private insurer when he or was employed, and the beneficiary has now enrolled in Part B). Part D could pay for these immunosuppressive drugs for these beneficiaries since Part B is prohibited by statute from paying for them. Therefore, we are soliciting comments concerning any drugs that may require specific guidance with regard to their coverage under Part D, and any gaps that may exist in the combined "Part D & B" coverage package.

b. Dispensing Fees

The Medicare Modernization Act (MMA) does not define the term "dispensing fee," although the terms "dispensing fee" and "dispense" appear several times throughout the Act. Section 1860D–2(d)(1)(B) states that negotiated prices available under Part D, "shall take into account negotiated price concessions * * * and include any *dispensing fees* for such drugs." Sections 1860D–15(b)(3) and (e)(1)(b) of the Act provide that reinsurance and risk corridor payments will be based on allowable costs that include "costs directly related to the *dispensing* of covered part D drugs during the year." The costs used in calculating the retiree drug subsidy also include the "costs directly related to the dispensing of covered part D drugs during the year" as provided in section 1860D–22(a)(3)(C)(ii) of the Act. Section 1860D–2(e)(1)(B) of the Act specifically includes the medical supplies associated with the injection of insulin (as defined in our proposed rule); this is the only reference to supplies associated with drug administration in the Part D drug benefit provisions of the MMA.

Because the statute is ambiguous on the meaning of "dispensing fee," in this proposed rule we are not proposing a specific definition of "dispensing fee," but instead are offering three different options we believe would be reasonable, permissible definitions of the term. We invite comments on each of the definitions proposed below.

Option 1: The dispensing fee would include only those activities related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary, including charges associated with mixing drugs, delivery, and overhead. The dispensing fee would not include any activities beyond the point of sale (that is, pharmacy follow-up phone calls) or any activities for entities other than the pharmacy.

Option 1 would differentiate between "dispensing" a covered Part D drug and "administering" one in order to restrict the scope of these fees to include only those charges for pharmacy services related to the preparation and delivery of a covered Part D drug. Under option 1, the dispensing fee could not include

any charges associated with administering the drug once the drug has already been transferred to the beneficiary. Thus, for example, the fee would not include any professional fees (such as skilled nursing services), durable medical equipment (such as an external infusion pump or an IV pole), supplies (such as tubes and dressings), or even follow-up telephone calls from the pharmacy to the patient to check on the patient's progress with the drug.

Option 2: The dispensing fee would include the activities included in Option 1, but in addition would include amounts for the supplies and equipment necessary for the drugs to be provided in a state in which they can be effectively administered.

Option 3: The dispensing fee would include the activities in Option 2, but in addition would include activities associated with ensuring proper ongoing administration of the drugs, such as the professional services of skilled nursing visits and ongoing monitoring by a clinical pharmacist.

Our proposed options 2 or 3 would also frame the definition so that supplies, equipment, and the professional services associated with administering the drug would be limited to cases where: (a) A typical patient with the condition at issue could not receive the benefit of the medication in the absence of the associated supplies, equipment or professional services, and (b) the patient is receiving home infusion therapy.

We believe that option 1 represents the best reading of the statute, since it would limit dispensing fees to a transfer of possession of the drug and would not include any fees associated with administering the drug. In addition, where Congress wished for CMS to include the cost of supplies under Part D, it specifically directed CMS to do so (by requiring that the supplies associated with the injection of insulin be included in the definition of covered Part D drug).

However, we also recognize that options 2 or 3 would eliminate current gaps in coverage relative to home infused drugs. We have limited options 2 and 3 to cases of home infusion because this is the only circumstance we know of where the additional services associated with administering the drug would not already be covered under Medicare Part A or B and would be necessary to ensure effective delivery of the drug. (For example, infusion therapy provided in a hospital outpatient setting or in a physician office could be covered under Part B. Infusion therapy by a hospice could be covered as part of the hospice benefit, if a patient meets the conditions for hospice care.) However, there may be related issues with respect to the administration of other drugs (for example, vaccines and injectable long-acting antipsychotic drugs), and we solicit comments regarding any implications for our proposed options for defining dispensing fees.

Home infusion therapy equipment, supplies, and services typically are used in order to administer medications to patients using intravenous, subcutaneous, and epidural routes. Drug therapies commonly administered via infusion include antibiotics, chemotherapy, pain management, parenteral nutrition and immune globulin. Generally, home infusion therapy includes coordinating the varied services a patient might need in order to receive infusion in the home. For example, a home infusion company might provide, or facilitate the provision of, skilled nursing services, durable medical equipment (such as an external infusion pump or an IV pole), supplies (such as tubes and dressings), education of the patient, pharmacy services (including mixing the drugs if necessary), and delivery services. A home infusion company might also call the patient periodically to monitor care. Based on our research, home infusion is covered under the medical benefits of most commercial insurers and MA plans as a cost-effective alternative to inpatient care for administering drugs that cannot be self-administered for treatment of acute or chronic medical conditions in patients who are sufficiently ill to be unable to visit an outpatient clinic or physician's office to receive the necessary therapy. Home infusion providers generally bill private insurance plans for these services by billing separately for the drug, and also charging a per diem for other services. The per diem charge represents the average daily expense associated with non-pharmaceutical expenses (including nursing services), such as equipment, supplies, labor, and non-nurse clinical services involved in the compounding, preparation, delivery, administration, and monitoring for a given drug therapy.

While Parts A and B pay for some home infusion therapies (through, for example, the drugs and supplies that are provided incident to the provision of a home infusion pump), in other cases home infusion therapies would not be covered by Medicare Parts A and B (for example, when the drug is administered in the home through an intravenous drip and not a pump). In addition, infusion therapy policies may vary from region to region based on local DMERC coverage policies.

Options 2 and 3 would therefore allow us to include in the Part D dispensing fee items and services that might be considered essential in order to effectively utilize the drug benefit. However, it would also extend the definition of dispensing fee beyond the mere transfer of possession of the drug. Also, to the extent that professional services are included in the definition of dispensing fees, we are concerned about double billing with regard to some of the skilled nursing costs associated with home infusion. In many cases these skilled nursing costs are separately billable to Part A, Medicaid, or supplemental insurance, and we are concerned about Part D supplanting these other sources of payment. In addition, as discussed in subpart D of this preamble, PDP sponsors and MA organizations offering MA–PD plans will be required to offer quality assurance and medication therapy management programs. These programs could be used for pharmacies to follow up with patients and ensure that patients are properly administering their drugs or adhering to their drug regimens. We are concerned about beneficiaries being charged for quality assurance services as part of the dispensing fee, when such charges might have already been included in the cost of the premium.

Finally, we note that any definition we adopt for purposes of Part D would not carry over to Part B of the Medicare program. Section 1842(o)(2) of the Act gives the Secretary discretionary authority to pay a dispensing fee to a licensed pharmacy that furnishes certain covered Part B drugs and biologicals to Medicare beneficiaries. While the term "dispensing fee" is not defined in section 1842(o)(2) of the Act, the considerations under Medicare Part B, a more comprehensive health insurance product that has separate payment mechanisms for durable medical equipment and professional services, are different from those under Part D. In addition, the Secretary is not required to pay any dispensing fee under section 1842(o)(2) of the Act, while in Part D, the dispensing fee is included in the negotiated price of a drug.

c. Long-Term Care Facility

We request comments regarding our definition of the term long-term care facility in § 423.100, which we have interpreted to mean a skilled nursing facility, as defined in section 1819(a) of the Act, or a nursing facility, as defined in section 1919(a) of the Act. We are

particularly interested in whether intermediate care facilities for the mentally retarded or related conditions (ICF/MRs), described in § 440.150, should explicitly be included in this definition given Medicare's special coverage related to mentally retarded individuals. It is our understanding that there may be individuals residing in these facilities who are dually eligible for Medicaid and Medicare. Given that payment for covered Part D drugs formerly covered by Medicaid will shift to Part D of Medicare, individuals at these facilities will need to be assured access to covered Part D drugs. Our proposed definition limits our definition to skilled nursing and nursing facilities because it is our understanding that only those facilities are bound to Medicare conditions of participation that result in exclusive contracts between long-term care facilities and long-term care pharmacies. However, to the extent that ICF/MRs and other types of facilities exclusively contract with long-term care pharmacies in a manner similar to skilled nursing and nursing facilities, we would consider modifying this definition.

2. Requirements Related to Qualified Prescription Drug Coverage (§ 423.104)

Under section 1860D–11(e)(2)(A) of the Act, we may approve as PDP sponsors or MA organizations offering MA–PD plans only those entities proposing to offer qualified prescription drug coverage in accordance with our requirements. As provided in section 1860D–2(a)(1) of the Act and § 423.104(d) of our proposed rule, qualified prescription drug coverage may consist of either standard prescription drug coverage or alternative prescription drug coverage. Alternative prescription drug coverage may include supplemental benefits, and this coverage is referred to as "enhanced alternative coverage" (these concepts are discussed in detail below).

We would review and approve current and potential PDP sponsors' proposed prescription drug plans and current and potential MA organizations' proposed MA–PD plans consistent with the rules described in section II.F.6 of this preamble. We will further articulate requirements regarding the approval of qualified prescription drug coverage in written policy guidelines and other CMS instructions.

Section 1860D–1(b)(1) of the Act provides that we establish an enrollment process for prescription drug plans that uses rules similar to, with limited exceptions, those governing enrollment in an MA plan under various subsections of 1851 of the Act, including portions of 1851(g). Section 1851(g)(1) of the Act provides that an MA organization must accept without restrictions individuals who are eligible to elect enrollment in its MA plan. Accordingly, section § 423.104(b) of our proposed rule provides that a PDP sponsor offering qualified prescription drug coverage would be required to offer its plan to all Part D eligible individuals residing in the plan's service area. We note that, unlike a local MA–PD plan, a prescription drug plan is not eligible for a capacity waiver as described in 42 CFR 422.60(b) of our proposed rule.

a. Standard Prescription Drug Coverage

As provided under section 1860D–2(b) of the Act and codified in § 423.104(e) of our proposed rule, "standard prescription drug coverage" would consist of coverage of covered Part D drugs subject to an annual deductible; 25 percent coinsurance (or an actuarially equivalent structure) up to an initial coverage limit; and catastrophic coverage after an individual incurs out-of-pocket expenses above a certain threshold. In 2006, the annual deductible would be $250, the initial coverage limit would be $2,250, and the out-of-pocket threshold would be $3600. Once a Part D enrollee reached the annual out-of-pocket threshold, his or her nominal cost-sharing would be equal to the greater of: (1) 5 percent coinsurance, or (2) a copayment of $2 for a generic drug or a preferred multiple source drug and $5 for any other drug, or an actuarially equivalent structure. (*See* Table C–1 for a summary version of standard prescription drug coverage benefits for 2006.)

A multiple source drug is defined under section 1927(k)(7)(A)(i) of the Act as a drug for which there are two or more drug products that are (1) rated as therapeutically equivalent by the Food and Drug Administration (FDA), (2) are pharmaceutically equivalent and bioequivalent, as defined in section 1927(k)(7)(C) of the Act, and as determined by the FDA, and (3) are sold or marketed in a State during the relevant time period. Section 423.100 of our proposed rule provides definitions for therapeutically equivalent and bioequivalent drugs based on the definitions provided in sections 1927(k)(7)(A) of the Act and section 505(j)(8) of the Food, Drug, and Cosmetic Act, respectively. The term therapeutically equivalent refers to drugs that are rated as therapeutic equivalents under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations." Section 423.4 of our proposed rule defines a generic drug as a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act is approved. To clarify, generic drugs are both bioequivalent and therapeutically equivalent to an innovator drug. Section 423.100 of our proposed rule also clarifies that a preferred drug refers to a covered Part D drug on a prescription drug plan or MA–PD plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug on the formulary.

According to section 1860D–2(b)(4)(C) of the Act, and as defined in § 423.100 of the proposed rule, beneficiary costs for covered Part D drugs are only considered incurred (for purposes of applicability toward beneficiary spending against the annual out-of-pocket limit) if they are—

1. Incurred against any annual deductible, any applicable cost-sharing for costs above the annual deductible and up to the initial coverage limit, and any applicable cost-sharing for costs above the initial coverage limit and up to the out-of-pocket threshold;

2. Incurred by the Part D enrollee (or by another person on behalf of that individual); paid on behalf of a low-income individual under the Part D subsidy provisions described in § 423.782 of the proposed rule; or paid on behalf of the enrollee under a State Pharmaceutical Assistance Program (SPAP) described in § 423.454 of the proposed rule; and

3. Incurred with respect to covered Part D drugs that are either included in a prescription drug plan or MA–PD plan's formulary or treated as being included in a plan's formulary as a result of a coverage determination, redetermination, or appeal under §§ 423.566, 423.580, and 423.600 of our proposed rule.

As a point of clarification, we also propose that beneficiary costs incurred under the following circumstances count as incurred costs consistent with the definition of that term in § 423.100 of our proposed rule (with plans explicitly accounting for such price differentials in the actuarial valuation of their coinsurance in their bids):

- Any differential between a network retail pharmacy's negotiated price and a network mail-order pharmacy's negotiated price for an extended (for example, 90-day) supply of a covered Part D drug purchased at a retail pharmacy, as described in section II.C.4.a of this preamble, and
- Any differential between an out-of-network pharmacy's usual and customary price for a covered Part D

drug purchased in accordance with the out-of-network access rules described in section II.C.5 of this preamble and the plan allowance for that covered Part D drug.

Section 1860D–2(b)(4)(C)(ii) of the Act provides that any costs for which a Part D individual is reimbursed by insurance or otherwise, a group health plan, or another third-party payment arrangement do not count toward incurred costs; only costs paid by a Part D enrollee, or on behalf of a Part D enrollee by another person, would count as incurred costs. This provision thus creates a distinction between all enrollee out-of-pocket expenditures and those that are counted toward the out-of-pocket threshold (incurred costs).

In § 423.100 of our proposed rule, we define the terms "person," "insurance or otherwise," "group health plan," and "third-party payment arrangement" in such a way as to strike what we believe to be an appropriate balance between: (1) allowing certain individuals or charitable organizations to provide financial assistance to Part D enrollees that would be counted toward those enrollees' incurred costs, and (2) reducing incentives for current employers, other insurers, and government programs to reduce their current levels of coverage and replace that coverage with Part D wrap-around benefits, thereby requiring Medicare to pay for drug costs that were previously borne by other payers. We propose defining "person" in such a way that other individuals, such as family members, could pay for covered Part D drug cost-sharing on behalf of Part D enrollees. The term "person" is also defined more broadly than a human being based on legal definitions of the term that include corporate entities or organizations. This definition of "person" is consistent with other statutory definitions of the term "person," including 1 U.S.C. 1, which provides that in interpreting an Act of Congress, unless the context indicates otherwise, the term "person" includes corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals.

We believe that *bona fide* charities unaffiliated with employers or insurers could not be excluded from financially assisting Part D enrollees with covered Part D drug expenditures and having those expenditures count toward enrollees' incurred costs. Although allowing such financial contributions to count toward incurred costs could increase Medicare expenditures by allowing more beneficiaries to qualify, and to qualify sooner, for coverage above the out-of-pocket threshold, we expect that the number of people who are both assisted by charitable organizations and have expenditures high enough to qualify for protection against high out-of-pocket expenditures would be small. Since there will be many Part D eligible beneficiaries with incomes higher than the low-income subsidy eligibility limits described in § 423.782 of our proposed rule, we believe it is a desirable goal to allow appropriate charitable assistance to count toward enrollees' incurred costs. This interpretation is consistent with (1) our interpretation of the term "person" and (2) our interpretation of the terms "insurance or otherwise," "group health plan," and "third-party payment arrangement" (as discussed subsequently in this preamble section). In addition, we note that any arrangements pursuant to which a charitable organization pays a Medicare beneficiary's cost-sharing obligations must comply with the Federal fraud and abuse laws, including the anti-kickback statute, section 1128B(b) of the Act, as well as the civil monetary penalty provision at section 1128A(a)(5) of the Act. We are considering whether assistance in paying enrollees' out-of-pocket cost-sharing obligations provided through prescription drug patient assistance program sponsored by pharmaceutical manufacturers would be allowed under the aforementioned Federal fraud and abuse laws.

We have defined the term "insurance or otherwise" consistent with our policy goal of reducing incentives for current employers, other insurers, and government programs to reduce their current levels of coverage and replace that coverage with Part D wrap-around benefits. The use of the term "insurance or otherwise" in section 1860D–2(b)(4)(C)(ii) of the Act suggests that the Congress understood that programs other than insurance programs would be helping beneficiaries pay for covered Part D drugs.

Section 1860D–24 of the Act, which extends the coordination of benefits provisions required for SPAPs to other types of plans—including Medicaid programs, Section 1115 waiver demonstrations, group health plans, FEHBP, military coverage (including TRICARE), and "such other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of Part D eligible individuals as the Secretary may specify"—appears to support our proposed definition of "insurance or otherwise," in § 423.100 of our proposed rule, as a plan (other than a group health plan) or program that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the Public Health Service Act). We note that our definition of "insurance or otherwise" does not modify the definition of "health plan" at 45 CFR 160.103 of the HIPAA Administrative Simplification Regulations, or any interpretation thereof issued by the Department of Health and Human Services.

Therefore, "insurance or otherwise" would include the following programs and entities:

- Government programs and entities (for example, Department of Veterans Affairs (VA), Department of Labor Federal Workers' Compensation Program, and Federally Qualified Health Centers (FQHCs);
- Government insurers (for example, Medicaid 1115 demonstrations and the State Children's Health Insurance Program (SCHIP); and
- Government-sponsored funds (for example, black lung benefits, Ryan White CARE Act funds, and State special funds that assist certain individuals with their medical costs, such as a special fund for AIDS patients).

Because costs for covered Part D drugs paid by insurance or otherwise on behalf of a Part D enrollee do not, as previously discussed, count as incurred costs, any Part D wrap-around coverage provided to beneficiaries by these entities would not count toward incurred costs. Wrap-around coverage provided to Part D enrollees by group health plans and other third-party payment arrangements would also not count as incurred costs. We have defined the term " *group health plan*" to have the same meaning as in 42 CFR 411.101. In addition, we have defined the term "third party payment arrangements" to mean any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs.

We request comments regarding the treatment of health savings account (HSAs) vis-à-vis our definition of "group health plan," "insurance or otherwise," and "third party payment arrangements." Our strong preference is not to treat HSAs as group health plans, insurance or otherwise, or third party payment arrangements and therefore to allow HSA contributions to count toward incurred costs, since we see these funds as essentially analogous to a beneficiary's bank account. We also seek comments on how to treat FSAs, health reimbursement accounts (HRAs), and Medicare savings accounts (MSAs), relative to our definitions of group

health plan, insurance or otherwise, and third party payment arrangements.

In proposing this policy, an assessment was made of the need for coordination of the Part D benefit with the Department of Health and Human Services' programs, including the Indian Health Service (IHS) and AIDS drug assistance programs. The IHS is the agency that fulfills the Secretary's unique relationship to provide health services to American Indians and Alaska Natives (AI/ANs) based on the government-to-government relationship between the United States and tribes. The Department has a long history of recognizing AI/AN beneficiaries' dual eligibility for services both from the HIS and from other Department programs. We expect many AI/AN beneficiaries will qualify for full and partial low-income subsidies under Part D. For those not receiving a full or partial subsidy, the IHS may wish to pay for premiums to eliminate any barriers to Part D benefits.

For AI/ANs not eligible for the low-income subsidies and enrolled in a prescription drug plan or MA–PD plan, the costs of covered Part D drugs obtained at an I/T/U pharmacy or a non-IHS retail pharmacy (through an appropriate IHS contract health services referral) will be applied to meet the beneficiary's deductible under qualified prescription drug coverage. These payments will not count as incurred costs towards meeting the out-of-pocket threshold, however. This will ensure that an IHS beneficiary receives a benefit for IHS expenditures between the deductible and the out-of-pocket limit. Once the deductible is met, the IHS will benefit from Part D coverage because the I/T/U pharmacy will be reimbursed for 75 percent of spending (on average) between the deductible and the initial coverage limit. We seek comments on how I/T/U pharmacies and IHS beneficiaries will achieve maximized participation in Part D benefits.

We also assessed the role of the Ryan White CARE Act, and in particular the AIDS Drug Assistance Program (ADAP), which addresses the pharmaceutical needs of the neediest HIV/AIDS population. The implementation of Part D will enable approximately one-half of the ADAP enrollees who are potentially eligible for Part D to qualify for full Medicare low-income subsidies, and an additional 30 percent may qualify for partial low-income subsidies. In addition, for those not receiving a full or partial subsidy, the Part D benefit would pay—depending on the cost-sharing structure employed by the particular prescription drug plan or MA–PD plan—75 percent, on average, of an enrollee's covered Part D drug expenditures between the deductible and initial coverage limit. Although ADAP may realize savings with the implementation of Part D, these may be offset by the increased costs of picking up expenses no longer covered by Medicaid for the dual eligible population.

To ensure coordination of benefits for the HIV/AIDS population, the ADAP program may wish to pay for this population's premiums to eliminate any barriers to Part D benefits. ADAP may also subsidize costs incurred toward a Part D plan's deductible or cost-sharing for those patients unable to afford these costs. It should be noted, however, that when ADAP does subsidize these costs, they would not count as incurred costs and thus may make it less likely that an eligible person would incur costs above the annual out-of-pocket threshold and thus qualify for catastrophic cost-sharing.

ADAPs and other Ryan White "titled" programs are eligible to participate in what is known as the 340B Drug Pricing program and are encouraged to do so. Under Section 340B of the Public Health Service Act; discounted outpatient drugs are available to certain Federally-funded grantees, such as Federally qualified health centers (FQHCs), AIDS drug assistance programs, and certain disproportionate (DSH) hospitals. Upon successful registration, these covered entities are eligible to purchase outpatient prescription medications from drug wholesalers and pharmaceutical manufacturers at significantly reduced prices. All but three ADAPs, which have State-based programs, participate in 340B. About one-half of these States purchase their drugs directly and receive an upfront discount. The other half operate under the rebate model and receive a rebate from manufacturers. Studies have indicated that the States receiving an upfront discount benefit more fully from the 340B program than those States receiving a rebate. States are encouraged to move toward the model of purchasing their drugs directly, as they can realize more savings than States using the rebate model.

We welcome comments on how to maximize the savings for people in need of HIV/AIDS medications under the 340B program. In particular, is it feasible for ADAP programs to participate with prescription drug plans so that the drugs offered to individuals with HIV/AIDS can be offered at 340B prices? In addition, because it is of critical importance for Medicare beneficiaries with HIV/AIDS to comply with their drug regimens, we are soliciting comments regarding the coordination of ADAP and Medicare Part D benefits.

We note that nothing precludes an insurer, group health plan, or other third party arrangement from paying for a Part D enrollee's deductible costs; while these payments will not count as incurred costs vis-à-vis the out-of-pocket threshold, they will not prevent a Part D enrollee from receiving a benefit for expenditures between the deductible and the out-of-pocket limit. In addition, these entities are not precluded from paying for a Part D enrollee's cost-sharing above the out-of-pocket threshold once a beneficiary has accumulated incurred costs in excess of the out-of-pocket threshold. Please refer to section II.J of this preamble for a detailed discussion regarding the collection of information regarding third-party reimbursement for covered Part D drugs for the purpose of determining enrollees' incurred costs.

Section 1860D–2(b) of the Act provides that, beginning in 2007, the annual deductible, initial coverage limit, out-of-pocket threshold, and beneficiary cost-sharing after the out-of-pocket threshold is met are to be adjusted annually. In accordance with section 1860D–2(b)(6) of the Act and as provided in § 423.104(e)(5)(iv) of our proposed rule, these amounts would be increased over the previous year's amounts by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs for the 12-month period ending in July of the previous year. The amounts for the annual deductible, initial coverage limit, out-of-pocket threshold, and catastrophic cost-sharing amounts would be rounded to the nearest $5, $10, $50, and $0.05, respectively, as required by sections 1860D–2(b)(1)(B), (b)(3)(B), (b)(4)(B)(ii), and (b)(4)(A)(ii) of the Act, and codified in §§ 423.104(e)(1)(ii), (e)(3)(ii), (e)(5)(iii)(B), and (e)(5)(i)(A)(2) of our proposed rule.

We anticipate that in the first several years after the implementation of Part D, determining the annual percentage increase will be difficult and will require the use of alternative sources of data. We request comments regarding possible alternative data sources we could use to determine the annual percentage increase in the first several years of the Part D program. We will provide further detail regarding the methods and data sources we would use to determine this annual percentage increase in operational guidance to PDP sponsors and MA organizations offering

MA–PD plans prior to the deadline for bid submissions.

TABLE C–1.—STANDARD PRESCRIPTION DRUG COVERAGE BENEFITS FOR 2006

	Cost-sharing percentage	Beneficiary out-of-pocket costs	Plan payment percentage	Plan payment
Annual Deductible ($0–$250 in spending on covered Part D drugs covered under the plan).	100	$250	0	$0
Initial Benefit ($251–$2,250 in spending on covered Part D drugs covered under the plan).	25[1]	500[2]	75[1]	1,500
No coverage of costs ($2,251–$5,100[3] in spending on covered Part D drugs covered under the plan).	100	2,850	0	0
Catastrophic Coverage (after the enrollee has incurred out of-pocket costs on covered Part D drugs covered by the plan greater than $3,600; this is generally equivalent to $5,100[3] in covered spending).	The greater of: (1) 5; or (2) $2 for a generic or preferred multiple source drug/$5 for other drugs[1].		95	

[1] Entities have the option of substituting a cost-sharing structure that is actuarially equivalent.
[2] $500 is the maximum out-of-pocket costs if coverage is based on 25 percent coinsurance. Under an actuarially equivalent cost-sharing structure, the maximum out-of-pocket costs and the maximum plan payment for any Part D enrollee could be higher or lower.
[3] This figure may, in fact, be higher to the extent that a Part D enrollee is reimbursed for out-of-pocket costs for covered Part D drugs covered under his/her plan by a group health plan, insurance or otherwise, or other third party arrangement.

We have interpreted the provisions of section 1860D–2(b) of the Act to provide for two distinct types of standard prescription drug coverage—"defined standard coverage" and "actuarially equivalent standard coverage." Defined standard coverage basically constitutes standard prescription drug coverage as defined in the statute—with 25 percent coinsurance for costs above the deductible but below the initial coverage limit and cost-sharing for costs above the annual out-of-pocket limit equal to the greater of: (1) A copayment (for 2006, and adjusted annually as specified earlier in this preamble) of $2 for a generic or preferred multi-source covered Part D drug, or $5 for other drugs; or (2) 5 percent coinsurance. Actuarially equivalent standard coverage is used to describe standard coverage with actuarially equivalent alternatives to these cost-sharing requirements and consistent with section 1860D–2(b) of the Act.

Section 1860D–2(b)(2)(A)(ii) of the Act provides that PDP sponsors and MA organizations offering actuarially equivalent standard prescription drug coverage would be permitted to substitute cost-sharing requirements (including tiered structures tied to plan formularies or particular pharmacies in a plan's network) for costs above the annual deductible and up to the initial coverage limit, provided that those alternative cost-sharing requirements were actuarially equivalent to an average expected coinsurance of 25 percent for costs above the annual deductible and up to the initial coverage limit. Alternative cost-sharing arrangements under actuarially equivalent standard coverage could include reducing cost-sharing to $0 for generic or preferred covered Part D drugs, as provided under section 1860D–2(b)(5) of the Act, as long as the cost-sharing structure is actuarially equivalent to an average expected coinsurance of 25 percent for costs above the annual deductible and up to the initial coverage limit. Plans with cost-sharing arrangements that are actuarially more generous than standard prescription drug coverage would be considered enhanced alternative coverage, as defined in section II.C.2.b.ii of this preamble. (Section II.F.2 of this preamble explains the methodology for determining actuarial equivalence).

Based on our interpretation of section 1860D–2(b)(5) of the Act, we also propose allowing plans offering actuarially equivalent standard coverage to establish cost-sharing of an amount that is actuarially equivalent to the expected cost-sharing under § 423.104(e)(5)(i) (taking into account both 5 percent coinsurance and $2/$5 copayments for costs above the out-of-pocket threshold required under defined standard coverage). As previously discussed, section 1860D–2(b)(5) of the Act indicates that plans cannot be prevented from reducing to $0 the cost-sharing applicable to preferred or generic drugs. While this provision only references reductions based on the need to retain a standard benefit, we propose requiring that any alternative cost-sharing structure for costs in the catastrophic range (whether under actuarially equivalent standard coverage or enhanced alternative coverage) be actuarially equivalent to standard prescription drug coverage's structure of 5 percent coinsurance or $2/$5 copayments. Our proposed requirement would function in the same manner as the requirement for actuarial equivalence to alternatives to the 25 percent coinsurance structure for costs above the deductible and below the initial coverage limit, as discussed in further detail in section II.F.4.b of this preamble. Any such alternative cost-sharing arrangements would be reviewed, along with the rest of a plan's benefit design, to ensure that they do not discriminate against certain Part D eligible individuals.

b. Alternative Prescription Drug Coverage

Section 1860D–2(c) of the Act and § 423.104(f) provide that a PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan may offer an alternative prescription drug benefit design, provided that the PDP sponsor or MA organization applies for and receives our approval for the proposed alternative. In order to receive approval to offer an alternative prescription drug benefit design, a PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan would have to meet the requirements related to actuarial equivalence described in section 1860D–2(c)(1) of the Act and discussed in further detail

below (as well as in section II.F.3 of this preamble). It is important to note that, in modifying the standard coverage design to offer alternative prescription drug coverage per the following requirements, plans would have to use defined standard coverage (and not actuarially equivalent standard coverage) as a fixed point of comparison. Because numerous variants of actuarially equivalent standard coverage are possible, it would not be feasible to use actuarially equivalent standard coverage as a point of comparison for alternative prescription drug coverage.

As provided under section 1860D–2(c)(2) of the Act and codified in § 423.104(f)(1) of our proposed rule, any alternative prescription drug benefit design would be required to include a deductible that was no greater than the deductible offered under standard prescription drug coverage. Section 1860D–2(c)(3) of the Act requires that alternative coverage provide the coverage required under section 1860D–2(b)(4), which specifies the requirements for coverage to protect beneficiaries against high out-of-pocket expenditures. As provided in § 423.104(f)(2) of our proposed rule, we are interpreting this requirement to mean that prescription drug plans and MA–PD plans must provide coverage above the out-of-pocket threshold that is at least as generous as that provided under defined standard coverage. In other words, plans could—at their option—reduce cost-sharing below that included under defined standard coverage (the greater of 5 percent coinsurance or $2/$5 copayments).

In addition, section 1860D–2(c)(1)(B) of the Act and § 423.104(f)(3) of our proposed rule would require that the actuarial value of alternative prescription drug coverage's unsubsidized coverage is at least equal to the actuarial value of unsubsidized defined standard coverage. Section 1860D–2(c)(1)(C) of the Act and § 423.104(f)(4) of our proposed rule would require that, under alternative prescription drug coverage, the plan payout at the dollar value of the initial coverage limit under standard coverage, for an individual whose total spending exceeds that limit, is at least equal to that provided under defined standard coverage.

i. Basic Alternative Coverage

Beyond the required parameters for alternative coverage discussed above, we are interpreting the provisions of section 1860D–2(c) of the Act, together with section 1860D–2(a)(1) of the Act, as providing for two forms of alternative coverage—either "basic alternative coverage" or "enhanced alternative coverage." Basic alternative coverage would refer to alternative coverage that is actuarially equivalent to defined standard prescription drug coverage, as described in section II.C.2.a of this preamble. Enhanced alternative coverage would refer to alternative coverage that exceeds defined standard coverage by offering supplemental benefits and is discussed in section II.C.2.b.ii of this preamble.

Within the parameters for alternative prescription drug coverage described above, a PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan with a basic alternative prescription drug benefit design could theoretically—by combining features such as a reduction in the deductible, changes in cost-sharing (for example, benefit designs that use tiered copayments or coinsurance in an actuarially equivalent manner to the 25 percent cost-sharing above the deductible and below the initial coverage limit under defined standard coverage), and a modification of the initial coverage limit—still be able to maintain an actuarial value of coverage equal to defined standard prescription drug coverage.

Although basic alternative prescription drug coverage within the parameters described above is allowed, it is unclear because of utilization effects whether PDP sponsors and MA organizations could, in fact, offer coverage that meets the statutory requirements other than by modifying cost-sharing as already allowed under actuarially equivalent standard coverage. We invite comments on whether there are basic alternative benefit designs that go beyond actuarially equivalent standard coverage.

ii. Enhanced Alternative Coverage

Section 423.104(g) of our proposed rule would permit PDP sponsors and MA organizations offering an MA–PD plan to provide qualified prescription drug coverage that includes supplemental benefits. Because the actuarial value of any prescription drug coverage benefit package that includes supplemental benefits would exceed that of standard coverage, such coverage must always be alternative drug coverage as described in section II.C.2.b of this preamble. Thus, we refer to any Part D benefit package that includes supplemental benefits as "enhanced alternative coverage."

Enhanced alternative coverage would include basic prescription drug coverage and supplemental benefits. The requirements for the supplemental benefits that may be included in enhanced alternative coverage are found in section 1860D–2(a)(2) of the Act and § 423.104(g)(1)(ii) of our proposed rule. These supplemental benefits would supplement basic prescription drug coverage, providing for a package of benefits that exceeds the actuarial value of defined standard coverage. Supplemental benefits could consist of:

- Reductions in cost-sharing (for example, a reduction in the deductible, a reduction in the coinsurance percentage or copayments applicable to covered Part D drugs obtained between the annual deductible and the initial coverage limit, or an increase in the initial coverage limit described in § 423.104(e)(2), provided these reductions in cost-sharing increase the actuarial value of the benefits provided above the actuarial value of basic prescription drug coverage); and/or
- Coverage of drugs that are specifically excluded as covered Part D drugs under section 1860D–2(e)(2)(A) of the Act and § 423.100 of our proposed rule.

We propose interpreting "value" to mean the total value as described in section 1860D–2(c)(1)(A) of the Act. We request comments on this interpretation.

Under section 1860D–2(a)(2)(B) of the Act, and proposed in § 423.104(g)(2), a PDP sponsor would not be permitted to offer a prescription drug plan that provided enhanced alternative coverage in a particular service area unless it also offered a plan that provided only basic prescription drug coverage in that same area. Section 1860D–2(a)(3) of the Act defines basic prescription drug coverage as either—

(a) Standard prescription drug coverage (as described in proposed § 423.104(e) and in section II.C.2.a of this preamble) with access to negotiated prices; or

(b) Basic alternative drug coverage (as described in § 423.100 and section II.C.2.b.i of this preamble) with access to negotiated prices.

Similarly, as provided under section 1860D–21(a)(1)(A) and codified in § 423.104(g)(3)(i) of our proposed rule, beginning on January 1, 2006, an MA organization could not offer an MA coordinated care plan, as defined in 42 CFR 422.4 of our proposed rule and section 1851(a)(2)(A) of the Act, in a service area unless that plan, or another MA plan offered by the same organization in the same service area, includes required prescription drug coverage. As defined in § 423.100, required prescription drug coverage, for the purposes of an MA organization

offering an MA–PD plan, would include either: (1) Basic prescription drug coverage, or (2) enhanced alternative coverage, provided there is no MA monthly supplemental beneficiary premium applied under the plan. Such enhanced alternative coverage could be provided without a monthly supplemental beneficiary premium only if a plan applied a credit against the otherwise applicable premium of rebate dollars available under section 1854(b)(1)(C) of the Act. Rebate dollars represent the dollars available for supplemental (and other) benefits when an MA plan's risk-adjusted non-drug bid is under the risk-adjusted non-drug monthly benchmark amount. In other words, to the extent that an MA–PD plan chose to provide enhanced alternative coverage for no additional premium through the application of rebate dollars, such enhanced alternative coverage would constitute required coverage for the purposes of meeting the requirement in section 1860D–21(a)(1)(A) of the Act.

This provision is similar in intent to the restrictions on the offering of enhanced alternative coverage by PDP sponsors found in § 423.104(g)(2) of our proposed rule. As previously mentioned, PDP sponsors are required to offer at least one plan offering basic prescription drug coverage in all areas they serve in order to offer any plan that enhances or supplements that basic coverage. The objective of both of these requirements is to assure that PDP sponsors and MA PD organizations offer at least one option for Part D coverage for a premium at the cost of basic prescription drug coverage.

As a note of clarification, provided a PDP sponsor offers at least one plan in a service area that provides basic prescription drug coverage only, it can offer as many plans that offer enhanced alternative coverage as it wishes. Similarly, an MA organization that offers at least one MA–PD plan that meets the aforementioned test of providing required prescription drug coverage is free to offer plans that provide other types of enhanced alternative coverage for which they can charge a monthly supplemental beneficiary premium, as well as plans that offer no qualified prescription drug coverage.

As provided under section 1860D–21(a)(1)(B)(i) of the Act and codified in our proposed rule at § 423.104(g)(3)(ii)(A), an MA organization could not offer prescription drug coverage (other than that required under Parts A and B of Medicare) to enrollees of an MSA plan. Under section 1860D–21(a)(1)(B)(ii) and § 423.104(g)(3)(ii)(B) of our proposed rule, an MA organization also could not offer prescription drug coverage (other than that required under Parts A and B of Medicare) under another type of MA plan—including a private fee-for-service plan—unless the drug coverage it provided under that MA plan consisted of qualified prescription drug coverage and met our requirements regarding required prescription drug coverage as articulated previously in this preamble section.

c. Negotiated Prices

Section 1860D–2(d)(1) of the Act requires, as implemented under § 423.104(h) of our proposed rule, that a PDP sponsor or MA organization offering an MA–PD plan provide beneficiaries with access to negotiated prices for covered Part D drugs. As required by section 1860D–2(d)(1)(B) of the Act, negotiated prices would have to take into account negotiated price concessions for covered Part D drugs such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, and would include any applicable dispensing fees. Access to negotiated prices would have to be provided even when no benefits would otherwise be payable on behalf of an enrollee due to the application of a deductible, the initial coverage limit, or other cost-sharing. We are interpreting the reference to the lack of payable benefits due to the application of the initial coverage limit as referring to that portion of covered Part D drug expenditures between the initial coverage limit and the out-of-pocket threshold. In that expenditure range, a beneficiary enrolled in standard prescription drug coverage would be responsible for 100 percent cost-sharing, and the plan would pay no benefits. We are also interpreting the phrase "or other cost-sharing" as a reference to plan designs that may include, as a part of their formulary design, access to negotiated prices on certain drugs but at a tier within their formulary in which the plan would pay no benefits and the beneficiary would be responsible for 100 percent cost-sharing (in other words, a negotiated price would be available and the drug would be on the plan's formulary, but the beneficiary would be responsible for 100 percent of that drug's negotiated price).

As required under section 1860D–2(d)(1)(C) of the Act, prices negotiated with manufacturers for: (1) Covered Part D drugs by either a prescription drug plan or an MA–PD plan; or (2) a qualified retiree prescription drug plan, as described in § 423.882 of our proposed regulation on the Medicare retiree drug subsidy program, with respect to covered Part D drugs provided on behalf of part D eligible individuals would not be taken into account in making "best price" determinations under the Medicaid program. Under current Medicaid best price policy, the largest discount a pharmaceutical manufacturer negotiates in the private market must be passed along to the Medicaid program; however, prices negotiated with manufacturers for covered Part D drugs would not be factored into these calculations as provided under § 423.104(h)(2) of our proposed rule.

Section 423.104(h)(3) would require, as stated in the provisions of section 1860D–2(d)(2) of the Act, that PDP sponsors offering a prescription drug plan and MA organizations offering an MA–PD plan disclose to us all aggregate negotiated price concessions—including discounts, direct or indirect subsidies, and direct or indirect remunerations—they obtain from each pharmaceutical manufacturer that are passed through to the Medicare program in the form of lower subsidies or to beneficiaries in the form of: (1) Lower monthly beneficiary premiums, and/or (2) lower covered Part D drug prices at the point of sale. We note that plans may fulfill this requirement through the data submission requirements articulated in proposed § 423.336(c)(1) and § 423.343(c)(1) and discussed in further detail in section II.G.4 of this preamble. In other words, we should be able to determine the proportion of total aggregate price concessions that are passed through to either the Medicare program or to beneficiaries based on the cost data plans would be required to submit to CMS.

As provided under section 1860D–2(d)(2) of the Act and § 423.104(h)(3)(ii) of our proposed rule, information on negotiated prices reported to CMS for the purposes of ascertaining the level of pass-through would be protected under the confidentiality provisions applicable to Medicaid pricing data under section 1927(b)(3)(D) of the Act. We note, however, that these confidentiality protections would not preclude audit and evaluation of negotiated price concession information by the HHS Office of the Inspector General (OIG) and, in fact, that such audits and evaluations may be necessary for carrying out the requirements of section 1860D–4(d)(1) of the Act.

We would specify in operational guidance the format and frequency of these reports. As discussed in section II.G.4 of this preamble, we are proposing to require plans to ensure that price concessions are accounted for separately

from any fair market value administrative fees pharmaceutical manufacturers may pay PDP sponsors or MA organizations. For a more detailed discussion of data submission requirements, please refer to section II.G.4 of this preamble.

As provided under section 1860D–2(d)(3) of the Act and codified in § 423.104(h)(4) of our proposed rule, we would be authorized to conduct periodic audits—either directly or through contracts with other organizations—of the financial statements and records of PDP sponsors and MA organizations pertaining to the prescription drug plans and MA–PD plans they offer. As required in section 1860D–2(d)(3) of the Act, this auditing would be performed with the ultimate goal of protecting the Medicare program against fraud and abuse, as well as ensuring proper disclosures and accounting under Part D. Section 423.504(d) of our proposed rule includes additional requirements with respect to auditing of PDP sponsors as a safeguard against fraud and abuse. These fraud and abuse protections incorporate those protections applicable to MA organizations under section 1857(d)(2)(B) of the Act and are discussed in detail in section II.K.6.a of this preamble.

3. Establishment of Prescription Drug Plan Service Areas (§ 423.112)

Section 1860D–11(a)(1) of the Act requires that a prescription drug plan's service area encompass an entire PDP region, as established by us under § 423.112(b), and § 423.112(a) of our proposed rule codifies that requirement. However, as provided under § 423.112(e) of our proposed rule, a prescription drug plan can be offered in more than one PDP region (provided the plan encompasses the entire PDP region for each region where offered), as well as nationally.

Section 1860D–11(a)(2) of the Act provides us with the authority to establish PDP regions, and such PDP regions must be established in a manner that is consistent with the establishment of MA regions under 42 CFR 422.445 of our proposed rule. Section 1860D–11(a)(2)(B) stipulates that PDP regions must be, to the extent practicable, consistent with MA regions as established under section 1858(a)(2) of the Act. As provided under § 423.112(b)(2), however, if we determine that access to Part D benefits would be improved by establishing PDP regions that are different than MA regions, we may establish PDP regions that vary from MA regions. Section 423.112(d) of our proposed rule would allow us to revise the PDP regions we establish as necessary.

In accordance with section 1860D–14(a)(3)(F) of the Act, residents of United States territories are not eligible for the Part D subsidies otherwise provided to low-income individuals. Such territorial residents, however, would be eligible for financial assistance for prescription drug expenses under section 1935(e) of the Act. Note that a new section 1935 of the Act was added by section 103 of the Medicare Modernization Act (MMA) through a redesignation of the current section 1935 as section 1936. The U.S. territories, unlike the 50 United States and the District of Columbia, may continue to receive federal Medicaid grants under section 1108 of the Act to compensate them for drug coverage provided to Part D eligible individuals under specific conditions. For this reason, section 1860D–11(a)(2)(C) of the Act and § 423.112(c) of our proposed rule stipulate that CMS designate a separate PDP region (or regions) for the U.S. territories.

We intend to initially designate both PDP and MA regions by January 1, 2005. In accordance with section 1858(a)(2)(C)(i) of the Act, there will be between 10 and 50 PDP regions within the 50 States and the District of Columbia and at least one PDP region covering the United States territories. The PDP regions, like the MA regions, will become operational in January 2006.

We conducted a public meeting on July 21, 2004, in order to obtain broad public comment on the methodology we should use in establishing both the PDP regions and MA regions for MA regional plans, which would operate as preferred provider organizations (PPOs). The information on that meeting is available at *https://www.cms.hhs.gov/medicarereform/mmaregions*. Using the feedback from that meeting and other research, we are considering a number of issues, including: how we should design PDP regions in order to ensure that all beneficiaries have access to prescription drug plans; how best to ensure access to prescription drug plans through the design of PDP regions that are the same as (or, if necessary, different than) MA regions; how to design a PDP region (or regions) in the U.S. territories; and how we can best discuss with the public the development of both the PDP and MA regions. Separate guidance on the designation of regions will be forthcoming.

Whereas § 423.112 provides that a prescription drug plan's service area must encompass one or more PDP regions, an MA–PD plan's service area would consist of either: (1) one or more MA regions (for a regional MA plan), or (2) one or more MA local areas (for a local MA plan). "MA region" is defined in 42 CFR 422.455(b) of our proposed rule as a region within the 50 States and the District of Columbia as established by CMS. As provided in § 423.112(b)(2) of our proposed rule, we will attempt to establish PDP regions that coincide with MA regions to the extent practicable. "Local MA area" is defined in 42 CFR 422.252 of our proposed rule as a payment area consisting of county or equivalent area that we specify.

4. Access to Covered Part D Drugs (§ 423.120)

a. Pharmacy Access Standards

As required by section 1860D–4(b)(1)(C) of the Act, prescription drug plans and MA–PD plans would be required to secure the participation in their pharmacy networks of a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to ensure convenient access to covered Part D drugs by plan enrollees. To achieve that goal, we are authorized to establish access rules that are no less favorable to enrollees than rules for convenient access established in the statement of work solicitation (#MDA906–03–R–0002) by the Department of Defense (DoD) on March 13, 2003, for purposes of the TRICARE Retail Pharmacy program. Consistent with the TRICARE standards, § 423.120(a)(1) of our proposed rule would require that prescription drug plans and MA–PD plans establish pharmacy networks in which:

- In urban areas, at least 90 percent of Medicare beneficiaries in the plan's service area, on average, live within 2 miles of a retail pharmacy participating in the prescription drug plan's or MA–PD plan's network;
- In suburban areas, at least 90 percent of Medicare beneficiaries in the plan's service areas, on average, live within 5 miles of a retail pharmacy participating in the prescription drug plan's or MA–PD plan's network; and
- In rural areas, at least 70 percent of Medicare beneficiaries in the plan's service area, on average, live within 15 miles of a retail pharmacy participating in the prescription drug plan's or MA–PD plan's network.

For the purposes of meeting these access standards, as also provided in DoD's statement of work of solicitation #MDA906–03–R–0002—

- Urban would be defined as a five-digit ZIP Code in which the population

density is greater than 3,000 persons per square mile;

- Suburban would be defined as a five-digit ZIP Code in which the population density is between 1,000 and 3,000 persons per square mile; and
- Rural would be defined as a five-digit ZIP Code in which the population density is less than 1,000 persons per square mile.

We are interpreting the access standard under § 423.120(a)(1) such that a prescription drug plan or regional MA–PD plan would have to meet or exceed the access standards across each region in which it operates, and a local–MA–PD plan would have to meet or exceed the access standards in its local service area. In other words, a prescription drug plan or regional MA–PD that operates in a multi-region or national service area could not meet the access standards proposed in § 423.120(a)(1) by applying them across the entire geographic area serviced by the plan; instead, it would have to meet the standards in each region of its multi-region or national service area. We believe that such an interpretation maximizes plan flexibility while assuring the best possible access to pharmacies for Part D enrollees, and we request comments on our proposed approach.

While prescription drug plans and MA–PD plans would not be precluded from including non-retail pharmacies (for example, institution-based pharmacies) in their networks under our proposed rule, we interpret the access requirements in section 1860D–4(b)(1)(C) of the Act as requiring prescription drug plans and MA–PD plans to count only retail pharmacies as part of their networks for the purpose of meeting the access standard in § 423.120(a)(1). We would consider a retail pharmacy to be any licensed pharmacy from which covered Part D enrollees could purchase a covered Part D drug without being required to receive medical services related to that particular covered Part D drug from a provider or institution affiliated with that pharmacy. In other words, prescription drug plans and MA–PD plans could—and would be encouraged to—include non-retail pharmacies (for example, hospital and clinic pharmacies) in their networks; however, given the limited populations served by such non-retail pharmacies, plans could not count these pharmacies toward our pharmacy access requirements.

We recognize, however, that prescription drug plans and MA–PD plans operating in rural areas with high concentrations of American Indian/Alaska Native (AI/AN) individuals may have a difficult time meeting our access standards if they cannot count pharmacies that are operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (hereinafter referred to as "I/T/U pharmacies") toward their pharmacy access requirements. We are considering allowing prescription drug plans and MA–PD plans to count I/T/U pharmacies toward their network access requirements, provided: (1) Such pharmacies are under contract with the plan; and (2) it would be impossible or impracticable for the plan to meet the access standard in rural areas of its service area without the inclusion of an I/T/U pharmacy (or pharmacies) in that count because there is not a sufficient number of non-I/T/U pharmacies in those areas willing or able to contract with the PDP sponsor or MA organization in accordance with its terms and conditions. We invite comments on this proposed exception to our pharmacy access rules, including any impact it might have on pharmacy access for non-AI/AN Part D enrollees residing in those areas.

Section 423.120(a)(1) of our proposed rule would not in any way preclude PDP sponsors or MA organizations offering an MA–PD plan from contracting with pharmacies outside their plans' service areas, provided that the plans meet the pharmacy access requirements within their service areas. Such a feature would be of particular benefit to beneficiaries who spend significant amounts of time outside their prescription drug plan's or MA–PD plan's service area (for example, "snowbirds") and could make a particular prescription drug plan or MA–PD plan more attractive to them. In addition, the fact that beneficiaries would have access to network pharmacies outside their plan's service area would obviate the need for out-of-network access (discussed in greater detail in section II.C.5 of this preamble) to covered Part D drugs in many cases. Thus, contracting with pharmacies outside a plan's service area could ultimately represent a cost-savings both to plans and beneficiaries, particularly if a plan enrolls a high proportion of beneficiaries who regularly travel outside the plan's service area.

Section 1860D–4(b)(1)(C)(iv) of the Act provides that, in establishing rules for convenient access to network pharmacies, we may include standards with respect to access to long-term care pharmacies for Part D enrollees who reside in skilled nursing facilities and nursing facilities (hereinafter referred to as "long-term care facilities"), as well as for American Indian/Alaska Native (AI/AN) Part D enrollees who obtain their prescription drugs at I/T/U pharmacies. We recognize that given their specialized missions and the narrowly defined subsets of beneficiaries they serve, access to long-term care and I/T/U pharmacies should be preserved. Such access would greatly enhance Part D benefits for enrollees in long-term care facilities, as well as for AI/AN enrollees.

As discussed in section II.C.5 of this preamble, we expect that the out-of-network access requirement articulated in § 423.124(a)(2) would assure access to covered Part D drugs provided by long-term care pharmacies for Part D enrollees residing in long-term care institutions that do not contract with their prescription drug plans or MA–PD plans. Since it is generally the case that long-term care facilities contract with a single long-term care pharmacy, Part D enrollees residing in a long-term care facility could not reasonably be expected to access their covered Part D drugs at another pharmacy if their facility's long-term care pharmacy is not part of their plan's network.

However, we are also considering whether to use the authority provided under section 1860D–4(b)(1)(C)(iv) of the Act to require prescription drug plans and MA–PD plans to approach some or all long-term care pharmacies in their service areas with at least the same terms available under their plans' standard pharmacy contracts. Given Federal nursing home regulations, nursing facilities contract with a long-term care pharmacy to provide prescription drugs and services to their residents. In the absence of direct collaboration between a plan and a Part D enrollee's long-term care pharmacy, it would be difficult for nursing facilities to meet Federal pharmacy management standards.

We are concerned, however, that to the extent that we require plans to solicit long-term care pharmacies in their service areas to join their networks, plans may be forced to negotiate preferential contracting terms and conditions (relative to the terms they would offer any other pharmacy willing to participate in its network) with a number of long-term care pharmacies in order to meet our requirement.

We also expect that long-term care pharmacies will be concerned about appropriate reimbursement for services (for example, clinical consultations, emergency medication access with 24-hour-a-day deliveries, specialized packaging, and IV and infusion therapies) that they currently provide long-term care facility residents. It is

possible that recognition of appropriate services would be addressed by provisions arranged by prescription drug plans and MA–PD plans and network pharmacies, with any resulting dispensing charges reflected in permissible dispensing fees. Section II.C.1 of this preamble discusses several options for defining the term "dispensing fees." However, it is our goal to balance convenient access to long-term care pharmacies with appropriate payment for dispensing fees of efficient facilities. To the extent that we require plans to contract with long-term care pharmacies, it is our goal to assure that long-term care pharmacies charge reasonable dispensing fees to plans (and indirectly to CMS through the direct subsidy paid to prescription drug plans and MA–PD plans). We welcome comments regarding how to balance convenient access to long-term care pharmacies with appropriate payment to long-term care pharmacies under the provisions of the MMA.

Alternatively, we would not require that plans contract with long-term care pharmacies and would, instead, strongly encourage PDP sponsors and MA organizations offering MA–PD plans to negotiate with and include long-term care pharmacies in their plans' pharmacy networks. We seek public comment regarding the advantages and disadvantages of these two approaches.

Similarly, we are considering two options for assuring access to I/T/U pharmacies by AI/AN Part D enrollees per the provisions of section 1860D–4(b)(1)(C)(iv) of the Act. There are currently 201 I/T/U pharmacies serving 107,000 senior and disabled AI/ANs in 27 States. In some areas, I/T/U pharmacies may be the only facilities capable of providing medication therapy management services to certain AI/AN beneficiaries due to language and cultural barriers. I/T/U pharmacies are unique in several different ways, including that they purchase drugs off the Federal Supply Schedule (FSS); can only serve AI/ANs; may have less experience than retail pharmacies (or none at all) with point-of-sale technology; are not typically well integrated into commercial pharmacy networks; generally stock a more limited range of drugs than would be required under a Part D formulary; and always waive co-pays.

One approach to assuring access to I/T/U pharmacies under Part D would be to use our authority under Section 1860D–4(b)(1)(C)(iv) of the Act to require that PDP sponsors and MA organizations approach any I/T/U pharmacies in their plan service areas with at least the same terms available under the plan's standard pharmacy contract. We are aware, however, that contracting with I/T/U pharmacies is potentially more complex than contracting with retail pharmacies given that there are a number of provisions in the standard contracts of commercial health plans that would likely need to be modified or deleted given statutory or regulatory restrictions to which I/T/U pharmacies are subject, as well as the particular circumstances of I/T/U pharmacies. Some examples of standard contract clauses that could be problematic for I/T/U pharmacies include:

- Prohibitions on waiving copays;
- Required provision of all drugs on a plan's drug formulary;
- Requirements that providers bill and/or receive funds electronically to participate in the network;
- Requirements that claims be submitted within a specific timeframe;
- Requirements that plans serve all patients without discrimination;
- Requirements that providers carry private malpractice insurance;
- Requirements that providers be licensed in the state in which they provide services; and
- Requirements that binding arbitration be used in the event that any dispute arises with regard to performance or interpretation of any terms of the agreement and the parties are unable to resolve the dispute in an informal fashion.

We expect that, to the extent that we require plan inclusion of I/T/U pharmacies in plan networks, we would provide plans with a model addendum to their standard contracts (should we require them) that would take the special circumstances of I/T/U pharmacies into account. Such an addendum could also be useful for facilitating the inclusion in prescription drug plan or MA–PD plan pharmacy networks of other types of pharmacies (Federally Qualified Health Centers, for example, which are subject to some of the same limitations described above for I/T/U pharmacies that make many standard contract clauses impracticable).

A requirement that plans contract with I/T/U pharmacies could potentially expand plans' market share in areas with high concentrations of AI/ANs. Plans may also benefit from cost-savings as a result of doing business with I/T/U pharmacies given I/T/U pharmacies' heavy reliance on the dispensing of generic drugs. Also, given that IHS/tribal government subsidies of Part D cost-sharing on behalf of beneficiaries will not, as discussed in section II.C.2.a of this preamble, count toward incurred costs, most IHS beneficiaries would almost never incur costs above the out-of-pocket limit; this would likely provide plans with additional cost-savings. On the other hand, we recognize that there is some potential for increased administrative costs for prescription drug plans and MA–PD plans given the need to modify standard contracts (should we require them) and, given the limited electronic capabilities of most I/T/U pharmacies, the processing of paper claims. In addition, the AI/AN population is one with which commercial health plans have little, if any, experience. Given these potential administrative costs, we are reluctant to require contracts with I/T/U facilities if that requirement discourages PDP sponsors and MA organizations from offering plans in service areas with large concentrations of AI/ANs.

Another option for assuring access to I/T/U pharmacies under Part D would be not to require that plans contract with I/T/U pharmacies and, instead, to strongly encourage PDP sponsors and MA organizations offering MA–PD plans to negotiate with and include I/T/U pharmacies in their plans' pharmacy networks. We are concerned, however, that—in the absence of a contracting requirement—plans may make assumptions regarding the administrative costs (whether real or perceived) of contracting with I/T/U pharmacies and may not actively solicit the inclusion of these pharmacies in their networks. It is our understanding that I/T/U pharmacies are not currently well integrated in commercial pharmacy networks. The lack of I/T/U pharmacies in Part D plan networks would render enrollment in Part D of little use to AI/AN beneficiaries who rely primarily on I/T/U facilities for their health care. We encourage comments regarding these two approaches, their advantages and disadvantages, and their ramifications for AI/AN enrollees who are eligible to enroll in Part D.

As noted earlier, federally qualified health centers (FQHCs) and rural pharmacies face many of the same barriers to inclusion in commercial plan networks as do I/T/U pharmacies. Beneficiaries served by FQHCs and rural pharmacies are often served in those settings because of their financial and geographic circumstances. Plans may have to contract with these pharmacies in order to meet the access requirements in § 423.120(a)(1) of our proposed rule—particularly in rural areas. However, to the extent that they are able to meet the access requirements without doing so, we are concerned about compromised access to network pharmacies by low-

income beneficiaries who rely on FQHC and rural pharmacies for their health care. We solicit comments on permissible ways for us to assure Part D enrollees' access to FQHC and rural pharmacies, among others.

As stated above, we have proposed three options for defining "dispensing fees." Two of these options take into account some of the costs associated with administering infused covered Part D drugs to the beneficiary. Based on our research, most commercial health plans cover home infusion drugs and services under their medical benefits, given the cost-savings resulting from averted hospitalizations. However, because prescription drug plans do not offer a medical benefit under which to experience cost-savings, we do not believe that prescription drug plans would have an incentive to include home infusion pharmacies in their networks. We are considering using the authority in section 1860D–4(b)(1)(C) of the Act to require that both MA–PD plans and prescription drug plans contract with a sufficient number of home infusion pharmacies in their service area to provide reasonable access for Part D enrollees. Such a requirement would be allowed under Section 1860D–4(b)(1)(C) of the Act because the rules established with respect to convenient access to network pharmacies for Part D enrollees would be at least as favorable to enrollees as those used under the TRICARE Retail Pharmacy program. We seek public comment regarding the advantages and disadvantages of such an approach, how such a requirement could be structured, and any other issues we should consider.

We recognize that some beneficiaries may prefer to obtain their prescription drugs from mail-order pharmacies. While prescription drug plans and MA–PD plans could not offer a mail-order-only option to their beneficiaries or count mail-order pharmacies as part of their networks for the purpose of meeting the access standard in § 423.120(a)(1), prescription drug plans and MA–PD plans would be permitted, as provided under § 423.120(a)(2), to offer a home delivery option via a mail-order pharmacy. Any such home delivery option would be in addition to the retail pharmacies in a plan's network.

As provided under section 1860D–21(c)(3) of the Act and codified in § 423.120(a)(3)(i) of our proposed rule, we are authorized to waive the pharmacy access standards in § 423.120(a)(1) in the case of an MA–PD plan that provides access (other than via mail order) to qualified prescription drug coverage through pharmacies owned and operated by the MA organization that offers the plan. However, in order for the pharmacy access standards to be waived, the MA–PD plan in question would be required to have a pharmacy network that, per our determination, provides comparable pharmacy access to its enrollees. We would evaluate whether such a plan's network provides comparable access to covered Part D drugs to its enrollees using the same considerations we currently use to evaluate MA plans' other provider networks under 42 CFR 422.112 of our proposed rule.

Similarly, § 423.120(a)(3)(ii) would codify section 1860D–21(d)(2) of the Act, which provides that if a private fee-for-service MA plan offering qualified prescription drug coverage provides coverage for drugs, including covered Part D drugs, purchased from all pharmacies—regardless of whether they are network pharmacies under contract with the MA plan, and provided that beneficiaries are not charged any cost-sharing above and beyond what they would be charged under standard prescription drug coverage—the pharmacy access requirements at § 423.120(a)(1) would also be waived.

As provided under section 1860D–4(b)(1)(A) of the Act and implemented in § 423.120(a)(4)(i), PDP sponsors and MA organizations offering an MA–PD plan would be required to permit the participation in their plan networks of any pharmacy that was willing to accept the plan's terms and conditions. However, it is unreasonable to assume that a PDP sponsor or MA organization could establish a network using a uniform set of terms and conditions throughout a service area. Modification of contracting terms and conditions might be necessary, for example, to assure access in remote rural areas or for beneficiaries who obtain their drugs from long-term care pharmacies. Varying terms and conditions might also be required in order for the sponsor to provide a cost effective benefit through rebates and price concessions. The cost estimates for Part D assume that PDP sponsors and MA organizations offering an MA–PD plan would be able to achieve savings from retail prices through formulary and network design. Thus, the requirement at § 423.120(a)(4)(i) of our proposed rule does not mandate a single set of terms and conditions for participation in a pharmacy network.

We seek comment on whether, in order to guarantee that any pharmacy willing to meet a PDP sponsor's or MA organization's contracting terms and conditions could participate in a plan's pharmacy network, we should require that PDP sponsors and MA organizations offering an MA–PD plan make available to all pharmacies a standard contract for participation in their plans' networks. That requirement would not preclude PDP sponsors and MA organizations from negotiating terms and conditions different from those in the standard contract with a subset of pharmacies. These varying terms and conditions would therefore not have to be made available to all pharmacies. We note that, if required, it is our expectation that these standard contracts would require network pharmacies (except for pharmacies—long-term care, I/T/U, and rural pharmacies, for example—for which paper claims are the norm given technology access or coordination of benefits issues) to maintain systems to adjudicate drug claims at the point-of-sale.

As stipulated under section 1860D–4(b)(1)(E) of the Act and § 423.120(a)(4)(ii) of our proposed rule, pharmacies could not be required to accept insurance risk as a condition of participation in a PDP sponsor's or MA organization's pharmacy network. As defined in § 423.4, "insurance risk" in relation to a network pharmacy refers to risk of the type commonly assumed only by insurers licensed by a State. Insurance risk does not include payment variations designed to reflect performance-based measures of activities within the control of a pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs, productivity).

Section 423.120(a)(5) of our proposed rule, based on section 1860D–4(b)(1)(B) of the Act, clarifies that a PDP sponsor or MA organization offering an MA–PD plan would have the option of reducing cost-sharing for its enrolled beneficiaries below the level that would otherwise apply for covered Part D drugs dispensed through network pharmacies. We interpret this provision as not restricting PDP sponsors and MA organizations offering MA–PD plans from varying cost-sharing not only based on type of drug or formulary tier, but also on a particular pharmacy's status within the plan's pharmacy network—in essence authorizing distinctions between "preferred" and "non-preferred" pharmacies. We believe that the statute allows these within network (preferred versus non-preferred pharmacy) distinctions to be made despite the "any willing provider"

provision at § 423.120(a)(4)(i) of our proposed rule.

While these within network distinctions are allowed, the statute also requires that any such tiered cost-sharing arrangements in no way increase our payments to PDP sponsors or MA organizations. We are therefore proposing that tiered cost-sharing arrangements based on within-network distinctions could be included in plans' benefits subject to the same actuarial tests that apply for tiered cost-sharing structures based on formulary. Thus, a reduction in cost-sharing for preferred pharmacies could be offered through higher cost-sharing for non-preferred pharmacies or as alternative prescription drug coverage. For further discussion of actuarial equivalence, please see section II.F.4 of this preamble.

We recognize the possibility that plans could effectively limit access in portions of their service areas by using the flexibility provided in § 423.120(a)(5) of our proposed rule to create a within-network subset of preferred pharmacies. In other words, in designing its network, a plan could establish a differential between cost-sharing at preferred versus non-preferred pharmacies—while still meeting the access standards in § 423.120(a)(1) of our proposed rule—that is so significant as to discourage enrollees in certain areas (rural areas or inner cities, for example) from enrolling in that plan. Our intent is to use the authority provided under section 1860D–11(e)(2)(D) of the Act to review, as part of the bid negotiation process described in § 423.272 of our proposed rule, the design of proposed prescription drug plan and MA–PD plan designs to ensure that they are not likely to substantially discourage enrollment by certain part D eligible individuals. Such a review would preclude the approval of bids submitted by plans that attempt to use strategies such as that outlined above to limit enrollment in portions of their service areas that are more difficult or costly to serve.

We recognize that some beneficiaries may prefer to purchase their prescription drugs at a community pharmacy rather than through a mail-order pharmacy and that community pharmacies typically dispense only 30-day supplies of prescription drugs at a time. Section 1860D–4(b)(1)(D) of the Act would require PDP sponsors and MA organizations offering an MA–PD plan to allow their enrollees to receive benefits at a network retail pharmacy instead of a network mail-order pharmacy, if they so choose. Such benefits could include an extended supply (for example, 45-day, 60-day, 90-day supply) of covered Part D drugs that is typically available only through a network mail-order pharmacy. However, because mail-order pharmacies are often able to provide lower prices to individuals than retail pharmacies, it is possible that the negotiated price for an extended supply (for example, a 90-day supply) of a covered Part D drug would be more costly at a network retail pharmacy than through the network mail-order pharmacy assigned to the enrollee by their prescription drug plan or MA–PD plan. Thus, as provided under § 423.120(a)(6) of the proposed rule, a plan enrollee who chooses to obtain an extended supply of a covered Part D drug through a network retail pharmacy would be responsible for any differential between the network retail pharmacy's and the network mail-order pharmacy's negotiated price for that covered Part D drug. Since any such differential costs would be associated with benefits covered under a Part D plan, we seek comments on our proposal that this price differential be counted as an incurred cost against the annual out-of-pocket threshold consistent with the definition of "incurred cost" in § 423.100. Under this approach, plans would be required to explicitly account for such price differentials in the actuarial valuation of their coinsurance in their bids. In addition, any such differential would also count toward the deductible for covered Part D expenditures between $0 and the plan's deductible.

b. Formulary Requirements

To the extent that a PDP sponsor or MA organization uses a formulary to provide qualified prescription drug coverage to Part D enrollees, it would be required to meet the requirements of § 423.120(b)(1) and section 1860D–4(b)(3)(A) of the Act to use a pharmaceutical and therapeutic (P&T) committee to develop and review that formulary. As a note of clarification, we interpret the requirement at section 1860D–4(b)(3)(A) of the Act that a formulary be "developed and reviewed" by a P&T committee as requiring that a P&T committee's decisions regarding the plan's formulary be binding on the plan. However, we request comments on this interpretation. In addition, it is our expectation that P&T committees will be involved in designing formulary tiers and any clinical programs implemented to encourage the use of preferred drugs (*e.g.*, prior authorization, step therapy, generics programs).

The majority of members comprising the P&T committee would be required to be practicing physicians and/or practicing pharmacists. In addition, at least one practicing pharmacist and one practicing physician member would have to be experts in the care of elderly and disabled individuals. However, we would also encourage that plans select P&T committee members representing various clinical specialties in order to ensure that all disease states are adequately considered in the development of plan formularies. Section 423.120(b)(1)(ii) of the proposed rule also provides that at least one practicing pharmacist and one practicing physician members on a plan's P&T committee be independent experts. We interpret the statutory language at section 1860D–4(b)(3)(A)(ii) of the Act requiring certain members of the P&T committee to be "independent and free of conflict with respect to the sponsor and plan" to mean that such P&T committee members must have no stake, financial or otherwise, in formulary determinations. In other words, these individuals would be required to be independent and free of conflict with respect not only to a PDP sponsor and its prescription drug plan or an MA organization and its MA–PD plan, but also with respect to pharmaceutical manufacturers. In addition, we solicit public comment with respect to the appropriateness of strengthening the statutory requirement in section 1860D–4(b)(3)(A)(ii) of the Act by requiring, in our final regulations, that more than just one pharmacist and one physician on the P&T committee be independent and free of conflict.

When developing and reviewing the formulary, the P&T committee would be required, under § 423.120(b)(1)(iii) and in accordance with section 1860D–4(b)(3)(B) of the Act, to base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature (for example, randomized clinical trials, pharmacoeconomic studies, outcomes research data, and such other information as the committee determined appropriate). We note that the Public Health Service has developed guidelines for the treatment of HIV disease and related opportunistic infections that may also be useful to plan's P&T committees; these guidelines can be found at *http://www.aidsinfo.nih.gov/guidelines/*. Pharmacoeconomic studies may be considered in clinical decision making by a P&T committee with respect to formulary development. It is our expectation, however, that any cost considerations will be balanced with

clinical considerations in the development and revision of a plan's formulary. The P&T committee would also take into account whether including a particular covered drug in the formulary (or in a particular formulary tier) had any therapeutic advantages in terms of safety and efficacy, per § 423.120(b)(1)(iv) of our proposed rule. Section 423.120(b)(1)(v) of our proposed rule would require that any decisions made by the P&T committee regarding development or revision of a plan's formulary be documented in writing.

As provided under section 1860D–4(b)(3)(C)(ii) of the Act, we will request the U.S. Pharmacopeia (USP) to develop a model set of guidelines that consists of a list of drug categories and classes that may be used by PDP sponsors and MA organizations to develop formularies for their qualified prescription drug coverage, including their therapeutic categories and classes. We expect that the model categories and classes developed by USP will be defined so that each includes at least one drug that is approved by the FDA for the indication(s) in the category or class. That is, no category or class would be created for which there is no FDA approved drug and which would therefore have to include a drug based on its "off label" indication. However, this would not preclude physicians and other prescribers from prescribing drugs for off label indications, though we strongly encourage prescribers to clearly document and justify off-label use in their Part D enrollees' clinical records. Additionally, the USP model guidelines would not preclude PDP sponsors or MA organizations from assigning an FDA approved drug to a category or class based on an off label use for that drug, provided the FDA has not made a determination that the drug is unsafe for that use. In addition to developing these initial model guidelines, the USP will revise its classification periodically to reflect changes in therapeutic uses of covered Part D drugs and any additions of new covered Part D drugs. As explained below, PDP sponsors and MA organizations will have some flexibility in developing formularies for prescription drug plans and MA–PD plans.

We expect that the development of these guidelines will require USP to conduct outreach to beneficiary groups and major industries affected by the development of model guidelines. We specifically envision USP conducting multiple consultations and a public meeting with related health care industries and providers (including national representatives of pharmacies); Medicare physicians and other practitioners, including pharmacists; other provider groups, including long-term care providers; the managed care industry; the health insurance industry; pharmacy benefit managers (PBMs); and Medicare beneficiary advocacy groups). These consultations would be conducted with the goal of researching current best practices in formulary development and existing commercial and other standards (for example Medicaid, the Medicare Prescription Drug Discount Card), as well as obtaining informed recommendations concerning the development of the Part D model guidelines. The goal of the public meeting would be to solicit comments on a draft of the model guidelines, which would be developed on the basis of the aforementioned consultations, as well as USP's research and recommendations. As our work with USP gets underway, we will provide further detail on the USP classification in upcoming operational guidance to entities wishing to become PDP sponsors or MA organizations offering MA–PD plans. Also, we wish to make clear that any guidelines established by the USP are applicable only to Part D benefits. They do not require the Secretary to make any decisions or take any actions with regard to classifying or categorizing drugs for any purpose other than implementing the Part D benefit.

Although the USP will develop guidelines, under section 1860D–4(b)(3) of the Act PDP sponsors and MA organizations would have the flexibility to develop their own classification schemes. The USP listing would simply serve as a model set of guidelines. As specified in 1860D–11(e)(2)(D)(ii) of the Act, if the therapeutic classifications within a plan's formulary conform to the USP classification model, we could not determine, based on the formulary's therapeutic classifications, that the plan violates the provision at 1860D–11(e)(2)(d)(i) of the Act and § 423.272(b)(2) that prohibits the design of a plan and its benefits (including any formulary and tiered formulary structure) that substantially discourages enrollment by certain Part D eligible individuals. It is important to note, however, that even if a plan's formulary classifications conform to the USP classification model, its overall formulary design could still be found to substantially discourage enrollment by certain Part D individuals (for example, based on particular drugs selected for inclusion in the formulary and/or proposed cost-tiering structure). If, on the other hand, a PDP sponsor or MA organization offering an MA–PD plan designs its formulary using therapeutic classes and categories that vary from the USP classification model, CMS would evaluate the submitted formulary design to ensure that the proposed therapeutic classification system does not substantially discourage enrollment by certain Part D eligible individuals. We invite comments regarding standards and criteria that we could use to determine that a PDP sponsor or MA organization's formulary classification system that is not based on the model classification system does not in fact discriminate against certain classes of Part D eligible beneficiaries.

Section 1860D–4(b)(3)(C) of the Act and § 423.120(b)(2) require the inclusion of "drugs" in each therapeutic category and class of covered Part D drugs in a plan's formulary, although not necessarily all drugs within such categories and classes. We interpret this requirement to mean that a PDP sponsor or MA organization's formulary would be required to include at least two drugs within each therapeutic category and class of covered Part D drugs within the PDP sponsor or MA organization's formulary (unless there is only one drug in a particular therapeutic class or category, in which case the inclusion of only one drug would be required). Section 423.120(b)(2) of our proposed rule would also require that the drugs included in each therapeutic class or category include a variety of strengths and doses to the extent this is feasible. We believe that the inclusion of at least two drugs in each therapeutic class or category (except for those classes or categories that include only one drug) strikes an appropriate balance between providing plans with the necessary leverage to negotiate with manufacturers for significant discounts on covered Part D drugs and ensuring sufficient drug choice for beneficiaries. We note, however, that it is our expectation that plans' formularies will provide Part D enrollees a comprehensive benefit—one that covers an amount and variety of drugs sufficient to treat all disease states. In addition, given that discounts on commonly used generic drugs are typically made available to enrollees under current industry practice and produce cost-savings both for plans and enrollees, we expect that prescription drug plan and MA–PD plan formularies will include a wide range of generic drugs.

As elaborated above, we will evaluate the formularies of plans using a classification system different from the USP model guidelines to ensure that the formulary does not discriminate against certain classes of beneficiaries. We also

intend to strictly enforce rules regarding plans' P&T committees, as described above, as well as coverage determination, reconsideration, and appeals processes, to ensure that Part D enrollees are able to access the drugs they need.

Within the aforementioned parameters, it is certainly possible that a prescription drug plan or MA–PD plan could develop a formulary that employs a number of strategies—for example, financial incentives to encourage use of generics, tiered cost-sharing and other mechanisms that create strong incentives for manufacturers to negotiate favorable prices for covered Part D drugs, prior authorization procedures, therapeutic interchange, step therapy, and use of mail order—to produce cost-savings both for plans and for Medicare. While we are open to these types of strategies as a way to minimize costs for enrollees and for the Medicare program, it is possible that certain vulnerable populations (enrollees in long-term care facilities or those suffering from mental illness or chronic diseases such as AIDS, for example) may be negatively impacted financially if they do not have access to a wide range of drugs in certain therapeutic classes and categories. We seek comments on ways to balance plans' flexibility to use some of the mechanisms described above to maximize covered Part D drug discounts and lower enrollee premiums with the needs of certain special populations of Part D enrollees.

One such population is Part D enrollees residing in long-term care facilities. Given the changes in Medicaid drug coverage introduced by the MMA, we believe it is particularly important to ensure that the drug needs of institutionalized Part D enrollees—most of whom are dually eligible for Medicare and Medicaid—are met. The institutionalized population is generally more sensitive to and less tolerant of many medications. Long-term care pharmacies typically provide an open formulary to prescribing physicians that allows immediate access to a wide variety of medications in many different dosages and delivery forms. We request comments regarding any special treatment (for example, offering certain classes of enrollees an alternative or open formulary that accounts for their unique medical needs, and/or special rules with respect to access to dosage forms that may be needed by these populations but not by other Part D enrollees), we should consider requiring of plans with respect to special populations, as well as suggestions regarding the particular special populations for whom we may want to make allowances.

Under § 423.120(b)(3) of our proposed rule and in accordance with section 1860D–4(b)(3)(C)(iii) of the Act, PDP sponsors and MA organizations could not change therapeutic categories and classes in a formulary other than at the beginning of a plan year, except as we would permit to take into account new therapeutic uses and newly approved covered Part D drugs. Section 423.120(b)(4) of our proposed rule specifies that, in accordance with section 1860D–4(b)(3)(F) of the Act, PDP sponsors and MA organizations offering MA–PD plans would periodically be required to evaluate and analyze treatment protocols and procedures related to their formularies to ensure that their plan members were receiving the best possible care for conditions related to their use of covered Part D drugs. We invite comments as to minimum timeframes for periodic evaluation and analysis of protocols and procedures related to a plan's formulary by PDP plans and MA organizations offering MA–PD plans (for example, quarterly, annually).

In addition, section 1860D–4(b)(3)(E) of the Act requires that PDP sponsors and MA organizations provide "appropriate notice" to us, affected enrollees, authorized prescribers, pharmacists, and pharmacies regarding any decision to either: (1) Remove a drug from its formulary, or (2) make any change in the preferred or tiered cost-sharing status of a drug. Section 423.120(b)(5) would implement that requirement by defining appropriate notice as at least 30 days prior to such change taking effect during a given contract year. We interpret the statutory term "affected enrollee" as referring to a plan enrollee who is currently taking a covered Part D drug that is either being removed from a plan's formulary, or whose preferred or tiered cost-sharing status is changing. In other words, plans would not be required to notify all enrollees regarding formulary changes during a contract year—only those directly affected by changes with respect to a particular covered Part D drug. We note that plans would still be required to provide at least two drugs within each therapeutic category and class of covered Part D drugs within the PDP sponsor or MA organization's formulary (unless there is only one drug in a particular therapeutic class or category), even if they choose to remove a covered Part D drug from their formularies in the middle of a contract year. In addition, we refer the reader to section II.M.5 of this preamble, which discusses formulary exceptions procedures and may be important for enrollees of plans whose formularies change mid-year.

We recognize that both current and prospective enrollees of a prescription drug plan or an MA–PD plan will need to have the most current formulary information by the time of the annual coordinated election period described in § 423.36(b) in order to enroll in the Part D plan that best suits their particular covered Part D drug needs. To this end, and as provided under § 423.120(b)(6) of our proposed rule, PDP sponsors and MA organizations would be prohibited from removing a covered Part D drug or from changing the preferred or tiered cost-sharing status of a covered Part D drug between the beginning of the annual coordinated election period described in § 423.36(b)(2) and 30 days subsequent to the beginning of the contract year associated with that annual coordinated election period. We believe this requirement will prevent situations in which prescription drug plans or MA–PD plans change their formulary early in the contract year, without providing appropriate notice, as described in § 423.120(b)(5), to new enrollees. Given that we are proposing that plans provide at least 30 days notice to affected enrollees prior to making formulary changes, it seems reasonable to require, as we propose doing in § 423.120(b)(6), that all marketing materials distributed during the annual coordinated election period reflect the formulary a plan will offer at the beginning of the contract year for which it is enrolling Part D eligible individuals.

As discussed in sections II.C.6.c and II.C.6.d of this preamble, PDP sponsors and MA organizations can get information regarding formulary changes to beneficiaries via an Internet Web site, as well as via explanations of benefits sent to enrollees who utilize their Part D benefits. However, other methods (for example, notification by mail) will have to be used to provide notice to CMS, all affected enrollees, authorized prescribers, pharmacists, and pharmacies about impending formulary changes.

Each PDP sponsor and MA organization offering qualified prescription drug coverage would also be required to establish policies and procedures to educate and inform health care providers and enrollees about its formulary, according to the provisions of § 423.120(b)(7) and section 1860D–4(b)(3)(D) of the Act. As required under section 1860D–4(b)(3) of the Act, the requirements regarding the development and application of formularies discussed in this preamble section may

be met by a PDP sponsor or MA organization directly, or through contracts or other arrangements between a PDP sponsor or MA organization and another entity or entities.

c. Use of Standardized Technology

In accordance with the requirements of section 1860D–4(b)(2)(A) of the Act, § 423.120(c) of our proposed rule would require that PDP sponsors and MA organizations issue (and reissue, as appropriate) a card or other technology that enrollees could use to access negotiated prices for covered part D drugs. Section 1860D–4(b)(2)(B)(i) of the Act mandates that we develop, adopt, or recognize standards relating to a standardized format for a card or other technology for accessing negotiated prices to covered Part D drugs. These standards would be compatible with the administrative simplification requirements of Title XI of the Act and could be based on standards developed by a standard setting organization.

As provided under section 1860D–4(b)(2)(B)(ii) of the Act, we will consult with the National Council for Prescription Drug Programs (NCPDP) and other standard setting organizations, as appropriate, to develop these standards. Given that NCPDP is recognized as the industry standard for current prescription drug programs, and we relied on its standards in developing requirements for discount card sponsors' cards under the Medicare Prescription Drug Discount Card and Transitional Assistance Program, we are proposing basing our card standards on NCPDP's "Pharmacy ID Card Standard." This standard is based on the American National Standards Institute ANSI INCITS 284–1997 standard titled *Identification Card—Health Care Identification Cards,* which may be ordered through the Internet at *http://www.ansi.org.* We will provide further operational guidance regarding our standards for a card (or other technology) to entities wishing to become PDP sponsors or MA organizations in time for these entities to use the standards (and have their cards approved for use by us) beginning January 1, 2006. It is our intent, however, that these standards require that plans use something other than an enrollee's social security number as an identifier on their cards.

5. Special Rules for Access to Covered Part D Drugs at Out-of-Network Pharmacies (§ 423.124)

Section 1860D–4(b)(1)(C)(iii) of the Act requires us to establish pharmacy access standards that include rules for adequate emergency access to covered Part D drugs by Part D enrollees. We reviewed the definition of an "emergency medical condition" (*see* § 422.113(b)(1)(i) of our proposed rule) under the MA program to determine whether the "prudent layperson" standard was an appropriate standard for ascertaining whether the need for a covered Part D drug constitutes an emergency. However, we do not believe that the definition of an emergency medical condition, or a variation thereof, is entirely appropriate to prescription drugs. To the extent that a physician (or other prescriber) prescribes a covered Part D drug, we consider that covered Part D drug to likely be medically necessary. The issue of urgency or emergency is difficult to determine from a clinical perspective, however.

Given the inherent difficulties in establishing emergency access standards for covered Part D drugs, we propose to meet the requirements of section 1860D–4(b)(1)(C)(iii) by establishing a broader out-of-network access requirement. As provided in § 423.124(a) of our proposed rule, we would require that PDP sponsors and MA organizations offering MA–PD plans assure that their enrollees have adequate access to drugs dispensed at out-of-network pharmacies when they cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy. We expect that out-of-network access would be guaranteed under at least the following four scenarios:

- In cases in which a Part D enrollee meets all of the following: is traveling outside his or her plan's service area; runs out of or loses his or her covered Part D drug(s) or becomes ill and needs a covered Part D drug; and cannot access a network pharmacy;
- In cases in which a Part D enrollee cannot obtain a covered Part D drug in a timely manner within his or her service area because, for example, there is no network pharmacy within a reasonable driving distance that provides 24-hour-a-day/7-day-per-week service;
- In cases in which a Part D enrollee resides in a long-term care facility and the contracted long-term care pharmacy does not participate in his or her plan's pharmacy network; and
- In cases in which a Part D enrollee must fill a prescription for a covered Part D drug, and that particular covered Part D drug (for example, an orphan drug or other specialty pharmaceutical typically shipped directly from manufacturers or special vendors) is not regularly stocked at accessible network retail or mail-order pharmacies.

We believe that enrollees under the aforementioned circumstances could not reasonably be expected to access a network pharmacy and must therefore be assured access to an out-of-network pharmacy as provided under § 423.124(a) of our proposed rule. We request comments on our proposed out-of-network access requirements.

We are aware that routine access to out-of-network pharmacies by Part D enrollees may undermine a plan's cost-savings incentives. However, provided adequate access is assured under § 423.124(a), PDP sponsors and MA organizations offering MA–PD plans would have some flexibility to design their out-of-network coverage policies. PDP sponsors and MA organizations offering MA–PD plans may therefore establish reasonable rules to assure that enrollees use out-of-network pharmacies appropriately. For example, PDP sponsors and MA organizations offering MA–PD plans could limit the amount of covered Part D drugs dispensed at an out-of-network pharmacy, require the use of mail order pharmacies as appropriate for extended out-of-area travel, and/or require a plan notification process for individuals who fill their prescriptions at out-of-network pharmacies.

As a point of clarification, enrollees would not be permitted to access prescription drugs that were not considered covered Part D drugs due to application of the prescription drug plan's or MA–PD plan's formulary at an out-of-network pharmacy. Enrollees who require a covered Part D drug that is not on their prescription drug plan or MA–PD plan's formulary would be required to use the coverage determination process described in § 423.566 of our proposed rule.

Both the enrollee and his or her prescription drug plan or MA–PD plan would be financially responsible for covered Part D drugs obtained at an out-of-network pharmacy as described in § 423.124(a) of our proposed rule (in other words, when an enrollee cannot reasonably be expected to access his or her covered Part D drugs at a network pharmacy), though we note that paper claims may have to be filed and payment reconciled after the drug purchase instead of (as would be the case with most, if not all, network pharmacies), at the point of sale. Section 423.124(b)(1) of our proposed rule would require that the Part D enrollee be liable for any cost-sharing, including a deductible, that would have otherwise applied had the covered Part D drug been obtained at a network pharmacy. Such cost-sharing would be applied relative to the plan allowance for that

covered Part D drug, which we propose defining in § 423.100 as the amount prescription drug plans and MA–PD plans use to determine their payment and Part D enrollees' cost-sharing for covered Part D drugs purchased at out-of-network pharmacies in accordance with the requirements of proposed § 423.124(b). We request comments on how to further define the term "plan allowance." Our understanding is that it is current industry practice to define the plan allowance as the lowest of the contractual discount offered to pharmacies in a plan's standard contract (as described above, we are soliciting public comment regarding whether we should require PDP sponsors and MA organizations to offer a standard contract to all pharmacies), maximum allowable cost (MAC), or the pharmacy's usual and customary price (described below).

Thus, for example, if the beneficiary would have been liable for 25 percent coinsurance at a network pharmacy, he or she would pay 25 percent of the plan allowance for that covered Part D drug. If, on the other hand, the beneficiary would have been liable for a $10 copay at a network pharmacy, he or she would still pay $10 at the out-of-network pharmacy.

In addition to this cost-sharing, and as provided under proposed § 423.124(b)(2), the enrollee would be responsible for any difference in price between the out-of-network pharmacy's usual and customary (U&C) price and the plan allowance for that covered Part D drug. The term "usual and customary price" refers to the price that a pharmacy would charge a customer who does not have any form of prescription drug coverage. Thus, for example, if an out-of-network pharmacy's U&C price for a covered Part D drug were $100, the plan's allowable cost (including beneficiary cost-sharing) for that covered Part D drug were $90, and the negotiated price for the covered Part D drug at the beneficiary's network pharmacy were also $90, a beneficiary obtaining a drug at the out-of-network pharmacy would pay the cost-sharing that would have otherwise applied at a network pharmacy (for example, 25 percent of the $90 plan allowance), plus the $10 difference—a total of $32.50, in this case (compared to $22.50 at the network pharmacy). We request public comments regarding our definition of usual and customary price. We are concerned that, given our proposed out-of-network access policy, pharmacies may increase their U&C prices to increase their total reimbursement. This would be prejudicial not only to beneficiaries in need of out-of-network access, but also to uninsured individuals purchasing drugs at retail pharmacies, and we seek feedback on permissible ways to prevent such an outcome.

When an enrollee purchases a covered Part D drug at an out-of-network pharmacy consistent with § 423.124(a) of our proposed rule, the cost-sharing he or she pays relative to the plan allowance ($22.50 in the example above) counts as an incurred cost against his or her annual out-of-pocket threshold because such out-of-network access to a covered part D drug is a covered benefit under those circumstances. As with the price differential that a beneficiary could incur by purchasing an extended supply (for example, 90-day) of covered Part D drugs purchased at a retail pharmacy rather than a mail-order pharmacy (discussed in section II.C.4.a of this preamble), the price differential between out-of-network pharmacies' U&C costs and the plan allowance would also be counted as an incurred cost against a beneficiary's annual out-of-pocket threshold. We seek comments on our proposal that this price differential be counted as an incurred cost against the out-of-pocket threshold consistent with the definition of "incurred cost" in § 423.100 of the proposed rule. Under this approach, plans would be required to explicitly account for such price differentials in the actuarial valuation of their coinsurance in their bids. In addition, any such differential would also count toward the deductible for covered Part D expenditures between $0 and the plan's deductible.

The plan in the example above would be responsible for payment of the plan allowance for the covered Part D drug minus the applicable beneficiary cost-sharing—$67.50, in this case—which is the same amount as the plan would have paid for that covered Part D drug at the network pharmacy. Given our proposed rules regarding financial responsibility for out-of-network access to covered Part D drugs, plans would in effect be financially held harmless for out-of-network use by their enrollees under § 423.124(a) of our proposed rule. We believe this is necessary in order to curb unnecessary use of out-of-network pharmacies and to ensure that plans can achieve cost-savings for both beneficiaries and the Medicare program. We welcome public comments regarding our proposed payment rules for covered Part D drugs obtained at out-of-network pharmacies when enrollees cannot reasonably obtain those drugs at a network pharmacy.

6. Dissemination of Plan Information (§ 423.128)

Section 423.128 of our proposed rule would establish beneficiary protection requirements concerning the dissemination of Part D information by PDP sponsors and MA organizations to enrollees in, and individuals eligible to enroll in, a prescription drug plan or MA–PD plan. Part D information disseminated by PDP sponsors and MA organizations to current or prospective Part D enrollees would constitute marketing materials, as described in § 423.50(b) of the proposed rule, and must be approved by us. For more information regarding the approval of marketing materials, please refer to section II.B.9 of this preamble).

As explained in greater detail below, we note that—with the exception of the drug-specific information dissemination requirements—many of the requirements of § 423.128 of the proposed rule duplicate information dissemination requirements contained in § 422.111 of our proposed rule that are applicable to all MA plans, including MA–PD plans. We have proposed applying the requirements of § 423.128 to MA–PD plans to ensure that Part D eligible enrollees have access to comparable drug-specific information from both prescription drug plans and MA–PD plans. We solicit comments on how best to coordinate the requirements of § 423.128 and § 422.111 of our proposed rule for MA–PD plans.

a. Content of Plan Description

Sections 423.128(a) and (b) of our proposed rule complies with the stipulation in section 1860D–4(a)(1) of the Act that requirements for the dissemination of Part D information be similar to the information dissemination requirements for MA organizations under section 1852(c)(1) of the Act and as interpreted in § 422.111(b) of our proposed rule.

In order to ensure that individuals who are either eligible for, or enrolled in, a plan offering qualified prescription drug coverage receive the information they need to make informed choices about their Part D coverage options, PDP sponsors and MA organizations offering an MA–PD plan would be required to disclose, to each enrollee in a plan offering qualified prescription drug coverage, a detailed description of that plan. This description would be provided in a clear, accurate, and standardized form at the time of enrollment and annually, at a minimum, after enrollment. The information provided would be similar to the information MA plans must disclose to

their enrollees under § 422.111(b) of our proposed rule. The plan description would include information about:

- The service area;
- Benefits offered, including information on cost-sharing requirements (for example, tiered or other copayment level applicable to a drug or class of drugs, deductibles, coinsurance), cost-sharing requirements for subsidy eligible individuals, and how a beneficiary may obtain further information about those cost-sharing requirements;
- How any formulary used by the plan works, the process for obtaining an exception to a prescription drug plan's or MA–PD plan's tiered cost-sharing structure, and how to obtain a copy of the formulary as well as information about formulary changes;
- Access to network pharmacies;
- Out-of-network coverage provided by the plan;
- Grievance, coverage determination, exceptions, reconsideration, and appeals procedures;
- A description of the plan's quality assurance program, including the medication therapy management program required under § 423.153(d) of our proposed rule; and
- Disenrollment rights and responsibilities.

b. Disclosure of Information Upon Request

In addition, according to section 1860D–4(a)(2) of the Act and as codified in § 423.128(c) of our proposed rule, a beneficiary who is eligible to enroll in a PDP sponsor's prescription drug plan or an MA organization's MA–PD plan would have the right to obtain, upon request, more detailed plan information. This information would be similar to that which MA organizations are required to disclose to their enrollees upon request under sections 1852(c)(2)(A), (B), and (C) of the Act and 42 CFR 422.111(c) and (f) of our proposed rule, and would include:

- General coverage information (for example, enrollment procedures; grievance, coverage determination, reconsideration, exceptions, and appeals procedural rights; the potential for the PDP sponsor or MA organization contract termination or service area reduction; benefits; premiums; formulary; service area; and quality and performance indicators);
- The procedures the organization would use to control utilization of services and expenditures;
- The number of disputes and their disposition in the aggregate; and
- The financial condition of the PDP sponsor or MA organization.

c. Provision of Specific Information

As required under section 1860D–4(a)(3) of the Act and § 423.128(d) of our proposed rule, PDP sponsors and MA organizations offering an MA–PD plan would be required to have in place a mechanism for providing, on a timely basis, specific information to current and prospective enrollees upon request. Such mechanisms would include:

- A toll-free customer call center;
- An Internet Web site; and
- Responses in writing upon beneficiary request.

As provided in § 423.128(d)(1)(i) and (ii) of our proposed rule, plans' customer call centers would be required to be open during usual business hours and provide customer telephone service, including to pharmacists, in accordance with standard business practices. We strongly recommend, however, that plans provide some sort of 24-hour-a-day/7 day-a-week access to their toll-free customer call centers in order to provide timely responses to time-sensitive questions (for example, on out-of-network pharmacy access) and request comments on whether we should require the more stringent 24-hour-a-day/7-day-a-week standard in our final regulations.

In addition, we are proposing requiring that plans maintain Web sites as one means of disseminating information to current and prospective Part D enrollees. The Internet has proved to be an inexpensive and widely available source of information on health plans. Almost all Federal Employees Health Benefits (FEHB) plans, most large employer plans, and almost all managed care organizations maintain websites for the convenience of enrollees. Such Web sites typically contain information on drug formularies, preferred providers, plan access and emergency procedures, claims procedures, and a wide array of other useful information. Health plans have found that up-to-date formulary and provider information can be conveyed to enrollees far more quickly, reliably, and inexpensively via Internet than through traditional paper processes. Survey evidence shows that roughly half of the elderly routinely use the Internet. Even those who do not have direct access usually have friends or family who can assist them in obtaining information from the Internet. Libraries and senior support and counseling groups are almost always able to provide Internet Assistance. Thus, a great number of Medicare beneficiaries could benefit from the existence of prescription drug plan and MA–PD plan Web sites.

As provided in § 423.128(d)(2)(i) of our proposed rule, PDP sponsors and MA organizations offering MA–PD plans would be required to include the detailed plan description information described in section II.C.6.a of this preamble. In addition, per §§ 423.128(d)(2)(ii) and (iii) of our proposed rule, plans would have to post current versions of their formularies, update those formularies at least weekly, and use the website as one mechanism to provide notice (at least 30 days in advance, as discussed in section C.4.b of this preamble) of upcoming formulary changes, including the removal of covered Part D drugs from a formulary or changes to the tiered or preferred status of covered Part D drugs. Plan websites would have to be available both to current and prospective Part D enrollees. We note that plans would continue to be required to make information available to Part D eligible individuals in written formats as is currently the case for MA plans, and the provision of plan information via the Internet would simply be one additional mechanism for plans to communicate with enrollees and potential enrollees.

Finally, prescription drug plans and MA–PD plans would be required to respond to beneficiary requests for specific information in writing, upon request. This requirement is codified in § 423.128(d)(3) of our proposed rule.

d. Claims Information

In accordance with the requirements of section 1860D–(4)(a)(4) of the Act, and as codified in § 423.128(e) of our proposed rule, PDP sponsors would furnish to enrollees who receive covered Part D drugs an explanation of benefits. Explanations of benefits would be required to be written in a form easily understandable to beneficiaries.

As provided in §§ 423.128(e)(1)–(5) of our proposed rule, plans' explanations of benefits would have to include:

- A listing of the item or service for which payment was made, as well as the amount of such payment for each item or service;
- A notice of the individual's right to request an itemized statement;
- Information regarding the cumulative, year-to-date amount of benefits provided relative to the deductible, the initial coverage limit, and the annual out-of-pocket threshold for that year;
- A beneficiary's cumulative, year-to-date total of incurred costs (to the extent practicable); and
- Information about any applicable formulary changes.

We would require, under § 423.128(e)(6) of our proposed rule, that an explanation of benefits be provided at least monthly for those utilizing their prescription drug benefits in a given month. This proposed requirement is consistent with our policy regarding the Medicare Summary Notice, which is provided monthly for beneficiaries with Part A or Part B utilization. It is also consistent with the standards followed by banking and other financial organizations, which provide their clients with monthly statements provided there is activity on their accounts.

A PDP sponsor or MA organization offering an MA–PD plan could provide the notice of benefits electronically in cases in which a beneficiary elected to receive notices in that form. If technically feasible, a PDP sponsor or MA organization could also provide the notice of benefits at the point of sale; this would allow the PDP sponsor or MA organization to provide enrollees with additional information (for example, this could facilitate the provision of information regarding the availability of lower-cost generic availability required under § 423.132 of the proposed rule).

7. Public Disclosure of Pharmaceutical Prices for Equivalent Drugs (§ 423.132)

Under § 423.132(a) of our proposed rule, which codifies the requirements of section 1860D–4(k)(1) of the Act, PDP sponsors offering a prescription drug plan and MA organizations offering an MA–PD plan would be required to ensure that pharmacies inform enrollees of any differential between the price of a covered Part D drug to an enrollee and the price of the lowest priced generic version of that drug and available under the plan at that pharmacy. Under § 423.132(b) of our proposed rule, this information would have to be provided at the time the plan enrollee purchases the drug, or in the case of drugs purchased by mail order, at the time of delivery of that drug. Disclosure of this information would not be necessary, however, if the particular covered Part D drug purchased by an enrollee was the lowest-priced generic version of that drug available at a particular pharmacy.

As provided under section 1860D–4(k)(2)(B) of the Act and § 423.132(c) of our proposed rule, we are permitted to waive the requirement that information on differential prices between a covered Part D drug and generic equivalent covered Part D drugs be made available to prescription drug plan enrollees at the point of sale (or at the time of delivery of a drug purchased through a mail-order pharmacy). Accordingly, we are proposing waiving the requirement in § 423.132(a) that information on lowest-priced generic drug equivalents be provided to enrollees for covered Part D drugs purchased by prescription drug plan and MA–PD plan enrollees when those covered Part D drugs are purchased at:

- Any pharmacy, when the individual is enrolled in an MA private fee-for-service plan that offers qualified prescription drug coverage and provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies, and does not charge additional cost-sharing for access to covered Part D drugs dispensed at all pharmacies;
- Out-of-network pharmacies;
- I/T/U network pharmacies; and
- Network pharmacies located in any of the U.S. territories (American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands).

Section 1860D–21(d)(2) of the Act specifically requires us to waive the public disclosure requirement for private fee-for-service MA plans meeting the criteria described above. Section 423.132(c)(1) of our proposed rule implements this waiver for private fee-for-service MA plans that meet those criteria.

Our rationale for proposing waiver of the public disclosure requirement for out-of-network pharmacies, as provided under § 423.132(c)(2) of our proposed rule, is that such a requirement necessitates a contract between a PDP sponsor or MA organization and a pharmacy. Since, by definition, out-of-network pharmacies are not under contract with a PDP sponsor or an MA organization, complying with the public disclosure requirement would be impracticable.

We also propose waiving the requirement in § 423.132(a) when prescription drug plan enrollees obtain covered Part D drugs in I/T/U pharmacies, as provided under § 423.132(c)(3) of our proposed rule. Because I/T/U pharmacies do not charge American Indians/Alaska Natives (AI/ANs) for drugs obtained at I/T/U pharmacies, AI/ANs obtaining drugs from these pharmacies would not benefit from the provision of information about covered Part D drug price differentials. Furthermore, because I/T/U pharmacies generally only stock the generic versions of brand name drugs, AI/ANs obtaining drugs from these pharmacies would already be receiving a generic equivalent of any brand name part D drug prescribed to them.

We believe it is appropriate to waive the public disclosure requirement for PDP sponsors when covered Part D drugs are provided in network pharmacies located in the territories given that few PBMs and health plans currently have contractual relationships with retail pharmacies in the territories. Our goal in waiving this requirement, as provided in § 423.132(c)(4) of our proposed rule, would be to reduce the administrative complexity of PDP sponsors and MA organizations' contracts with participating retail pharmacies in the territories, which we believe would enhance organizations' willingness to offer qualified prescription drug coverage in the territories. However, mail order drugs sent to residents of the territories would be required to include information about the price differential between a covered Part D drug and its lowest-priced generic version in the same manner as such information would be provided to Part D enrollees in the 50 States and District of Columbia who obtain mail order drugs under Part D.

Finally, as provided in § 423.132(c)(5) of our proposed rule, we propose waiving the public disclosure requirement in § 423.132(a) under such circumstances as we deem to be impossible or impracticable. We request comments on the appropriateness of the circumstances we have proposed for waiver of the requirements in § 423.132(c), as well as any additional circumstances we may wish to consider. We note that a similar public disclosure requirement was waived for endorsed discount card sponsors under the Medicare Prescription Drug Discount Card (42 CFR 403 and 408) for covered discount card drugs dispensed under several of the same circumstances as those described above.

In § 423.132(d)(1) of our proposed rule, we propose waiving the requirement that information on differential prices between a covered Part D drug and generic equivalent covered Part D drugs be made available to prescription drug plan and MA–PD plan enrollees at the *point of sale* when prescription drug plan enrollees obtain covered Part D drugs in long-term care pharmacies. Long-term care pharmacies generally provide drugs directly to the skilled nursing facilities and nursing facilities where the patient resides, not directly to the patient, under a medical benefit. They also engage in a significant coordination of benefits effort that would require that at least some claims be processed off-line, and not in real time. Given the manner in which long-term care pharmacies provide prescription drugs to residents of long-

term care facilities, as well as the way in which they process claims, it would be impracticable for these pharmacies to provide beneficiaries with information regarding covered Part D drug price differentials at the point of sale. Although long-term care network pharmacies would be exempt from the requirement that information about lower-priced generic alternatives be provided at the point of sale, they would not be exempt from the public disclosure requirement in § 423.132(a) altogether. We request comments regarding appropriate standards with regard to the timing of such disclosure by long-term care pharmacies to the institutionalized Part D enrollees they service. We note, as well, that under § 423.132(d)(2) of our proposed rule, we may modify the timing of the public disclosure requirement under such other circumstances as we deem compliance with that requirement to be impossible or impracticable.

8. Privacy, Confidentiality, and Accuracy of Enrollee Records (§ 423.136)

To the extent that the prescription drug plan offered by a PDP sponsor maintains medical records or other health information regarding Part D enrollees, § 423.136 of our proposed rule would require the PDP sponsor to meet the same requirements regarding confidentiality and accuracy of enrollee records as MA organizations offering MA plans must currently meet under 42 CFR 422.118, according to the stipulations of section 1860D–4(i) of the Act. PDP sponsors would therefore be required to—

- Abide by all Federal and State laws regarding confidentiality and disclosure of medical records or other health and enrollment information, including the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the privacy rule promulgated under HIPAA;
- Ensure that medical information is released only in accordance with applicable Federal or State law;
- Maintain the records and information in an accurate and timely manner; and
- Ensure timely access by enrollees to records and information pertaining to them.

Prescription drug plans would be considered covered entities under the HIPAA Privacy Rule because they meet the definition of "health plan," as described in 45 CFR 160.103. The HHS Office for Civil Rights (OCR) is responsible for implementing and enforcing the HIPAA Privacy Rule. OCR has authority to investigate complaints, to conduct compliance reviews, and to impose civil money penalties for HIPAA Privacy Rules violations. Thus, any violations by an endorsed sponsor with respect to its obligations under the Privacy Rule as a covered entity are subject to such enforcement by OCR. OCR maintains a Web site with frequently asked questions and other compliance guidance at *http://hhs.gov/ocr/hipaa*.

D. Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

1. Overview (§ 423.150)

Subpart D of part 423 implements provisions included in sections 1860D–4(c), 1860D–4(d), 1860D–4(e), 1860D–4(j), and 1860D–21(d)(3) of the Act and sections 102(b) and 109 of Title I of the MMA. This subpart sets forth the following requirements:

- Cost and Utilization Management Programs, Quality Assurance Programs, Medication Therapy Management Programs (MTMP), and Programs to control fraud, abuse, and waste for PDP sponsors and MA Organizations offering MA–PD plans that offer qualified prescription drug coverage;
- CMS consumer satisfaction surveys of PDP and MA–PD plan enrollees.
- Electronic prescription programs.
- Compliance deemed on the basis of accreditation.
- Accreditation organizations.
- Procedures for the approval of accreditation as a basis for deeming compliance.

2. Cost and Utilization Management, Quality Assurance, Medication Therapy Management, and Programs To Control Fraud, Abuse, and Waste (§ 423.153)

Section 423.153(a) of our proposed rule would require each PDP sponsor or MA Organization offering a MA–PD plan that provides qualified prescription drug coverage under a prescription drug plan to establish a cost-effective drug utilization management program, a quality assurance program, a MTMP, and a program to control fraud, abuse, and waste as described in §§ 423.153(b), 423.153(c), 423.153(d), and 423.153(e), respectively.

We have combined these requirements into one section of the proposed regulation because each of these requirements would impact the quality and cost of care provided to beneficiaries. Our intent is to ensure that the prescription drug benefit would be provided using state of the art cost management and quality assurance systems. We also understand the overlapping nature of these requirements and that provisions under one requirement might complement another requirement. For example, drug utilization management early-refill edits used to prevent stockpiling of medications could also identify potential medication misuse by patients.

Although these requirements are similar in their underlying goals, they can also be quite different. For example, drug utilization management and quality assurance systems are generally considered to be population based, while medication therapy management involves targeted, direct patient care.

While we understand that some members of industry use various quality assurance measures and systems for controlling utilization and reducing medication errors, less information is available regarding medication therapy management. Medication therapy management has been used to describe a broad range of professional activities and responsibilities. We are familiar with state Medicaid programs (for example, Wisconsin, Mississippi) paying for cognitive services as part of their prescription drug benefit, but we have less information about current similar practices in the private sector. Therefore, our regulatory approach for utilization management, quality assurance, and controlling fraud, abuse, and waste will be different than our approach for medication therapy management. We particularly ask for comments on this section of the proposed regulation.

In general, and within the parameters described later in this preamble and in regulation, PDP sponsors and MA Organizations offering MA–PD plans would have flexibility to design drug utilization management programs, quality assurance measures and systems, MTMPs, and programs designed to control fraud, abuse, and waste.

a. Cost Effective Drug Utilization Management

Section 423.153(b) of our proposed rule would require each PDP sponsor or MA Organization offering a MA–PD plan that provides qualified prescription drug coverage under a prescription drug plan to provide a cost-effective drug utilization management program. The program would include incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs as defined in section 1927(k)(7)(A)(i) of the Act. For example, plans could utilize different dispensing fees that would encourage the use of these multiple source drugs as opposed to more expensive single source drugs. This should not be

confused with the practice of "switching" one branded drug product with another similar branded drug product, commonly referred to as "therapeutic substitution." Therapeutic substitution would always require explicit prescriber notification and approval.

We believe that a cost-effective drug utilization management program could also employ the use of prior authorization, step therapy, tiered cost-sharing, and other tools to manage utilization. We are aware that these are tools commonly used today to manage pharmacy benefit costs for many commercial and State programs. We believe that the competitive bidding and premium setting processes, combined with the requirements for transparency and information availability, provide powerful incentives for plans to innovate and adopt the best techniques available. We invite comment on whether there are industry standards for cost effective drug utilization management and whether CMS should adopt any of these standards for PDPs and MA–PDs.

Although we have not included proposed regulations, we are considering for the final rule a requirement that these tools should be under the direction and oversight of a Pharmacy and Therapeutics Committee to ensure an appropriate balance between clinical efficacy and cost effectiveness. We seek comments on this issue. We also seek comments on requiring the direct involvement of a Pharmacy and Therapeutics Committee not only with cost containment measures, but also with other areas of quality assurance and medication therapy management. Again, although we have not included proposed regulations requiring this standard, we are considering this standard for our final rule.

In addition, appropriate drug utilization management programs would have policies and systems in place to assist in preventing overutilization and underutilization of prescribed medications. PDP sponsors and MA Organizations offering MA–PD plans must inform enrollees of program requirements and procedures in order to prevent unintended interruption in drug therapy. For example, enrollees would be made aware of how to proceed if special circumstances require their prescriptions to be refilled before the targeted refill date.

b. Quality Assurance

Section 423.153(c) of our proposed rule would require each PDP sponsor or MA Organization offering a MA–PD plan that provides qualified prescription drug coverage under a prescription drug plan to provide a quality assurance program. That program would include quality assurance measures and systems for (1) reducing medication errors, (2) reducing adverse drug interactions, and (3) improving medication use.

We are proposing that quality assurance programs include requirements for drug utilization review, patient counseling, and patient information record-keeping. We believe these requirements would generally need to comply with section 4401 of the Omnibus Reconciliation Act of 1990 as codified in 42 CFR 456.705 and section 1927(g)(2)(A) of the Act, and we are considering such specific requirements for the final rule. Although these regulations were written specifically for the Medicaid population, we understand that they describe currently accepted standards for contemporary pharmacy practice and our intent is to require plans to continue to comply with contemporary standards. We solicit comment on whether the Medicaid standards are in fact industry standards, whether they are appropriate standards for part D, and if they are, how they should be adapted for use in part D. Therefore, we have chosen not to add further specification in the regulation text. We also understand that some members of industry use additional quality assurance measures and systems. We invite comments on whether there are industry standards, above and beyond those mentioned above, that we might adopt. Furthermore, PDP sponsors and MA Organizations offering MA–PD plans will be required to have systems and measures established to ensure that network pharmacy providers are complying with their quality assurance requirements. We are requesting comments on the costs and challenges associated with these systems and measures.

The elements that are currently viewed as desirable for quality assurance systems are—(1) electronic prescribing (which will become a requirement in the future as discussed later in this preamble); (2) clinical decision support systems; (3) educational interventions, which could be provided by QIOs or could rely on other mechanisms; (4) bar codes; (5) adverse event reporting systems; and (6) provider and patient education. We do not expect PDPs and MA–PD plans to adopt all of these elements. However, we expect substantial innovation and rapid development of improved quality assurance systems in the new competitive and transparent market being created by the new Part D benefit. We invite comments on which, if any, elements of a quality assurance system should be contained in our program requirements. We are particularly interested in best practices in quality assurance, costs and benefits associated with each element, the challenges involved in implementing quality assurance measures and systems, types of data useful for reducing medication errors, associated costs and challenges with collecting this data, and how this data could be best communicated to providers and beneficiaries to improve medication use.

We note that the MMA does not define or explain the term "medication error." Nevertheless, we believe a common definition is important. In the future, we may require quality reporting that includes error rates. We could use this information to evaluate plans. In addition, we may publish this information for enrollees to use when comparing and choosing their individual plans. Therefore, we particularly invite comments on how we could evaluate PDPs and MA–PDs based on the types of quality assurance measures and systems they have in place, how error rates can be used to compare and evaluate plans, and how this information could best be provided to beneficiaries to assist them in making their choices among plans.

Medication error reduction programs and requirements have been discussed in many venues and various definitions of "medication error" have been used. For example, in its proposed rule requiring bar codes on most human drug products, the Food and Drug Administration adopted the following definition of a medication error:

> Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice; healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. (*See* 68 FR 12500 (March 14, 2003)).

This definition of "medication error" is identical to that used by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). (*See* National Coordinating Council for Medication Error Reporting and Prevention, "What is a Medication Error?" (Undated)).

We are citing this definition in this preamble as one that we would use initially in interpretive guidance. We believe that this definition could be

applied to, and include, adverse drug events and interactions as they pertain to quality assurance. As the state of industry practice evolves, we may, from time to time, update this definition by manual issuance. We invite comments on this definition.

c. Medication Therapy Management Programs

Section 1860D–4(c)(1)(C) of the Act requires PDP sponsors and MA organizations offering MA–PD plans to establish a MTMP, and § 423.153(d) would codify that requirement. As stated earlier, neither we, nor many private insurers, have extensive experience requiring or reimbursing for MTMPs. As a result, we seek comments on what requirements and/or guidelines for MTMPs should be formulated in our regulation. In this section of the preamble, we are providing a broad overview of the types of activities that a PDP sponsor or MA organization offering a MA–PD plan could provide as part of a MTMP. We also discuss various options for determining which beneficiaries might qualify as "targeted individuals" and what types of clinicians might provide MTMP services. We plan to conduct further research and seek comments before establishing requirements with respect to MTMPs. We are interested in current MTMP best practices, essential components of MTMPs, and which quality assurance requirements, if any, should be included in MTMPs. We are also interested in measures and information on effective MTMP services that could be publicized and used by beneficiaries who wish to use these services. We are particularly interested in the most effective steps to make valuable, proven MTMP services available to beneficiaries to improve health care quality and reduce costs. We are mindful of the importance of stimulating the evolution of the most appropriate and efficient form of MTMPs, without stifling innovation or prematurely locking-in specific attributes.

The description of a MTMP in section 1860D–4(c)(2) of the Act would allow for plans to establish a broad range of additional services. The purpose of a MTMP is to provide services that will optimize therapeutic outcomes for targeted beneficiaries. Specific services to be provided under a MTMP would be distinct from those required for dispensing medication. Medication therapy management services would be reimbursable when adopted by a plan and only when provided to targeted beneficiaries as defined in § 423.153(2) of our proposed rule and discussed later in this preamble.

Section 1860D(4)(c)(2)(B) of the Act states that MTMPs may include elements designed to promote (for targeted beneficiaries):

- Enhanced enrollee understanding—through beneficiary education counseling, and other means—that promotes the appropriate use of medications and reduces the risk of potentially adverse events associated with the use of medications.
- Increased enrollee adherence to prescription medication regimens (for example, through medication refill reminders, special packaging, and other compliance programs and other appropriate means).
- Detection of adverse drug events and patterns of overuse and underuse of prescription drugs.

In order to promote these elements and optimize therapeutic outcomes for targeted beneficiaries, we envision MTMPs potentially spanning a range of services, from simple to complex. In addition to those mentioned in the statute, services could include, but not be limited to, performing patient health status assessments, formulating prescription drug treatment plans, managing high cost "specialty" medications, evaluating and monitoring patient response to drug therapy, providing education and training, coordinating medication therapy with other care management services, and participating in State-approved collaborative drug therapy management. We would also anticipate that these services could be offered as components of more coordinated disease management programs, but would not expect provision of these services to be limited to such programs.

In addition to MTMPs providing for different types of services, we would also anticipate the need for different levels of service based on the individual requirements of targeted beneficiaries. For example, one beneficiary may require only a fifteen-minute phone consultation, while another would be better served by a one-hour in-person visit with the pharmacist. The level of service should be determined by time and resources required to accommodate the specific needs of the individual beneficiary. Therefore, we would anticipate that a MTMP would include policies and procedures for ensuring targeted beneficiary access to the appropriate types and levels of service offered by the particular PDP or MA–PD plan.

Within this broad framework, we believe that PDP sponsors and MA Organizations offering MA–PD plans can customize their MTMPs and that a competitive market supported by useful information on MTMP services will provide the best mechanism for establishing optimal MTMPs. We believe that MTMPs can lead to improved overall health for individuals, while at the same time decreasing overall healthcare costs resulting from improper medication use and adverse drug events. We may provide a mechanism for plans to demonstrate the types of services, levels of service, and quality outcomes associated with their MTMPs to further aid beneficiaries with choosing the plan that will best meet their needs.

In addition, as provided in § 423.153(d)(3), a MTMP, as adopted by a plan, would have to be developed in cooperation with licensed practicing pharmacists and physicians.

Beyond these broad parameters for a MTMP, there are several issues to consider as we provide additional guidance to PDP sponsors and MA organizations. First, we consider MTMPs to be administrative activities similar to quality assurance drug utilization review or measures to control fraud, abuse and waste. Like these other quality improvement services intrinsic to the drug plan, MTMP services would not involve direct beneficiary cost-sharing and Part D enrollees would not be required to pay separate fees for these services (although the cost could be reflected in the premium rate). The cost of a MTMP is considered an administrative cost incident to appropriate drug therapy and, therefore, not an additional benefit. Nevertheless, unlike the general quality assurance and fraud, abuse, and waste control requirements, MTMP services can be limited to targeted beneficiaries. To the extent that MTMPs reduce drug spending by more than their costs, they have the potential to lower overall Part D costs. To the extent that MTMP services lower overall medical costs for beneficiaries with chronic illnesses, we also seek comment on how to integrate MTMP services and financial incentives into the Medicare Chronic Care Improvement program (section 721 of the Act).

Second, section 1860D4(c)(2)(A)(ii) of the Act requires that MTMP services be provided only for targeted individuals. In other words, not all members of a plan would be entitled to receive these services. As provided under § 423.153(d)(2), "targeted beneficiaries" would be plan enrollees who have multiple chronic diseases, are taking multiple Part D covered drugs, and are likely to incur annual costs that exceed a certain level that we determine. We

invite comments on how we should provide guidance to drug plans in defining "multiple chronic diseases" and "multiple covered Part D drugs" for the purposes of determining which Part D enrollees would qualify for MTMP services, or whether such determinations are best left to the plans as part of their benefit design.

While the statute states that CMS sets the level of annual costs that must be incurred by a beneficiary to qualify for the receipt of MTMP services, our preferred policy is to delegate this function to the private drug plans, as they would be able to evaluate their patients with greater specificity and information. We request comments on this policy as both a policy and legal matter. We believe that, given current evidence, the level of annual costs that must be incurred by a beneficiary to qualify for the receipt of MTMP services should be determined by the drug plan. We do not think there is sufficient evidence at this point to specify a threshold of annual drug costs to be used for targeting these services to particular Part D enrollees. However, we seek comments on what guidance we could provide to plans to ensure these services are targeted in the most efficient manner and to the most appropriate beneficiaries.

In addition, we are concerned about the method that plans should use to determine the costs that enrollees are "likely to incur" to ascertain whether they qualify as targeted beneficiaries. Once plans have historical data on specific patients, determining how to target such services should become easier and more effective. For example, based on their previous experience with providing prescription drug services, plans could qualify enrollees for MTMP services based on whether the enrollees have multiple chronic diseases and whether they are using multiple drugs. As they develop more experience with their Medicare enrollees, past medication history might become another useful guide.

We believe that plans would benefit from additional guidance on interpreting the level above which a beneficiary's incurred costs would qualify him or her for MTMP services. We invite comments on all the disease, drug, and cost issues that we should consider in further refining the definition of a targeted beneficiary for receipt of MTMP services.

Another issue to be considered relates to which clinicians would be providing MTMP services and the method for providing those services. Section 1860D–4(c)(2)(A)(i) of the Act specifically states that a pharmacist may furnish MTMP services. While we believe that pharmacists will be the primary providers of these services, MTMPs could also include other qualified health care professionals as providers of services. The individual needs of the targeted beneficiary should determine the appropriate provider and setting for MTMP services. For example, consultant pharmacists will likely provide services to beneficiaries in long-term care facilities; retail pharmacists could provide those same services to ambulatory beneficiaries.

Furthermore, we believe beneficiary choice and on-going beneficiary-provider relationships should play a role in determining the best provider for MTMP services. Improved therapeutic outcomes through MTMP services will frequently require active beneficiary, or caregiver, participation. While population based quality assurance and cost control measures might adequately be served by impersonal telephone services, we believe that telephone services are only one mode of providing medication therapy management services. Active beneficiary participation and consistent delivery of quality MTMP services will require developing and maintaining on-going beneficiary-provider relationships. Therefore, to the extent that these services are adopted by plans in their MTMPs, we would expect the range of services offered to reflect this important component and maximize beneficiary participation by considering beneficiary preference and existing beneficiary-provider relationships in determining the appropriate provider and setting for delivery of MTMP services.

Section 1860D–4 (c)(2)(E) of the Act states that in establishing fees for pharmacists or others providing MTMP services, to the extent that these services are adopted by a plan in its MTMP, a PDP sponsor must take into account the resources and time associated with implementing the MTMP. Section 423.153(d)(5) codifies that requirement. We propose to implement this requirement as follows:

(1) First, we would expect potential PDP sponsors to describe, as part of their applications, their plan to consider the resources used and the time required to implement their MTMP in establishing fees for pharmacists and others providing services under the MTMPs.

(2) Second, in the event that we receive complaints that a PDP sponsor is not paying pharmacists or others in accordance with the fees discussed in the application for the MTMP it has elected to adopt, we would investigate further.

While section 1860D–4(c)(2)(E) of the Act specifies that the time and resources necessary to implement the MTMP must be taken into account when establishing fees, it does not specify how these fees should be paid. We believe that fees associated with provision of medication therapy management services are separate and distinct from dispensing fees discussed in section § 423.100 of the preamble for this proposed regulation. Although section 1860D–4(c)(2)(E) of the Act states that PDP sponsors must disclose to the Secretary the amount of "any such management or dispensing fees", it merely governs disclosure and does not require that MTMP be included in the dispensing fee (indeed the Act distinguishes management fees from dispensing fees that are part of individual prescriptions).

Therefore, costs associated with MTMPs, including these management fees, are included as part of the general administrative overhead costs in the plan bid. For purposes of evaluating the administrative component of a PDP's bid, we will ask a PDP sponsor or MA organization to disclose the fees it pays to pharmacists or others, including an explanation of those fees attributable to MTMP services. The fee information provided to us under this authority would be protected under the confidentiality provisions of section 1927(b)(3)(D) of the Act. Under those provisions, we would be prohibited from disclosing the specific fees in a manner that links the fees to the particular pharmacy or other provider providing the MTMP services—except to the extent necessary to administer the Part D program, to permit the Comptroller General to review the information, or to permit the Director of the Congressional Budget Office to review the information. If we were to discover situations in which plans systematically did not pay the fees described in their applications—and, if those errors were not corrected upon notification, we might, at our discretion, employ the broad ranges of intermediate sanctions or termination provisions available under subparts K and O of the regulations.

While we expect to perform the due diligence described above through application review and potentially following up on any complaints we do not believe we have the authority to mandate that PDP sponsors or MA organizations pay pharmacists or other providers a certain amount for MTMP services. We also would not adjudicate any specific disputes between PDP sponsors or MA organizations and pharmacists or other providers

regarding the specific fees due for MTMP services.

Finally, as specified in section 1860D–4(c)(2)(D) of the Act, we are required to establish guidelines that MTMPs operated by PDP sponsors are coordinated with the "chronic care improvement program" (CCIP) under section 1807 of the Act. The CCIP is a new program established by section 721 of the MMA, which added a new section, section 1807, to the Act. The new section 1807 creates a method for us to assist beneficiaries with multiple chronic conditions in managing their care. The program is targeted only to beneficiaries in original fee-for-service Medicare—not beneficiaries enrolled in MA plans. Therefore, we anticipate that our guidelines will be targeted toward PDP sponsors and not to MA organizations that offer MA–PD plans. As stated above, the CCIP is a new program. By statute, the first agreements under that program with chronic care improvement organizations should be entered into within 12 months of the MMA's date of enactment. On April 23, 2004, we published in the **Federal Register** (69 FR 22065–22079), the solicitation for the CCIP program. Because the program has not yet been established, however, we cannot provide a great deal of guidance at this time regarding how the MTMPs under Part D would coordinate with the CCIP. We are concerned with the possibility of beneficiaries receiving duplicative services. We seek comments on how MTMP services provided through CCIP can be effectively coordinated with MTMP services provided by PDPs. There are several different ways that communication could take place so that a beneficiary enrolled in both the CCIP and a PDP receives efficient assistance with managing their chronic diseases. For example, the CCIP might collect information at intake, obtain a beneficiary information release, and inform the PDP of enrollment. An alternate approach is for us to use the enrollment files from the two programs to communicate to the respective parties. We invite comments on this issue and these proposed options. We may provide further interpretive guidance on coordination with the CCIP once the section 1807 agreements are finalized and the new program is in place. We invite comments from interested parties relating to specific key issues that should be addressed in this guidance.

d. Fraud, Abuse and Waste

Section 423.153(e) of our proposed rule would require PDP sponsors and MA Organizations offering MA–PD plans that provide qualified prescription drug coverage under a prescription drug plan to provide a program to control fraud, abuse, and waste. These requirements overlap to some extent with those in subpart K of this regulation, but cover somewhat different territory.

We would expect these plans, as prudent purchasers, to implement programs to control their expenditures. We would be interested in comments on the following discussion as to possible requirements in this area over and above the incentives operating in at risk plans. We would also like comments on the value added from requiring plans to develop comprehensive performance standards for use in evaluating internal processes that would appropriately and efficiently research, identify, monitor, and take immediate action to mitigate fraud, abuse, and waste. Fraud, abuse, and waste apply not only to both the PDPs and MA–PDs and their staffs, but also to the PBMs, pharmacies, physicians, and other providers that they deal with. For instance, PDPs and MA–PDs need to determine whether or not physicians are illegally prescribing narcotics. In addition to available appropriate data that might be supplied by us, the plans could develop and utilize methods such as data analysis, record audit of PBMs, pharmacies, physicians, and other providers, DUR (note these DURs overlap with those described previously, but these focus on those related to fraud, abuse, and waste), and methods used to consider and resolve disputes related to pharmacies, physicians', and other provider's dissatisfaction to ensure the integrity of all entities (government, beneficiary, PDP sponsor, PBMs, pharmacies, physicians, and other providers).

One area of concern is inappropriate switching of prescriptions by a PDP or MA–PD plan without consulting a prescribing physician. For instance, switching from brand to generic may be appropriate, but switching brands, *e.g.* Lipitor to Zocor, may not without consultation.

We also seek comments on the appropriateness, value and need for requiring the plans to test program integrity analytic tools for effectiveness, efficiency, and adaptability to the Medicare Benefit environment. For example, one approach could require the plans to provide any of the following in periodic reports: (1) Summary of data analysis activities, (2) resources, (3) tools, or (4) trend analysis. Alternatively, the plans could be required to develop their strategy and propose what each plan determines to be the best approach for detecting and deterring fraud and abuse. Furthermore, the plans could be asked to demonstrate that the agreed upon activities and outcomes that the plans achieve are in relation to priorities established by us. We seek comments on the likely value of these requirements. We also seek comments on the implementation, scope, and operation of an effective and robust fraud, abuse, and waste control program for plan sponsors.

e. Exception for Private Fee for Service Plans

Section 423.153(f) of our proposed rule would implement section 1860D–421(d)(3) of the Act by exempting private fee-for-service MA plans that offer qualified prescription drug coverage from the requirement to establish a drug utilization management program and a MTMP; however, these private fee-for-service MA plans would still be required to establish a quality assurance program and program to control fraud, abuse and waste as described in § 423.153(c) and § 423.153(e), respectively.

3. Consumer Satisfaction Surveys (§ 423.156)

Under § 423.156, we would conduct consumer satisfaction surveys among enrollees of PDPs and MA Organizations offering MA–PD plans in order to provide comparative information about qualified prescription drug coverage to enrollees as part of our information dissemination efforts. Section 1860D–4(d) of the Act specifies that these surveys be conducted in a manner similar to that in which they are currently conducted under § 422.152(b) (that is, annually) for MA plans by using the Consumer Assessment of Health Plans (CAHPS). We believe a CAHPS-like instrument (or perhaps a modification of CAHPS for MA Organizations offering MA–PD plans) will most likely be the vehicle used to collect this information. As we have done in the past in developing surveys of Medicare beneficiaries in various settings, we will work with the Agency for Healthcare Research and Quality (AHRQ) to develop a survey measuring the experience of beneficiaries with their qualified prescription drug coverage, a sampling strategy, and an implementation strategy. We will provide further information regarding this survey as it is developed.

4. Electronic Prescription Program (§ 423.159)

Section 1860D–4(e) of the Act contains provisions for electronic prescription programs. The statute

contains specific provisions on when voluntary initial standards may be adopted (not later than September 1, 2005), and when final standards should be published (not later than April 1, 2008) and then effective (not later than 1 year after the date of promulgation of final standards).

The statute requires the National Committee on Vital and Health Statistics (NCVHS) to develop recommendations, in consultation with a specific group of constituencies, for possible adoption by the Secretary according to the schedule set forth above. Those constituencies include physicians, hospitals, pharmacists and pharmacies, PBMs, State boards of pharmacy and medicine, Federal agencies and other electronic prescribing experts for uniform standards. The law also requires a pilot project once the Secretary has adopted or announced the initial standards. The pilot will run from January 2006 through December of that year, and it will be completed prior to the promulgation of the final standards. The law further states that a pilot is not needed if there is already adequate industry experience with whatever standards the Secretary is planning to adopt.

To fulfill the statute's responsibilities, the NCVHS' Subcommittee on Standards and Security has already held two public hearings on issues related to e-prescribing. The hearings on March 30 and 31, 2004, and May 25, 26, and 27, 2004 included testimony from e-prescribing networks, providers, software vendors, and industry experts on patient safety and drug knowledge databases. National electronic prescribing studies were also presented. In order to further refine their recommendations to the Secretary, the NCVHS Subcommittee on Standards and Security will continue to hold additional hearings on the state-of-the-art of electronic prescribing including testimony from a broad representation of stake holders in July, August and September 2004. Readers interested the NCVHS' hearing schedule for e-prescribing standards, testimony presented at the hearings and standards recommendations should consult the NCVHS Web site at *http://www.ncvhs.hhs.gov/*.

Many in the industry urge us to move expeditiously to establish electronic prescribing standards. However, the statute intentionally provided for a deliberative process by directing the NCVHS to study, select and recommend electronic prescribing standards. Any comments received in response to this proposed rule will be considered along with the NCVHS' recommendations in the development of the proposed rule on the electronic prescribing standards. We are particularly interested in comments that help us identify consensus or reach consensus on e-prescribing standards ahead of the statutory time frame, and to help us identify and evaluate industry experience based on pilot programs engaged in e-prescribing activities in 2004 and 2005.

To ensure that our regulations are as comprehensive as possible, we have included language at § 423.159(a) that would require PDP sponsors and MA Organizations offering MA–PD plans to have the capacity to support e-prescribing programs in accordance with the final e-prescribing standards established by the Secretary, including any standards that are established before the drug benefit begins in 2006. In addition, once final standards are set, any prescriptions that are transmitted electronically under the Part D drug benefit for Medicare beneficiaries will have to conform to those standards. Aside from PDP and MA–PD plans having the capacity to support final e-prescribing standards, there is, however, no requirement that prescriptions be written or transmitted electronically (by for example physicians or pharmacies). Until e-prescribing standards are effective, of course, our regulations at § 423.159(a) also will not be in effect.

Although there is no requirement that physicians write prescriptions electronically, our regulations state that PDP sponsors and MA Organizations offering MA–PD plans who participate in the Part D program must be able to support the final e-prescribing program as specified in section 1860D–4(e)(2) of the Act. The statutory language is quite specific that e-prescribing will not just be used for a physician to send a prescription to a pharmacy, but also will transmit data that can only be supported by the PDP sponsor or MA organization offering an MA–PD plan. For example, the e-prescribing program is intended to ensure that pharmacies receive electronic information on the drugs included on the PDP's or MA–PD's formulary, any tiering of the formulary, the patient's medical history, the possibility of any adverse drug-interactions (based on other prescriptions the patient is already taking) and the availability of lower-priced, alternative prescriptions. Since the PDP sponsor or MA organization offering an MA–PD plan will most likely be the warehouse for all this information, without participation of the PDP sponsors or MA Organizations offering MA–PD plans, the e-prescribing program would not be able to provide the results the Congress intended. In addition, if plans do not have this program, beneficiaries participating in those plans would not benefit from the patient safety aspects of the program. Also, under section 1860D–12(b)(3)(D) of the Act, we have the authority to add additional contract terms to the PDP and MA–PD contracts.

While PDP sponsors and MA Organizations offering MA–PD plans will be required to support the final e-prescribing standards issued by us, they will not be required to support the pilot standards, which are voluntary under section 1860D 4(e)(4)(C) of the Act. Therefore, only those entities that participate in a pilot testing of certain e-prescribing standards will be required to implement an e-prescribing program using the initial standards adopted by the Secretary. Others in the health care industry will not be required to use the initial standards at the time they are issued, but will be encouraged to do so.

Finally, we note that the pilot test specified in the MMA is not required if there is adequate industry experience with the standards. In that case, the Secretary may propose them as final standards in a proposed rule, thereby expediting a portion of the standards adoptions process. Therefore, to the extent we determine, after consultation with affected standard setting organizations and industry users, that there already is adequate industry experience with certain standards, we may propose to finalize those standards through notice and comment rulemaking even if we have not completed the pilot testing of other standards so that a portion of the standards adoptions process could be expedited. We seek comments on the desirability of this strategy, including any concerns about potential unintended consequences.

In order to facilitate electronic prescribing by a PDP or MA–PD sponsor, we invite public comment on additional steps to spur adoption of electronic prescribing, overcome implementation challenges, and improve Medicare operations. For example, we have added regulations at § 423.159(b) of this proposed rule that would allow an MA–PD plan to provide a separate or differential payment to a participating physician who prescribes covered Part D drugs in accordance with electronic prescription standards. (Note that this provision only applies to MA–PD plans and not to PDPs.) Section 102(b) of the MMA makes it clear that this differential payment may occur when a participating physician prescribes drugs in accordance with an

electronic prescription drug program that meets standards established under section 1860D–4(e) of the Act. These differential payments are to reward physicians for using electronic prescriptions rather than handwritten ones. These payments would not be used to encourage physicians to prescribe more frequently or inappropriately steer their use of particular drugs. Since the standards established under section 1860D–4(e) of the Act include the initial, voluntary standards, which may be tested on a pilot basis as early as January 1, 2006, we believe the differential payments envisioned by section 102 of the MMA may occur as early as January 1, 2006 (for physicians who prescribe in accordance with the standards adopted by the Secretary in September 2005). We believe the fact that section 102 of MMA has an effective date of January 1, 2006, supports this determination. Differential payments, at the MA organization's discretion, could take into consideration the cost to the physician in implementing the program and could be increased for participating physicians who use e-prescribing to significantly increase—

(1) Formulary compliance where medically appropriate;

(2) Use of lower cost, therapeutically equivalent alternatives;

(3) Reductions in adverse drug interactions as evidenced by appropriate use of drug interaction checking functions in electronic prescribing; and

(4) Efficiencies in filling and refilling prescriptions through reduced administrative costs.

The additional or increased payments made to the physicians could be structured in the same manner as fees for services under § 423.153(d) of this proposed rule. We have not provided a great deal of specificity in our regulations regarding how the differential payments may be structured because we believe the MA Organizations offering MA–PD plans should have discretion in structuring these added payments, if any.

We note that any payments must be in compliance with other Federal and State laws, including "the physician self-referral prohibition at section 1877 of the Act" and the Federal anti-kickback provisions at section 1128B(b) of the Act. We are soliciting the public's view of the application of these legal authorities to the differential payments described in this section. We will share any comments regarding the anti-kickback statute with the Office of Inspector General.

We also seek comment on measures of MA–PD plan quality related to the use of e-prescribing, and other MA–PD quality measures that reflect effective e-prescribing systems. The use of electronic prescribing shows promise for improving Medicare operations by reducing costs in the administration of the Part D drug benefit and in the use of prescription drugs, for example promoting generic drug use and creating timely interface with formularies supported by up-to-date evidence. Likewise, it has the potential to improve the quality of the care provided to Medicare beneficiaries through the therapeutic monitoring of allergies and adverse events. Yet, implementing electronic prescribing effectively poses a number of challenges. While electronic prescribing is gradually gaining acceptance by health care providers, fewer than 10 percent of U.S. doctors currently engage in the practice. The adoption rate is particularly low among solo practitioners, those in rural areas, and certain medical specialties. The electronic prescribing process and the technology that enables it must be cost effective, the systems must be fast and easy to use, and alerts and other data passed backed to the prescriber must demonstrate value. We invite comments on these challenges and on possible Federal activities that would promote the effective use of e-prescribing by providers, including publishing best practices, and making technical information on e-prescribing products available. In addition receptivity to the use of electronic prescribing by consumers is not well understood especially among the elderly and disadvantaged populations. We seek additional information on how those populations may view electronic prescribing and what step may be taken to get them to use this modality and, thus, take advantage of the safety and quality benefits it offers.

We also invite comments on how to promote the use of electronic prescribing by providers, health plans and pharmacies and other entities involved in the provision and payment of health care to Medicare beneficiaries. Beyond the grants authorized in § 423.159(b) of this proposed rule, we invite comments on what incentives could be used to spur more widespread adoption, especially for early implementers. We also invite your comments on what educational efforts or data analyses might be undertaken to help health practitioners understand, or empirically confirm, and ultimately realize, the benefits of electronic prescribing. Lastly, we seek public input on the ways electronic prescribing can further reduce costs to the Medicare program and promote quality of care to beneficiaries.

5. Quality Improvement Organizations (QIO) Activities (§ 423.162)

Section 109 of the MMA expands the work of QIOs to include Part C and Part D. This provision explicitly covers the full range of Part C organizations. QIOs are required to offer providers, practitioners, MA organizations, and PDP sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy. We plan to issue guidance on how QIOs can provide this assistance and would coordinate the activities of the QIOs with the quality related activities of other stakeholders.

To fulfill this responsibility, QIOs would need access to data from the transactions between pharmacies and PDPs and MA–PD plans providing the Part D benefit. This data would be extracted from the claims data submitted to us. Although the agency is still developing plans for the QIO activities related to the Part D benefit, we expect that this data primarily from the NCPDP telecommunications format between pharmacies and plans will be used. The data would include payment-related information (that is, plan identification, beneficiary HIC, date prescription filled, NDC, quantity dispensed, ingredient cost, dispensing fee, and pharmacy zipcode) and additional items such as prescriber identifiers, pharmacy identifiers, dose, days supply, and other dispensing information. Potentially, the information gathered will be aggregated in our data warehouse, and then distributed to QIOs to fulfill their requirements for quality improvement as specified in their contracts and in response to requests.

We have been consulting, on an individual, organization by organization basis, with representatives from pharmacy benefit managers, managed care organizations, programs that have monitored drug utilization, and others who have utilized pharmacy claims data. We welcome comments related to the collection and use of information for providing quality improvement assistance related to Part D.

We are proposing that any information collected by the QIOs would be subject to confidentiality requirements in Part 480 of our regulations. For purposes of applying these confidentiality regulations, we are also proposing that MA organizations offering MA–PD plans and PDP sponsors fall within the definition of health care facilities. This means that

the confidentiality provisions in Part 480 of our regulations would apply to PDP sponsors and MA–PD plans in the same manner as they apply to institutions.

6. Treatment of Accreditation (§ 423.165, § 423.168, and § 423.171)

Section 1860D–4(j) of the Act requires that the provisions of section 1852(e)(4) of the Act relating to the treatment of accreditation will apply to PDP sponsors with respect to—(1) access to covered Part D drugs including the pharmacy access requirements and the use of standardized technology and formulary requirements; (2) quality assurance, drug utilization review, medication therapy management, and a program to control fraud, abuse and waste; and (3) confidentiality and accuracy of enrollee records. Thus, the requirements in § 423.165, § 423.168, and § 423.171 are similar to the requirements found in § 422.156, § 422.157, and § 422.158 for the MA program, except for subject areas that are deemed.

A PDP sponsor may be deemed to meet the requirements that relate to access to covered Part D drugs; quality assurance, drug utilization review, medication therapy management, and a program to control fraud, abuse, and waste; and confidentiality and accuracy of enrollee records, if it is accredited and periodically reaccredited by a private national accrediting organization under a process that we have determined meets a process and standards that are no less stringent than our applicable requirements. National accreditation organizations are those entities that offer accreditation services that are available in every State to every organization wishing to obtain accreditation status. The process that we would use to deem compliance with PDP requirements would mirror the process used for deeming compliance with fee-for-service requirements and the MA program.

Section 423.165 would provide the conditions under which a PDP sponsor may be deemed to meet our requirements permitted under paragraph (b) of this section. The first condition would be that the PDP plan be fully accredited (and periodically reaccredited) by a private, national accreditation organization that we approve. The second condition would be that the PDP organization be accredited using the standards that we approved for the purposes of assessing the PDP sponsors' compliance with Medicare requirements.

Consistent with our approach in the MA program, we would analyze on a standard-by-standard basis whether an accreditation organization applies and enforces requirements no less stringent than those in part 422 with respect to the standard at issue. We would determine the scope of the accreditation organization's approval (and, thus, the extent to which PDP organizations accredited by the organization are deemed to meet our requirements) based on a comparison of the accreditation organization's standards and its procedures for assessing compliance with our deemable requirements and our own decision-making standards. We would make those determinations on the basis of the application materials submitted by accreditation organizations seeking our approval in accordance with § 423.168. We would also conduct surveys to validate the accreditation organization's enforcement on a standard-by-standard basis.

Section 423.165(d) would establish the obligations of deemed PDP sponsors. A PDP sponsor would have to submit to our surveys that are intended to validate an accreditation organization's process and authorize the accrediting organization to release to us a copy of its most current accreditation survey, together with any information related to the survey that we may require (including corrective action plans and summaries of our unmet requirements). These activities are part of our ongoing oversight strategy for ensuring that the accreditation organization applies and enforces its accreditation standards in a manner comparable to ours.

Section 423.165(e) would address removal of deemed status. We would remove part or all of a PDP sponsor's deemed status if—

(1) We determine, on the basis of our own survey or the results of the accreditation survey, that the PDP organization does not meet the Medicare requirements for which deemed status was granted.

(2) We withdraw our approval of the accreditation organization that accredited the PDP organization; or

(3) The PDP fails to meet the requirements of § 423.165(d).

Section 423.165(f), would explain that we retain the authority to initiate enforcement action against any PDP sponsor that we determine, on the basis of our own survey or the results of the accreditation survey, no longer meets the Medicare requirements for which deemed status was granted. We expect the accreditation organization to have a system in place for enforcing compliance with our standards (such as sanctions for motivating correction of deficiencies), but we cannot delegate to the accreditation organization the authority to impose the intermediate sanctions established by section 1860D–12 of the Act or termination of the PDP contract.

Deeming applies only to our enforcement of this regulation, and neither our enforcement of this regulation nor accreditation by an accrediting body undercuts the Office for Civil Rights enforcement of the HIPAA privacy rule.

Section 423.168 would discuss the 3 conditions for our approval of an accreditation organization. We could approve an accreditation organization if the organization applies and enforces standards for PDP sponsors that are at least as stringent as Medicare requirements and, if the organization complies with the application and reapplication procedures proposed in § 423.171.

Section 423.168(c) of our proposed rule would establish ongoing accreditation organization responsibilities. These responsibilities largely parallel those currently imposed upon accreditors under original Medicare. One exception is the proposed requirement that an accreditation organization notify us in writing within 3 days of identifying, with respect to an accredited PDP sponsor, a deficiency that poses immediate jeopardy to the PDP sponsor's enrollees or to the general public.

Section 423.168(d) of our proposed rule would establish specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization. Oversight consists of equivalency review, validation review, and onsite observation.

We could withdraw our approval of an accreditation organization at any time if we determine that deeming based on accreditation no longer guarantees that the PDP organization meets the Medicare requirements, that failure to meet those requirements could jeopardize the health or safety of Medicare enrollees or constitute a significant hazard to the public health, or that the accreditation organization has failed to meet its obligations under § 423.165 through § 423.171.

Section 423.171 of our proposed rule would address the procedures for approval of accreditation as a basis for deeming compliance. As mentioned, the process that we would use to deem compliance with PDP requirements is virtually identical to the process that is being used for deeming compliance with fee-for-service requirements. One proposed requirement that would

appear in § 423.171, and which also appears in regulations governing MA plans at § 422.158(a)(11), but does not appear in regulations governing original Medicare, is the requirement that an accreditation organization applying for approval of deeming authority submit the name and address of each person with an ownership or control interest in the accreditation organization. This information would be used to determine whether the accreditation organization is controlled by the organizations it accredits for the purposes of § 423.168. Section 423.171 would further provide for reconsideration of adverse determinations of accreditation applications.

F. Submission of Bids and Monthly Beneficiary Premiums: Determining Actuarial Valuation

1. Overview

Subpart F would implement most of the provisions in sections 1860D–11 and 1860D–13 of the Act, as well as sections 1860D–12(b)(2) (on limitation on entities offering fallback plans), 1860D–15(c)(2) (on geographic adjustment of the national average monthly bid amount), 1860D–21(d) (on special rules for private fee-for-service (PFFS) plans), 1860D–21(e)(3) (on cost contractors), and 1860D–21(f)(3) (on PACE) of the Act. In this section we address submission, review, negotiation, and approval of bids for prescription drug plans and MA–PD plans; the calculation of the national average bid amount; and determination and collection of enrollee premiums. References to 42 CFR part 422 of our regulations are to the new MA rules.

As discussed in subpart C, the statute provides a framework for the provision of subsidized prescription drug coverage. Within this framework, PDP sponsors and MA organizations have some flexibility to design coverage that is different from defined standard coverage to meet the needs of Part D-eligible Medicare beneficiaries. This framework plays a critical role in bid submissions, and the actuarial evaluation and approval of bids.

As part of our discussion we specify the actuarial equivalency tests plan sponsors would have to meet when offering coverage other than defined standard coverage. Please note that the coverage definitions are discussed in detail in subpart C of the preamble. In order to determine actuarial equivalency, plan sponsors would compare their plans to the defined standard coverage baseline to assess the various tests of actuarial equivalency that we discuss in detail in the sections below.

2. Requirements for Submission of Bids and Related Information

As provided under section 1860D–11(b) of the Act, each applicant to become a PDP sponsor or MA organization would be required to submit a bid for prescription drug coverage for each plan it intends to offer. Most bids would be expected to represent *full risk plans,* meaning that the prescription drug plan is not a limited risk plan or a fallback prescription drug plan, and is not asking for any modification of the statutory risk sharing arrangements. A bid from a full risk plan may be referred to as a full risk bid. PDP sponsors may choose to participate as *limited risk plans,* meaning that they provide basic prescription drug coverage and request a modification of risk level (as described in § 423.265(d)) in its bid submitted for the plan. A bid with a modified level of risk is referred to as a limited risk bid. This term does not include a fallback prescription drug plan. A risk bid (whether full risk or limited risk) could not be accepted from any entity applying to become a PDP sponsor or MA organization offering an MA–PD plan that—(1) also submits a bid for the same year to act as a fallback plan; (2) will be offering a fallback plan in any region for the upcoming year; or (3) currently offers a fallback plan in the region for which they are submitting the bid. In determining whether an entity is barred from submitting a risk bid according to these rules, we would use, as our reference point, the calendar year that they are submitting their bids. For example, the limitation would work as follows:

An applicant submitting a risk bid for sponsoring a PDP in 2009 would be excluded from the risk bidding if it—

(1) Also submits a bid to act as a fallback plan in 2009 (where 2009 is the first year of a multi-year fallback contract);

(2) Already is approved to act as a fallback in any PDP region for 2009; or

(3) Offers a fallback in 2008 for the same region for which they would be submitting their 2009 risk bid.

This fallback prohibition also applies if an applicant (or related entity) acted as, or will act as a subcontractor to an entity offering a fallback plan. In other words, an entity would be treated as having submitted a bid under the fallback contracting process, and thus not be an eligible risk bidder, if that entity was acting as a subcontractor for an integral part of the drug benefit management activities of an eligible fallback entity. Thus, for example, if an applicant was a subcontractor to a fallback in 2008, it cannot submit a risk bid for the same region for 2009. Similarly, an applicant for a 2009 risk bid cannot include as its subcontractor an entity already approved or applying to act as a fallback plan for 2009. Because awards for 2006 will not be known at the time the initial bids are due in 2005 (for contracts in 2006), any entity that bids as a fallback plan (or a subcontractor to a fallback plan) is barred from bidding as a non-fallback plan in any and all regions for that year.

Bids would be due to us no later than the first Monday in June for each plan to be offered in the subsequent calendar year. This date stems from the requirement in section 1860D–11(b) of the Act that bid data from potential PDP sponsors be submitted at the same time and in a similar manner as the information described in section 1854(a)(6) of the Act for MA plans. Since section 1854(a)(1) of the Act requires initial data to be submitted on the first Monday of June of each year after 2004, we have also incorporated this date into our regulations. In the case of MA–PD plans, the prescription drug bid would be a component of the unified MA bid described in § 422.254(b)(1) with benefits beyond basic coverage (if any) incorporated into the supplemental benefits portion of the prescription drug benefit bid.

We are clarifying that this bid would represent the expected monthly average cost (including reasonable administrative costs) to be incurred by the plan applicant for qualified prescription drug coverage in the applicable area for a Part D eligible individual with a national average risk profile for the factors described in section 1860D–15(c)(1)(A) of the Act and in § 423.329(b)(1) of this proposed rule. We plan to develop and publish the risk adjustment factors and identify the characteristics of an average individual no later than the date of the 45-day notice for the announcement of 2006 rates, which is February 18, 2005. Any modifications to these characteristics for subsequent years would be announced by the date of the annual 45-day notice. (For further discussion of prescription drug risk adjustment, see Subpart G of this preamble.) We are interested in providing information to potential bidders to help eliminate the uncertainty of drug trend for Medicare beneficiaries and in delaying the submission of pricing information as long as we can under the law and consistent with our need to inform beneficiaries. We solicit comment on

the nature of any additional information needed to prepare bids and suggestions for any other methods that the bid submission process could be structured to provide for later pricing data submission.

The costs represented in each plan bid should be those for which the plan would actually be responsible. Given the structure of qualified prescription drug coverage, these costs would not include payments made by the enrollee for deductible, coinsurance (including 100 percent coinsurance between the initial coverage limit and the out-of-pocket threshold), copayments, or payments for the difference between a plan's allowance and an out-of-network pharmacy's usual and customary charge (as discussed in § 423.124(b)). It also does not include costs reimbursed by us through the reinsurance subsidy. However, we require the separate identification, calculation, and reporting of costs assumed to be reimbursed by us through reinsurance. For standard coverage, defined or actuarial equivalent, these costs would include the plan's share of costs above the deductible and up to the initial coverage limit, as well as the plan's share of costs above the annual out-of-pocket limit. If enhanced alternative coverage is provided, the plan costs for supplemental benefits would be distinguished from those for basic coverage. The costs attributable only to basic coverage, once approved, are known as the standardized bid amount.

In § 423.265(c) we would require that, with the exception of potential employer group waivers under section 1860D–22(b) and 1857(i) of the Act, late enrollment penalties and low-income premium and cost sharing subsidies, the bid represents a uniform benefit package based upon a uniform level of premium and cost sharing among all beneficiaries enrolled in the plan. This means that all enrollees in a given PDP or MA–PD plan would be subject to the same cost sharing structure and would be charged the same premium for benefits the PDP sponsor or MA organization chose to offer.

We note that while benefits are required to be uniform for all enrollees under the drug benefit, this is not the case for enrollees under a prescription drug discount card program. To avoid any confusion between these related programs, we would like to make this distinction clear. Because of the limited low-income assistance under the card program, card sponsors have been permitted to negotiate lower prices for low-income members. Also, in some cases there may be reduced cost sharing sponsored by manufacturers for low-income members after the $600 in transitional assistance is used that does not apply to other card members. Under the Part D prescription drug program, however, both the negotiated prices and the benefit structure would be the same for all enrollees in a given PDP or MA–PD plan. While the low-income subsidies will result in low-income beneficiaries' actual out-of-pocket costs being lower than for beneficiaries who do not qualify for this assistance, the benefit structure to which the subsidies apply is the same for all enrollees in a plan.

3. General CMS Guidelines for Actuarial Valuation of Prescription Drug Coverage

As directed by section 1860D–11(c) of the Act, we would develop processes and methods using generally accepted actuarial principles and methodologies for determining the actuarial valuation of prescription drug coverage. Although we plan to provide additional information in the future in the form of interpretive guidance on these processes, we are currently considering the following processes and methods for calculating "actuarial valuation" and "actuarial equivalence" in the context of risk bids:

- Sponsors offering standard coverage with cost-sharing variants either to the 25 percent coinsurance (before the initial coverage limit) or the greater of 5 percent coinsurance or $2 generic/preferred/$5 any other drug (after the out-of-pocket threshold is met) would be required to demonstrate the actuarial equivalence of their variations.
- Sponsors offering basic or enhanced alternative prescription drug coverage would be required to demonstrate that—
  + The actuarial value of total or gross plan coverage is at least equal to the actuarial value of total or gross coverage of the defined standard benefit.
  + The actuarial value of total coverage of their alternative is at least equal to the actuarial value of defined standard coverage;
  + The actuarial value of unsubsidized coverage of their alternative is at least equal to the actuarial value of the unsubsidized portion of defined standard coverage; and
  + The plan payout at the dollar value of the initial coverage limit under standard coverage, for individuals whose total spending exceeds that limit, is at least equal to that provided under defined standard coverage.
- All sponsors would determine the actuarial value of the defined standard benefit, either because it is—
  + Offered to the beneficiaries;
  + Used as a comparison for either of the following:

Standard coverage with actuarially equivalent cost-sharing variants.

Alternative coverage; or

+ Used to determine the basic component in enhanced alternative coverage.

- Sponsors that offer enhanced alternative coverage would also be required to determine the actuarial value of coverage beyond basic coverage.
- We anticipate that we would specify data sources, methodologies, assumptions, and other techniques in accordance with generally accepted actuarial principles as either recommended or required in further guidance. We would also specify the data elements (including format) to be sent to us for evaluation. We would then evaluate the analysis and assumptions for compliance and reasonableness. For example, we would evaluate the source, size, and timeframe of data on which assumptions are based, the demographic characteristics of enrollees, the distribution of risk levels, the average costs in each cost-sharing tier, and the update factors used, among other considerations.
- We would also have reported and separately identified administrative costs. Since the level of the bid will directly affect the premium paid by the beneficiary and the attractiveness of the plan, we expect that plans will have a strong incentive to keep administrative costs and return on investment at reasonable levels. Any review of administrative costs would likely focus primarily on outliers from the competitive range identified in the bids received. All proposals would contain a description of how certain costs (those related to appeals that result in payment for non-formulary drugs) are included in the calculations. Processes and methods for determining actuarial valuation would take into account the effect that providing actuarially equivalent standard coverage or alternative prescription drug coverage (rather than defined standard coverage) has on drug utilization. This includes utilization effects attributable to different benefit structures, such as from tiered cost sharing, as well as those attributable to supplemental benefits. The utilization effect of supplemental benefits on basic benefits would have to be loaded into the supplemental portion of the bid. In other words, since the existence of supplemental coverage would increase total average per capita spending, that increase over the average spending (if coverage were limited to basic coverage) would be included in the portion of the

bid attributable to supplemental coverage. Section 1860D–11(c)(1)(D) of the Act specifies "the use of generally accepted actuarial principles and methodologies." We are interpreting this to require that a qualified actuary certify the plan's actuarial valuation (which may be prepared by others under his or her direction or review). Actuarial certification would give better assurance that the actuarial values in the bid were prepared in conformance with actuarial standards and methodologies.

• Section 1860D–11(c)(3)(B) of the Act specifies that PDP sponsors or MA organizations offering MA–PD plans may use qualified independent actuaries in certifying the actuarial values in their bids. (The actuarial valuation may be prepared by others under the direction or review of a qualified actuary). We interpret this provision as encouraging PDP sponsors and MA organizations that do not employ qualified actuaries, to use outside actuaries in their processes. We propose to specify that a qualified actuary is an individual who is a member of the American Academy of Actuaries because members of the Academy must meet not only educational and experience requirements, but also a code of professional conduct and standards of practice. These standards create a common ground for actuarial analysis. Furthermore, a member of the Academy is subject to its disciplinary action for violations of the code and standards. This same requirement is specified in the SCHIP legislation at section 2103(c)(4)(A) of the Act. Moreover, the National Association of Insurance Commissioners (NAIC) imposes significantly stricter requirements on actuaries preparing the financial statements of insurance companies.

4. Determining Actuarial Equivalency for Variants of Standard Coverage and for Alternative Coverage

When considering the specific requirements for actuarial equivalence and valuation in the Act, we are aware that there is no official definition of actuarial equivalence. Moreover, the concept of actuarial equivalence is applied in multiple contexts. We must address actuarial equivalence requirements regarding cost sharing, expected benefits, and bid submissions. We plan to address the application of actuarial equivalence within these separate contexts in this discussion and in separate detailed guidance to the industry. Thus, we plan to use interpretive guidance to further explain the process and methodology for determining actuarial equivalence and valuation. The processes and methods for determining actuarial equivalence and valuation would be in keeping with generally accepted actuarial principles. We would require prospective PDP sponsors and MA organizations wishing to offer MA–PD plans to include all of the requirements discussed in the following sections in the information submitted with the bid, when applicable. The MMA contains some specific requirements for actuarial equivalence or valuation. These actuarial equivalence tests are discussed below.

a. Actuarial Equivalence as Applied to Actuarially Equivalent Standard Coverage—Cost-Sharing

As required in section 1860D–2(b)(2)(A) of the Act, standard prescription drug coverage must have "coinsurance for costs above the annual deductible * * * and up to the initial coverage limit that is equal to 25 percent; or is actuarially equivalent * * * to an average expected payment of 25 percent of such costs." We interpret this to mean that sponsors would be required to demonstrate that the actuarial value of their alternative cost-sharing as a percent of the actuarial value of both cost-sharing and plan payments for claims up to the initial coverage limit is the same percentage as for 25 percent coinsurance under defined standard coverage. In calculating these percentages, sponsors would reflect the utilization impacts of the two structures, but hold constant formulary (drug list), drug pricing (except to the extent that the plan incorporated differential pricing and cost sharing based on participation status within the plan's network), and the group whose utilization is modeled. This would allow plans to have variable co-payments or coinsurance, including tiered structures for preferred and non-preferred drugs, in the initial coverage interval as long as the actuarial equivalence test is met. As a simple example, a plan could have a tiered coinsurance benefit with coinsurance higher than 25 percent for brand name drugs and lower than 25 percent for generics. Some beneficiaries with expenses between the deductible and the initial coverage limit would be expected to pay more than 25 percent, and others to pay less, depending on their usage of brand versus generic drugs. Overall, however, the total coinsurance would have to be actuarially equivalent to an average of 25 percent for all beneficiaries with expenses in this interval, even if the total expenditures beneath the initial coverage limit ($2,250 in 2006) are lower than would be expected under defined standard coverage (due to increased use of generics, for example).

If sponsors wanted to provide a variant on defined standard cost sharing after the out-of-pocket threshold is met, an actuarial test similar to that described above for variants on the 25 percent coinsurance would apply. In this case, based on the group of individuals projected to exceed the out-of-pocket threshold, the sponsor would compute total cost sharing once the true out-of-pocket (TROOP) threshold has been met as a percentage of the sum of that cost sharing plus the comparable plan payout. This percentage would have to equal the percentage computed in the same manner using the defined standard benefit (that is, the greater of $2/$5 or 5 percent). We note that any variant in cost sharing could not lead to discrimination against certain beneficiaries, for example, by increasing the cost sharing of a drug used for a particular illness well above the cost sharing for other drugs.

b. Tests for Alternative Coverage

As required by section 1860D–2(c) of the Act, sponsors offering alternative coverage, that is, benefit structures different from standard coverage, must satisfy five tests (three of the five are actuarial equivalency tests). As discussed in Subpart C, alternative coverage would include coverage actuarially equivalent to defined standard coverage (basic alternative coverage) or coverage that would include supplemental coverage (enhanced alternative coverage). All alternative coverage would have to meet all five of the coverage standards or tests discussed in section b.1–5 of this preamble. Tests one through three were established by the Congress to assure that alternative coverage would be at least actuarially equivalent to standard coverage. Tests four and five are additional tests imposed by the Congress through section 1860D–2(c) of the Act.

1. Test for Assuring at Least Equivalent Value of Total Coverage

As required in section 1860D–2(c)(1)(A) of the Act, a plan could offer alternative prescription drug coverage as long as the actuarial value of total or gross coverage is at least equal to total or gross coverage provided under standard coverage. Based on a typical distribution of enrollee utilization, the average plan payout (including costs reimbursed by Medicare through the reinsurance subsidy) would have to be at least equal to the sponsor's estimate of the payout under defined standard coverage (holding various factors

constant as described above under section 4.a.).

Alternative benefit structures, such as a decrease in the deductible with an increase in coinsurance below the initial coverage limit, or a lower initial coverage limit with a corresponding decrease in coinsurance, or a lower initial coverage limit with a corresponding decrease in deductible, could be accommodated as basic alternative coverage as long as the actuarial value of this coverage equaled that of defined standard coverage. Alternative structures could not increase the deductible or provide less than the protection offered against high out-of-pocket expenditures described in section 1860D–2(b)(4) of the Act. To the extent that the alternative coverage exceeds the value of defined standard coverage, the plan would be offering enhanced alternative coverage, that is, alternative coverage that includes supplemental benefits (as discussed in subpart C).

2. Test for Assuring Equivalent Unsubsidized Value of Coverage

In section 1860D–2(c)(1)(B) of Act, a plan could offer alternative coverage as long as the unsubsidized value of coverage (the value of the coverage exceeding subsidy payments) is at least equal to the sponsor's estimate of unsubsidized value under defined standard coverage (holding various factors constant as described above section 4.a.). We interpret the unsubsidized value of coverage to mean the value of the benefit attributable to the beneficiary share of the premium.

There is a basic question about how this test could be applied during the plan review and approval process. In order to determine the unsubsidized value of coverage, one would have to know the projected reinsurance payments, and the value of the direct subsidy. While the projected reinsurance payments would be known at the time of the submission (since the actuarial value of the benefit is reduced by projected reinsurance payments to produce the bid), the value of the direct subsidy would not be known (since it would require computing the national weighted average bid and bids have not yet been approved). In the face of this problem, one approach could be to remove reinsurance payments as estimated by the sponsor and to use an estimate of the direct subsidy that we would provide. For instance, in the first year we might provide the estimate used for budgeting purposes, and in subsequent years, an estimate based on prior years' actual experience updated for trend. We are requesting comments on this approach.

In trying to assess the impact of the test of total value (section 1860D–2(c)(1)(A) of the Act) and the test of unsubsidized value (section 1860D–2(c)(1)(B) of the Act), we have been unable to identify an example of a plan meeting the first test but not the second. We are seeking comment with regard to this question.

3. Test for Assuring Standard Payment for Costs at Initial Coverage Limit

Under section 1860D–2(c)(1)(C) of the Act, sponsors are to determine the average payout "with respect to costs incurred that are *equal* to the initial coverage limit" for "an actuarially representative pattern of utilization." This projected payout is compared to a dollar amount that is equal to what defined standard coverage would pay for someone with costs equal to the initial coverage limit. Given the comparison, this raises the question of what represents "an actuarially representative pattern of utilization." As with the other tests, we believe that it would be reasonable for plans to use either anticipated plan utilization or a typical utilization pattern based on the Medicare population. However, given the implicit comparison to payout under defined standard for someone with costs equal to the initial coverage limit, it would not be valid to include individuals with expenses below the value of the initial coverage limit. After excluding individuals with total expenses below the value of the initial coverage limit, the plan would compute the actuarial value of plan payout at the point where total expenses are equal to the initial coverage limit under standard coverage. Under this interpretation, a plan could offer alternative coverage as long as the coverage is designed to provide an actuarial value of plan payout that is equal to at least 75 percent of costs between the standard deductible and initial coverage limit ($1,500 in 2006). In other words, considering only plan enrollees with expected expenses greater than or equal to the dollar value of the standard initial coverage limit, the plan would have to demonstrate that the expected plan payout associated with expenses equal to that dollar value would be at least 75 percent of benefit costs between the deductible and initial coverage limit (75 percent of $2,000 per beneficiary in CY 2006) including taking into account their expected behavioral response to the different benefit structure. This test, combined with the prohibition on increasing the deductible under alternative coverage (described below), would ensure that the benefit below the dollar level of the standard initial coverage limit is always actuarially equivalent to standard coverage. As a defined standard benefit it is not permissible to trade off benefits above the initial coverage limit for benefits below.

4. Test for Assuring the Deductible Does not Exceed the Standard Deductible.

In keeping with the requirements of section 1860D–2(c)(2) of the Act, alternative coverage could not be structured so that the deductible is any higher than what it is in standard coverage ($250 in 2006).

5. Test for Assuring the Same Protection Against High Out-of-Pocket Costs

As specified by section 1860D–2(c)(3) of the Act, any alternative coverage must provide "the coverage" specified for costs above the catastrophic limit in standard coverage. We interpret this to mean that both enhanced and basic alternative coverage would have to offer at least the coverage available above the catastrophic limit through defined standard coverage. We would apply this test in the same way that we do for standard coverage with a variant of cost sharing above the catastrophic limit. That is, examining the group of individuals the sponsor projects would exceed the out-of-pocket threshold, total cost sharing once TROOP has been met, as a percentage of the sum of such cost sharing plus comparable plan payout, must be less than or equal to the percentage computed using the defined standard benefit (that is, the greater of $2/$5 or 5 percent). Again, we note that any variant in cost sharing could not lead to discrimination against certain beneficiaries, for example, by increasing the cost sharing of a drug used for a particular illness well above the cost sharing for other drugs.

c. Value of Qualified Coverage

In accordance with section 1860D'11(b)(2)(B) of the Act, with the bid, each PDP sponsor and MA organization offering an MA–PD plan must submit the actuarial value of qualified coverage in the region for the Part D eligible individual with a national average risk profile for the factors described in section 1860D'15(c)(1)(A) of the Act. We interpret this to mean that the weighted average of the plan's expected risk-standardized costs will represent the plan's cost for the theoretical national average-risk Part D individual. Any increase in costs attributable to increased utilization as the result of enhanced alternative coverage must be

excluded from this calculation. (Any alternative coverage that does not include supplemental coverage would be, by definition, actuarially equivalent to standard coverage. In this case, there is no need to make a further utilization adjustment since the test of actuarial equivalence for the 25 percent cost-sharing requirement has already taken into account utilization.) Any utilization effect that supplemental coverage has on the basic benefit should be priced into the supplemental portion of the bid.

5. Information Included With the Bid

a. Bid Format

We have not yet determined the exact format for the bid submission and we would provide future guidance on these requirements. We believe that we would develop a fully automated process that would include electronic signatures for certifications of the actuarial analysis and the plan benefit package. Section 1860D–11(c)(1)(D) of the Act specifies "the use of generally accepted actuarial principles and methodologies." We would require that an actuary (a member of the American Academy of Actuaries) certify the actuarial valuation, which may be prepared by others under his or her direction or review. Actuarial certification would give better assurance that the actuarial values in the bid were prepared in conformance with actuarial standards and methodologies. Section 1860D–11(c)(3)(B) of the Act permits use of outside qualified independent actuaries. We expect that plans would use outside actuaries, especially if they did not have qualified in-house actuaries.

As provided in section 1860D–11(b)(3) of the Act, we would develop the bid submission format to facilitate the submission of bids for multiple regions and in all regions, and we would take this into account in process development. This approach would need to ensure that separate bids were provided for each region in order to calculate the national average monthly bid amount and any geographic adjustment required. Our overall approach would be to increase our flexibility to develop appropriate methodologies in response to program changes, while minimizing burden, rather than codifying these processes in regulation. We believe that we would have the authority to develop these methodologies through interpretive guidance because our regulations state that sponsors provide the actuarial value of their plans in accordance with generally accepted actuarial principles and methodologies.

The information included with the bid should be sufficient for our review of the acceptability of a proposed plan based on actuarial principles and for negotiation of terms and conditions of an entity's participation in the provision of Part D benefits. As provided in section 1860D–11(b)(2) of Act and § 423.265(d) of this proposed rule, the information that would accompany the bid submission would, at a minimum, include the following:

- Information on the prescription drug coverage to be provided, including the structure of the benefit, including deductibles, coinsurance (including any tiers), initial (or subsequent) coverage limits at which coinsurance levels change, and out-of-pocket thresholds. This would also include the plan's formulary and any drugs, or types of drugs, excluded from coverage, and all documents provided to beneficiaries explaining the benefit, including the Evidence of Coverage, and would be certified by an officer of the plan. We solicit comments on the best way to obtain clear information on what drugs are included in the formulary.
- The actuarial value of the qualified prescription drug coverage in the region for a beneficiary with a national average risk profile certified by a qualified actuary.
- The portion of the bid attributable to basic benefits.
- The portion of the bid attributable to supplemental benefits, if applicable.
- The actuarial basis for the portion of the bid attributable to basic coverage and to supplemental benefits, if applicable, certified by a qualified actuary.
- The assumptions regarding reinsurance subsidy payments.
- The assumptions regarding administrative expenses.
- The plan's service area and the plan's network of pharmacies serving that service area.
- (For PDP sponsors only) the level of risk assumed in the bid, including whether the sponsor requires a modification of risk level (see discussion below) and, if so, the extent of the modification. Although our procedures may subsequently seek this information, we may only review it to the extent that the initial submission of bids does not yield the statutory minimum number of full risk bidders in each region and area. Our goal in designing the bidding process will be to maximize the level of risk borne by contracting plans and to minimize the need for fallback plans, and we would welcome comments on facilitating risk bidding; and
- Any other information that we would require.

b. Risk Adjustment of Supplemental Premium

The portion of the bid attributable to supplemental benefits represents the supplemental premium for a beneficiary with a national *average* risk profile. The payment process provided in section 1860D–15 of the Act would only address risk adjustment of the basic portion of the bid, and there are no other provisions for risk adjusting the supplemental benefit portion of the bid. If not addressed, this would result in plans with average risk scores above 1.0 being under-compensated by enrollees for supplemental benefits, and plans with average risk scores below 1.0 being over-compensated, as illustrated below.

TABLE F–1.—SUPPLEMENTAL PREMIUM RISK ADJUSTMENT

	Plan A	Plan B	Plan C
Plan Average Risk Profile	0.80	1.00	1.10
1.0 Supplemental Premium	100	100	100
Supplemental Premium if Risk-Adjusted	80	100	110
Over or (under) compensation	$20.00	$0.00	$(10.00)

Table F–1 illustrates the case of three equally efficient plans that each estimate the cost of the same supplemental benefits at $100. Plan B has an average risk profile, that is, the arithmetic average of the risk scores of all of its enrollees is equal to 1.0. Plan A and Plan C, however, have healthier and sicker than average risk pools, with enrollee risk scores averaging .80 and 1.10, respectively. Plan A only needs an average risk-adjusted premium of $80 to

meet the revenue requirements of providing those supplemental benefits to its healthier enrollees, but would receive $20 more on average from enrollees if it collects the whole $100 unadjusted premium. In contrast, Plan C needs to collect $10 more than it would receive from the unadjusted (1.0) premium to fully fund the expected needs of its sicker enrollees. Consequently, we are proposing to require additional information on the projected risk profiles of its projected enrollees for accurate valuation of the supplemental portion of the bid with the bid submission. We intend, through the negotiation process, to reach agreement on a supplemental premium based on the bid submission that would account for the risk profile of enrollees and, thus, meet the plan's revenue requirements. Our goal is to maintain a level playing field that would facilitate the fair competition envisioned in the MMA. Review and approval of this information is discussed in section F.3. of this preamble.

c. Modification of Risk in PDP Bids

As provided under section 1860D–11(b)(2)(E) of Act and in § 423.265(d)(4), PDP sponsors may request a modification of certain risk sharing arrangements provided under section 1860D–15(e) of the Act, thus, becoming a limited risk plan. Modification of risk could include an increase in the Federal percentage assumed in the risk corridors or a decrease in the size of the risk corridors. Any modification of risk would have to apply to all PDP plans offered by a PDP sponsor in a region.

Section 1860D–11(b)(2)(E)(i) of the Act states that modification of risk will not be available to MA–PD plans. Therefore, in discussing the possibility of including in the bid a request for a modification of risk, we include only PDP sponsors. Limited risk plans would only be accepted if the access requirements in section 1860D–3(a) of the Act could not otherwise be met through the approval of a sufficient number of full risk plans. These requirements call for at least two qualifying plans offered by different entities, one of which must be a stand-alone prescription drug plan. If other bidders meet these requirements, a bid from a limited risk plan could not be approved and might not be reviewed.

6. Review and Negotiation of Bid and Approval of Plans

a. Authority To Review Bids

We would review the information filed by the PDP sponsor or MA organization in order to conduct negotiations on the terms and conditions proposed in the bid. The MMA grants use the authority to negotiate bids and benefits "similar to" the statutory authority given the Office of Personnel Management (OPM) in negotiating health benefits plans under the FEHBP program. We believe that the Congress used "similar to" in the statute because of the differences between the two programs. For example, while the OPM authority applies to level of benefits, standard Part D drug coverage is defined. With regard to rates, in some cases the context for FEHBP negotiations is not applicable to Part D. For example, the rates for community-rated plans under FEHBP are related to the rate the entity provides to similarly sized groups, and there is no comparable concept in Part D. Arguably the degree of competition among plans, and price signaling through premium and benefits, might be significantly greater in Part D than in FEHBP. Although these differences do exist there are also similarities. OPM is concerned about trend factors used to establish the premium for experience-rated plans, and we would have similar concerns about the reasonableness of a sponsor's trend assumptions. OPM is concerned about cost-sharing changes proposed by plans, and we would have similar concerns with regard to supplemental benefits. OPM wants to maintain high member satisfaction and ensure top quality service by plans, and we would have similar interests.

Chapter 89 of title 5 U.S.C. gives OPM broad discretion to negotiate prices and levels of benefits. For example, 5 U.S.C. 8902(i) states that OPM may negotiate with carriers if it believes the rates charged do not "reasonably and equitably" reflect the cost of the benefits provided. In addition, rates may be determined "on a basis which, in the judgment of the Office, is consistent with the lowest schedule of basic rates generally charged for new group health benefit plans issued to large employers." OPM is permitted to ensure that any adjustment in rates from one year to the next is consistent with the general practice of carriers which issue group health benefit plans to large employers. We interpret this to mean that we would have the authority not only to determine whether the bids submitted accurately reflect the costs of the plan, but also to determine whether the bids are in keeping with premiums charged in other insurance contexts. If bids increase at a rate higher than the premiums in the general insurance market (with appropriate adjustments for comparable populations), we may determine that further negotiations are needed. In addition, OPM has broad authority to negotiate the level of benefits, including the ability to prescribe "reasonable minimum standards for health benefits plans." (*See* 5 U.S.C. 8902(c).) We are considering similar regulations to those used by OPM in 48 CFR Chapter 16 and are soliciting comments on this subject. To the maximum extent feasible and consistent with the appropriate discharge of our responsibilities, we prefer to rely on competition rather than negotiation.

b. Bid and Benefit Package Review

We believe we have the authority to negotiate in four broad areas—(1) administrative costs; (2) aggregate costs; (3) benefit structure; and, (4) plan management, if dissatisfied with some or all aspects of bid submissions. We would evaluate administrative costs for reasonableness in comparison to other bidders and in comparison to a PDP sponsor's other lines of business. We would examine aggregate costs to determine whether the revenue requirements for qualified prescription drug coverage are reasonable and equitable. We would be interested in steps that the sponsor is taking to control costs, such as through various programs to encourage use of generic drugs. We would examine and discuss any proposed benefit changes. Finally, we would discuss indicators and any identified issues with regard to plan management, such as customer service.

In addition to the negotiation process, we would assure that bids and plan designs meet statutory and regulatory requirements. In general, we would examine bids to determine whether the bid meets the standard of providing qualified prescription drug coverage, as described in § 423.104(b) of this proposed rule and in subpart C of this preamble. We would examine the actuarial analysis accompanying the bid to ensure that it has been prepared in accordance with our actuarial guidelines and properly certified. We would examine bids to determine whether the revenue requirements for qualified prescription drug coverage are accurate and reasonable, and that the requirements relating to actuarial determinations are met. We note that section 1860D–11(e)(2)(c) of the Act requires that the portion of the bid attributable to basic prescription drug coverage must be supported by the actuarial bases and reasonably and equitably reflect revenue requirements for benefits provided under the plan, less the sum of the actuarial value of reinsurance payments. We would also

review the structure of premiums, deductibles, copayments, and coinsurance charged to beneficiaries and other features of the benefit plan design to ensure that it is not discriminatory. We would review cost sharing both above and below the out-of-pocket threshold with regard to its impact on groups of beneficiaries. We would also look to see that there is no differential impact on groups of beneficiaries by geographical location within the plan's region or service area attributable to different levels of cost sharing between preferred and non-preferred network providers.

As required under section 1860D–11(e)(2)(D)(i) of the Act and in § 423.272(b)(2), the structure of the benefit design (including cost sharing provisions and formulary design) must not be discriminatory; that is, it must not discourage enrollment by any Part D eligible enrollee on the basis of health status, including medical condition (related to mental as well as physical illness), claims experience, receipt of health care, medical history, genetic information, evidence of insurability, and disability. In general, this means that we would review benefit plans for features that, when applied, have differential impacts on beneficiaries with particular medical conditions. Factors we would consider in determining whether a benefit structure is discriminatory include, but are not limited to—(1) the benefit design—including the initial coverage limit, the tiered cost-sharing, the use of categories and classes in a formulary, and the choice of drugs provided in each category. (For example, if the tiered cost-sharing for drugs used to treat HIV is much higher than the cost-sharing for other types of drugs, we would view this benefit structure to be discriminatory); (2) the use of any discriminatory limits such as 90-day limits or requirements for pre-authorization; and (3) supplemental benefits such as supplemental coverage of drugs that would encourage a healthier population to join the PDP. As provided in section 1860D–11(e)(2)(D)(ii) of the Act, plans using formulary designs based on categories and classes that are consistent with the guidelines established by the U.S.P. as discussed in subpart C, will be recognized as satisfying the non-discrimination design related to formulary structure as it pertains to categories and classes. However, adopting the USP model categories and classes would not prohibit us from reviewing other aspects, including the use of any limits or tiers, as discussed above.

c. Approval of the Supplemental Premium

As provided under section 1860D–11(e)(2)(C)(ii) of the Act, we will determine that the portion of the bid attributable to supplemental benefits reasonably and equitably reflects the revenue requirements for that coverage under the plan. Unless the supplemental portion of the bid (which is paid by the enrollee in the form of the supplemental premium) is risk adjusted for the average level of risk among enrollees, plans with average risk scores above or below 1.0 would be over compensated or under compensated by enrollees for supplemental benefits. Therefore, on the basis of this authority, we are proposing to require additional information, consisting of estimates of the projected risk scores of the plan's enrollees in the subsequent year, to be submitted by each plan for purposes of negotiating the appropriate risk adjustment of the supplemental portion of the bid. We would review and negotiate that information, and would approve a uniform supplemental premium reflecting the average risk factor for the plan's expected enrollment.

d. Rebate Reallocation for MA–PD Plans

The negotiation process for MA–PD plans could include the resubmission of modified benefit structures (other than changes in that portion of their supplemental benefits related to drugs) once we know the outcome of the national average monthly bid calculation and its impact on beneficiary premiums. Part D drug benefits, including benefits offered through supplemental Part D coverage) could not be changed during this process because any changes would have an impact on government reinsurance payments and, therefore, on the portion of the bid related to basic drug benefits. The MMA requires that all MA bid and benefit package submissions be provided to us no later than the first Monday in June. In the prescription drug program enrollee premiums must be based on a percentage of the national average monthly bid amount that can only be calculated once all bids have been received, if not actually approved. (While the enrollment weights are determined from the previous year's reference month, the bid amounts are not.) Therefore, the prescription drug portion of benefit packages submitted by MA–PD plans would be based on estimates of monthly beneficiary premiums. Some of these MA–PD plans would have allocated portions of their Part C rebates to buy-down of the Part D premium. Once the final national average monthly bid amount and the base beneficiary premium have been calculated, some of these rebate allocations in the bids could be either excessive or insufficient to achieve the desired premium level.

Excessive rebate allocation would result in a portion of the rebate that is not provided to the beneficiary as required by law, since a premium of less than zero is not permitted. Compliance with the statute will require a reallocation of the excessive portion of the rebate credit back to other allowed uses of the Part C rebate, that is, to supplemental benefits (including reduced cost sharing other than cost sharing for Part D drugs) or to credits to the Part B or supplemental premiums. On the other hand, insufficient rebate allocation may result in minimal premiums that may be seen as burdensome by plans, enrollees, and the financial institutions managing electronic funds transfer.

The statute does not address this situation, but section 1860D–11 of the Act does grant us broad authority to negotiate the terms and conditions of the proposed bids and benefit plans. Our proposed regulatory approach would be to allow the negotiation process for MA–PD plans to include the resubmission of modified benefit structures once the outcome of the premium finalization process is known. MA–PD plans would be able to redistribute their Part C rebates to correct for the difference between the projected and final national average monthly bid amounts and to achieve the previously proposed level of Part D premiums. Under no circumstances could plans submit modified bids.

For example, an MA–PD organization submitted its bid and benefit package based on the assumption that the levels of the national average monthly bid amount and its prescription drug standardized bid would result in a $35.00 monthly beneficiary premium for basic coverage, and that it would use $35.00 of its Part C rebate to completely buy down the Part D premium. If the national average monthly bid amount is determined to be higher than expected, the plan's bid would end up below the benchmark and its base beneficiary premium would be adjusted by subtracting the difference between the bid and national average monthly bid amount. Therefore, the plan's monthly beneficiary premium would be less than the projected premium, for instance, $34.00, and the $35.00 amount allocated

from the Part C rebate for Part D premium buy-down would be excessive. In that case, we would require the MA organization to amend its benefit package to reallocate the excessive $1.00 of the Part C rebate credit to additional supplemental benefits (other than for Part D drugs) or to Part B or supplemental premium credits. These adjustments would be mandatory in order to ensure that the entire amount of the rebate was provided to the beneficiary in some form.

Under an alternative scenario, the national average monthly bid amount is determined to be lower than expected and the plan's bid ends up above the benchmark. In this case, the plan's base beneficiary premium would be adjusted by adding the difference between the bid and national average monthly bid amount. Therefore, the plan's monthly beneficiary premium would be higher than projected, for instance $36.00, and the $35.00 amount allocated from the Part C rebate for Part D premium buy-down would no longer be sufficient to eliminate the Part D premium as planned. In that case, we would allow the MA organization to amend its benefit package to reallocate an additional $1.00 of the Part C rebate credit from additional supplemental benefits (other than for Part D drugs) or from Part B or supplemental premium credits to eliminate the Part D premium. These adjustments would be optional since the Part C rebate has already been provided to the enrollee. We would not permit an MA organization to simply eliminate a minimal premium instead of reallocating the rebate because doing so would mean that the cost of providing the prescription drug benefit had been overstated. However, the MA organization could elect to charge the new increased premium and to amend its benefit package submission accordingly.

e. Private Sector Price Negotiation and Formulary Design

The Act envisions that most price negotiation including discounts, rebates, or other direct or indirect subsidies or remunerations would take place between PDP sponsors or MA organizations (or their subcontractors) and pharmacies and pharmaceutical manufacturers. (Section 1860D–11(i) precludes CMS from interfering with negotiations between drug manufacturers and pharmacies, or PDP sponsors, or requiring a particular formulary or pricing structure.) In other words, price negotiation would be conducted by the private drug benefit managers and plans that are already familiar with negotiating prices of prescription drugs on a local, regional or national basis. Moreover, we expect that providing information on discounted drug prices to beneficiaries will encourage further competition on lower prices. Because beneficiaries will choose a drug plan based on drug prices and formulary coverage, the plans have strong incentives to negotiate lower prices on drugs that beneficiaries use—just as private benefit managers currently do on behalf of the Federal government, state governments, and employer and retiree plans. We expect that in addition to price levels for drugs, these negotiations will also include such terms as prohibitions on substitutions of drugs if the net result would be higher costs for patients or the plans. The nature of the negotiations that we propose to conduct with bidders is discussed later with respect to full-risk and limited-risk bids, and in subpart Q of this preamble with respect to fallback plans.

We expect that the private negotiations between PDP sponsors and drug manufacturers would achieve comparable or better savings than direct negotiation between the government and manufacturers, as well as coverage options that better reflect beneficiary preferences. This expectation reflects the strong incentives to obtain low prices and pass on the savings to beneficiaries resulting from competition, relevant price and quality information, Medicare oversight, and beneficiary assistance in choosing a drug plan that meets their needs. This is similar to the conclusion of other analyses, for example, CBO's recent statement that "Most single-source drugs face competition from other drugs that are therapeutic alternatives. CBO believes that there is little, if any, potential savings from negotiations involving those single-source drugs. We expect that risk-bearing private plans will have strong incentives to negotiate price discounts for such drugs and that the Secretary would not be able to negotiate prices that further reduce federal spending to a significant degree." In accordance with the Medicaid best price exemption provided under section 1860D–2(d)(1)(c) of the Act and codified in § 423.104(h)(2) of our proposed rule, drug plans may even be able to negotiate better prices than those paid under Medicaid. It also reflects Medicare's recent experience with drug price regulation for currently-covered drugs, in which regulated prices for many drugs have significantly exceeded market averages.

By not allowing us to require any particular formulary, the statute ensures that the Pharmacy and Therapeutics committees of prescription drug plans and MA–PD plans have the flexibility to make changes in their classifications and lists of preferred drugs based on the most current evidence-based information (subject to the limitations of § 423.120(b)). We will evaluate plan formulary categories and classes in comparison to the model guidelines developed by U.S.P. In addition to evaluating any discriminatory features, as discussed above, we will evaluate the number of categories in formularies that do not meet the model guidelines and the choice of drugs available in those categories with respect to meeting the needs of the Medicare population. After the initial year of the program, we will also review the history of plan formulary appeals to identify issues with the plan's formulary. We will conduct additional research on evaluating formularies and drug benefit designs and we would welcome comments on evaluation. As noted previously, we may also review plan cost sharing (that is, tiers).

f. Bid Level Negotiation

The FEHBP standard in 5 U.S.C. 8902(i) requires us to ascertain that the bid "reasonably and equitably reflects the costs of benefits provided." In addition, we note that section 1860D–11(e)(2)(c) of the Act requires that the portion of the bid attributable to basic prescription drug coverage must "reasonably and equitably" reflect revenue requirements * * * for benefits provided under that plan, less the sum * * * of the actuarial value of reinsurance payments." Analogous to the manner in which FEHBP views its management responsibilities, we see this requirement as imposing the fiduciary responsibility to evaluate the appropriateness of the overall bid amount.

In general, we expect to evaluate the reasonableness of bids submitted by at-risk plans by means of the actuarial valuation analysis. This would require evaluating the plan's assumptions regarding the expected distribution of costs, including average utilization and cost by drug coverage tier, for example, in the case of standard coverage—(1) those with no claims; (2) those with claims up to deductible; (3) those with claims between the deductible and the initial coverage limit; (4) those with claims between the initial coverage limit and the catastrophic limit; and (5) those with claims in excess of the catastrophic limit. We could test these assumptions for reasonableness through actuarial analysis and comparison to industry standards and other comparable bids. Bid negotiation could take the form of

negotiating changes upward or downward in the utilization and cost per script assumptions underlying the bid's actuarial basis. We ask for comment on the most effective and least burdensome way to obtain pricing and utilization data for use in our actuarial review, as well as comments on the broader issues discussed in this section.

Arguably, appropriate assurance that plan bids reasonably and equitably reflect the revenue requirements associated with providing the Part D benefit requires knowing the final drug price levels the plans are paying that are implicit in their bids. Consequently, in addition to looking at final aggregate prices, if we found that a plan's data differed significantly from its peers without any indication as to the factors accounting for this result, we could also ask bidders to provide information about rebates and discounts they are receiving from manufacturers and others, in order to ensure that they are negotiating as vigorously as possible. Section 1860D–11(b)(1)(C) of the Act allows us to ask for necessary "information on the bid". In other words, we would be able to inquire as to the "net cost" of drugs since this is the key dollar value we would need to make accurate "apples to apples" comparisons on drug prices between PDPs. Under this approach, if the particular bids appear to be unusually high (or low), we could go back to the bidders and request that they explain their pricing structure, the nature of their arrangements with manufacturers, and we might ask further questions and take further action to perform due diligence to ensure that there is no conflict of interest leading to higher bids. For instance, we would look at certain indicators, such as unit costs or growth rates in the bid amounts to see if they are in keeping with private market experience to the extent feasible for a comparable population (for example, retirees). (In this case, we would be using the authority in 5 U.S.C. 8902(i) to negotiate bids that are "consistent with the group health benefit plans issued to large employers".) If the overall bids were unjustifiably high, we would have the authority to negotiate the bids down to a level that is more in keeping with bids that a private market would provide. While there is not a private drug-only insurance market, we could look at the rates used in overall coverage or determine which part of such coverage is made up by drug coverage, and make appropriate adjustments for Medicare utilization differentials. We could exercise our authority to deny a bid if we do not believe that the bid and its underlying drug prices reflect market rates. Our strong expectation, however, is that we will be able to rely on the incentives provided by competitive bidding, and we would use our authority under this part only on the rare occasion we find that a plan's data differs significantly from its peers without any indication as to the factors accounting for this result.

Under the previous M+C program, we permitted M+C organizations to waive premiums or to offer mid-year benefit enhancements to their benefit packages. However, in order to maintain the integrity of the bidding process, we believe that it is no longer appropriate to allow either MA organizations or PDP sponsors to waive premiums or offer mid-year enhancements as they would be *de facto* adjustments to benefit packages for which bids were submitted earlier in the year. These adjustments would be *de facto* acknowledgement that the revenue requirements submitted by the plan were overstated. Allowing premium waivers or mid-year benefit enhancements would render the bid meaningless. Excessive amounts included in the bid will be subject to recovery by the government in the risk corridor calculations following the coverage year.

Consequently, we are proposing to interpret the statutory provisions on competitive price negotiation as prohibiting us from setting a regulated price of any particular drug or imposing by regulation an average discount in the aggregate on any group of drugs (such as single-source brand-name drugs, multiple-source brand name drugs, or generic drugs), but as allowing justification of aggregate price levels for groups of drugs. In addition, we could, under the specific circumstances previously discussed, negotiate regarding the level of the overall risk bid. This approach would allow us to exercise the authority similar to FEHBP as visualized in the MMA to ensure that per capita rates charged "reasonably and equitably" reflect the cost of the benefits provided, and that beneficiaries receive the full benefits of vigorous price negotiation by their drug plans.

g. Approval of Plans

After negotiations on the terms and conditions of the bid, we must approve or disapprove the bid. After negotiations, we would approve a plan only if—

- The plan is found to be in compliance with requirements specified in this regulation;
- The plan meets the actuarial valuation requirements; and
- The plan design does not discourage enrollment by certain eligible beneficiaries.

In § 423.272(c), we would approve limited risk plans only if fewer than two qualifying prescription drug plans offered by different entities, one of which must be offered by a stand-alone PDP sponsor, were submitted and approved in a region. We would approve only the minimum number of limited risk plans needed to meet these access requirements and would give priority to plans bearing the highest levels of risk; however, we may take into account the level of the bids submitted by these plans. Except as authorized under section 1860D–11(g) of the Act and in § 423.863 with regard to fallback plans, we would not, under any circumstances, approve a plan that elected to bear no risk or a minimal level of risk.

h. Special Rules for PFFS Plans

As provided in section 1860D—21(d) of the Act, and codified in § 423.272(d), PFFS plans that offer prescription drug coverage are exempt from review and negotiation (under sections 1860D–11(d) and (e)(2)(C)) of their prescription drug bids and premium amounts but are otherwise subject to all other requirements under this part, with the following exceptions. While we will not negotiate PFFS bids, those bids must meet the actuarial valuation requirements applicable to all risk bids. These plans are not required to negotiate discounted prices for prescription drugs. If they do negotiate, the proposed requirements under § 423.104(h) related to negotiated prices would apply. If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost sharing, and without regard to whether they are participating pharmacies. § 423.120(a) and § 423.132 of this proposed rule (requiring certain network access standards and the disclosure of the availability of lower cost bioequivalent generic drugs) would not apply to the plan. PFFS plans are also exempt from drug utilization management program and medication therapy management program requirements.

Finally, we note that section 1860D–21(d)(7) of the Act provides that costs incurred for off-formulary drugs will not be excluded in determining whether a beneficiary has reached the out-of-pocket threshold if a PFFS plan does not use a formulary. We believe that section 1860D–21(d)(7) is a tautology and simply states that PFFS plans without formularies, by definition, cannot have

non-formulary drugs to exclude from the out-of-pocket threshold calculation.

7. National Average Monthly Bid Amount

In § 423.279, we outline the calculation of the national average monthly bid amount. For each year, beginning in 2006, we would compute a national average bid based on approved bids in order to calculate the national base beneficiary premium. As a practical matter, we realize that we might need to calculate and announce the national average monthly bid amount before negotiations on all bids were completed in order to allow time for finalization of premiums and benefit packages. Therefore, we anticipate that we would identify a date by which the national average monthly bid amount would be published, and we would use the bids that had passed a certain level of approval as of that date as the basis for the calculation.

As provided in section 1860D–13(a)(4)(A) of the Act, in computing the national average monthly bid amount, we would exclude bids submitted for MA private fee-for-service (PFFS) plans, specialized MA plans for special needs individuals, PACE programs under section 1894 of the Act (pursuant to section 1860D–21(f) of Act) and reasonable cost reimbursement contracts under section 1876(h) of the Act (according to section 1860D–21(e) of the Act). The exclusion from the calculation of bids of PFFS, cost plans, specialized MA plans, and PACE suggests that they are different from, and not comparable to, the average bid in some way. We interpret this difference to be based solely on price levels because the legislation—

- Does not define any other basis for determining these bids;
- Continues to compare these bids to the national average bid amount to determine adjustments to enrollee premiums; and
- Provides for payments to such plans (including risk adjustment) in the same manner as to non-excluded plan types.

Therefore, these excluded plan types would still submit bids on the same basis as all other plans, that is, the 1.0 risk prescription drug plan beneficiary, even though these bids are not included in the national average bid amount at this time.

The national average bid amount would be equal to the weighted average of the standardized bid amounts for each PDP and for each MA–PD plan described in section 1851(a)(2)(A)(1) of the Act. The national average monthly bid amount would be a weighted average, with the weights being equal to the proportion of Part D eligible individuals enrolled in each respective plan in the reference month (as defined in § 422.258(c)(1)). For calendar year (CY) 2006, we would determine the enrollment weights on the basis of assumptions that we would develop. One possible approach would be to use the following procedure to assign weights to individual bids for PDPs and MA–PD plans for CY 2006:

- Obtain total Medicare enrollment by region, and enrollment in each (local) MA plan that offers a drug benefit by region. These enrollments would be as of a specific date, for example, March 31, 2005.
- Assign each (local) MA–PD plan in each region a weight equal to its MA enrollment.
- Subtract the MA enrollment from the total Medicare enrollment for each region to arrive at the PDP-eligible enrollment.
- Divide the PDP-eligible enrollment for each region by the number of companies offering PDPs in each region to arrive at the weight for each company in each region.
- For each company in a region, divide the company weight by the number of plans offered by that company to arrive at the PDP weight.
- The regional average monthly bid amount would be calculated by weighting each plan's bid by its assigned weight.
- The national average monthly bid amount would be calculated by weighting each regional average monthly bid amount by the region's proportion of Part D eligible individuals (Medicare enrollment) and summing these products.

Using this methodology, after subtracting MA enrollments, each company offering PDP(s) in a region gets equal weight. An exception might occur based on capacity limits indicated by MA–PD plans. This assumes that beneficiaries would select a company, and then select a plan from that company. It also dilutes the effect of any potential artificially high bids designed solely to increase the national average monthly bid amount. If a company offers multiple plans in a region, each plan gets an equal allocated share of its company's assigned weight.

New MA–PDs would get a zero weight. This treatment is consistent with the weight assignment specified in the statute for subsequent years. Starting with the second year, all new plans would get zero weight because they have no prior year enrollment. We request comments on the "unequal" inclusion of plans in the calculation of the national average monthly bid. We note that many MA–PDs would operate in small geographic areas with small potential enrollment, and so we believe that the impact of this approach for new local MA–PDs is likely limited. We recognize, however, that this approach is perhaps more problematic related to the treatment of the new regional MA–PD plans, as these plans in a given region are likely to have larger enrollment than local MA–PD plans. This particular approach implicitly assigns persons in new MA–PD plans (both local and regional) to the PDP weights, hence giving potentially too much weight to the PDPs.

Alternatively, assigning equal weights to PDPs and new MA–PD plans (even if limited to just the regional MA–PDs) could likely assign too much weight to the new regional MA–PD plans, which at least in 2006 are expected to have lower enrollment. Another possible alternative would be to base weights on regional MA–PD plan projections of enrollment, subject to our assessment of reasonableness of the estimates. In this approach we would use the proportion of projected enrollment for each plan as weights. However, particularly in the first year or so, projections may be quite inaccurate, leading to a distorted and unrepresentative benchmark. We welcome comments on these and other alternative approaches for how to weight bids in 2006.

The assigned weights are price inelastic, that is, the recommended weight assignment methodology implies that price is not a factor in plan selection. In the absence of experience on which to base the relationship between price and plan choice in this population, and, therefore, on how many people would be expected to join each plan, we believe that the fairest method for 2006 is simply to assume an equal weight for each plan.

In subsequent years, the weights for the weighted average would be calculated as a percentage with the numerator equal to the number of Part D eligible individuals enrolled in the plan in the reference month and the denominator equal to the total number of Part D eligible individuals enrolled in all plans (except for those plans whose bids are not include in the national average bid amount, as described above) in the reference month. It represents the proportion of the Part D eligible enrolled individuals in the plan. We would multiply the portion of each plan bid attributable to basic benefits by its proportion of total Part D enrolled individuals and sum each product to arrive at the national average monthly bid. In § 423.279(c), we would also establish an appropriate methodology

for adjusting the national average monthly bid amount to take into account any significant differences in prices for covered Part D drugs among PDP regions. We welcome comments on the existence of regional price variation in drug prices and on any factors that could lead to that variation. As part of carrying out the Congress' requirement that our geographic adjustment methodology be "appropriate," we believe the method would first require gathering data from PDPs and MA–PDs on regional drug prices. Therefore, we may not implement a geographic adjuster for the first few years of the program unless we have acquired sufficient information on pricing to accurately characterize that variation. If we were to determine that there is significant geographic variation in prices, we anticipate that we would announce the adjustment factors in advance of the bidding process for any year in which geographic adjustment would be applied to bids in the calculation. (This would be subject to notice and comment like any other change in payment methodology.) If we were to determine that there is only minimal price variation, we would not implement a geographic adjuster for the national average monthly bid calculation. Additionally, we would implement any geographic adjuster in a budget neutral manner to avoid a change in aggregate payments from the total amount that would have been paid if we had not applied an adjustment.

8. Rules Regarding Premiums

In § 423.286, we propose that the monthly beneficiary premium would be the result of the calculation of a national base beneficiary premium subject to certain adjustments. Congressional intent was to arrive at an average monthly beneficiary premium in CY 2006 representing a certain percentage of the average total estimated benefit provided by the drug plans on a national basis (including benefits subject to Federal reinsurance subsidies). Taking into account that projected reinsurance subsidies are excluded from plan bids, the applicable percentage becomes approximately 32 percent, which is applied to the national average monthly bid amount.

To determine the uniform plan premium, in § 423.286(d), we would adjust the base beneficiary premium for certain plan characteristics including whether the plan's bid would be above or below the national average bid, and whether the plan offers supplemental benefits. (Since the bid has to be approved and premiums established for the entire year, we are interpreting the phrase "if for a month" in section 1860D'13(a)(1)(B)(i) of the Act and 1860D'13(a)(1)(B) (ii) of the Act as referring to the beneficiary premium as a monthly amount.) The base premium is adjusted to reflect the full difference between the plan's standardized bid amount and the national average monthly bid amount (which may be adjusted for regional price differences). To the extent that the plan's standardized bid amount is below the national average monthly bid amount, the base premium is adjusted downward by the difference. To the extent that the plan's standardized bid amount is above the national average monthly bid amount, the base premium is adjusted upward by the difference. The base premium would also be adjusted by adding the premium amount approved after negotiations for risk adjustment of the supplemental benefits, if any (as discussed above). Table F–2 illustrates a calculation of the base beneficiary premium and the adjustment for the difference between the bid and the national average monthly bid amount.

TABLE F–2.—PREMIUM ILLUSTRATION

Benchmark	Plans in region	Bids	Beneficiary premium		
National average monthly bid amount [1]	Plans	Approved plan bid	Amount by which bid exceeds benchmark	Amount by which bid is below benchmark	Applicable percent of nat'l premium ± difference
111	Plan 1	125	14.00	0.00	$50
	Plan 2	111	0.00	0.00	36
	Plan 3	101	0.00	(10.00)	26
Est. Reinsurance Percentage			21.25	(Assumed)	
Applicable Percent =			0.3238	(25.5 /(100 − 21.25)	
Base Beneficiary Premium =			36.00	(111 * .3238) [2]	

[1] A. *Assumes no geographic adjustment.*
[2] B. *Rounded to nearest dollar.*

The sum of the base beneficiary premium, the adjustment for difference between the bid and the national average bid, and the supplemental benefit premium would be the monthly beneficiary premium. The monthly beneficiary premium (except for any supplemental premium) would be eliminated or reduced for low-income subsidy-eligible individuals, as described in section 1860D–14 of the Act and § 423.780. (This adjustment reflects the fact that the government would pay all or a portion of the monthly beneficiary premium for subsidy-eligible individuals.)

In § 423.286(d)(3), the monthly beneficiary premium would be increased for enrollees subject to the late enrollment penalty. The penalty amount for a Part D eligible individual for a continuous period of eligibility (as described in § 423.46) would be the greater of an amount that we determine is actuarially sound for each uncovered month in the same continuous period of eligibility; or 1 percent of the base beneficiary premium for each uncovered month in that period. The beneficiary premium amount is cumulative which means that each month the beneficiary is subject to a penalty, the penalty accumulates. Once the beneficiary enrolls in Part D, that accumulated penalty would be added to their premium amount each month. So for example, if the penalty amount is $.36 per month in 2004, and is subject to 12 months of this penalty, the beneficiary would pay an additional $.36 * 12 or $4.32 per month for as long as they are enrolled in Part D. During the first several years of the program, we currently expect that we would specify

the penalty amount would be 1 percent of the base beneficiary premium per month. Once we have sufficient data on experience under the program with respect to individuals who enroll after their Initial Enrollment Periods, we will be able to determine the appropriate penalty amount, that is, either one percent or a greater amount to be adopted.

We note that achieving very high (indeed, virtually universal) access to prescription drug coverage for beneficiaries who participate in Part D was a key Congressional consideration in enacting MMA. We would encourage comments from insurers, actuaries, and others with experience, data, or expertise in this area. We are particularly interested in receiving comments on the most appropriate level for the late enrollment penalty, the likelihood of whether a $.36 per month of delay penalty (that is, 1 percent for each month of delayed enrollment) constitutes an adequate safeguard against selection bias, and the importance of strongly encouraging widespread enrollment to maximize the affordability and stability of Part D premiums."

Except as provided with regard to any enrollment penalty, low-income assistance, or employer group waivers under section 1857(i) and section 1860D–22(b) of the Act and § 423.458(c) (as discussed in Subpart J of the preamble to our proposed rule), the monthly beneficiary premium for a prescription drug plan or MA–PD in a PDP region must be the same for all Part D eligible individuals enrolled in the plan. The monthly beneficiary premium charged under a fallback plan is discussed in § 423.867 of our proposed rules and in Subpart Q of this preamble.

9. Collection of Monthly Beneficiary Premiums

a. Means of Collection

In § 423.293(a), the beneficiary would have the same options on the method for premium payments as under Part C. Section 1860D–13(c)(1) of the Act applies the provisions of section 1854(d) of the Act (as amended by the MMA) to Part D premium collection. The beneficiary would have the option of having the amount withheld from his or her social security benefit check similar to the way Part B premiums are withheld. Beneficiary premium payments could also be paid directly to the PDP sponsor or MA organization through an electronic funds transfer mechanism (for example, an automatic charge of an account at a financial institution or a credit or debit card account). We could specify other means of payment, including payment by an employer or under employer-based retiree health coverage (as defined in section 1860D–22(c)(1) of the Act) on behalf of an employee or former employee (or dependent). All premium payments withheld from social security checks would be credited to the appropriate Trust Fund (or Account) and would be paid by us to the PDP sponsor or MA organization involved. Premiums from beneficiaries enrolled in fallback plans would not be collected by the plan. Instead, these premiums would be withheld from social security checks (or from other benefits as permitted under section 1840 of the Act). Beneficiaries who do not receive social security checks or otherwise have premiums deducted from other benefits or annuities would pay us directly. Failure to make premium payments could result in disenrollment as provided under section 1854(d)(1) of the Act and § 423.44(d) of our proposed regulations.

b. Collection of Late Enrollment Penalties

Concerning collection of the late enrollment penalty calculated under § 423.286(d)(3), after the early years of the program we would estimate and specify the portion of the penalty that would be attributable to increased actuarial costs assumed by the PDP sponsor or MA organization (and not taken into account through risk adjustment provided under § 423.329(b)(1) or through reinsurance payments under § 423.329(c)) as a result of that late enrollment. When the premium is withheld from social security benefits, we would pay only the portion of the late enrollment penalty attributable to the increased actuarial costs to the PDP sponsor or MA organization. When the premium is paid directly to the plan, we would reduce payments otherwise made to the PDP sponsor or MA organization by an amount equal to the amount of the enrollment penalty not attributable to increased actuarial cost. (Fallback plans would not receive any enrollment penalties applicable to their enrollees because they are not at risk.)

At least in the initial years of the program we do not anticipate paying plans additional funds related to late enrollment individuals. In the initial years there will not be a significant number of people who can have delayed enrollment for a significant period of time. Moreover, in the initial years of the program the risk corridors are more generous and afford more protection. Consequently we do not think it is necessary to provide a portion of the enrollment penalty to plans until experience indicates that actual risk has increased.

G. Payments to PDP Sponsors and MA Organizations Offering MA–PD Plans for All Medicare Beneficiaries for Qualified Prescription Drug Coverage

1. Overview (§ 423.301)

Subpart G of part 423 implements section 1860D–15 and the deductible and cost sharing provisions of 1860D–14(a) of the Act. This section sets forth rules for the calculation and payment of CMS direct and reinsurance subsidies for prescription drug plans and MA–PD plans; the application of risk corridors and risk-sharing adjustments to payments; and retroactive adjustments and reconciliations to actual enrollment and interim payments. References to part 422 of our regulations are to the new MA rules published elsewhere in this issue of the **Federal Register**.

2. Definitions

We propose definitions for a number of terms used in the computation of payments under this subpart, such as "allowable reinsurance costs", "actually paid" and "coverage year" in § 423.308 of our regulations, but discuss these separately in the appropriate sections of this preamble. We do this because these terms are complex and are best clarified in the context of the discussion of the pertinent provisions.

3. General Payment Provisions (§ 423.315)

The payment provisions required by section 1860D–15 of the Act include 4 different payment mechanisms. The first payment mechanism involves monthly payments that (along with reinsurance subsidies) subsidize on average 74.5 percent of the value of the basic prescription drug benefit, thereby maintaining beneficiary premiums for basic coverage on average at 25.5 percent. The direct subsidy is determined based on a national bidding process. Sponsors who wish to offer plans submit bids based on the projected costs of an average beneficiary. After our review and approval, these bids become the basis for the direct subsidy that is equal to the plan's standardized bid, risk-adjusted for health status as provided in § 423.329(b), minus the base beneficiary premium (as determined in § 423.286(c) and as adjusted for any difference between the standardized plan bid and the national average monthly bid amount (as described under § 423.286(d)(1))). The risk-adjustment

applied to the bid compensates the plan for individual enrollee differences in health status from the average beneficiary and thus reduces the impact from any adverse risk selection. Further adjustments to the direct subsidy payments would be made to account for actual enrollment and updated health status information.

The second and third payment mechanisms would substantially reduce the uncertainty and risk of participating in this new program. Since the Medicare prescription drug benefit is new, there is uncertainty surrounding the utilization, costs, and risk profiles (participation rates and characteristics) of potential enrollees. Federal reinsurance subsidies and risk corridor payment adjustments work along with the risk-adjustment included in the direct subsidy to substantially reduce the uncertainty and risk of participating in this new program. Through reinsurance subsidies, in which we act as the re-insurer, we would subsidize a large portion of any catastrophic expenses (defined as expenses over an individual's out-of-pocket limit) through a reinsurance subsidy. Through risk corridor arrangements, exposure to unexpected non-catastrophic expenses would be limited. These risk sharing arrangements are structured by the statute as symmetrical risk corridors, that is, agreements to share a portion of the losses or profits resulting from expenses above or below expected levels, respectively.

Finally, according to section 1860D–14 of the Act, PDP sponsors and MA organizations would receive payments to cover certain premium, cost-sharing, and extended coverage subsidies for low-income subsidy eligible individuals. With the exception of interim estimated payments of cost-sharing subsidies, these payments are discussed separately in subpart P of this preamble and in § 423.780 of our proposed regulations.

Certain payments would be exceptions to these general payment provisions. Under private fee-for-service (PFFS) plans, reinsurance would be calculated differently and risk sharing would not be available. Reinsurance subsidies and risk sharing would not be available for fallback plans, and are paid in accordance with contractual terms related to actual costs and management fees tied to performance measures.

4. Requirement for Disclosure of Information (§ 423.322)

a. Data Submission.

As provided under sections 1860D–15(c)(1)(C), 1860D–15(d)(2) and 1860D–15(f) of the Act and in § 423.322 of our proposed regulations, we would condition program participation and payment upon the disclosure and provision of information needed to carry out the payment provisions. Such information would encompass the quantity, type, and costs of pharmaceutical prescriptions filled by enrollees that can be linked to individual enrollee data in our systems; that is, linked to the Medicare beneficiary identification number (HIC#). We would appreciate comments on the content, format and optimal frequency of data feeds. We believe that more frequent feeds than annually (weekly, monthly, quarterly) would allow us to identify and resolve data issues and assist the various payment processes.

We are evaluating our minimum data requirements with regard to prescription drug claims. Our goal would be to determine the least burdensome data submission requirements necessary to acquire the data needed for purposes of accurate payment and appropriate program oversight. Our view is that we will need at least the following data items for 100 percent of prescription drug claims for the processes discussed below:

- Beneficiary name (first, middle initial, last).
- Beneficiary HIC#.
- Beneficiary birth-date.
- Eleven-digit NDC code.
- Quantity dispensed.
- Prescription drug cost before co-payment (ingredient cost, dispensing fee, sales tax amount).
- Beneficiary co-payment amount, and
- Date prescription filled.

We assume that ingredient cost and dispensing fee reflect point of sale price concessions in accordance with purchase contracts between plans (or their agents, such as PBMs) and pharmacies, but do not reflect subsequent price concessions from manufacturers, such as rebates. We anticipate that we will need similar data on prescription drug claims for appropriate risk-adjustment, reconciliation of reinsurance subsidies, calculation of risk sharing payments or savings, and program auditing. Data will also be required for assessing and improving quality of care. We will welcome comments on the nature and format of data submission requirements for the following processes:

- Risk adjustment process would require 100 percent of drug claims in order to develop and calibrate the weights for the model for this new benefit. Consequently, PDP sponsors and MA organizations offering MA–PD plans would be required to submit 100 percent of prescription drug claims for Part D enrollees for the coverage year. Risk adjustment would require the submission of prescription drug agent identifying information, such as NDC codes and quantity, in order to allow the standardized pricing of benefits in the model. Because we would use standardized pricing, cost data on each prescription is not a requirement for risk adjustment, although it is needed for other purposes.
- The reinsurance subsidy payment process would require 100 percent of claims for each enrollee for whom the plan claimed allowable reinsurance costs. (Although reconciliation of the reinsurance subsidy does not require NDC codes or quantities, it does require member, cost and date of service data.) All claims for enrollees with expenses in excess of the out-of-pocket limit would be necessary to verify that the costs were allowable because the totality and order in which the claims are incurred would define which claims would be eligible for reinsurance payments. While the start of reinsurance payments begins with claims after the out-of-pocket threshold has been reached, which is $5,100 in total spending (2006) for defined standard coverage, it may be associated with a higher dollar total spending amount under alternative coverage. Whatever the level, we would need to receive all claims by date of service including the amount of beneficiary cost sharing in order to determine the occurrence of the out-of-pocket threshold. Any plan-incurred costs for claims for supplemental benefits cannot be included in determining whether the out-of-pocket threshold has been met.
- The risk sharing process would require 100 percent of claims for all enrollees for the calculation of total allowable risk corridor costs. The plan would need to segregate costs attributable to supplemental benefits from those attributable to basic benefits since supplemental benefit costs are not subject to the risk corridor provisions. Again, all claims would be necessary to verify that the costs were allowable because the order in which the claims were incurred would help determine whether the claims were solely for basic coverage. For instance, a claim processed between a beneficiary's deductible and initial coverage limit (in standard coverage) would count towards risk sharing, but another claim (processed identically but immediately after the initial coverage limit has been reached) would not. Unlike the reinsurance subsidy, which is limited to

individuals with expenses in excess of the out-of-pocket threshold, risk sharing involves costs (net of discounts, chargebacks and rebates, and administrative costs) for all enrollees for basic coverage, but only those costs that are actually paid by the sponsor or organization. Because all plans participate in risk sharing, potentially all claims for all Part D enrollees in all plans must be reviewed. Like the reinsurance reconciliation, risk sharing does not require NDC codes or quantities, but does require member, cost, and date of service data.

• The program audit process would require at least a statistically valid random sample of all Part D drug claims. We believe that several points of reference including HIC#, cost, date of service, and NDC code would be required for unique identification of individual claims in any random sample drawn from the population. If we receive 100 percent claims to support the payment processes, this sample could be drawn from our records. We believe it would be useful to obtain the prescribing physician's National Provider Identifier (NPI) number, as required by the administrative simplification provisions of HIPAA, in the elements of collected data for purposes of fraud control once it is available. Prior to May 2007 when the NPI is expected to be used, we would be interested in alternative means for identifying the physician prescriber.

(Nothing in this data collection discussion should be construed as limiting OIG authority to conduct any audits and evaluations necessary for carrying out our proposed regulations.)

b. Allowable Costs

Section 1860D–15(b)(2) and 1860D–15(e)(1)(B) of the Act and § 423.308 of our proposed regulations, specify that to determine "allowable costs" for purposes of both the reinsurance and risk corridor payments, only the net costs actually paid after discounts, chargebacks, and average percentage rebates, as well as administrative costs, are to be counted. We encourage comments on appropriate methodologies and data sources that can be used in making these adjustments. For example, we would like to receive comments on how price concessions (discounts, chargebacks, rebates, or any other periodic financial remuneration) would be most accurately and efficiently applied to prescription drug claims data to satisfy this requirement. We would also be interested in any information or data on the effect on costs such adjustments can be expected to yield. We are particularly interested in how data would be appropriately allocated and applied to the reinsurance subsidy tied to individual expenses in excess of the out-of-pocket limit.

We understand that much of the rebate accounting is not applied in the context of point of sale claims data, but rather in periodic accounting adjustments, and that rebates are frequently reported along with administrative fees paid by the manufacturer. We are concerned that these accounting practices would be incompatible with the need to report all price concessions for purposes of determining allowable reinsurance and risk corridor costs and we, therefore, are proposing to require that they be segregated. Moreover, we are proposing to require that any administrative fees paid to Part D plans be based on the fair market value of services rendered, and that any fees determined to be above or below fair market value would be considered additional price concessions.

Due to the nature and timing of rebate accounting, we believe that this will require a form of step-down cost reporting in which rebates received at the aggregate level may be apportioned down to the level of plan enrollees incurring reinsurance expenses on a reasonable basis. Since Medicare beneficiaries would be expected to have higher per capita prescription drug utilization than other populations, we believe it would be appropriate to allocate rebates (and other similar price concessions) on the basis of percentage of dollars spent rather than of covered lives. Alternatively, one could create a ratio of total rebate amounts to total spending and reinsurance-related spending to total spending to derive the share of rebates to be allocated to reinsurance, and then adjust down the reinsurance amount. A similar ratio could be created for risk corridor spending. Another way that the current market expresses these relationships is in an average rebate per script value that could even be differentiated by brand versus generic rebates per script. In apportioning rebates and other financial remunerations to Medicare costs, we would look to ensure that plans appropriately take into account the distribution of claims between basic and supplemental benefits, and apportion price concessions in a proportionally accurate way.

In whatever manner price concessions will be apportioned, plans must require and keep accurate records on all price concessions and ensure that these are clearly accounted for and segregated from administrative fees. All cost reporting would be subject to inspection and audit (including periodic audits) by us and the OIG. As stated below, to the extent either we or the OIG discover that a sponsor was overpaid for reinsurance or risk sharing (that is, the records do not support the payments made, or there is insufficient documentation to determine whether the payments are correct), we may recoup the overpayments. The reopening and overpayment provisions are discussed at the end of this part G.

c. Coverage Year

In § 423.308 we propose that the term "coverage year" would mean a calendar year in which covered Part D drugs are dispensed if the claim for such drugs (and payment on such claim) is made not later than 3 months after the end of the year. In other words, drug claims paid past the close of the 3-month period would not be considered part of that coverage year (or the next), and would not be used to calculate that year's payments or in reconciling risk adjustment payments for the year.

This limit would be imposed in order to provide timely closure for payment determination processes such as reinsurance, risk corridors and employer subsidies. While the period of 3 months would be significantly less than the fee-for-service Medicare medical claims standard of 18 months, we believe that a shorter period is warranted due to the highly automated and point of sale nature of prescription drug claim processing. We understand that the vast majority of prescriptions are not filled without the claim being simultaneously processed and therefore, there is a much shorter claims lag to be considered. We believe that the number and value of drug claims that would potentially be missed would be immaterial, consisting primarily of paper claims. The 3-month close-out window would not limit the liability of the plan or its claims processing contractor for reimbursing any lagging claims, but would simply establish a timely cut-off for finalizing payments. Any rebates for the coverage year not reflected in the fourth quarter data (sent to close out the year) must be credited against future payments. Although we are closing the year for claims purposes, the plan must account for all rebates that occur throughout the coverage year and send us all the data.

A shorter period would allow for payment processes that are dependent on the knowledge of total allowable costs for each coverage year to be concluded on approximately the same schedule as other reconciliations involving enrollment or risk adjustment data. On this schedule, calculations of

risk sharing could begin as soon as five to six months after the close of the payment year. If the claims submission standard were a longer period, final reconciliations would be significantly delayed. We are interested in receiving comments on this timetable, specifically whether we should adopt a shorter or longer period than 3 months, and including data with which to estimate the proportion and value of drug claims that could be excluded with a 3-month close-out window.

5. Determination of Payment (§ 423.329)

a. Direct Subsidies

As directed in section 1860D–15(a)(1) of the Act and codified in § 423.329(a), we would provide direct subsidies to PDP sponsors and MA organizations offering MA–PD plans. These subsidies would be in the form of advance monthly payments. Payments would be equal to the plan's standardized bid, risk adjusted for health status as provided in § 423.329(b), minus the base beneficiary premium (as determined in § 423.286(c) and adjusted for any difference between the standardized plan bid and the national average monthly bid amount (as described under § 423.286(d)(1))). The standardized bid would be the portion of the plan's bid attributable to basic coverage. This portion would be risk-adjusted by multiplying by the prescription drug risk score attributable to each enrollee. Between the government direct subsidy and the adjusted base beneficiary premium, the plan would receive its entire risk-adjusted standardized bid in advance each month. Payment for supplemental benefits would come from enrollees in the form of additional premium. By statute, the sponsor must bear all risk for such supplemental benefits.

We would note that a plan's total per capita payment could never exceed its bid, risk-adjusted for the beneficiary's health status. This would be the case even if the difference between the plan's bid and the national average monthly bid amount were greater than the beneficiary monthly premium, mathematically resulting in a "negative premium" amount. We do not believe that the statute envisions plan payments in excess of negotiated costs, since this would violate the revenue requirements provisions discussed in the Subpart F of this preamble.

b. Risk Adjustment

In section 1860D–15(c)(1) of the Act, we are directed to develop and publish a prescription drug risk adjustment methodology taking into account the similar methodologies under § 422.308(c)(1) to adjust payments to MA organizations for benefits under Part C on the basis of costs incurred under original Medicare. In § 423.329(c) we propose to establish this risk adjustment methodology. We would develop and publish this risk adjustment methodology in the 45-day notice for the announcement of 2006 Medicare Advantage rates. Section 1860D–15(c)(1)(D) of the Act requires us to publish the risk adjustment for Part D at the same time we publish risk adjustment factors under section 1853(b)(1)(B)(i)(II) of the Act. Because these risk adjustment factors under Part C can only be published after 45-day advance notice under section 1853(b)(2) of the Act, we would use the same notice procedures we use under Part C for risk adjustment. We believe this would promote consistency and uniformity in the process, and, especially for MA–PD plans, allow entities to review notices published on the same day for purposes of commenting on or learning about risk adjustment. As usual, the 45-day notice would solicit public comment on any change in proposed payment methodologies. We are expecting that this new prescription drug risk adjustment methodology would initially be based on the relationship of prescription drug utilization within the entire Medicare population to medical diagnoses, and that it would be applied at the individual beneficiary level. Our longer-term plan would be to refine the risk adjustment model to account for predictable risk based on both medical and drug claim data.

Section 1860D–15(c)(1)(C) of the Act and § 423.329(b)(3) of this proposed rule authorize us to specify and require the submission of data from PDP sponsors regarding drug claims that can be linked at the individual level to part A and part B data in a form and manner similar to the Medicare Advantage process provided in § 422.310 and such other information as we determine necessary. Similarly, MA organizations that offer MA–PD plans must submit data regarding drug claims that can be linked at the individual level to other data that these organizations are required to submit to us. A primary requirement, therefore, would be claims linked to the Medicare beneficiary HIC#. Other proposed data submission elements are discussed in section 3(a) of this part of the preamble. We may also be interested in linking this data to the plan level and would then require the inclusion of the PDP or Medicare Advantage plan identifier (H#). We would use this data to further refine our prescription drug risk adjustment factors and methodology in order to make payments that accurately reflect plan risk.

Any risk adjustment methodology we adopt should adequately account for low-income subsidy (LIS) individuals (and whether such individuals incur higher or lower-than average drug costs). Our risk adjustment methodology should provide neither an incentive nor a disincentive to enrolling LIS individuals, and we request comments on this concern and suggestions on how we might address this issue.

Our particular concern is that a risk adjustment methodology, coupled with the statutory limitation restricting low-income subsidy (LIS) payments for premiums to amounts at or below the average, could systematically underpay plans with many LIS enrollees (assuming LIS enrollees have higher costs than average enrollees). If the risk-adjustor fails to fully compensate for the higher costs associated with LIS recipients, an efficient plan that attracts a disproportionate share of LIS eligible individuals would experience higher costs to the extent the actual costs of the LIS beneficiaries are greater than the risk-adjustment compensation. Failing to discourage enrollment by LIS beneficiaries in 2006, the plan would experience higher than expected costs in that year and presumably be driven to reflect these higher costs (due to adverse selection, not efficiency) in its bid for 2007. In this hypothetical, plans would have a disincentive to attracting a disproportionate share of LIS beneficiaries. One possible solution would be to assure that the initial risk-adjustment system, which will be budget neutral across all Part D enrollees, does not undercompensate plans for enrolling LIS beneficiaries. In fact, to the extent that an initial risk-adjustor might at the margin tend to overcompensate for LIS beneficiaries, plans would have a strong incentive to disproportionately attract such beneficiaries. Plans could attract LIS beneficiaries both by designing features that would be attractive to such beneficiaries but also by bidding low. We would appreciate comments on this concern and suggestions on how we might address this potential problem.

c. Risk Adjustment Budget Neutrality

In accordance with section 1860D–15(c)(1)(A) of the Act and § 423.329(b)(1), our risk adjustment methodology would be implemented in a budget-neutral manner. A requirement for budget neutrality assumes that there is a known budget. We interpret the statute to require that the risk

adjustment methodology must not result in a change in aggregate amounts payable in section 1860D–15(a)(1) of the Act, that is, the risk adjustment methodology must be "budget neutral" to some aggregate of direct subsidy payments made before risk adjustment. (Since direct subsidy payments are made only to full-risk or limited risk plans, this budget by definition would not include payments to fallback plans.)

For comparison, in the current M+C (now Medicare Advantage) program the budget for risk-adjustment budget neutrality is defined to be the aggregate government payments made to plans under the 100 percent demographic payment system. Since the health-status-risk-adjustment methodology currently results in lower aggregate payments than the demographic methodology, M+C budget neutrality distributes among participating plans the difference between total payments under the 2 methodologies via a factor that allocated the difference in the same proportion as the allocation of risk-adjusted payments. However, there is no corresponding predetermined limit to aggregate payments in Title I, that is, to the aggregate government direct subsidy payments made before risk adjustment, so there is no amount to use as a basis for comparison in determining budget neutrality.

In the M+C program, the reason for the difference between the total payments under the demographic methodology and total payments under health status risk adjustment is that the average health status of enrollees in M+C is different than the average health status for the program as a whole (that is, M+C plus original Medicare). In Part D, there is no equivalent to original Medicare since beneficiary access subsidized coverage through enrollment in private plans. The Part D risk adjustment system would be based on these enrollees. Since there is no group of beneficiaries outside the system like there is under Part C, total payments with and without risk adjustment are always equal or budget neutral. Therefore, we believe that risk adjustment as applied to Part D benefits should be budget neutral to the risk of the individuals who actually enroll without any additional adjustment. We would appreciate comments on this approach.

d. Reinsurance Subsidies

i. Allowable Reinsurance Costs

As provided in section 1860D–15(e) of the Act and § 423.329(c), we would reduce the risk of participating in this new program by providing reinsurance subsidies. Subsidies would be limited to 80 percent of allowable reinsurance costs for drug costs incurred after an enrollee has reached the annual out-of-pocket threshold. The annual out-of-pocket threshold would be $3,600 in 2006. Under standard coverage this corresponds to total gross covered prescription drug costs of $5,100, and would be increased annually as provided in section 1860D–2(b)(4)(B)(i)(II) of the Act and 1860D–2(b)(4)(B)(ii) (with regard to rounding).

In meeting the various actuarial tests required of alternative coverage, there could be instances where a sponsor wanting to provide basic alternative coverage would have to enhance plan benefits in order to meet the test of equal total actuarial value relative to defined standard coverage. This could occur with the use of a tiered co-pay benefit structure that could shift utilization to a cheaper set of drugs, thus allowing plans to lower cost sharing to achieve the same total dollar value as defined standard coverage. In these instances, since cost sharing is reduced relative to defined standard coverage, the out-of-pocket threshold would be associated with a higher total drug costs than the $5,100 under standard coverage in 2006. For sponsors offering enhanced alternative coverage, the out-of-pocket threshold would also be associated with higher total drug spending. In this instance, however, it would be due to fact that the plan's supplemental benefits would be displacing part of the cost sharing that enrollees would otherwise have incurred.

Allowable reinsurance costs are a subset of gross covered prescription drug costs. Gross covered prescription drug costs are those costs incurred under the plan, excluding administrative costs, but including costs related to the dispensing of covered Part D drugs during the year and costs relating to the deductible. These costs are determined whether paid by the individual or under the plan, and regardless of whether the coverage under the plan exceeds basic prescription drug coverage. Allowable reinsurance costs, on the other hand, are the subset of these costs that are attributable solely to basic or standard benefits and that are actually paid by the sponsor or organization or by (or on behalf of) an enrollee under the plan. Actually paid—means that these costs must be net of any discounts, chargebacks, and average percentage rebates, and would exclude any amounts not actually incurred by the sponsor. The reinsurance payments are then calculated by determining the portion of allowable reinsurance costs that are incurred after the enrollee has reached the out-of-pocket threshold ($3,600 out of pocket in 2006). The reinsurance subsidy would provide 80 percent of such excess amount.

ii. Payment of Reinsurance Subsidy

Since allowable reinsurance costs can only be fully known after all costs have been incurred for the payment year, we would propose to make payments on an incurred basis to assist PDP sponsors and MA organizations with cash flow. Under § 423.329(c)(2)(i), we would provide for payments of reinsurance amounts based on plan actual reinsurance-eligible allowable costs with a one-month lag period. In other words, no payments would be made until enrollees reached the true out-of-pocket threshold. This would require timely submission of drug claim data. In this approach rebates would be recognized in the month after they were received and would be offset against the previous month's actual costs.

Alternatively, we could consider payments of reinsurance amounts on a monthly prospective basis based on the reinsurance assumptions submitted and negotiated with each plan's approved bid. We would take these assumptions into account in developing either a plan-specific or program-wide approach. We note that any program-wide approach involving some kind of average of the amounts included in the bids would have to adjust for the fact that plans providing enhanced alternative benefits would incur lower reinsurance costs. We are also aware that allowable reinsurance costs would be predominantly incurred in the latter parts of the coverage year and are considering the most appropriate methodology for distributing interim payments. One possible approach would require the submission of a schedule of the estimated timing of incurred allowable reinsurance costs along with the bid. For example, we might take schedules from each plan or we could propose an incremental schedule (X% of the total in January, Y% in February, etc.). We are aware that the prospective payment of estimated costs would create an incentive to overstate reinsurance, however, and are interested in ensuring that payments are not excessive. Since equal payments would be most compatible with our systems, in the first two years of the program (and for the first two years of new plans thereafter) we could also consider another approach paying 1/12th of the net present value of estimated allowable reinsurance costs in each month of the coverage year. The net

present value would be calculated on the basis of all estimated reinsurance payments due at the end of the year and discounted by the most recently available rate for one-year Treasury bills. We would welcome comments on these approaches and on the appropriate treatment of interest in such a system.

For subsequent years of the program, we could consider an approach of paying 1/12th of the two-year prior year's actual expenses. Such an approach would need to be trended forward by an appropriate index to account for expected growth in plan costs. In other words, in 2008 the interim payments would be based on actual reconciled reinsurance payments for 2006 trended forward by an estimated two-year growth factor. Regardless of which process we used for making reinsurance payments, as discussed below, if, at the end of the year, the data demonstrates the sponsor was overpaid through the interim payments—or if there is insufficient evidence to support the reinsurance payments claimed—we would recover the overpayments either through a lump sum recovery or by reducing future payments during the coverage year. Similarly, if the data demonstrates that the sponsor was underpaid, we would pay the sponsor.

iii. Adjustments to Reflect the True Out-of-Pocket Threshold

The statute provides that the reinsurance subsidy would be paid only for the plan's share of individual expenses in excess of an enrollee's true out-of-pocket (TrOOP) threshold. As indicated above, if the PDP sponsor offers enhanced alternative coverage or an MA–PD plan offers benefits beyond basic coverage as part of its supplemental benefits, the plan's spending for these benefits would not count toward the TrOOP threshold. Since benefits beyond basic coverage reduce cost sharing that would otherwise be incurred, they shift the effective prescription drug catastrophic limit beyond the associated total spending under the standard benefit ($5,100 in 2006) and raise the effective reinsurance attachment point at the same time.

In addition, to the extent that plan cost sharing is paid or reimbursed by secondary insurance coverage or otherwise, that cost sharing does not count toward the out-of-pocket threshold. Beneficiaries are required to report the existence of secondary coverage or other types of coverage we identify and plans must identify these payments and ensure that true out-of-pocket spending is accounted for accurately in claims processing. This is more fully discussed in subpart C and subpart J of this preamble.

iv. Adjustments for the Insurance Effect of Supplemental Coverage

Supplemental benefits increase the level of total drug spending after which reinsurance payments begin (reinsurance attachment point). Assuming 2 identical groups of enrollees with respect to utilization, one enrolled in enhanced alternative coverage and one in defined standard coverage, the total allowable reinsurance costs for the group with standard coverage would be greater than for the group with enhanced alternative coverage. Thus, one might hold that the differences in benefit packages are accounted for without the need for further adjustment. If one would examine average total spending for both groups, however, one would find that the average spending under enhanced alternative coverage would be greater than the average under defined standard coverage because of the impact of the insurance effect (or "moral hazard", that is, the tendency of increased coverage resulting in increased utilization due to decreased financial stake in the costs associated with utilization). All other things being equal, this higher total spending would result in higher allowable reinsurance costs than would otherwise occur if the total spending under enhanced alternative coverage were comparable to that under standard coverage.

We are therefore proposing (in the definition of allowable reinsurance costs) to adjust allowable reinsurance costs to reflect the impact of this induced utilization. We would make this adjustment to comply with the requirement in section 1860D–15(b)(2) of the Act that in no case shall the allowable reinsurance costs exceed the costs "that would have been paid under the plan if the * * * coverage * * * were standard prescription drug coverage". We are looking for comments on whether this adjustment should be made and how best to adjust the experience of PDPs with enhanced alternative coverage or MA–PD plans offering supplemental coverage to account for the insurance effect.

v. Reinsurance Subsidies to Private Fee-For-Service Plans

As provided under section 1860D–21(d)(4) of the Act and proposed in § 423.329(c)(3), we would base reinsurance payments for PFFS plans on an alternative methodology. Rather than negotiating reinsurance assumptions submitted with the PFFS plan bid or otherwise adjusting for potential price level differences between PFFS and other MA organization bids, we would estimate the amount of reinsurance payments that would be payable if the plan were an MA–PD plan described in section 1851(a)(2)(A)(i) of the Act. In doing so we would take into account the average reinsurance payments made under § 423.329(c)(2) for basic benefits for populations of similar risk under such MA–PD plans. Estimated payments would not be subject to any reconciliation process to compare the amounts paid to the actual allowable reinsurance expenses, and would not allow for payment recoveries in the event that actual allowable reinsurance costs exceed payments.

6. Low-Income Cost-Sharing Subsidy Interim Payments

As provided under section 1860D–14 of the Act and in § 423.780 of our proposed regulations, CMS will provide additional assistance for certain low-income beneficiaries in the form of premium, deductible and cost-sharing subsidies. Since actual expenses incurred by these low-income beneficiaries can only be fully known after all costs have been incurred for the payment year, we would propose to make estimated payments on an interim basis to assist PDP sponsors and MA organizations with cash flow. Under § 423.329(d)(2)(i), we would provide for interim payments of low-income deductible and cost-sharing amounts on a monthly prospective basis based on estimates of low-income cost sharing submitted and negotiated with each plan's approved bid. Like the possible option of reinsurance subsidy interim payments discussed above, a decision on whether these assumptions would be taken into account in developing a plan-specific or program-wide approach has yet to be determined.

We are aware that low-income cost sharing would not necessarily be incurred evenly throughout the coverage year and are considering the most appropriate methodology for distributing interim payments. Since equal payments would be most compatible with our systems, in the first two years of the program (and for the first two years of new plans thereafter) we are considering an approach paying 1/12th of the net present value of estimated low-income cost sharing in each month of the coverage year. The net present value would be calculated on the basis of all estimated costs due at the end of the year and discounted by the most recently available rate for one-year Treasury bills. An alternative approach would require the submission of a schedule of the estimated timing of

incurred low-income cost sharing along with the plan bid. For example, we might take schedules from each plan or we could propose an incremental schedule (X% of the total in January, Y% in February, etc.). We are aware that the prospective payment of estimated costs creates an incentive to overstate low-income cost sharing, and are interested in ensuring that our interim payments are not excessive. We would welcome comments on these approaches and on the appropriate treatment of interest in any methodology. For subsequent years of the program, we are considering an approach of paying 1/12th of the two-year prior year's actual expenses. Such an approach would need to be trended forward by an appropriate index to account for expected growth in plan costs. In other words, in 2008 the interim payments would be based on actual reconciled low-income cost sharing subsidy payments for 2006 trended forward by an estimated two-year growth factor. Again, any reconciliation at the end of the year would need to be based on the sponsor providing adequate information in order to determine the subsidy amounts for the year. If the sponsor could not provide such information, interim payments would be recovered. In addition, the low-income payments would be subject to the same inspection and audit provisions applying to the other payments made under section 1860D–15 of the Act.

7. Risk Sharing Arrangements

a. Risk Sharing Methodology and the Target Amount

As provided under section 1860D–15(e) of the Act and proposed in § 423.336, we would establish risk corridors. Risk-sharing payments would limit exposure to unexpected expenses not already included in the reinsurance subsidy or taken into account through risk adjustment. These would be structured as symmetrical risk corridors that are agreements to share a portion of the losses or profits resulting from expenses for basic benefits either above or below expected levels, respectively. However, plans would always be at full financial risk for all spending on supplemental drug coverage. In addition, in accordance with section 1860D–21(d)(5) of the Act and section 1860D–15(g) of the Act, the risk sharing provisions are not available to PFFS and fallback plans.

The expected level of expenses for basic benefits included in the standardized bid is known as the "target amount". The target amount for any plan would be equal to the total amount of direct subsidy payments from us, and premium payments from enrollees to that plan for the year based upon the risk-adjusted standardized bid amount, less the administrative expenses and return on investment assumed in the standardized bid. Since the standardized bid is the portion of the accepted bid amount attributable to basic prescription drug coverage, the target amount can be thought of as "prepayments" of prescription drug expense for basic benefits. The standardized bid has also taken into account (and excludes) any utilization effects of offering supplemental coverage. The objective of risk sharing would be to compare total actual incurred prescription drug expenses to the prepayments, to compute the difference, and to reimburse or recover a portion of the difference.

In § 423.336(a)(2)(A), we would establish risk corridors, defined as specified risk percentages above and below the target amount. For instance, in § 423.336(a)(2)(ii), for 2006 and 2007, the first risk corridor is defined as 2.5 percent above the target amount and the second as 5 percent above the target amount. This means that, for 2006 and 2007, the first risk corridor is between 100 percent and 102.5 percent of the target amount and the second risk corridor is between 102.5 percent and 105 percent of the target amount. A third risk corridor is above 105 percent of the target amount.

The term, symmetrical risk corridors—means that the same size corridors exist below the target amount as above it. The actual upper or lower limits of each corridor equal the target amount plus or minus the product of the risk percentage times the target amount, as illustrated in Table G–1. Since these risk corridors would be symmetrical, plans with adjusted allowable costs below the 1st threshold lower limit would have to share the savings with the government.

b. Allowable Risk Corridor Costs

The costs applicable to the computation of risk sharing are known as allowable risk corridor costs. These costs are defined in section 1860D–15(e)(1)(B) of the Act and proposed in § 423.308 as the part of costs for covered Part D drugs that are only attributable to basic benefits. Allowable risk corridor costs cannot include costs attributable to benefits outside the basic benefit. We would interpret this as both the actual differences in benefits structure and the insurance effect of supplemental coverage on basic coverage. In section 1860D–15(e)(1)(B) of the Act, reference is made to section 1860D–11(c)(2) of the Act that provides for a utilization adjustment using as its reference point standard prescription drug coverage. We are interpreting this to mean the statutorily defined standard prescription drug coverage described in Subpart C. Also, allowable risk corridor costs must actually be paid by the sponsor or organization under the plan and must be net of any chargebacks, discounts or average percentage rebates. The allowable risk corridor costs also do not include any administrative expenses of the sponsor or organization. (Administrative expenses would not include costs directly related to dispensing of Part D drugs during the year.) Note that unlike allowable reinsurance costs, allowable risk corridor costs do not include any amount paid by the enrollee. In § 423.336(a)(1), we propose that allowable risk corridor costs must be adjusted in accordance with section 1860D–15(e)(1)(A) of the Act, by subtracting expenses reimbursed through other separate payments. Thus, reinsurance payments made under § 423.329(c)(2) and the non-premium low-income subsidy payments made under § 423.782 [in Subpart P] of these proposed regulations to the sponsor of the plan for the year must be subtracted. The PDP sponsor or MA organization would already have received compensation for these costs, and thus they do not fall within the construct of risk corridors that are directed at limiting exposure to unexpected expenses.

If adjusted allowable risk corridor costs exceed the prepayments by a certain amount, we would reimburse a percentage of the difference to help plans with a portion of the unanticipated expenses associated with their drug coverage. On the other hand, if prepayments exceed adjusted allowable risk corridor costs, we would reduce future payments or otherwise recover a percentage of the difference to reduce the impact on the Trust Fund of excessive bids.

TABLE G–1.—ILLUSTRATION OF RISK SHARING ARRANGEMENTS FOR HYPOTHETICAL PLAN

A. Assumptions in bid	PMPM	Totals	Actual costs for basic benefit	PMPM	Totals
Enrollees		10,000			
(Subsidy-eligible)		0			
Avg. Payment	114.00				
Premium	30.60				
Avg. Direct Subsidy	83.40				
Admin	17.00				
Est. Allowable Cost	97.00	970,000		100.00	1,000,000
Reinsurance Cost	0.00				
Total Premiums		306,000			
Total Direct Subsidy		834,000			
Less Total Admin		(170,000)			
Target Amount		970,000			

B. Risk corridor limits	Risk corridor limit %	C. Threshold	Risk sharing %	Allowable costs minus threshold	Payment change
2nd upper limit	.050	1,018,500	80%		
1st upper limit	.025	994,250	50%	5,750	+2,875
Target Amount	.000	970,000	0%		
1st lower limit	(.025)	945,750	(50%)		
2nd lower limit	(.050)	921,500	(80%)		

In Table G–1, a hypothetical plan with average payments of $114 per-member-per-month (PMPM), based on expected prescription drug costs of $97 PMPM, actually incurs costs equal to $100 PMPM. In this simplified example there are no reinsurance or low-income subsidies. The actual incurred costs are compared to the "prepayment" included in the risk-adjusted standardized bid (in this case the target amount of $970,000) by looking at the risk corridors in which they fall. The risk corridors have been calculated based on the target amount plus or minus the risk percentages associated with each risk corridor limit. For instance the 1st upper limit is defined as the target amount ($970,000) plus 2.5 percent of the target amount ($24,250), so the 1st upper limit is calculated to be $994,250. The actual allowable costs of $1,000,000 fall between the 1st upper limit and the 2nd upper limit, so the costs eligible for risk sharing is the difference between the allowable costs ($1,000,000) and the 1st threshold upper limit ($994,250), or $5,750. Since the amount of risk sharing in this corridor is set at 50 percent, the actual change in payment due to risk sharing is 50 percent of $5,750, or an additional $2,875.

As mentioned above, in order to arrive at a value for actual risk corridor costs that can be appropriately compared to the target amount, allowable risk corridor costs would be adjusted to remove expenses reimbursed through total reinsurance payments and *non-premium* low-income subsidy payments. The statute indicates that allowable risk corridor costs should be reduced by reinsurance payments and by the subsidy payments for low-income individuals. The subsidy payments for low-income individuals under section 1860D–14 of the Act include subsidies for both premium and for cost sharing. We are proposing to interpret "the total subsidy payments made under section 1860D–14" under section 1860D15(e)(1)(A)(ii)(II) of the Act in the context of "*costs* incurred by the sponsor or organization" in the definition of allowable risk corridor costs. Since premiums are not a cost, we propose to limit our interpretation of "the total subsidy payments" to payments related to cost sharing.

In proposing this interpretation, we note that when adjusted allowable risk corridor costs are calculated by subtracting only non-premium subsidies, as we are proposing to do, the results are the same as for an identical plan without any subsidy-eligible individuals. However, if the adjusted allowable risk corridor costs are calculated by subtracting total low-income subsidies (that is, for premiums, cost sharing and coverage above the initial coverage limit), the risk sharing calculation results in lower recouped costs on the part of the plan and a different outcome from that in a plan without subsidy-eligible individuals. Since there should be no difference in these amounts, the calculation subtracting only non-premium subsidies must be the appropriate one. We believe that to do otherwise would result in a major disincentive for PDP and MA–PD plans to enroll individuals eligible for the low-income subsidies, and we do not believe that this would be the logical outcome that was intended by the statute. We would welcome comments on our interpretation.

c. Changes in Risk Corridor Limits and Percentages (§ 423.336(a) and (§ 423.336(b))

The risk corridors and the percentage of risk to be shared would be set at certain levels for 2006 and 2007 with flexibility for us to increase the risk sharing percentage if bids, and therefore target amounts, are off during the early years of the program by a certain percentage set by the statute in section 1860D–15(e)(2)(B)(iii) of the Act. During 2006 and 2007, plans would be at full risk for adjusted allowable risk corridor costs within 2.5 percent above or below the target. Plans with adjusted allowable costs above 102.5 percent of the target would receive increased payments. If their costs were between 102.5 percent of the target (1st threshold upper limit) and at or below 105 percent of the target (2nd threshold upper limit), they would be at risk for 25 percent of the increased amount; that is, their additional payments would equal 75 percent of adjusted allowable costs for spending in this range. If their costs were above 105 percent of the target they would be at risk for 25 percent of the costs between the first and second threshold upper limits and 20 percent of the costs above that amount. That is, their additional payments would equal 75 percent of the difference between the first and second

threshold upper limits and 80 percent of the adjusted allowable costs over the second threshold upper limit. Conversely, if plan spending fell below the 97.5 percent of target, plans would share the savings with the government. They would have to refund 75 percent of the savings for any costs less than 97.5 percent of the target amount but at or above 95 percent of the target level, and 80 percent of any savings below 95 percent of the target.

In § 423.336(b)(2)(iii) the program will cover a higher percentage of the risk for costs between the 1st and 2nd upper threshold limits would apply in 2006 and 2007 if we were to determine that (1) 60 percent of prescription drug plans and MA–PD plans have adjusted allowable costs that are more than the first threshold upper limit for the year; and (2) these plans represent at least 60 percent of beneficiaries enrolled in such plans. In this case, additional payments to plans would increase from 75 percent to 90 percent of adjusted allowable costs between the first and second upper threshold limits. Conversely, there would be no change in savings shared with the government if costs fell below 97.5 percent of the target level.

For 2008–2011, the risk corridors and the percentage of risk to be shared would be modified so that PDP and MA–PD sponsors would assume an increased level of risk. Plans would be at full risk for drug spending within 5 percent above or below the target level. Plans would be at risk for 50 percent of spending exceeding 105 percent and at or below 110 percent of the target level. Additionally, they would be at risk for 20 percent of any spending exceeding 110 percent of the target level. Payments would be increased by 50 percent of adjusted allowable costs exceeding the first threshold upper limit and up to the second threshold upper limit and 80 percent for any additional costs exceeding the second threshold upper limit. Conversely, if plan spending fell below the target, plans would share the savings with the government. They would have to refund 50 percent of the savings if costs fell between 95 percent and 90 percent of the target level, and 80 percent of any amounts below 90 percent of the target.

For years after 2011, we would establish the risk threshold percentage as deemed necessary to create incentives for plans to enter the market. The only required parameters would be that the first threshold risk percentage could not be less than 5 percent and the second threshold risk percentage could not be less than 10 percent of the target amount.

d. Risk Sharing Payments or Recoveries

As proposed in § 423.336(c), we will make payments or recover savings after a coverage year after obtaining all of the information necessary to determine the amount of payment. In § 423.336(c)(1) we are proposing that within six months of the end of a coverage year, the PDP sponsor or MA organization offering a MA–PD plan would provide us with the information necessary to calculate the risk sharing as discussed in section 3(a) of this part of the preamble. This would include prior final reconciliation of reinsurance and low-income subsidies since allowable risk corridor costs must be reduced by the total reinsurance payments and non-premium low-income subsidies for the year. Once this information has been received, under § 423.336(c)(2) we would either make lump-sum payments or adjust monthly payments in the following payment year based on the relationship of the plan's adjusted allowable risk corridor costs to the predetermined risk corridor thresholds in the coverage year. We would not make payment if we did not receive the necessary information from the PDP sponsor or MA organization. In addition, as stated, below, we are considering certain corrective actions to recoup risk-sharing payments, in the event of lack of information.

8. Retroactive Adjustments and Reconciliation (§ 423.343)

In § 423.343(a) and § 423.343(b) we propose to make retroactive adjustments to the aggregate monthly payments to a PDP or MA–PD for any difference between the actual number and characteristics, including health status, of enrollees and the number and characteristics on which we had based the organization's advance monthly payments. Reconciliation of actual payments made would be done as needed. In order for total payments to be properly accounted for in all steps, the order of reconciliation processes would be first, enrollment; second, risk adjustment; third, low-income cost sharing; fourth, reinsurance; and finally, risk sharing.

Under § 423.343(c) and (d), we would provide for a final reconciliation process to compare the payments for reinsurance subsidies and low-income cost-sharing subsidies made during the coverage year to actual allowable reinsurance expenses and low-income cost sharing and to make additional payments or payment recoveries accordingly. The form and manner in which actual allowable reinsurance costs would be submitted for reconciliation has yet to be determined. We are proposing that PDP sponsors and MA organizations offering a MA–PD plan would provide us with the information necessary to finalize reinsurance payments as discussed in section 3(a) of this part of the preamble within six months of the end of a coverage year. Once complete data were received for a coverage year, we would compare 80 percent of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred in the coverage year after an individual has incurred costs that exceed the annual out-of-pocket threshold to the monthly reinsurance payments and compute the difference. We would then either make lump-sum payments or adjust monthly payments throughout the remainder of the payment year following the coverage year to pay out or recover this difference.

If an entity did not provide us with sufficient documentation for us to reconcile payments, we would reconcile by recovering payments for which the entity lacked documentation. For example, if CMS makes interim payments during the year for the low-income subsidy, but at the end of the year, the PDP sponsor or MA organization cannot provide documentation demonstrating the amounts of beneficiary cost-sharing, the reconciliation process would involve recouping the interim payments for such subsidy. The need to provide sufficient documentation to support final payment determinations applies even in the event of a change of ownership. Thus, new owners of a PDP sponsor or MA organization would be responsible for obtaining the documentation necessary to support payment, and the reconciliation process would be used to recover any payments for which the new owner lacked documentation. We believe this authority stems from the direction of the Congress that each PDP sponsor and MA–PD organization "provide the Secretary with such information as the Secretary determines is necessary to carry out this section," (section 1860D–15(f)(1)(A) of the Act) and that "payments under this section * * * are conditioned upon the furnishing to the Secretary in a form and manner specified by the Secretary, of such information as may be required to carry out this section," (section 1860D–15(d)(2)(A)of the Act)).

We also request comment on the remedy that should be imposed in the event a PDP sponsor or MA organization offering an MA–PD plan fails to provide us with adequate information regarding risk-sharing arrangements. In the case of

risk corridor costs, the organization or sponsor may owe the government money if, for example, prepayments exceed adjusted allowable risk corridor costs. In this case, failure to provide information could result in a shortfall to the government, since the entity would not have the information necessary for the Secretary to establish the proper amount owed. Although we have not proposed regulations on this issue, some of the remedies we are considering for the final rule are: (1) Assume that the sponsor's or organization's adjusted allowable risk corridor costs are 50% of the target amount; (2) assume that the sponsor's or organization's adjusted allowable risk corridor costs are the same percentage of the target amount as the mean (or median) percentage achieved by all PDPs or MA–PDs whose costs are lower than the target amount; (3) assume that the sponsor's or organization's adjusted allowable risk corridor costs are the same percentage of the target amount as the mean (or median) percentage achieved by all PDPs or MA–PDs (whose costs are both higher and lower than the target amount). We use a 50% threshold for option (a) because we believe this threshold would constitute a lower limit; and it would be unlikely for any organization or sponsor to have costs lower than 50% of their total payments. We request comments on these options, as well as proposals of other options that would allow us to recoup risk-sharing payments in the event a sponsor fails to provide us the adequate information necessary to determine appropriate risk-sharing payments.

9. Reopening (423.346)

Finally, we believe that the provision in 1860D–15(f)(1) of the Act providing the Secretary with the right to inspect and audit any books and records of a PDP sponsor or MA organization regarding costs provided to the Secretary would not be meaningful, if upon finding mistakes pursuant to such audits, the Secretary were not able to reopen final determinations made on payment. In addition, we believe that sections 1870 and 1871 of the Act provide us with the authority to reopen final determinations of payment to PDP sponsors and MA organizations. Therefore, we propose in this rule to include reopening provisions patterned after those used in Medicare claims reopening, found in Part 405 of the regulations, subparts G and H. Including reopening provisions would allow CMS to ensure that the discovery of any overpayments or underpayments could be rectified. Under our proposed provisions, reopening could occur for any reason within one year of the final determination of payment, within four years for good cause, or at any time when there is fraud or similar fault. CMS could initiate a reopening on its own, or a sponsor or organization could request reopening, but such requests would be at the discretion of CMS. The Supreme Court has determined that in the context of reopening cost reports, a fiscal intermediary's decision not to reopen a final determination is not subject to judicial review, *see Your Home Visiting Nurse Services, Inc.* v. *Shalala,* 525 U.S. 449, 456 (1999), and we believe the same reasoning would apply in the context of Part D.

Good cause would be interpreted in the same manner as in Part 405 (*see* Medicare Carriers Manual section 12100). Thus, good cause would exist, if (a) new and material evidence, not readily available at the time of the determination, is furnished; (b) There is an error on the face of the evidence on which such determination or decision is based; or, (c) There is a clerical error in determination. In order to meet the standard under (a) the evidence could not have been available at the time the determination was made. A clerical error constitutes such errors as computational mistakes or inaccurate coding. An error on the face of the evidence exists if it is clear based upon the evidence that was before CMS when it reached its initial determination that the initial determination is erroneous. Thus, for example, good cause would exist in cases where it is clear from the files that rebates or administrative costs were not appropriately accounted for, where computation errors had been made, where a sponsor or organization included non-Part D drugs in their calculations, where individuals not enrolled in the plan were included in calculating payment, and in similar situations. Reopening could occur at any time in cases of fraud or similar fault, such as in cases where the sponsor or organization knew or should have known that they were claiming erroneous Medicare payment amounts.

I. Organization Compliance With State Law and Preemption by Federal Law

1. Overview

In our proposed regulation at § 423.401 we would implement the requirements of section 1860D–12(a) of the Act that address licensing, the assumption of financial risk for unsubsidized coverage and solvency requirements for unlicensed sponsors or sponsors who are not licensed in all States in the region in which it wants to offer a PDP. The provisions of this section specify that a sponsor of a PDP must be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State that it offers a PDP. However, as required by section 1860D–12(a)(1) of the Act, we have provided in our proposed regulations at § 423.410 for a waiver of the State licensure requirement for the reasons and under the conditions set forth under section 1860D–12(c) of the Act. In addition, under the requirements of section 1860D–12(a) of the Act, to the extent an entity is at risk, it must assume financial risk on a prospective basis for covered benefits that are not covered by reinsurance. The PDP sponsor can obtain insurance or make other arrangements for the cost of coverage provided to enrollees to the extent that the sponsor is at risk for providing the coverage.

In § 423.420, we specify that sponsors that have been granted a waiver by us or those operating in States that do not have licensing requirements for PDPs must maintain reasonable financial solvency and capital adequacy. We intend to develop these reasonable standards through guidance, after consulting with the National Association of Insurance Commissioners (NAIC), as required by statute. The guidance would be issued by January 1, 2005. Although we believe these standards would be interpretive guidance, we are interested in receiving comments on the issue. In addition, as noted in § 423.410, we would establish an application and certification process for waiver applicants.

We expect that the development of solvency standards for purposes of PDP sponsors under Part D will be less complex than the situation presented to us by the development of solvency standards for provider-sponsored organizations (PSOs) under the Balanced Budget Act of 1997. (PDP sponsors in contrast to PSOs are fairly straightforward insurance risk models whereas the PSO situation involved having to consider such issues as the role that physical plant assets played in establishing solvency standards.) Although drug only plans are not a common product in the insurance market today, there are other single lines of business plans licensed by States (for example, dental plans, behavioral mental health plans) that can provide some possible models.

We also have experience from determining solvency standards for federally qualified health maintenance organizations under Title XIII of the Public Health Service Act and competitive medical plans under

Section 1876 of the Social Security Act. In addition, we are aware that the solvency standards have been applied to at least two drug-only plans (Medica and PacifiCare) and believe that these could also provide a model for the licensing of the entities. However, we believe that these two products are lines of business operated under a current insurance license, and therefore, our greatest concern would be how to go about developing standards for organizations that may have experience managing a drug benefit but have not had any experience as risk bearing entities and/or are not structured as risk-bearing entities. We would welcome comments regarding this issue.

Factors which may be considered in discussions with the NAIC include the ability of an organization to maintain assets greater than total unsubordinated liabilities and the ability of the organization to generate a surplus on a consistent basis as demonstrated by history or an acceptable financial plan.

2. Waiver To Expand Choice

a. Overview

In our regulations at § 423.410 we would implement the provisions of section 1860D–12(c) of the Act that address waiver of certain requirements to expand choice. Generally, section 1860D–12(c) of the Act specifies that in order to expand access to prescription drug plans, we may waive the State licensure requirement under circumstances similar to those permitted under Part C for provider-sponsored organizations, as described in section 1855(a) of the Act. However, we note that the States would be expressly preempted from regulating in all areas except licensure and solvency (see section 1860D–12(g) of the Act and § 423.440). Additional requirements referenced under section 1855(a) of the Act such as State consumer protection and quality standards, do not apply to and are not incorporated in these regulations

b. Waiver When State Imposes Certain More Stringent Standards

Section 1860D–12(c) of the Act provides that a prospective PDP sponsor may request a waiver from State licensure requirements from us under the waiver provisions at section 1855(a)(2)(B), 1855(a)(2)(C) and 1855(a)(2)(D). Because the Congress directed us to use many of the same grounds for approving a waiver as used pursuant to § 1855(a)(2)(B), § 1855(a)(2)(C), and § 1855(a)(2)(D), We have adopted the regulatory provisions in proposed § 422.372. Thus, our regulation at § 423.410(c)(1) would use the same standard used in § 422.372(b)(1) and allows a waiver when the State has failed to complete action on a licensing application within 90 days of receipt of a substantially complete application.

c. Distinct Waivers

Proposed § 423.410(c)(2) uses the same standards as used in § 422.372(b)(2) for determining when a State has denied an application based on discriminatory treatment. The regulation provides that the following activities may also constitute a basis for us to waive State licensure requirements: (1) The State denies an application based on requirements that are not generally applicable to PDP sponsors or other entities engaged in a similar business or (2) the State requires as a condition of licensure that the PDP sponsor offer any product or plan other than a prescription drug plan.

Section 423.410(c)(3) of our proposed regulations, addresses denial of an application based on application of different solvency requirements—when a State imposes solvency requirements that are more stringent than the solvency standards that would be established by us under § 423.420. In addition, a waiver may be granted if the State imposes procedures or standards relating to solvency that are different from the solvency requirements established by us. CMS will utilize a waiver application process similar to that used under its federally waivered PSO program in which the waiver applicant will be required to submit certain documents that would indicate that the State is imposing procedures or standards relating to solvency that are different from CMS standards. CMS would utilize this documentation in its waiver determination process.

In our regulations at § 423.410(c)(4), we would implement section 1860D–12(c)(2)(A)(ii) of the Act, which provides that we may grant a waiver when a State imposes requirements other than those required under Federal law.

Section 1860D–12(c)(2)(B) of the Act also establishes special rules for the approval of a waiver by us. We propose to implement these special rules at § 423.410(d) and (e) of these regulations. The special rules allow that we will grant a waiver when a State does not have any licensing process for PDP sponsors. Also, even if a State does have a licensing process for years beginning before January 1, 2008, a waiver will be granted if the PDP sponsor merely submits its completed application for licensure to the State. The PDP sponsor seeking a waiver will submit a waiver application indicating its understanding of State law which CMS will confirm through contacts with the State regulator.

d. Relationship of Waiver to State Regulation

The statute requires, at section 1860D–12(c)(3) of the Act, that the waivers granted under the provisions of section 1855 of the Act must also meet the conditions of approval established at section 1855(a)(2)(E), 1855(a)(2)(F) and 1855(a)(2)(G) of the Act. Accordingly, we would implement the applicable waiver requirements from section 1855(a)(2)(E) and 1855(a)(2)(F) that relate to licensure or solvency in the regulations at § 423.410(f)(1) through § 423.410(f)(3).

Section 423.410(f)(1) of our proposed regulations establishes that except in States without a licensing process for PDP sponsors and except in the case of regional plan waivers described in § 423.410 (b), a waiver only applies to a specific State, is effective for 36 months and cannot be renewed. We propose to implement section 1855(a)(2)(F) of the Act at § 423.410(f)(2) where we specify our requirement concerning prompt action on applications. This requirement would establish that we would grant or deny a waiver application under this section within 60 days after we determine that a substantially complete waiver application has been filed. A substantially complete application would have to clearly demonstrate and document a PDP sponsor's eligibility for a waiver. In addition, section 1860D–12(c)(3) of the Act establishes that if a State does not have a licensing requirement for PDP sponsors, then the requirements of section 1855(a)(2)(E)(i) and section 1855(a)(2)(E)(ii) do not apply. We propose to implement these provisions at § 423.410(f)(3) where we would establish that if a State does not have a licensing process for PDP sponsors, we would approve a waiver for a PDP sponsor that meets our solvency standards and that this waiver would not be time limited.

With respect to section 1855(a)(2)(E)(i) of the Act, we believe that the most reasonable interpretation of this provision is that when a PDP sponsor is granted a waiver (because the State does not have a PDP sponsor licensing process), one waiver that we grant can be applied to all States in which there are no PDP sponsor licensing requirements. However, the waiver granted on the basis that a State does not have a licensing process cannot be applied in a State that does have a

PDP sponsor licensing process. In a State that may have denied licensure to the entity in question, one of the other bases for approving a waiver may be applicable. In addition, a waiver granted for other reasons such as failure to act on an application on a timely basis, or denial based on discriminatory treatment will apply only to the States in question and not other States.

We would implement the regional plan waiver rule provided at section 1860D–12(c)(1)(B) of the Act in the regulations at § 423.410(b) of our proposed rule. This allows us to use the proposed waiver authority at section 1858(d) of the Act—Temporary Waiver. of State Licensure Requirement for the licensing of PDPs. This temporary waiver would be available in the event a prospective PDP sponsor proposes that its prescription drug plan would cover a multi-State region, but is not yet licensed in all of the States. (Under those circumstances, we can waive the State licensure requirement until the State has completed processing of the application.) In the interim, the PDP sponsor would be required to comply with the solvency standards established by us. In the event the State ultimately denies the application, we can extend the waiver through the contract year as we deem appropriate to provide for transition.

3. Preemption of State Laws and Prohibition of Premium Taxes

Section 1860D–12(g) of the Act incorporates section 1856(b)(3) of the Act which states: "the standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) for MA organizations under this part." Accordingly, we specify in our proposed regulations that to the extent there are Federal standards, those standards supersede any State Law. For purposes of this section, with the exceptions of State licensing laws or State laws related to plan solvency, State laws do not apply to prescription drug plans and PDP sponsors.

We do not believe, however, that the language in 1856(b)(3) means that each and every State requirement applying to PDP sponsors would now become null and void. In areas where we have neither the expertise nor the authority to regulate, we do not believe that State laws would be superseded or preempted. For example, State environmental laws, laws governing private contracting relationships, tort law, labor law, civil rights laws, and similar areas of law would, we believe, continue in effect and PDP sponsors in such States would continue to be subject to such State laws. Rather, our Federal standards would merely preempt the State laws in the areas where Congress intended us to regulate-such as the rules governing pharmacy access, formulary requirements for prescription drug plans, and marketing standards governing the information disseminated to beneficiaries by PDP sponsors. We believe this interpretation of our preemption authority is in keeping with principles of Federalism, and Executive Order 13132 on Federalism, which requires us to construe preemption statutes narrowly.

By the same token, in areas where Congress specifically stated that State law would not be preempted—that is, State licensing laws and State laws related to plan solvency—we would construe the preemption exception narrowly, and only view the exception as applying to true licensing or solvency requirements. By this we mean that if a State conditioned licensing on a PDP sponsor meeting requirements in an area we also regulate outside of licensure or solvency, then such condition could not be viewed as a "licensing" law and would not be excepted from preemption. For example, if a State conditioned licensure on a PDP sponsor adhering to the State's guidelines for prescription drug plan marketing materials, we would not view the marketing guidelines as a licensure requirement and we would still view the Federal marketing rules as preempting the State requirements.

Additionally, in accordance with the incorporation of section 1854(g) of the Act into section 1860D–12(g) of the Act, States are expressly prohibited from imposing a premium, or similar type of tax, on premiums paid by us to prescription drug plans or PDP sponsors, on premiums applicable to Medicare enrollees of the prescription drug plans under Part F, or on any other payments made by us to PDP sponsors under subpart G of the regulations,—including the direct subsidy, reinsurance payments and risk corridor payments.

J. Coordination Under Part D Plans With Other Prescription Drug Coverage

1. Overview and Terminology

We propose in subpart J of part 423 to implement sections 1860D–2(a)(4), 1860D–2(b)(4)(C), 1860D–2(b)(4)(D), 1860D–11(j), 1860D–21(c), 1860D–22(b), 1860D–23(a), 1860D–3(b), 1860D–23(c), 1860D–24(a), 1860D–24(b), and 1860D–24(c) of the Act that were added by section 101 of the MMA. We provide a brief summary of each of these provisions. Following this overview we provide a more detailed discussion of how we propose implementing each of these statutory provisions in this subpart.

We propose to implement section 1860D–21(c) of the Act at § 423.458 of the proposed rule and explain that the requirements of Part D generally apply under Part C for prescription drug coverage offered by MA–PD plans although certain waivers are available. We propose to implement section 1860D–22(b) of the Act at our proposed § 423.458(c) that provides employer group waiver authority for prescription drug plans.

We outline options that we have identified related to the data-exchange that will be necessary between both State pharmaceutical assistance programs and other insurers and Part D plans in order to accurately apply incurred costs to appropriate Part D enrollee records. For purposes of this subpart, provisions in the statute that address coordination requirements generally apply in a similar manner to both State pharmaceutical assistance programs and other drug plans and to both prescription drug plans and MA–PD plans. The main difference between coordination requirements related to SPAPs and other drug plans is that we are prohibited from charging user fees to SPAPs. On the other hand, Part D plans may impose fees only related to the cost of coordination on both SPAPs and other drug plans.

We propose to implement section 1860D–11(j) of the Act at § 423.464(a) of the proposed rule and require sponsors of Part D plans to coordinate with State pharmaceutical assistance programs and other prescription drug plans. In this section we specify the other plans with which Part D plans must coordinate benefits in accordance with section 1860D–24(b) of the Act and define State Pharmaceutical Assistance Programs, in accordance with section 1860D–23(b) of the Act.

a. Part D Plans

Wherever we mention or reference "Part D plans" we mean any or all of "MA–PD plans, prescription drug plans (PDPs) and fallback prescription drug plans". Likewise, the term "Part D plan sponsor" refers to MA organizations offering MA–PD plans, PDP sponsors, and eligible fallback entities offering fallback plans. If a statement or reference applies exclusively to a specific type of plan, we use that exact term to limit the reference.

b. Employer-sponsored Group Prescription Drug Plan

Section 1860D–22(b) applies to "employment-based retiree health coverage" that is defined under section 1860D–22(c)(1) of the Act. This term means coverage for individuals (or their spouses and dependents) under a group health plan based on their status as retired participants. We use the term "employer-sponsored group prescription drug plan" to mean a prescription drug plan under a contract between a PDP sponsor and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations to furnish prescription drug benefits under employment-based retiree health coverage.

c. State Pharmaceutical Assistance Program

A State Pharmaceutical Assistance Program is a program operated by or under contract with a State for purposes of this part if it: (1) Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals; (2) provides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls; (3) meets the benefit coordination requirements specified in this part; and (4) does not change or affect the primary payor status of a Part D plan. Since an SPAP cannot discriminate under the Part D plans with respect to either eligibility or the amount of assistance provided, in accordance with section 1860D–23(b)(2) of the Act and in our proposed rule at § 423.464(e)(1)(ii), to the extent that a program does discriminate it cannot, by definition, be considered an SPAP. A non-conforming State program that did discriminate in either of these ways (eligibility or amount of assistance provided) would not meet the definition of a State Pharmaceutical Assistance Program.

We are interpreting the non-discrimination language to mean that SPAPs, if they offer premium assistance or supplemental assistance on Part D cost sharing, must offer equal assistance by all PDPs or MA–PD plans available in the State and may not steer beneficiaries to one plan or another through benefit design or otherwise. State programs cannot, for example, use the threat of withholding SPAP enrollees to negotiate coverage, premium or formulary changes with PDPs or MA–PD plans. Violations of the non-discrimination rule will jeopardize the program's special status with respect to true out-of-pocket costs. That is, a State program that discriminates does not qualify under the definition of an SPAP, and consequently, its contributions to cost sharing do not count toward the out-of-pocket limit.

Section 1860D–23(b) of the Act also provides that an SPAP is a State program that provides financial assistance for the purchase or provision of prescription drugs, and we interpret this to mean that it provides that assistance with State funds. Therefore, the definition of SPAP would exclude State Medicaid programs, section 1115 demonstration programs, and any program where program funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding. (We would clarify that this does not exclude some Federal administrative funding or incidental Federal monies.)

For purposes of this part, we are proposing that a Pharmacy Plus demonstration waiver under section 1115 of the Act shall not be considered a State pharmaceutical assistance program. Pharmacy Plus waivers are granted to allow states to treat these individuals as Medicaid eligible for the purposes of receiving drugs and primary care services. Expenditures for these limited services receive federal matching payments in the same manner as do services for full benefit Medicaid beneficiaries. We do not believe that these waivers, having expenditures that are federally matched in this manner, should be considered SPAPs as the effect of this would be to allow federally matched payments to be used to meet an out of pocket expense to gain further payments from the Federal Medicare program.

2. Application of Part D Rules to MA–PD Plans on and After January 1, 2006 (§ 423.458)

In accordance with section 1860D–21(c)(1) of the Act, and as provided under proposed § 423.458(a), the provisions of Part D apply under Part C to prescription drug coverage provided by an MA–PD in lieu of other Part C provisions that would apply to such coverage, unless otherwise provided. As permitted under section 1860D–21(c)(2) of the Act, we will waive Part D provisions to the extent that we determine they duplicate, or conflict with, provisions under Part C, or as necessary in order to improve coordination of Part D benefits with the Part C program. For instance, under section 1860D–21(c)(3) of the Act, we will waive the pharmacy network access requirements as described at § 423.120(a)(3) of the proposed rule in the case of an MA–PD plan that provides access (other than through mail order pharmacies) to qualified prescription drug coverage through pharmacies owned and operated by the MA organization if we determine that the organization's pharmacy network is sufficient to provide comparable access for enrollees under the plan. As discussed in other parts of this preamble, Part D rules generally apply to section 1876 cost HMOs/CMPs and PACE organizations in the same or in a similar manner as the rules apply to MA–PD local plans. The waiver provision under section 1860D–21(c)(2) of the Act applicable to MA–PD plans similarly extends to section 1876 cost HMOs/CMPs and PACE organizations. We provide for this waiver authority for cost HMOs/CMPs and PACE organizations by adding a paragraph (d) to section 423.458 of our proposed rule.

In reviewing requested waivers we will follow a process similar to the process we initially established under the M+C program related to the employer group waiver authority provided in section 1857(i) of the Act and codified in regulation at § 422.106(c). Under § 422.106(c), MA organizations could submit written requests to our permission to waive requirements that hinder the design of or offering of MA plans to employers. We would make approved waivers available to all similarly situated MA organizations that meet the conditions of the waiver. Accordingly, we will use a similar approach to the one we established under § 422.106(c) in implementing our authority to waive those Part D provisions that can be shown to (1) duplicate or conflict with Part C requirements or (2) should be waived in order to improve coordination of the benefits provided under Parts C and D of Medicare. However, we will not, under our waiver authority, waive Part D rules that are specifically directed to MA–PDs or to the Part C program. We ask for your comments on both the process we propose for authorizing additional waivers under this section and for what additional waivers should, or should not, be permitted under this waiver authority.

3. Application to PACE Plans

Section 1860D–21(f) of the Act indicates that Part D provisions shall apply to PACE organizations in a manner that is similar to those of an MA–PD local plan and that a PACE organization may be deemed to be an MA–PD local plan. As discussed in detail in Subpart T, PACE organizations

would not be deemed as MA–PD plans but would be treated in a manner that is similar to MA–PD plans for purposes of payment. Proposed § 423.458(d) establishes regulatory authority for CMS to waive Part D provisions for PACE organizations and indicates that PACE organizations may request waivers from CMS. Because many of the Part D requirements duplicate, conflict with, or inhibit coordination of existing PACE requirements, we anticipate a significant number of waivers would necessary for PACE organizations. We are concerned about the potential burden this would place on PACE organizations and propose to include a provision that would allow for CMS to identify all Part D provisions requiring waivers and waive these provisions on behalf of PACE organizations. In other words, we are considering a special rule for PACE organizations that would automatically apply the waivers granted in the final rule (*see* discussion in subpart T of this preamble) without a plan-specific application process.

We would like to receive comments on this proposed approach and on any other related suggestions for minimizing burden on PACE plans.

4. Application to Employer Groups

a. Employer Group Waivers

Section 1860D–22(b) of the Act extends the waiver authority that is provided for MA organizations related to Part C by section 1857(i) of the Act and implemented at § 422.106(c) to prescription drug plans related to Part D. This waiver authority is intended to provide prescription drug plans an opportunity, similar to the opportunity afforded MA organizations under Part C, to furnish Part D benefits to participants or beneficiaries of employment-based retiree health coverage sponsored by employers and labor organizations in the most efficient and effective manner possible. Section 1860D–21(b) of the Act specifically authorizes prescription drug plans to establish separate premium amounts for Part D enrollees who are participants or beneficiaries of employment-based retiree health coverage sponsored by employers and labor organizations. It also contemplates separate Part D plans for participants and beneficiaries of such employment-based retiree health coverage. In administering this waiver, we propose to follow the template first established at § 422.106(c) that we created under Part C to implement the waiver authority under section 1857(i) of the Act.

While we discuss coordination of Part D coverage with employment-based retiree health coverage at some length later in this part, we believe it is important to include a brief discussion here on the Part D waivers that we specifically would not permit related to employer group retiree coverage under the authority provided in section 1860D–22(b) of the Act. Although the statute permits "* * * in relation to employers, including authorizing the establishment of separate premium amounts for enrollees in a prescription drug plan * * *" we interpret "separate premium amounts" to mean the amount of premium the retiree or the enrollee pays. Under the MA program many employer groups subsidize the premiums that would otherwise be payable by their retirees through partial or full payment or subsidization of the MA plan premiums on their members' behalf. We believe that a similar practice related to PDP Part D plan premiums would be permissible and find support in section 1860D–22(a)(6)(B) of the Act. Alternatively, we do not believe that the statutorily defined Part D premium could be different for employees or retirees than it is for individuals enrolled in the same PDP plan. Thus, the combined Part D premium contributed by the employee or retiree and the employer group would need to be identical to the premium charged to an individual enrolled in the same PDP plan. These principles apply to waiver requests by MA–PD plans under section 1857(i) of the Act.

Generally, we also would not permit waivers that directly increase Medicare spending. For example, a section 1860D–22(b) waiver would not be permitted that had the effect of changing the definition (in Subpart C of our proposed rules) for incurred costs (which are defined for purposes of calculating the true out-of-pocket threshold—TrOOP). An alternative example of a waiver we would not permit would be a waiver that would increase the premium subsidy. We also note that section 1860D–22(b) applies to "prescription drug plans," not non-Part D plans that "wrap around" or supplement the benefits provided under the PDP. Consequently, section 1860D–22(b) of the Act would not apply to a request to waive rules under this Part that effect an employer-sponsored non-Part D plan that wraps around a Part D plan, including the TrOOP rules. The exclusion of costs paid by group health plans from TROOP is irrelevant when the group health plan is itself a part D plan (in other words, the exclusion applies when the group health plan pays costs not otherwise covered under the part D plan).

We invite comment on the process we propose for authorizing additional waivers that prescription drug plan sponsors can request under this section. We also ask for comment on the manner in which additional waivers should be permitted and what additional waivers, if any, we should not allow.

b. Employer Options

The enactment of Title I of the MMA has provided sponsors of retiree prescription drug plans with multiple options for providing drug coverage to their retirees. For the benefit of the employers and unions, we discuss these options. We believe the availability of these various options will make it easier for sponsors to continue to assist their retirees in having access to high-quality prescription drug coverage.

Generally, employers and unions who offer drug benefits to their retirees (and their dependents) who are eligible for Medicare Part D may do so as follows:

1. Provide prescription drug coverage through employment-based retiree health coverage. If those coverage is at least actuarially equivalent to the standard prescription drug coverage under Part D, the sponsor is eligible for a special Federal subsidy for each individual enrolled in the sponsor's employment-based retiree health coverage who is eligible for Part D but elects not to enroll in Part D, directly reducing the cost of providing a high-quality drug benefit. It is important to note that employers can still make arrangements with Medicare Advantage organizations to offer a Medicare Advantage (MA) only plan without the Part D benefit, but then still take the retiree drug subsidy and through a separate private contract with the MA organization arrange for an employer-sponsored retiree drug benefit that is not subject to the application of the true out-of-pocket provision and retains the employer's flexibility to design a benefit that is at least equivalent to the Part D benefit.

2. Provide prescription drug coverage that supplements, or "wraps-around," the coverage offered under the PDP or MA–PD plans in which the retirees (and their dependents) enroll. For example, this option would permit beneficiaries who receive retiree coverage from employers who provide some financial assistance, but not enough to qualify for the retiree drug subsidy, to supplement the new drug benefit subsidy from Medicare with their existing employer assistance and thereby receive more generous coverage than they have now.

3. Subsidize the monthly beneficiary premium for whatever PDP or MA–PD plan in which the employer or union's

retirees (and their dependents) elect to enroll.

4. Provide a prescription drug plan (PDP) or Medicare Advantage-prescription drug plan (MA–PD plan) either under contract with a PDP sponsor or Medicare Advantage (MA) organization or by directly sponsoring a PDP or an MA–PD plan. This plan may consist of enhanced alternative coverage (as defined under proposed § 423.104(g)), or drug coverage that is more generous than that offered under the standard prescription drug coverage under Part D (as defined under proposed § 423.104(e)). Medicare would subsidize the cost of this coverage through direct and reinsurance subsidies (as calculated under proposed § 423.329(a)(1) and (2)). At its option, the employer or union may elect to subsidize the monthly beneficiary premium (as calculated under proposed § 423.286). Many employers already have arrangements with Medicare Advantage plans and we expect that this will continue, as well as new arrangements being established.

The first option is the subject of subpart R of this preamble. The latter three options, all of which involve the employer or union's retirees (and their dependents) enrolling in Part D, are discussed in this subpart.

We note that if employers or unions elect to sponsor enhanced alternative coverage under Part D or to provide supplemental coverage that wraps around Part D, either election will have an impact on when its retirees (and their dependents) are eligible for the additional Medicare subsidies for catastrophic drug coverage. By delaying the provision of government-financed catastrophic coverage, these plans would lower the cost of Part D to the Federal government by lowering our reinsurance payments while preventing beneficiaries from facing any gaps in coverage. As discussed in Subpart C, individuals enrolled in a PDP or MA–PD plan are eligible for Medicare subsidies on top of their employer subsidies for catastrophic drug coverage after they incur out-of-pocket drug costs in the amount specified under proposed § 423.104(e)(5)(iii). Under the reinsurance provisions discussed in subpart G, Medicare would reimburse PDP sponsors and MA organizations offering MA–PD plans 80 percent of their gross costs for providing this catastrophic coverage (excluding administrative costs and net of discounts, rebates, and similar price concessions). Only drug costs paid by a Part D enrollee, or on behalf of a Part D enrollee by another person, would count toward the annual out-of-pocket threshold, with the exception of amounts reimbursed by insurance or otherwise, a group health plan, or another third-party payment arrangement. We refer to those drug expenditures that count toward the out-of-pocket threshold as "true out-of-pocket (TrOOP) expenditures."

Under these rules, employers and unions who provide retirees (and their dependents) enhanced alternative coverage or wrap-around coverage in effect push out the total drug spending that triggers the Medicare subsidy for catastrophic coverage, since participants in the plan will have lower cost-sharing, and thus have lower out of-pocket costs. This approach limits the "crowd-out" of employer contributions by the new Medicare subsidy, resulting in more comprehensive coverage at a lower cost to the Federal government by lowering reinsurance payments.

When an employer or union elects to provide a PDP or MA–PD plan under contract with the PDP or MA–PD sponsor, the PDP sponsor, under proposed § 423.458(c), or the MA organization, under 42 CFR 422.106(c), may submit written requests to us for permission to waive requirements under Part D that hinder the design of or offering of PDP or MA–PD plans to employers. We believe these waivers will help efficient administration and integration of their enhanced Part D coverage with other retiree health benefits offered by the sponsor. For example, the PDP sponsor or MA organization could request permission to restrict enrollment in its PDP or MA–PD plan to the sponsor's retirees (and their dependents) and offer a benefit that resembles or enhances the sponsor's existing coverage. We encourage employers and unions to carefully review each option and determine which one is most beneficial to it and its retirees (and their dependents). The variety of options gives employers many ways to retain and enhance drug coverage for their retirees, and we seek comment on how we can use all of these subsidized options to maximize enhancements in retiree coverage.

c. Implications for Beneficiaries

For beneficiaries, the significance of the above discussion, as well as of the earlier discussion (in subpart C) of incurred costs that count toward the true out-of-pocket threshold, is that these rules would lead to new options for drug coverage. All Medicare Part D coverage would at a minimum provide basic coverage, funded with a generous Federal subsidy that did not exist before. In addition, there would be a number of ways in which some beneficiaries can get access to more comprehensive benefits, such as filling in any coinsurance requirements in coverage in whole or in part. Such access will be dependent on individual eligibility for other subsidies or coverage, and individual willingness to continue to pay for enhancements in their coverage, such as:

- If they are eligible for a more comprehensive retiree health benefits policy sponsored by their former employer, their retiree plan sponsor may qualify for a subsidy payment.
- If they have limited income, they may be eligible for Part D low-income subsidies of premium and cost sharing through a Part D plan.
- They may be eligible for financial assistance through a State Pharmaceutical Assistance Program that can pay for an enrollee's cost sharing and still have these payments count toward the out-of-pocket limit.
- They may qualify for charitable assistance from bona fide non-profit charities that can also pay for an enrollee's cost sharing and still have these payments count toward the out-of-pocket limit.
- They may have access to a PDP or MA–PD (through either individual enrollment or employer group enrollment) that offers an enhanced alternative prescription drug plan for an additional premium. In this case, either the plan sponsor and/or the beneficiary must bear some of the drug costs that would otherwise have been subsidized by Part D reinsurance subsidies. While they would consequently not receive the additional subsidy until they reached a higher level of drug expenditures, the substantial savings in drug costs as a result of the highly subsidized, standard drug benefit would permit such coverage to be financed while still saving money for the beneficiary and the plan sponsor.

5. Medicare Secondary Payer Procedures

Section 1860D–2(a)(4) of the Act extends the Medicare secondary payer (MSP) procedures applicable to MA organizations under section 1852(a)(4) of the Act and 42 CFR 422.108 to PDP sponsors. Section 1852(a)(4) of the Act provides that an MA organization may charge or authorize a provider to seek reimbursement for services from a beneficiary or third parties to the extent that Medicare is made a secondary payer under section 1862(b)(2) of the Act. Accordingly, under § 423.462 of this proposed rule, PDP sponsors would be required to follow the same rules as MA organizations regarding:

- Their responsibilities under MSP procedures;
- Collection of payment from insurers, group health plans and large group health plans, the enrollee, or other entities for covered Part D drugs; and
- The interaction of MSP rules with State laws.

Because Medicare would not pay for covered Part D drugs to the extent that there is a third party that is to be the primary payer under the provisions of section 1862(b)(2) of the Act and 42 CFR part 411, PDP sponsors must, for each prescription drug plan: (1) identify payers that are primary to Medicare under section 1862(b)(2) of the Act and 42 CFR part 411, (2) determine the amounts payable by those payers, and (3) coordinate their benefits to plan enrollees with the benefits of the primary payers.

The PDP sponsor may charge other individuals or entities for covered Part D drugs for which Medicare is not the primary payer. If an enrollee receives from a PDP sponsor covered Part D drugs that are also covered under State or Federal workers' compensation, no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the PDP sponsor may charge the insurance carrier, the employer, any other entity that is liable for payment for the covered Part D drugs under section 1862(b) of the Act and 42 CFR part 411, or the prescription drug plan enrollee, to the extent that he or she has been paid by the carrier, employer, or entity for covered Part D drugs.

When Medicare, and thus a Part D plan, is secondary to other payers, beneficiary costs incurred for covered Part D drugs would not be considered "covered" costs under the Part D plan. Consequently, these costs would be excluded from a beneficiary's incurred costs, as described in section II.C.2.a of this preamble and would not count as incurred costs against the annual deductible or the out-of-pocket threshold.

When Medicare is a secondary payer to employer coverage in the case of certain working Medicare beneficiaries, a PDP sponsor may charge a group health plan (GHP) or large group health plan (LGHP) for covered Part D drugs it furnishes to a Medicare enrollee who is also covered under the GHP/LGHP, and may charge the Medicare enrollee to the extent that he or she has been paid by the GHP/LGHP.

Because Medicare Part D coverage is a Federal program operated under Federal rules, State laws do not—and should not—apply, with the exception of State laws regarding licensing or related to plan solvency or as otherwise provided by statute or regulation. Given the requirement in section 1860D–2(a)(4) of the Act that we extend MSP procedures applicable to MA organizations to PDP sponsors, PDP sponsors would also be permitted, under section 1852(a)(4) of the Act, to fully recover from liable third parties according to section 1862(b)(2) of the Act. In accordance with section 1860D–12(g) of the Act that extends the State preemption provisions under section 1856(b)(3) to Part D, under § 423.462 of our proposed rule that mirrors § 422.108(f), States would be prohibited from exercising authority over prescription drug plans in any area governed by Medicare Part D (including our regulations under chapter 423) other than State licensing laws and State laws relating to plan solvency. This is consistent with specific preemption authority now provided by section 1856(b)(3) of the Act with respect to MA organizations.

6. Coordination Of Benefits With Other Providers Of Prescription Drug Coverage

Section 1860D–23(a) of the Act authorizes us to establish procedures and requirements to promote the effective coordination of benefits between a Part D plan and a State Pharmaceutical Assistance Program with respect to payment of premiums and coverage, and payment for supplemental prescription drug benefits. We are to establish procedures and requirements before July 1, 2005, to ensure effective coordination. In developing these procedures and requirements, we are to consult with State pharmaceutical assistance programs, prescription drug plan sponsors, MA organizations, States, pharmaceutical benefit managers, employers, data processing experts, pharmacists, pharmaceutical manufacturers, and other experts. In addition, as specified at section 1860D–24(a) of the Act and implemented in this section of the regulations, we will apply the coordination requirements for State pharmaceutical assistance programs to other prescription drug plans including Medicaid (including a plan operating under a waiver under section 1115 of the Act), group health plans, the Federal employees health benefits plan, military coverage (including TRICARE), and other coverage that we specify. Under section 1860D–23(c)(1) of the Act, coordination between State pharmaceutical assistance programs and Part D plans does not change or affect the primary payor status of a Part D plan with respect to a State pharmaceutical assistance program. Nor does it affect the primary or secondary payment position of the Part D plan related to the payments made by other plans providing prescription drug coverage. Under the requirements of section 1860D–11(j) of the Act, Part D plan sponsors will not be permitted to impose fees on SPAPs or other plans providing prescription drug coverage that are unrelated to the costs of that coordination.

The elements to be coordinated would include enrollment file sharing, claims processing, payment of premiums for both basic and supplemental drug benefits, third-party reimbursement of out-of-pocket costs, application of protection against high out-of-pocket expenditures (defined in section 1860D–2(b)(4) of the Act), and other administrative processes and requirements that we specify. Enrollment file sharing might include information such as beneficiary name, date of birth, health insurance claim number, sex, name and address of benefit administrator, insured's identification number, electronic transaction routing information (RxBin, RxPCN, RxGRP), group number, patient relationship, and coverage effective dates. Claims processing information might include collecting information similar in nature to that currently contained in a Medicare provider Remittance Advice statement. Information must be sufficient to successfully link with enrollment files and in order to allow Part D plans to make a correct determination of true out-of-pocket (TrOOP) expenditures on the part of beneficiaries.

On rare occasions Part D plans would also be required to coordinate benefits with other Part D plans. In the event that a beneficiary disenrolled from one plan mid-year and enrolled in another, the two plans would be required to exchange information sufficient to allow the beneficiaries' claims to be processed as if there had been no break in enrollment. Specifically, the second plan would need to obtain the enrollee's claim data and adjust its claims processing system accumulators to reflect that a certain level of expenditures and out-of-pocket costs had already been incurred in order that the correct sequence of claims processing could be maintained. This is not to say that the second plan could claim the first plan's costs as their own allowable costs, but that their systems would process future claims as if the earlier costs had been incurred by the second plan. We solicit comments on any other issues that may be involved in

coordination of benefits between Part D plans.

We may impose user fees for the transmittal of information necessary for benefit coordination related to third party reimbursement (other than by a SPAP) of Part D enrollees' costs for covered Part D drugs. Please see our later discussion on options we are considering related to coordination of benefits under the Part D program and also the critical nature of securing accurate and timely information for purposes of the TrOOP calculation. As we mention in that discussion, the statute permits us to impose user fees on the employer (or other third party) plan, but not on SPAPs under any method of operation, for the transmittal of benefit coordination information under Part D. Section 1860D–24(a)(3) of the Act specifically provides authority for imposing user fees under Part D similar to the authority under section 1842(h)(3)(B) of the Act for collection of user fees (otherwise known as "claim-based cross-over fees") under fee-for-service coordination with Medicare supplemental policies. However, we are also provided authority to retain a portion of these users fees to offset costs we incur for determining whether enrollee out-of-pocket costs are being reimbursed by third parties and for alerting Part D plans when, in fact, they are being reimbursed.

As we also later discuss in this preamble, any user fees, if collected, would not be assessed until the benefit is implemented in 2006. Before that time, we will fund the development and implementation of coordination of benefit requirements. We will also fund the development and implementation of a system to assist in the coordination of benefits—if and when it is determined that our development of the system is the appropriate option. We request comment on the method we should employ in imposing user fees and especially concerning whether it would be advisable to impose user fees on a monthly or quarterly basis based on the volume of data exchanged, and whether we should require electronic payment of user fees.

In section 1860D–24(c)(1) of the Act, a Part D plan sponsor may continue to use cost management tools (including differential payments) when administering benefits. This could include cost management tools related to managing supplemental benefits financed by a State pharmaceutical assistance program or another plan providing prescription drug coverage offered through a Part D plan. However, we believe that the intent of the statute at section 1860D–24(c)(1) of the Act is clear in allowing Part D plans to continue to use cost management tools (such as tiered or differential cost sharing) even if an SPAP or other drug plan provides wrap-around or supplemental coverage for individuals enrolled in the Part D plan. We solicit comment on how we can ensure that wrap-around coverage offered by SPAPs and other insurers does not undermine or eliminate the cost management tools established by Part D plans. We also request comment on the most effective way to administer this provision without creating undue administrative burden on either Part D plans or the SPAPs and other insurers that might choose to provide wrap-around coverage for eligible individuals.

a. Coordination With SPAPs

The statute envisions a closer coordination of benefits between SPAPs and Medicare drug plans. For example, as provided in § 1860D–23(c) and in § 423.464(e)(3), a Part D enrollment card may also be used to access benefits under an SPAP, and the SPAP's emblem may be used on the card. Additionally, payments for beneficiary cost sharing made by an SPAP may be counted toward the incurred costs that count in the calculation of the true out-of-pocket (TrOOP) threshold in providing protection against catastrophic costs as provided in § 1860D–2(b)(4)(C)(ii) and in § 423.464(e)(2) of this proposed rule. SPAPs have filled a significant gap in prescription drug coverage for many Medicare beneficiaries in the absence of a Medicare drug benefit. Now that so many States are involved and so many beneficiaries have relationships with these programs, it will be important to ensure that coordination between Medicare Part D and SPAPs occurs as efficiently and effectively as possible. However, section 1860D–23(c)(5) of the Act provides that nothing in the statute should be construed to require that a State Pharmaceutical Assistance Program coordinate or provide financial assistance with respect to any Part D plan.

For purposes of this part, we are proposing that a Pharmacy Plus demonstration waiver program under section 1115 of the Act not be considered an SPAP. We grant Pharmacy Plus waivers that allow States to treat individuals participating in these waiver programs as Medicaid eligible only for the purpose of receiving prescription drug and primary care services. We do not believe that Pharmacy Plus waiver programs should be considered SPAPs. The statute makes a clear distinction between SPAPs, defined in section 1860D–23(b) of the Act, and the Medicaid program (which includes State plans operating under Title XIX of the Act as well as State plans operating under a waiver under section 1115 of the Act) described in section 1860D–24(b)(1) of the Act. In so far as the Pharmacy Plus waiver programs operate under 1115 waivers, they are considered part of the Medicaid program and thus are not considered SPAPs. This distinction is important for purposes of the application of TrOOP. Section 1860D–2(b)(4)(C)(ii) of the Act is clear in allowing only a person, CMS, or an SPAP to make payments that will count toward TrOOP for an individual Part D enrollee. In so far as beneficiary cost sharing is reimbursed under Title XIX of the Act, including a waiver operating under section 1115 of the Act, or through any other mechanism including public assistance, it cannot be counted toward TrOOP. However, since the MMA allows states to use state-only SPAP funds to assist beneficiaries with out-of-pocket expenditures, States would be better off using their current contributions to wrap around the Federal Medicare Part D benefit than in continuing their Pharmacy Plus programs.

Medicare Part D plans may coordinate with SPAPs in a number of ways including accepting premiums for basic Part D or enhanced alternative coverage; accepting a lump sum per capita payment from the State for enrollee coverage through Part D plans; and coordinating on a claim-specific basis when Part D plan pays first and the SPAP is the secondary payor. All data exchanges between SPAPs and Part D plans are to be consistent with applicable privacy laws, in order to ensure the confidentiality of individually identifiable beneficiary information. In accordance with section 1860D–23(c)(2) of the Act, and in order to help coordination between State pharmacy assistance programs and Part D plans, a single card may be used to access benefits under both Part D and State pharmacy assistance programs. These cards may contain an emblem or symbol indicating that a connection between the two programs exists. We do not know how SPAPs will actually choose to coordinate with Medicare drug plans, and we welcome comment in this regard—particularly from States. We would like to better understand what SPAPs plan to do in 2006 relative to Part D interaction (such as in payment of premiums or claim-specific wrap-around), and how Medicare can assist State preferences in this regard. Our goal is to make the coordination of benefits process as functional for the

beneficiary, pharmacy, and States as possible.

We assume that some SPAPS will pay Part D plans' premiums on behalf of enrollees. For SPAPs that choose to wrap-around coverage rather than paying premiums, we propose to include SPAP information in a coordination of benefits system described below. In this way, pharmacies will know that a claim should be sent to the SPAP following adjudication by the Part D plan.

We request comment on this proposed approach, including the feasibility of the approach for SPAPs and the ease of administration for pharmacies. We also request comment on whether or not SPAPs that choose to coordinate benefits on a wrap-around basis should be required to provide feedback on how much of the remainder of the claim they have actually paid. Since SPAP payments count as true out-of-pocket spending toward catastrophic coverage, the Part D plans could simply assume that any amounts not paid by the Part D plan and sent to an SPAP for reimbursement would count toward calculating TrOOP. We are concerned that we may need information from SPAPs to determine more precisely the SPAP contribution or payment. But we are also mindful of systems implications for States and would appreciate comments in this regard, particularly from SPAPs.

b. Coordination With Other Prescription Drug Coverage

Other plans providing prescription drug coverage that Part D plans would need to coordinate with are any of the following (1) Medicaid programs (including a State plan operated under a waiver under section 1115 of the Act); (2) Group health plans, as defined in § 411.101; (3) FEHBP; (4) Military Coverage (including TRICARE) under chapter 55 of title 10 of the United States Code; and (5) other prescription drug coverage as we specify. We discuss coordination issues in detail in sections (d) and (e), below.

There is a relatively limited applicability of coordination of benefits between Part D plans and State Medicaid programs under the statute. The drugs that must be excluded from Medicare coverage are, with limited exception, drugs that may also be excluded from Medicaid coverage under section 1927(d)(2) of the Act. We anticipate that there may be situations involving State Medicaid programs that choose to continue coverage of a drug that is excluded from Medicare Part D coverage. For example, States may wish to continue coverage for barbiturates, benzodiazepines, or prescription vitamins. In these situations, a Part D plan providing primary coverage would need to coordinate this coverage with a State on behalf of a dually eligible beneficiary. We request public comment on other situations that may involve benefit coordination between States and Part D plans (other than situations where the State is acting as an employer). In general, we invite comment on the other administrative processes and requirements that we might identify in order to help coordination between Part D of Medicare and other prescription drug plans.

c. Coordination of Benefits

Sections 1860D–23(a)(1) and 1860D–24(a)(1) of the Act require that, by July, 1, 2005, we establish requirements for coordination of benefits between Part D plans and SPAPs and other insurers including Medicaid programs, group health plans, the Federal Employees Health Benefits Plan (FEHBP), military coverage (including TRICARE), and other coverage we may specify at a later date. As discussed previously, the elements that are to be coordinated must include: Enrollment file sharing; claims processing and payment; application of the protection against high out-of-pocket expenditures (by tracking TrOOP and the annual out-of-pocket threshold); and, other processes we specify.

We envision a system of information sharing between Medicare, Part D plans, SPAPs, group health plans, insurers, and other third-party arrangements. Our goal is that the design and implementation of a Part D coordination of benefits system enable pharmacies to obtain information about secondary insurers as well as the correct billing order. Ideally, we would anticipate that a pharmacy would query the system and be provided with information it can use to bill all the insurers involved in the correct order, as well as ascertaining and applying the correct TrOOP calculation in order to assess the correct beneficiary co-payment at the point of service. Since prescription drug benefits are administered at the point of sale, coordinating insurance coverage at the point of sale is a technical communications challenge. In the case of administering a drug benefit, the goal is that the beneficiary pays the correct coinsurance or co-payment at the point of sale and that the pharmacy is subsequently reimbursed the correct amount from the other source or sources. Unlike coordination of benefits under Medicare when data is exchanged in only a single direction (from Medicare to the employer or other insurer), coordination of benefits for beneficiaries enrolled in Part D plans must include a reliable feedback loop of paid claims data from the employer, union or other insurer back to the Part D plan for purposes of tracking TrOOP. Additionally, given the real-time claims environment for pharmacy benefits, the feedback would ideally be in real-time so that beneficiary liability (if any) can be known at the point of sale, the correct insurer pays the correct share of the total drug cost, and the TrOOP calculation can be updated as quickly and accurately as possible. This suggests the need for an organized system to share, update, and push data back and forth between pharmacy benefit managers and pharmacies. This will be further discussed in the section on tracking true out-of-pocket (TrOOP) costs, below.

As mentioned above, under section 1860D–23(c)(1) of the Act, coordination between State pharmaceutical assistance programs and Part D plans does not change or affect the primary payor status of a Part D plan with respect to a State pharmaceutical assistance program. Nor does it affect the primary or secondary payment position of the Part D plan related to the payments made by other plans providing prescription drug coverage. Part B of Medicare has historically included limited coverage of certain outpatient prescription drugs. Part A of Medicare covers prescription drugs more extensively, but only when an individual is an inpatient in a Medicare-certified facility receiving Medicare-covered inpatient care. In additional circumstances, for instance when a person has elected Medicare hospice coverage, prescription drugs are also covered under original Medicare.

The new statutory definition of a covered Part D drug excludes drugs covered and paid for under Part A or Part B of Medicare for a given individual. Section 1860D–2(e)(2)(B) of the Act provides that a drug that would otherwise be a covered Part D drug will not be so considered if payment for the drug as so prescribed and dispensed or administered is available under Parts A or B for that individual. This language indicates that the Congress was aware that some drugs could qualify for payment under Part A or B in some circumstances, and Part D in other circumstances, depending on setting of dispensing or administration. This means, for example, that if a form of administration of a drug is covered under Part B in a region when injected incident to a physician office visit, that drug administered in that manner in that setting cannot meet the definition

of a covered Part D drug. However, that same drug can be covered under Part D when picked up at a retail pharmacy to be self-administered by the patient. For another example, in certain instances a drug could be covered under Part B at certain times and under Part D at other times. Many patients, for instance, take their medicines at specific times throughout the day. If these patients receive a service in a hospital outpatient department and remain in the hospital for several hours of post surgery observation, he/she may receive one or more doses from the hospital pharmacy. This medication would be considered part of their Part B service and covered under the hospital OPD payment.

We note that individuals can elect Part D of Medicare if they are entitled to Part A or enrolled in Part B. This means that individuals with only Part A or only Part B will still have access to Part D. Although most Medicare beneficiaries have both Parts A and B, there are nearly 2 million Medicare beneficiaries who have only Part A, while there are approximately 500,000 Medicare beneficiaries who have only Part B. We interpret the definition of covered Part D drug to exclude coverage under Part D for drugs otherwise covered and available under Parts A or B for individuals who choose not to enroll in either program. We interpret the words "payment is available" to mean that payment would be available to any individual who could sign up for A or B, regardless of whether they are actually enrolled. All individuals who are entitled to premium-free Part A are eligible to enroll in Part B. This includes individuals who are entitled to Part A based on age, disability, and ESRD. All individuals who are entitled to Part B only are age 65 and, in almost all instances, not eligible for premium-free Part A. However, they are eligible to buy into Part A for a premium. Thus, for all Part D individuals, Part A drugs and Part B drugs are "available" if they choose to pay the appropriate premiums. Consequently, Part D would not be required to pay for drugs covered under Parts A and B on the basis of a Part D eligible individual's status with regard to Parts A and B. In addition, we believe that the phrase "for that individual" in § 1860D–2(e)(2)(B) of the Act is intended to capture the fact that under local medical review policies, a drug that might be covered under Part B for an individual in one area of the country may not be covered under Part B in another area of the country. Thus, what is covered "under Part B for that individual" may be different in different geographic regions. The result of these interpretations would be that any drug covered under A or B could not be covered under D, whether it was covered for that individual or not.

We would wish to ensure that Part D coverage coordination works seamlessly for beneficiaries with Parts A and B of Medicare, and that beneficiaries do not lose Medicare coverage otherwise available to them due to unforeseen difficulties encountered in the coordination process. This is a critical consideration for effective and efficient coordination between the original Medicare program and the new coverage provided under Part D. Specific options concerning coordination of benefit procedures that we are considering are outlined below.

Pharmacy-dispensed drugs covered by Part B (for instance, DME drugs, immunosuppressive drugs, and oral anti-cancer drugs) are not reimbursed unless the pharmacy has a Medicare supplier number; thus, a beneficiary could lose Part B coverage by filling a prescription at the wrong pharmacy. (We recognized this problem in the interim final rule on the discount card program and stated that, for drugs potentially covered by Part B, "non-Medicare participating pharmacies should refer the beneficiary to a participating pharmacy." *See* 68 FR 69840, 69852). To reduce this risk, we are proposing to—

1. Encourage Part D plans to enroll pharmacies with Medicare supplier numbers in their networks;

2. Encourage Part D plans to inform beneficiaries whether their network pharmacies have a Medicare supplier number, and explain why this is important when filling prescriptions for drugs potentially covered by Part B; and

3. Develop educational materials reminding pharmacies without Medicare supplier numbers that they must refund any payments collected from beneficiaries enrolled in Part B for Part B drugs unless they first notify the beneficiary (through an advanced beneficiary notice (ABN)) that Medicare likely will deny the claim.

Statutory "refund requirements" apply to claims for "medical equipment and supplies" that Medicare denies because the supplier lacked a supplier number, unless—

1. The beneficiary signed an ABN notifying him or her that Medicare would deny payment, and agreed to be personally responsible for payment; or

2. The supplier did not know and could not reasonably have known that Medicare would deny payment.

For this purpose, coverage of medical equipment and supplies includes durable medical equipment (DME), certain drugs and other supplies necessary for use of an infusion pump, oral immunosuppressive drugs and anti-cancer drugs, and "such other items as the Secretary may determine." (*See* the Medicare Claims Processing Manual, Chapter 30, sections 150.1.3 and 150.1.5.) Suppliers are presumed to know that Medicare will not pay for medical equipment and supplies furnished by a supplier that lacks a supplier number. (*See* section § 150.5.4 of Chapter 30 of the Medicare Claims Processing Manual.) We are considering whether a drug denied Part B coverage for this reason should become a covered Part D drug, and the claim should thus be processed under Part D, and would like to receive comments on the relative likelihood of this occurrence and on alternative means of addressing such circumstances.

We are also considering whether a drug denied Part B coverage for any other reason should become a covered Part D drug. For instance, we believe that a drug denied Part B coverage and payment for therapeutic inappropriateness, drug-disease contraindication, incorrect drug dosage, duration of drug treatment or for similar reasons related to medical necessity should *not* be considered a covered Part D drug. Rather, we believe that such a denial or non-coverage decision under Part B, while appealable under Part B, would not cause the drug to become a covered Part D drug. We welcome comment in this area.

For drugs potentially covered by Part B that are dispensed by a pharmacy that is a Medicare supplier, we are considering the development of automatic cross-over procedures. That is, we are considering requiring that: (1) The pharmacy submit the claim to the appropriate Part B carrier; and (2) the carrier, if it denies the claim, submit the claim automatically to the PDP (or its claims processing agent) through which the beneficiary has Part D coverage. This assumes that the beneficiary receives Part D through a PDP. For beneficiaries enrolled in MA–PD plans, coordination of benefits will generally occur internally within the MA organization. (Similar cross-over procedures are used today in connection with dual-eligibles—individuals entitled to both Medicare and Medicaid and related to coordination between Medicare and Medicare supplemental insurers.)

We also believe that similar cross-over procedures for any physician-administered drugs that may be covered under Part B or Part D will need to be developed. This would involve: (1) The physician submitting the claim to the appropriate Medicare carrier; and (2) the

carrier automatically submitting the claim to the Part D plan (or its claims processing agent) if it denies payment under Part B. We particularly welcome comment on the feasibility of these proposed Part D and Part B coordination of benefits proposals and welcome suggestions on other methods or procedures that might be more efficient or better suited to coordination of prescription drug benefits.

Another type of coordination of benefits occurs when Medicare pays secondary to another insurance (MSP). Medicare currently pays secondary when payment has been made or can reasonably be expected to be made by another party such as workers compensation, automobile insurance, a liability insurance policy, or another health insurance policy (for example, when a beneficiary's spouse has primary insurance through their employment). Beneficiaries provide information, when available, regarding third party coverage as part of the initial enrollment questionnaire. Medicare also attempts to identify additional situations in which Medicare should pay secondary, and when we believe this is the case we follow up with employer plans for information. We do not anticipate significant changes to this mechanism, except that Medicare will now, in relatively limited circumstances, pay secondary for a Part D beneficiary who has other insurance. We do not know how many beneficiaries with employer-sponsored insurance that is the primary payor to Medicare will enroll in Part D. We do know that approximately two-thirds of individuals with primary employer-sponsored insurance do voluntarily pay for Part B coverage. We request public comment on the likelihood that beneficiaries with primary employer-sponsored insurance will elect Part D. We believe that the number of instances where automobile, workers' compensation or liability insurance will be paying primary on behalf of Part D enrollees will be relatively small. So, generally, we believe that most instances of coordination of benefits of under Part D will occur when Medicare is primary and another insurer is secondary.

d. Collection of Data on Third Party Coverage

Section 1860D–2(b)(4)(D)(i) of the Act authorizes us to establish procedures for determining whether a beneficiary's Part D out-of-pocket costs are actually reimbursed by a group health plan, insurance or otherwise, or another third-party arrangement. These procedures provide for—

- Determining whether costs for a Part D enrollee are being reimbursed through insurance or otherwise, a group health plan, or other third-party arrangement; and Alerting Part D plans in which beneficiaries are enrolled about reimbursement of prescription drug costs they receive through insurance or otherwise, a group health plan, or other third party arrangement.
- Section 1860D–2(b)(4)(D)(ii) of the Act permits Part D plans to request information on third party insurance from beneficiaries. We would expect Part D plans to update Medicare records based on the information provided by beneficiaries to reflect changes in coverage, including the primary or secondary status of such coverage relative to Medicare. As discussed in the subpart B preamble, beneficiaries who materially misrepresent (as defined in standards and processes we propose to establish in § 423.108(b)(4)(iv) of the proposed rule) information on third parties may be disenrolled from any Part D plan for a period specified by CMS and may also be subject to late enrollment penalties upon enrollment in another plan.

In the current Medicare fee-for-service claims processing environment, coordination of benefits when Medicare is the primary payor and another insurer is secondary (for example, employer-based retiree insurance, Medicaid, or Medigap) is performed as a convenience to the beneficiary and employer plan (coordination of benefits is required by statute for claims involving Medigap plans) and is voluntary on the part of the employer plans. The coordination of so-called "cross-over" claims is a one-way communication of claims information from Medicare to the secondary plan. This "cross-over" does not occur in real time. Instead, Medicare communicates with employer plans on a batch basis, and claims information may not reach the secondary insurer until weeks after the covered service is rendered. Coordination of benefits is, nonetheless, a valuable service to employers and Medicaid since these payors get an electronic claim that has already been subjected to claims edits and on which Medicare has already paid its portion. As a matter of fact, the service is so cost effective that employers willingly pay Medicare for the "cross-over" service. We have agreements with numerous employers purchasing "cross-over" data. In 2004 Medicare expects approximately 550 million Part A and Part B claims to "cross-over" to a secondary insurers including Medigap, Medicaid, employers, other insurers, and third party administrators providing wrap-around coverage.

Section 1860D–2(b)(4)(D)(i) of the Act authorizes us to establish procedures for determining if costs for Part D enrollees are reimbursed by other payors, and for alerting Part D plans about such arrangements. This provision could be read to mean that we only have to determine the presence of alternative coverage and merely has to alert Part D plans of such. However, it could also be read to mean that we have to determine if specific claim costs have been reimbursed by alternative coverage. In contrast, section 1860D–24(a) of the Act directs us to establish requirements for Part D plans to coordinate benefits with other payors in the same manner as we are directed to coordinate Part D benefits with SPAPs. This provision could mean that the responsibility for coordination of benefits lies with the Part D plans. However, section 1860D–24(c)(2) of the Act provides that the requirements of section 1860D–24 shall not affect the application of procedures established under section 1860D–2(b)(4)(D) of the Act. This arguably preserves the flexibility CMS has under the later section to impose requirements on alternative coverage arrangements. In addition, section 1871 of the Act generally authorizes us to prescribe such regulations as may be necessary to carry out administration of the insurance programs under title XVIII of the Act that now includes Part D.

We assume that employer and union plans may respond to the new Medicare prescription drug benefit in a number of ways. We expect that many of the employers and unions that currently provide supplemental drug coverage to their retirees will opt to pay premiums to Part D plan sponsors. In today's Medicare Advantage market, the most prevalent model is one that employers and unions pay premiums to MA organizations. We expect this model to continue to have wide appeal under Part D. In the case of the PDP market, while many employers and unions may choose to pay premiums to PDPs for Part D for their retirees, others may choose to coordinate benefits with PDPs. In general, employers and unions that continue to offer assistance to Medicare-eligible retirees will either (1) provide qualified coverage of prescription drugs in such a way that retiree-beneficiaries do not need to enroll in Part D of Medicare, in which case the employer may qualify for a Federal subsidy under section 1860D–22(a) of the Act; or (2) provide assistance that requires retiree-beneficiaries to enroll in Part D (either by paying Part D basic or supplemental

premiums); or (3) provide supplemental ("wrap-around") benefits through alternative secondary coverage. The last option has implications for coordination of benefits between Part D plans and employer/union-sponsored retiree drug coverage, and in particular, on the accurate processing of claims with respect to the out-of-pocket threshold.

e. Tracking True Out-of-Pocket (TrOOP) Costs

As we discuss in the preamble to subpart C of this rule, section 1860D–2(b)(4)(C) of the Act provides that beneficiary costs for covered Part D drugs are only considered incurred when those costs are incurred by a Part D enrollee for covered part D drugs covered under (or treated as covered under) a Part D plan that are not paid for under the Part D plan due to the application of any annual deductible or other cost-sharing rules for covered part D drugs prior to the Part D enrollee satisfying the out-of-pocket threshold under proposed § 423.104(e)(5)(iii), including any price differential for which the Part D enrollee is responsible under proposed § 423.120(a)(6) and § 423.124(b)(2). Further, section 1860D–2(b)(4)(C)(ii) of the Act provides that costs shall be treated as incurred by a Part D eligible individual only when they are paid by another person (such as a family member, on behalf of the individual) and the individual (or other person) is not reimbursed by insurance or otherwise, a group health plan, or other third-party arrangements, with the exception of amounts reimbursed by a SPAP or under the low-income subsidy provided for under proposed § 423.782. We refer to beneficiary expenditures for covered Part D drugs meeting these requirements as "true out-of-pocket costs", or TrOOP. We are considering a number of options for facilitating the exchange of data needed to track TrOOP, and will discuss alternatives around both mandatory versus voluntary reporting of claim and out-of-pocket costs, and centralized versus distributed responsibility for tracking the information in the extended discussion, below.

The case in which the employer or union arranges wrap-around coverage through a third party administrator or insurer other than through a Part D plan in which the retiree-beneficiary is enrolled is the potentially complex and challenging to administer, especially given the true out-of-pocket costs (TrOOP) requirements. The degree of difficulty in making coordination of benefits work with respect to wrap-around coverage is related to the ability of plans to efficiently coordinate insurance coverage at the point of sale. We cannot estimate the number of employer/labor plans that might choose to wrap-around prescription drug coverage other than through a Part D plan. We welcome comment that would help us estimate the scope and impact of such coverage, as well as the impact on the operational capabilities of plans (and their subcontractors).

Medicare Part D plans will need to be particularly involved with employer/union plans that wrap-around Part D coverage due to the implications such wrap-around coverage has for administering TrOOP maximums. Payments made on behalf of a beneficiary by a third party (such as by employer/labor-sponsored supplemental prescription drug coverage) are not considered incurred costs and, therefore, do not count in the TrOOP calculation. Thus, employer/labor-sponsored wrap-around coverage effectively pushes out the total spending "attachment point" or starting point at which protection from high out-of-pocket beneficiary expenditures begins.

As discussed in subpart G of this preamble, although Part D plans will receive reinsurance payments from us for a portion of the costs they incur for prescription drug coverage provided to beneficiaries after the true out-of-pocket threshold has been met, Part D plans will also bear "risk" for a portion of the costs they incur above the threshold. The critical nature of the TrOOP calculation makes coordination of benefits under the Part D program of vital interest to all parties. Both CMS and Part D plans must know how much an employer/union-based plan or other plan pays on a prescription drug claim following adjudication of that claim by the Part D plan. Likewise, beneficiaries have a vested interest in the TrOOP calculation due to the financial relief they receive after meeting the annual out-of-pocket threshold.

Responsibility for tracking TrOOP costs is somewhat unclear. On the one hand, the government is given authority to establish procedures for tracking TrOOP costs. For instance, as we discuss later in this preamble section and as we propose to codify in regulation at § 423.464(c), section 1860D–24(a)(3) of the Act authorizes us to impose user fees for disseminating information necessary for benefit coordination. On the other hand, responsibility for obtaining and applying the necessary information to prescription drug claims is assigned to the Part D plan sponsors. It is of great importance to establish clear responsibilities for TrOOP tracking and calculation processes in regulation in order to ensure that qualified beneficiaries receive appropriate coverage once they have met the out-of-pocket cost limit.

There is sufficient ambiguity in the statutory language to support a proposal to mandate that group health plans, insurers, and otherwise, and other third-party arrangements provide claims data for Part D enrollees to us for purposes of administering TrOOP. Exercising such authority would not be in violation of HIPAA confidentiality requirements. However, exercising such authority would impose administrative burden on group health plans, insurers, and otherwise, and other third-party arrangements that provide coverage or reimbursement of health care expenses to Medicare Part D beneficiaries. Moreover, mandatory reporting of enrollment file and claims data will not be sufficient, in and of itself, to capture all forms of enrollee cost-sharing reimbursement.

For instance, if the third party reporting of claims payments and reimbursements are strictly voluntary, serious challenges to implementing a system for tracking TrOOP will continue to exist. A voluntary system would be incomplete and all payors that rely on voluntarily reported data would need to have back-up procedures for accounting for initially unreported data. A voluntary system would also leave CMS and Part D plans open to criticism that the data is incomplete and that benefits paid out based on TrOOP calculations are inaccurate. However, group health plans, insurers and otherwise, and other third-party arrangements might prefer a voluntary system.

By way of comparison, the current (voluntary) Medicare Secondary Payor (MSP) program achieves $4.5 billion in savings. This means that there is some compliance with the provisions even though there is no mandatory insurer-reporting requirement. However, under the MSP provisions there are enforcement provisions. There are tax penalties for non-compliance with the MSP rules. In addition, there is a mandated reporting of some information through the IRS/SSA/CMS data match project that obtains tax and spousal information from the IRS and SSA. Our contractor then sends the employer a questionnaire concerning the identified Medicare beneficiary or spouse of a beneficiary to determine if there is coverage that is primary to Medicare. Failure to complete the questionnaire can result in the imposition of a Civil Monetary Penalty. However, even with these enforcement provisions, it is estimated that Medicare is still losing millions of dollars where employer

plans should be primary. Payments made by plans primary to Medicare under the Medicare Secondary Payer provisions 1862(b) would not count against the TrOOP.

In the cross-over area discussed previously in this section of the preamble, we are more successful, but there are still numerous payers who do not have cross-over agreements with us. So although there is substantial participation related to cross-over claims, there is also significant room for improvement. In the context of the current discussion, the issue is primarily that the sending of paid claims data to us for its use in the TrOOP calculation will be an added administrative cost on third-party payers, which (without explicit reporting requirements in the statute or an even an enforcement mechanism) may lead to lower compliance.

We are considering the following options for operationalizing the data exchange related to the Part D coordination of benefits system and TrOOP accounting:

Option 1: The PDPs and MA–PD plans would be solely responsible for tracking TrOOP costs. This option places the entire responsibility for tracking TrOOP costs with the PDPs and MA–PD plans. As part of their overall benefit management responsibility they would be responsible for establishing the systems infrastructure and ensuring that all data points are reporting timely and accurate data about beneficiaries' Part D costs. Each PDP and MA–PD plan must establish arrangements with all payers for enrollment file sharing and claims payment information exchanges. This coordination applies equally to plans that are primary or secondary payer to Medicare. Under this scenario, any payer who had a beneficiary on behalf of whom they expected to make either a primary or secondary payment to Medicare Part D would need to be able to (1) identify the Part D plan in which the beneficiary was enrolled, (2) establish the telecommunications links; (3) transmit enrollment information to the specific PDP or MA–PD plan in which their covered individual is enrolled, and (4) transmit claims payment data to the PDP or MA–PD each time a claim was paid which may need to be included in the TrOOP calculation. Data collected by a PDP or MA–PD plan would be annotated to the Medicare Beneficiary Database and be available to pharmacies for the purposes of proper billing.

Option 2: We would procure a TrOOP facilitation contractor to establish a single point of contact between payers, primary or secondary. Under this scenario, we would procure a TrOOP facilitation contractor based on a strategy of voluntary compliance, similar to the existing MSP coordination of benefits model. We would procure a contractor to receive enrollment and claims payment information from all plans primary and secondary to Medicare. This would establish a single point of contact between the Medicare program and employers, State Pharmacy Assistance Programs, as well as primary and secondary payers for enrollment and claims payment information.

Under this single point of contact option, a payer primary or secondary to a Part D plan would be required to send an enrollment file to the TrOOP facilitation contractor (a contractor procured by us). The TrOOP facilitation contractor would match the payer enrollment information to Medicare enrollment records and update the Medicare Beneficiary Database with the information. The other payer enrollment file information would also be used the TrOOP facilitation contractor to match claims payment data which would also be submitted to the TrOOP facilitation contractor. Once a claim was matched against the enrollment data, the TrOOP facilitation contractor would aggregate the claim records files by Part D plan and transmit the information. The PDP or MA–PD plan would be responsible for using the data in applying the TrOOP and applying other TrOOP requirements such as the application of a formulary.

PDPs and MA–PD plans would also request information about other coverage during the enrollment process and could add change or delete information input into the system by the TrOOP facilitation contractor. We can use existing fee-for-service coordination of benefits processes to implement many of the processes needed to implement these provisions. Information concerning primary and secondary plans would be shared with and PDPs and MA–PD plans, as well as annotated in the Medicare common working file/Medicare Beneficiary Database to enhance pharmacy billing and beneficiary customer service.

Under either option, we would enter into voluntary data sharing agreements with employers/unions and other plans to participate in a shared system. The same mechanism would accept information provided directly by Part D plans, SPAPs, group health plans, FEHBP, military plans, and other insurance or payors as we may specify.

We are committed to ensuring that claims are processed appropriately under Part D. Therefore, to foster proper billing and coordination of benefits we are also considering the establishment of the Medicare beneficiary eligibility and other coverage query system using the HIPAA 270/271 eligibility query. Information collected under this section for the purpose of TrOOP application would be available to be queried by pharmacies to facilitate proper billing. We are concerned that with the significant expansion of health care options available to beneficiaries that providing information to pharmacies about Medicare and other coverage is essential to facilitate proper claims processing. We are requesting comments concerning the development of this system.

In either event, the system(s) would need to be operational by January 1, 2006. Note that user fees might be imposed on third-party payers (but not on SPAPs) for the transmittal of information under either model. Were responsibility to reside solely with Part D plans to develop and operate a coordination of benefits system or systems (without a defined role for us in such development and operation), the statute would still permit imposition and collection of user fees. Please see our preamble discussion on user fees earlier in this preamble related to proposed § 423.464(c).

We could propose (with or without mandatory reporting by insurers) placing requirements on Part D plans and enrollees that would facilitate private market arrangements to report the data. We are considering mandating that beneficiaries enrolling in Part D plans provide third-party payment information and consent for release of data held by third parties as part of their enrollment application and which could be validated through a HIPAA-compliant beneficiary "release" or authorization. For instance, if we were to clearly require that all Part D plans coordinate benefits and that all Part D enrollees provide consent for release of third-party data on their Part D enrollment forms, the Part D plans would have the authority to implement inter-plan reporting mechanisms in order to coordinate benefits. However, back-up procedures would still be necessary to capture expense reimbursements made outside prescription drug claim processing systems as, for instance, by HRA administrators. Thus, although the statute is unclear as to which entity should have primary responsibility for tracking TrOOP costs (CMS or the Part D plans), to facilitate the accurate calculation of TrOOP we could do this either through reliance on data collection provisions in section 1860D–15(c)(1)(C) of the Act, or in reliance on

our authority to collect information related to contracting in section 1860D–12(b)(3)(D) of the Act that incorporates into Part D section 1857(e) of the Act, allowing the contract to require the contracting organization to provide to us the information as we decide necessary and appropriate. However, section 911(c)(2) of the MMA strictly forbids matches of data between Medicare contractors and us to identify MSP situations. The fact that the MMA is silent with regard to matches or data exchanges for the purposes of Part D TrOOP cost administration could be taken in different ways. One way to read the statute would be that the omission was intentional and the Congress specifically intended for the type of exception not to be applicable for TrOOP. However, an equally good case could be made that TrOOP administration procedures were to be defined by us and therefore the spirit of the provision contained in 911(c)(2) should be considered as it applies to TrOOP.

We ask for comment on these options and are seeking input on the best means to ensure an efficient and effective coordination of benefits related to the Part D Medicare program. We are also interested in discussion of other temporary or phased-in approaches that may be necessary or advisable given the short timeframe between publication of the final rule and program implementation. Under any of the scenarios presented it is clear that the ultimate responsibility for calculating TrOOP belongs to the Part D plan. The only issues are what role in facilitating TrOOP tracking CMS should have, if at all.

It is important to note that the sequencing of primary and secondary insurance claims will be a critical issue for tracking TrOOP costs. If, for example, a secondary plan does not provide feedback to the system in real time, it is possible that the TrOOP cost information the Part D plan has access to may not be entirely up to date at any given time. Also, if a paper claim is submitted after the fact to the Part D plan or supplemental insurer (due to an appeal reversal, for instance), the TrOOP calculation would not be up to date in real time at the point of service. Another complicating factor in the sequencing of claims is cancelled prescriptions. Generally, a claim is adjudicated when a prescription is filled. If the prescription is not picked up, and is eventually cancelled, the claim needs to be cancelled. If, in the meantime, other claims have been adjudicated, the sequencing is thrown off by the cancelled prescription, potentially disrupting the calculation of the initial deductible and TrOOP, and making coordinating benefits and tracking TrOOP costs more difficult.

Ideally, we would prefer that the system actually coordinate the adjudication of claims and provide real-time claims processing across multiple insurers, but we do not believe that such a complex and unique system could be operational by January 1, 2006. And, as previously mentioned, we do not have statutory authority to enforce a mandatory reporting requirement that employers, group health plans, other insurance or third-party arrangements participate in such a system. We believe, however, that the type of voluntary system we envision would provide information sufficient to permit the coordination of benefits that the statute requires and that beneficiaries and pharmacies desire. In any case, the goal would be to minimize the prevalence of paper claims submitted post point of service. In addition, we request public comment on methods for Part D plans to receive information from beneficiaries or others regarding payment made by entities that do not participate in this coordination of benefits system, since there is no requirement that third-party payers participate in this voluntary system.

We anticipate that the majority of employers, group health plans and other third-party payment arrangements would participate in a voluntary system since they would receive a clean claim from the pharmacy that has already been adjudicated by the Part D plan. In return for the clean claim, we would request that third-party payers provide information back to the coordination of benefits system regarding how much they paid on the claim for purposes of calculating the TrOOP under Part D. We anticipate that there will be times that the information in the system is not consistent with what the beneficiary informs the pharmacy is the most current state of insurance. We request comment and relevant information (if any exists from current market practices) on how these situations should be resolved under Part D at the point of sale.

K. Proposed Application Procedures and Contracts With PDP Sponsors

(If you choose to comment on issues in this section, please include the caption "Subpart K—Proposed Application Procedures and Contracts with PDP Sponsors" at the beginning of your comments.)

1. Overview

Subpart K of proposed part 423, would implement provisions established by sections 1860D–12(b)(1), 1860D–12(b)(3)(A), 1860D–12(b)(3)(B), 1860D–12(b)(3)(C), 1860D–12(b)(3)(D) and 1860D–12(b)(3)(F) of the Act that relate to contract requirements for PDP sponsors. The proposed provisions in this rule would address conditions necessary to contract with Medicare as a PDP sponsor, as well as contract requirements and termination procedures that would apply to Medicare-contracting PDP sponsors.

2. Background

Section 1860D–12(b)(1) of the Act provides that an entity seeking to participate in the Medicare program as a PDP sponsor must enter into a contract with us for that offering. The contract may cover more than one prescription drug plan in a region or across multiple regions and would require the PDP sponsor to adhere to all applicable requirements and standards included in Part D of Title XVIII of the Act and our provisions at proposed part 423, as well as the terms and conditions for payments described in regulation and the statute. While the provisions discussed in proposed subpart K would, in general, also apply to "fallback plans", eligibility limitations and contract requirements for applicants that have offered or are offering "fallback plans" are discussed in proposed subpart Q of this preamble.

Section 1860D–12(b)(3) of the Act states that certain MA contracting provisions in the Act should be applied to contracts with PDP sponsors in the same manner that they apply to contracts with MA organizations. Therefore, it is our intent to apply, where applicable, the contracting provisions used for MA organizations to contracts with PDP sponsors. The contracting provisions in this proposed rule are, for the most part, the current MA contract requirements with some changes made to accommodate the differences between MA and PDP sponsors and to implement specific changes mandated in the Act. However, we realize that the programmatic differences between this proposed rule and the existing MA contracting provisions will require changes. We are studying this issue, requesting comments and planning to implement the appropriate changes in the final rule.

We discuss the following five requirements in this subpart:

- Protection against fraud and abuse (proposed § 423.504(d));

- Contract provisions (proposed § 423.505);
- Effective date and term of contract (proposed § 423.506);
- Procedures for non-renewal (proposed § 423.507) and termination (proposed § 423.508 through § 423.510); and
- Minimum enrollment (proposed § 423.512).

The sixth requirement (intermediate sanctions) identified in section 1860D–12(b)(3) of the Act is discussed in more detail in proposed subpart O of this preamble.

In addition, section 1860D–12(b)(3)(D) of the Act incorporates section 1857(e) of the Act, which provides the Secretary the authority to include in the contract "such other terms and conditions not inconsistent with this part * * * as the Secretary may find necessary and appropriate." Since the contracting aspects of the proposed MA and PDP programs are quite similar, as are the procedures and requirements, we need to support their contracts. We propose to apply the provisions of part 422 to PDP sponsor contractors and applicant organizations, with few exceptions, in proposed subpart K. In some cases it was necessary to make changes to accommodate differences between MA and PDP sponsors, for example, application timeframes, payment, provider contract requirements, and certifications. We have noted these changes where they occur throughout the preamble.

We are interested in receiving comments on the contracting provisions of this rule. We are interested in receiving comments on provisions that should not be applied, and whether for PDPs there are other contracting considerations that are not addressed in these MA contract provisions. Specific issues on which we seek comment include: the type of business transactions which should be reported to CMS, the proposed required administrative and management arrangements, how these provisions should be applied to large companies with multiple business units, and the record maintenance requirements.

Maintenance of a single application and evaluation procedure, and a single set of contract requirements for both the MA and PDP programs would bring simplicity, consistency, and reduced administrative burden for those entities that are managing both programs. The requirements at proposed § 423.501 through § 423.516 would be similar to the requirements in § 422.500 through § 422.524. A summary of our proposed provisions are discussed below.

3. Definitions

In proposed § 423.501, we would define contract-related terms that would be limited to use in this proposed subpart. These definitions would be almost the same as those in § 422.500 for application to the MA program except in cases where the MA definition is inapplicable—such as in definitions that reference hospitals or hospital services. Of particular note are the proposed terms "first tier" and "downstream" entity because a PDP sponsor may often accomplish its responsibilities under its Medicare contract by contracting with these entities. For purposes of this proposed subpart the following definitions would apply:

Business transaction would mean any of the following kinds of transactions:

(a) Sale, exchange, or lease of property.

(b) Loan of money or extension of credit.

(c) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(1) Salaries paid to employees for services performed in the normal course of their employment; or

(2) Health services furnished to the PDP sponsor's enrollees by pharmacies and other providers, and by PDP sponsor staff, medical groups, or independent practice associations, or by any combination of those entities.

Significant business transaction would mean any business transaction or series of transactions of the kind specified above in the definition of "business transaction" that, during any fiscal year of the PDP sponsor, have a total value that exceeds $25,000 or 5 percent of the PDP sponsor's total operating expenses, whichever is less.

Downstream entity would mean a party that enters into a written arrangement below the level of the PDP sponsor's contract with the "first tier" entity. These written arrangements would continue down to the level of the ultimate provider of both health and administrative services. Usually in the context of the drug benefit the ultimate provider would be the pharmacist but it might also include other entities, such as an organization providing medication therapy management.

First tier entity would mean any party that enters into a written arrangement with a PDP sponsor or contract applicant to provide administrative services or health services for a Medicare eligible individual under Part D.

Party in interest would mean the following:

(a) Any director, officer, partner, or employee responsible for management or administration of a PDP sponsor.

(b) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(c) In the case of a PDP sponsor organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law.

(d) Any entity in which a person described in paragraphs (a), (b), or (c) of this definition—

(1) Is an officer, director, or partner; or

(2) Has the kind of interest described in paragraphs (a), (b), or (c) of this definition.

(e) Any person that directly or indirectly controls, is controlled by, or is under common control with the PDP sponsor.

(f) Any spouse, child, or parent of an individual described in paragraphs (a), (b), or (c) of this definition.

Related entity would mean any entity that is related to the PDP sponsor by common ownership or control and—

(a) Performs some of the PDP sponsor's management functions under contract or delegation;

(b) Furnishes services to Medicare enrollees under an oral or written agreement; or

(c) Leases real property or sells materials to the PDP sponsor at a cost of more than $2,500 during a contract period.

4. Proposed Application Requirements

Under proposed § 423.502, in order to obtain a determination on whether it meets the requirements to become a PDP sponsor, an entity, or an individual authorized to act for the entity (the applicant), would be required to complete and submit a certified application in the form and manner required by us. In addition to the application, the entity or individual authorized to act for the entity would be required to submit documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards as described in proposed subpart I of this proposed part; or submit a Federal waiver as described in proposed subpart I of this proposed part. The authorized individual would be required to describe thoroughly how the entity would meet the proposed

requirements described in this proposed part.

We would be responsible for determining whether an entity is qualified to be a PDP sponsor and if that entity meets the proposed requirements of part 423. Also, in this proposed section, we would specify that an applicant that submits material that he or she believes would be protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exceptions provided in 45 CFR part 5 (the Department's regulations providing exceptions to disclosure), would have to label the material "privileged" and include an explanation of the applicability of an exception described in 45 CFR part 5.

Current fallback plans, entities that bid to be fallback plans, and, in some circumstances, entities that served as fallback plans the prior year would not be eligible to apply as a PDP sponsor. (*See* proposed subparts F and Q of this preamble for details on proposed "fallback plans".)

5. Proposed Evaluation and Determination Procedures For Applications To Be A Sponsor

Proposed § 423.503 would establish procedures for us to evaluate and determine an entity's application for a contract as a PDP sponsor. These provisions mostly mirror the provisions applicable to MA specified at 42 CFR 422.502. This evaluation and determination of the application would be done on the basis of information contained in the application itself and any additional information that we would obtain through on-site visits, publicly available information, and any other appropriate procedures.

If the application is incomplete, we would notify the contract applicant, and we propose to allow 10 days from the date of the notice for the contract applicant to furnish the missing information. After evaluating all relevant information, we would determine if the contract applicant's application meets the applicable requirements of proposed § 423.504. We note that the MA provision in § 422.502(a)(2) currently provides a 30-day window for the MA program to furnish missing information. We believe a 10-day period is necessary for the Part D program because of the June bidding deadline specified at § 423.265(b). An organization would need to apply as close to the first of the year as possible in order to have its contract approved before submitting bids. Once a contract is approved, an organization is not required to reapply each year. *See* § 423.506(c) for renewal of contract information.

If a PDP sponsor, MA organization, or Medicare cost plan fails to comply with the terms of a previous year's contract with us under Title XVIII of the Act, or fails to complete a corrective action plan during the term of the contract, we may deny an application from a contract applicant based on the contract applicant's failure to comply with that prior contract with us even if the contract applicant meets all of the current proposed requirements.

We would notify each applicant that applies for a contract as a PDP sponsor under this part, of its determination on the application and the basis for the determination. The determination may be one of the following:

- *Approval of application.* If we approve the application, we would give written notice to the contract applicant, indicating that it meets the requirements for a contract as a PDP sponsor.
- *Intent to deny.* If we find that the contract applicant does not appear to meet the requirements for a PDP sponsor contract, we would give the contract applicant "notice of intent to deny" the application for a PDP contract and a summary of the basis for this preliminary finding. Within 10 days from the date of the notice, the contract applicant would have to respond in writing to the issues or other matters that would be the basis for our preliminary finding and would have to revise its application to remedy any defects we identify. We note that the MA provision in § 422.502(e)(2) currently provides a 60-day window for the MA program to remedy any defects we identify. We believe a 10-day period is necessary for the Part D program because of the June bidding deadline specified at § 423.265(b). An organization needs to apply as close to the first of the year as possible in order to have its contract approved prior to submitting a bid.

If we deny an application, written notice would be given to the contract applicant that would indicate the following:

- That the contract applicant does not meet the contract requirements under Part D of Title XVIII of the Act.
- The reasons why the contract applicant does not meet the contract requirements.
- The contract applicant's right to request reconsideration in accordance with the proposed procedures specified in proposed § 423.645.

This proposed section would also establish oversight of a PDP sponsor's continued compliance with the proposed requirements for a PDP sponsor. If a PDP sponsor fails to meet those proposed requirements, we would terminate the contract in accordance with proposed § 423.509 of this proposed rule.

6. General Provisions

Proposed § 423.504 would specify the general provisions that would apply to PDP sponsor contracts. Again, for the most part, we would adopt the provisions that already apply to MA organizations through the regulations at 42 CFR 422.501. We have recently proposed changes to the compliance program requirements for MA organizations at 42 CFR 422.501(b)(3)(vi)(G) to include provisions that would require MA organizations to report misconduct it believes may violate various criminal, civil or administrative authorities. These self-reporting requirements are identified below in the discussion of the elements of a PDP compliance program. We have based the compliance program requirements for PDP sponsors on these new and recently proposed MA requirements. We believe that mandatory reporting of potential fraud by government contractors is critical, especially in light of the corporate fraud scandals that occurred over the past several years. It is also in keeping with the Sarbanes-Oxley Act of 2002, under which the Securities and Exchange Commission adopted new regulations designed to make corporate compliance and disclosure requirements stronger and more effective. In short, we believe that the self-reporting requirements included in this rule are keeping with the change in the legal, regulatory, and business climates since the compliance program requirements were first implemented. Subject to the provisions at proposed § 423.265(a)(1), in subpart F—Submission of bid, we are proposing that in order to enroll beneficiaries in any prescription drug plan it offers and be paid on behalf of Medicare beneficiaries enrolled in those plans, a PDP sponsor would have to enter into a contract with us. The contract could cover more than one prescription drug plan.

In accordance with those regulations, we also propose that any entity seeking to contract as a PDP sponsor would be required to meet the following conditions:

- Complete an application as described in proposed § 423.502.
- Be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan, or have secured a Federal waiver, as

described in proposed subpart I of this preamble.

• Meet the proposed minimum enrollment requirements of proposed § 423.512(a) unless waived under proposed § 423.512(b).

• Have administrative and management arrangements satisfactory to us that could be demonstrated by at least the following:

+ A policy making body that would exercise oversight and control over the PDP sponsor's policies and personnel that would ensure that management actions would be in the best interest of the organization and its enrollees.

+ Personnel and systems that would be sufficient for the PDP sponsor to organize, implement, control, and evaluate financial and marketing activities, the furnishing of prescription drug services, the quality assurance, medication therapy management, and drug-utilization management programs, and the administrative and management aspects of the organization.

+ At a minimum, an executive manager whose appointment and removal would be under the control of the policy making body.

+ A fidelity bond or bonds, procured and maintained by the PDP sponsor, in an amount fixed by its policymaking body, but not less than $100,000 per individual, that would cover each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the PDP sponsor.

+ Insurance policies or other arrangements, secured and maintained by the PDP sponsor and approved by us, that would insure the PDP sponsor against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

+ A compliance plan that would consist of the following:

– Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State standards.

– The designation of a compliance officer and compliance committee accountable to senior management.

– Effective training and education between the compliance officer and organization employees.

– Effective lines of communication between the compliance officer and the organization's employees.

– Enforcement of standards through well-publicized disciplinary guidelines.

– Procedures for internal monitoring and auditing.

– Procedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the organization's contract as a PDP sponsor.

– If the PDP sponsor discovers from any source evidence of misconduct related to payment or delivery of prescription drug items or services under the contract, it must conduct a timely, reasonable inquiry into that misconduct;

– If, after reasonable inquiry, the PDP sponsor has determined that the misconduct may violate criminal, civil or administrative law, the sponsor must report the existence of the misconduct to the appropriate Government authority within a reasonable period, but not more than 60 days after the determination that a violation may have occurred. If the potential violation relates to federal criminal law, the civil False Claims Act, federal Anti-Kickback provisions, the civil monetary penalties authorities (primarily under sections 1128A and 1857 (as incorporated through section 1860D–12) of the Act), or related statutes enforced by the HHS Office of Inspector General, the report must be made to that Office.

– The PDP sponsor must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees, etc.) in response to the potential violation referenced above.

The PDP sponsor's contract must not have been non-renewed under proposed § 422.507 within the past 2 years, unless—

+ During the 6-month period beginning on the date the organization notified us of the intention to non-renew the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing PDP sponsor payments in the payment area or areas at issue; or

+ We have otherwise determined that circumstances warrant special consideration.

Section 1860D–4(b)(1)(A) of the Act assures pharmacy access by requiring a PDP sponsor to permit the participation of any pharmacy that meets the terms and conditions under the plan. Based on this requirement, we are considering adding the following language to the contract provisions: The PDP sponsor would agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy. We are interested in public comment on the inclusion of such a provision.

Section 1857(c)(5) of the Act, which is incorporated by section 1860D–12(b)(3)(B) of the Act, authorizes us to exercise the authority granted to the Secretary under Part D of Title XVIII without regard to provisions of the statute or regulations that we determine to be inconsistent with the furtherance of the purpose of Title XVIII of the Act. Based on this authority, we propose to provide, in proposed § 423.504(c) (Contracting authority), that we may enter into contracts under this proposed subpart without regard to Federal and Departmental acquisition regulations set forth in title 48 of the CFR. We note that some of the Federal Acquisition Regulation (FAR) provisions may apply to "fallback plans". (*See* proposed subparts F and Q for any contracting provisions unique to fallback plans.)

In proposed § 423.504(d) (Protection against fraud and beneficiary protections), we set forth the proposed requirements that we would have in place to protect against fraud and abuse in our PDP sponsor contracts. As directed by the statute, these are the same requirements as those in sections 1857(d)(1) and (d)(2) of the Act. The proposed requirements are as follows:

• We would annually audit the financial records (including, but not limited to, data relating to Medicare utilization, costs, reinsurance cost, low-income subsidy payments, and risk corridor cost) of at least one-third of the PDP sponsors, including fallback plans, offering prescription drug plans. We welcome comments on whether fallback plans, because of the payment arrangements, require a different audit approach, possibly more frequent. The Comptroller General would monitor these auditing activities.

• Each contract under this proposed section would be required to provide that we, or any person or organization designated by us, would have the right to—

+ Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the PDP sponsor's contract;

+ Inspect or otherwise evaluate the facilities of the organization when there is reasonable evidence of some need for such inspection; and

+ Audit and inspect any books, contracts, and records of the PDP sponsor that pertain to the ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or services performed or determinations of amounts payable under the contract.

Section 1860D–12(b) of the Act allows contracts with PDP sponsors to cover more than one prescription drug plan. At proposed § 423.504(e) (Severability of contracts), we are proposing that the contract would provide, upon our

request, that the contract could be amended to exclude any State-licensed entity, or a PDP plan specified by us; and a separate contract for any excluded plan or entity would be deemed to be in place when such a request is made.

7. Contract Provisions

Section 1860D–12(b)(3)(D) of the Act requires that provisions of section 1857(e) of the Act relating to additional contract terms of MA contracts would apply in the same manner to PDP sponsors. Section 1857(e) of the Act allows that the contract would contain other terms and conditions not inconsistent with Part D of the Act, including requiring the organization to provide us with the information that we may find necessary and appropriate. The additional contract provisions for the MA program are adopted for use in this proposed rule with modifications as necessary to accommodate differences between the MA program and the prescription drug program. Elsewhere in this preamble, we have also identified additional contract terms that would apply uniformly to both MA organizations offering MA–PDs and PDP sponsors (*see,* for example, subpart D discussing e-prescribing). In proposed § 423.505 (Contract provisions), we would require the contract between the PDP sponsor and us to contain the provisions specified in proposed § 423.505(b). The following is a summary of the proposed additional contract provisions that reflect any changes from the MA contract provisions:

• Specific Provisions.

In proposed § 423.505(b), we would list the specific provisions that would be contained in the contract between the PDP sponsor and us. Changes were made from the MA provisions to accommodate the different bidding and payment system for PDP sponsors. The PDP sponsor would be required to agree to comply with the following proposed provisions:

+ All the applicable proposed requirements and proposed conditions set forth in this proposed part and in general proposed instructions.

+ To accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in proposed subpart B of this proposed part.

+ To comply with the proposed prohibition in proposed § 423.34(a) on discrimination in beneficiary enrollment.

+ To provide the basic benefits as proposed under proposed § 423.108 and, to the extent applicable, supplemental benefits proposed under proposed § 423.112.

+ To disclose information to beneficiaries in the manner and the form prescribed by us under proposed § 423.128.

+ To operate quality assurance, cost and utilization management, medication therapy management, and fraud, abuse and waste programs as proposed under proposed subpart D of this proposed part.

+ To comply with all proposed requirements in proposed subpart M of this proposed part governing coverage determinations, grievances, and appeals.

+ To comply with the proposed reporting requirements in proposed § 423.514 and the proposed requirements in proposed § 423.329(b)(3) of proposed subpart G for submitting drug claims and related information to us for its use in risk adjustment calculations;

+ Each contract under this proposed part would provide that—

– The PDP sponsor offering a prescription drug plan would be required to provide us with the information as we determine is necessary to carry out proposed payment provisions in proposed subpart G of this proposed part; and

– We would have the right, as applied under section 1860D–12(b)(3)(C) of the Act and in accordance with section 1857(d)(2)(B) of the Act, to inspect and audit any books, contracts, and records of a PDP sponsor or MA organization that pertain to the information regarding costs provided to us under proposed § 423.504(d)(2)(iii) of this proposed section.

+ To be paid under the contract in accordance with the proposed payment rules in proposed subpart G of this proposed part.

+ To submit its bid, including all required information on premiums, benefits, and cost-sharing, by the proposed due date, as provided in proposed subpart F of this proposed part.

+ That its contract could possibly not be renewed or could be terminated in accordance with this proposed subpart and proposed subpart N of this proposed part.

+ To comply with the proposed confidentiality and proposed enrollee record accuracy requirements described in proposed § 423.136.

+ To comply with State Law and preemption by Federal Law requirements described in proposed subpart I of this proposed part.

+ To comply with the proposed coordination requirements with plans and programs that provide prescription drug coverage as described in proposed subpart J of this proposed part.

+ To provide benefits by means of point of service systems to adjudicate drug claims, except where necessary to provide access in underserved areas, I/T/U pharmacies (as defined in proposed § 423.100), and long-term care pharmacies.

• Communication with CMS.

In proposed § 423.505(c), we would require the PDP sponsor to have the capacity to communicate with us electronically in the manner we specify.

• Maintenance of records.

In proposed § 423.505(d), we are proposing to detail the proposed requirements for record maintenance and retention, which would be unchanged from the MA regulations. We would require PDP sponsors to maintain books, records, documents, and other evidence of accounting procedures and practices for a period of 6 years so as not to prematurely foreclose our ability to pursue fraudulent or other abusive activities. The other evidence of accounting procedures and practices would have to be sufficient to do the following:

+ Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the bid of PDP sponsors).

+ Enable us to inspect or otherwise evaluate the quality, appropriateness and timeliness of services performed under the contract, and the facilities of the organization.

+ Enable us to audit and inspect any books and records of the PDP sponsor that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.

+ Properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the PDP sponsor's bid and necessary for the calculation of gross covered prescription drug costs, allowable reinsurance costs and allowable risk corridor costs (as defined in proposed § 423.308).

+ Establish the basis for the components, assumptions and analysis used by the PDP in determining the actuarial valuation of standard, basic alternative, or enhanced alternative coverage offered in accordance with our guidelines described in proposed § 423.265(b)(3).

We would also require the PDP sponsor to include at least records of the following:

+ Ownership and operation of the PDP sponsor's financial, medical, and other record keeping systems.
+ Financial statements for the current contract period and 6 prior periods.
+ Federal income tax or informational returns for the current contract period and six prior periods.
+ Asset acquisition, lease, sale, or other action.
+ Agreements, contracts, and subcontracts.
+ Franchise, marketing, and management agreements.
+ Matters pertaining to costs of operations.
+ Amounts of income received by source and payment.
+ Cash flow statements.
+ Any financial reports filed with other Federal programs or State authorities.
+ All prescription drug claims for the current contract period and 6 prior periods.
+ All price concessions for the current contract period and 6 prior periods accounted for separately from other administrative fees. This includes concessions offered by manufacturers to PDP sponsors.

• Access to Facilities and Records.

In proposed § 423.505(e), the PDP sponsor would be required to agree to the same access to facilities and records as under the MA program. The PDP sponsor would be required to agree to the following:

+ HHS, the Comptroller General, or their designee could evaluate, through inspection or other means—
– The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;
– The facilities of the PDP sponsor; and
– The enrollment and disenrollment records for the current contract period and six prior periods.
+ HHS, the Comptroller General, or their designees could audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of the PDP sponsor, related entity(s), contractor(s), subcontractor(s), or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.
+ The PDP sponsor would have to agree to make available, for the purposes specified in this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that we could require.
+ HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 6 years from the end of the final contract period or completion of audit, whichever is later unless—
– We determine there is a special need to retain a particular record or group of records for a longer period and notify the PDP sponsor at least 30 days before the normal disposition date;
– There is a termination, dispute, or allegation of fraud or similar fault by the PDP sponsor, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or
– We determine that there is a reasonable possibility of fraud, in which case we may inspect, evaluate, and audit the PDP sponsor at any time.

• Disclosure of Information.

Under proposed § 423.505(f), the PDP sponsor would be required to agree to submit to us certified financial information that would have to include the information, as we could require, that would demonstrate that the organization has a fiscally sound operation. The certified financial information would include the information, as we could require, pertaining to the disclosure of ownership and control of the PDP sponsor. Also, the certification would include all information that would be necessary for us to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining prescription drug coverage. This information would include, but would not be limited to—

+ The benefits that would be covered under a prescription drug plan;
+ The PDP monthly basic beneficiary premium and PDP monthly supplemental beneficiary premium, if any, for the plan;
+ The service area of each plan;
+ Plan quality and performance indicators for the benefits under the plan including—
– Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;
– Information on Medicare enrollee satisfaction;
– The recent records regarding compliance of the plan with requirements of this part, as determined by us; and
– Other information determined by us to be necessary to assist beneficiaries in making an informed choice regarding PDP plans;
+ Information about beneficiary appeals and their disposition;
+ Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization; and
+ Any other information deemed necessary to CMS for the administration or evaluation of the Medicare program.

The PDP sponsor would also be required to disclose all informational requirements to its enrollees, under proposed § 423.128(b) and, upon an enrollee's request, the financial disclosure information required under proposed § 423.128(c)(4). (*See* proposed subpart C of this proposed part.)

• Proposed Beneficiary Financial Protections.

Under proposed § 423.505(g), the PDP sponsor would be required to adopt and maintain arrangements satisfactory to us to protect its enrollees from incurring liability (that is, as a result of an organization's insolvency or other financial difficulties) for payment of any fees that would be the legal obligation of the PDP sponsor. The beneficiary financial protection provisions would remain unchanged from the MA program. To meet this proposed requirement, the PDP sponsor would have to ensure that all contractual or other written arrangements prohibit the organization's contracting agents from holding any beneficiary enrollee liable for payment of any such fees; and the PDP sponsor would have to indemnify the beneficiary enrollee for payment of any fees that would be the legal obligation of the PDP sponsor for covered prescription drugs furnished by non-contracting pharmacists, or that would not have otherwise entered into an agreement with the PDP sponsor, to provide services to the organization's beneficiary enrollees.

To meet these proposed requirements of this proposed section, other than the proposed provider contract requirements discussed above, the PDP sponsor would use contractual arrangements; insurance acceptable to us; financial reserves acceptable to us; or any other arrangement acceptable to us.

• Proposed Requirements of Other Laws and Regulations.

One of the requirements we have incorporated from the existing MA rules is the requirement that plans comply with all Federal, State and local laws and regulations (see proposed § 422.505(h)). We have updated the list to include HIPAA Administrative and Simplification rules. Proposed

§ 423.505(h) would require the PDP sponsor to comply with—

+ Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 84.

+ The Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91.

+ The Rehabilitation Act of 1973.

+ The Americans with Disabilities Act.

+ HIPAA Administrative Simplification rules at 45 CFR Parts 160, 162, and 164

+ Other laws applicable to recipients of Federal funds.

+ All other applicable laws and rules.

PDP sponsors receiving Federal payments under PDP sponsor contracts, and related entities, contractors, and subcontractors paid by a PDP sponsor to fulfill its obligations under its contract with us, would be subject to certain laws that are applicable to individuals and entities receiving Federal funds. PDP sponsors would be required to inform all related entities, contractors and subcontractors that payments they receive would be, in whole or in part, from Federal funds. These proposed provisions would remain unchanged from the MA program.

• Proposed Requirements for PDP Sponsor Relationship with Related Entities, Contractors, and Subcontractors.

In proposed § 423.505(i), notwithstanding any relationship(s) that the PDP sponsor may have with related entities, contractors, or subcontractors, the PDP sponsor would maintain ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with us. The PDP sponsor would have to agree to require all related entities, contractors, or subcontractors that provide Part D items or services (including administrative services) to agree that—

+ The Department of Health and Human Services (HHS), the Comptroller General, or their designees would have the right to inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records of the related entity(s), contractor(s), or subcontractor(s) involving transactions related to our contract with the PDP sponsor; and

+ HHS', the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period should exist through 6 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

This proposed section would also require all contracts or written arrangements between PDP sponsors and providers, related entities, contractors, subcontractors, "first tier", and "downstream" entities that provide Part D items or services (including administrative services) to contain the specified proposed provisions. These proposed provisions would remain unchanged from the MA program.

• Proposed Additional Contract Terms.

In proposed § 423.505(j), the PDP sponsor would agree to include, in the contract, other terms and conditions as we may find necessary and appropriate in order to implement proposed requirements in this proposed part.

• Severability of Contracts.

In proposed § 423.505(k), the PDP sponsor would have to agree to include in the contract a severability provision that would establish that, upon our request, the contract would be amended to exclude any State-licensed entity, or PDP sponsor specified by us; and a separate contract for any excluded plan or entity would be deemed to be in place when the request is made.

• Certification of Data that Determines Payment.

In proposed § 423.505(l), we would require, as a condition of receiving a monthly payment under proposed subpart G of this proposed part, the PDP sponsor to agree that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, would request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data could include specified enrollment information, claims data, bid submission data, and other data that we specify. We recommend that PDP sponsors collect such certifications from their downstream partners to support their best knowledge, information and belief in signing their own certifications. In addition, we propose a certification for when PDP sponsors submit updated drug pricing data to CMS for beneficiary enrollment purposes.

The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, would be required to certify (based on best knowledge, information, and belief) that each enrollee for whom the organization would request payment is validly enrolled in a program offered by the organization and the information relied upon by us in determining payment) is accurate, complete, and truthful.

The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, would be required to certify (based on best knowledge, information, and belief) that the claims data it would submit under proposed § 423.329(b)(3) are accurate, complete, and truthful. If the claims data are generated by a related entity, contractor, or subcontractor of a PDP sponsor, the entity, contractor, or subcontractor would be required to similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data. The PDP sponsor or related entity, contractor, or subcontractor would acknowledge that the claims data would be used for the purpose of obtaining Federal reimbursement.

The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, would be required to certify (based on best knowledge, information, and belief) that the information in its bid submission and assumptions related to projected reinsurance and low income cost sharing subsidies is accurate, complete, truthful, and fully conforms to the requirements specified in proposed § 423.265. The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs, as defined in § 423.308, is accurate, complete, truthful, and fully conforms to the requirements in § 423.336(c) and § 423.343(c).

The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of price comparison is accurate, complete, and truthful.

8. Effective Date and Term of Contract

Section 1860D–12(b)(3)(B) of the Act provides that we include the contract period and effectiveness requirements that are included in section 1857(c) of the Act. Proposed § 423.506 would provide that contracts be effective on the date specified in the contract, and that the contracts would be for a term of 12 months. The contract period for a fallback plan is specified in

§ 423.871(b). In addition, contracts could be renewed from year to year, but only in the event that we inform the PDP sponsor that a renewal is authorized and only if the PDP sponsor does not provide us with a notice of intention not to renew. We do not require an application process for contract renewals. Because of the need for us to establish a national average monthly bid amount from approved bids in order to calculate the base beneficiary premiums, we propose to not allow a PDP contract to be effective at any time other than the first of the year. These proposed provisions would be similar to the MA provisions in § 422.505.

9. Non-Renewal of Contract

Section 1860D–12(b)(3)(F) of the Act requires that the provisions of section 1857(h) of the Act relating to procedures for termination (or non-renewal) of MA contracts would apply to PDP sponsors with respect to determinations and appeals. A non-renewal would be different from a termination in that either the PDP or us chooses to end the contract by following the proposed provisions described below.

In proposed § 423.507, we are proposing that a PDP sponsor could elect not to renew its contract with us as of the end of the term of the contract for any reason, provided it would notify us in writing by the first Monday of June in the year in which the contract would end. The PDP sponsor would also have to notify each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice would have to include a written description of alternatives available for obtaining Medicare prescription drug services within the PDP region, including MA–PDs, and other PDPs, and would have to receive our approval. The general public would also have to be notified at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area.

If a PDP sponsor chooses to non-renew a contract as described in proposed § 423.507(a)(3), we would not enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.

For purposes of this section, we could elect not to authorize renewal of a contract for any of the reasons listed in proposed § 423.509(a), which would also permit us to terminate the contract, or if the PDP sponsor commits any of the acts in proposed § 423.752 that supports the imposition of intermediate sanctions or civil money penalties under proposed § 423.750 of proposed Subpart O.

We would provide notice of our decision whether to authorize renewal of the contract to the PDP sponsor by May 1 of the contract year. If we decide not to authorize a renewal of the contract, we would provide notice to the PDP sponsor's Medicare enrollees by mail at least 90 days before the end of the current calendar year. We would also notify the general public at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area. We would give the PDP sponsor written notice of its right to appeal the decision not to renew in accordance with proposed § 423.642(b).

10. Modification or Termination of Contract by Mutual Consent

In proposed § 423.508, we are proposing that a contract could be modified or terminated at any time by written mutual consent. If the contract is terminated by mutual consent, the PDP sponsor would have to provide notice to its Medicare enrollees and the general public as provided in proposed § 423.507. If the contract is modified by mutual consent, the PDP sponsor would be required to notify its Medicare enrollees of any changes that we determine are appropriate for notification within timeframes specified by us. This proposed section would remain unchanged from the MA program.

11. Termination of Contract by CMS

In proposed § 423.509, we may terminate a contract with the PDP sponsor for any of the following reasons:

- The PDP sponsor fails substantially to carry out the terms of its contract with us (proposed § 423.509(a)(1)).
- The PDP sponsor carries out its contract with us in a manner that would be inconsistent with the effective and efficient implementation of this proposed part (proposed § 423.509(a)(2)).
- We determine that the PDP sponsor no longer meets the proposed requirements of this proposed part for being a contracting organization (proposed § 423.509(a)(3)).
- There is credible evidence that the PDP sponsor committed or participated in false, fraudulent, or abusive activities affecting the Medicare program, including submission of false or fraudulent data (proposed § 423.509(a)(4)).
- The PDP sponsor experiences financial difficulties so severe that its ability to provide necessary prescription drug coverage is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that a risk to health exists (proposed § 423.509(a)(5)).
- The PDP sponsor substantially fails to comply with the requirements in proposed subpart M of this proposed part relating to grievances and appeals (proposed § 423.509(a)(6)).
- The PDP sponsor fails to provide us with valid risk adjustment, reinsurance and risk corridor related data as required under proposed § 423.329 (proposed § 423.509(a)(7)).
- The PDP sponsor substantially fails to comply with the proposed service access requirements in proposed § 423.120 (proposed § 423.509(a)(8))
- The PDP sponsor substantially fails to comply with the proposed marketing requirements in proposed § 423.128 (proposed § 423.509(a)(9)).
- The PDP sponsor substantially fails to comply with the coordination with plans and programs that provide prescription drug coverage as described in proposed subpart J of this proposed part (proposed § 423.509(a)(10)).
- The PDP sponsor substantially fails to comply with the proposed cost and utilization management, proposed quality improvement, proposed medication therapy management, and fraud, abuse and waste program requirements as described in proposed subpart D of this proposed part (proposed § 423.509(a)(11)).

If we decide to terminate a contract for reasons other than the grounds described above in proposed § 423.509(a)(4) or (a)(5), we would notify the PDP sponsor in writing 90 days before the intended date of the termination. The PDP sponsor would then notify its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination. The PDP sponsor would also notify the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area.

We propose adding § 423.509(a)(4) as a reason for immediate termination without corrective action. If we have credible evidence that a PDP sponsor committed or participated in false, fraudulent, or abusive activities affecting the Medicare program, we may

determine that providing the sponsor with additional time to submit a corrective action plan would only expose beneficiaries to a plan we have already determined engaged in fraudulent or abusive behavior. Therefore, we propose to terminate the contract as soon as possible in order to protect the beneficiaries enrolled with the affected sponsor as well as the Medicare trust fund.

For terminations based on violations described in proposed § 423.509(a)(4) or § 423.509(a)(5), we would notify the PDP sponsor in writing that its contract has been terminated effective the date of the termination decision by us. If termination is effective in the middle of a month, we would have the right to recover the prorated share of the prospective monthly payments made to the PDP sponsor covering the period of the month following the contract termination.

We would also notify the PDP sponsor's Medicare enrollees in writing of our decision to terminate the PDP sponsor's contract. This notice would occur no later than 30 days after we notify the plan of our decision to terminate the contract. We would also simultaneously inform the Medicare enrollees of alternative options for obtaining prescription drug coverage, including alternative PDP and MA–PDs in a similar geographic area. We would notify the general public of the termination no later than 30 days after notifying the plan of our decision to terminate the contract. This notice would be published in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area.

Before terminating a contract for reasons other than the grounds specified in proposed § 423.509(a)(4) or § 423.509(a)(5), we would provide the PDP sponsor with reasonable opportunity to develop and receive our approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination. If a contract is terminated based on § 423.509(a)(4) or § 423.509(a)(5), the PDP sponsor would not be given the opportunity to submit a corrective action plan. If we decide to terminate a contract, we would send written notice to the PDP sponsor informing it of its termination appeal rights in accordance with proposed § 423.642 of this proposed part.

12. Termination of Contract by the PDP Sponsor

In proposed § 423.510, we are proposing that the PDP sponsor may terminate its contract if we fail to substantially carry out the terms of the contract. The PDP sponsor would be required to give advance notice as follows:

- To us, at least 90 days before the intended date of termination. This notice would have to specify the reasons why the PDP sponsor is requesting contract termination.
- To its Medicare enrollees, at least 60 days before the termination effective date. This notice would have to include a written description of alternatives available for obtaining Medicare drug services within the services area, including alternative PDPs, MA–PDs, and original Medicare and would have to receive our approval.
- To the general public at least 60 days before the termination effective date by publishing a notice approved by us in one or more newspapers of general circulation in each community or county located in the PDP sponsor's geographic area.

The effective date of the termination would be determined by us and is at least 90 days after the date we receive the PDP sponsor's notice of intent to terminate. Our liability for payment to the PDP sponsor would end as of the first day of the month after the last month for which the contract is in effect. We would not enter into an agreement with an organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by us. This proposed section would remain unchanged from the MA program.

13. Proposed Minimum Enrollment Requirements

Section 1860D–12(b)(3)(A) of the Act applies the minimum enrollment requirements of section 1857(b)(1) and section 1857(b)(3) of the Act to Part D of the Act. However, the statute also gives the Secretary the authority to increase the minimum number of enrollees as the Secretary deems appropriate. In proposed § 423.512, we are proposing to retain the minimum enrollment requirements used for the MA program and that appear in section 1857(b)(1) of the Act. Our rationale for retaining the MA minimum enrollment level is to avoid conflicts that could occur if we adopted a higher minimum for Part D, which could imply that MA plans that could not meet the higher Part D standard would be unable to offer a drug benefit as required by law. In reality, we expect that stand-alone PDPs would have enrollments that far exceed these minimum levels. We are interested in receiving comments on whether these numbers should be increased for PDP sponsors. We are also interested in receiving comments on whether the 1,500 standard, which was directed at local MA organizations, has applicability in the context of PDPs. Thus, our regulations would provide that, in general, the Secretary would not enter into a contract with a prospective PDP sponsor, unless the organization has at least 5,000 individuals who are enrolled for the purpose of receiving prescription drug benefits from the organization. Another option would be for the prospective PDP sponsor to have a minimum enrollment number of 1,500 individuals if the organization primarily serves individuals residing outside of urbanized areas. Urban area is defined in § 412.62(f) as essentially including MSAs and NECMAs as defined by OMB. The PDP sponsor would be required to maintain a minimum enrollment as discussed in this proposed section, however, as directed by section 1860D–12(b)(3)(A)(ii) of the Act, the proposed minimum enrollment requirements would be waived for any PDP sponsor in its first contract year in a region.

14. Proposed Reporting Requirements

In proposed § 423.514, we would require each PDP sponsor to have an effective procedure to develop, compile, evaluate, and report to us, to its enrollees, and to the general public, at the times and in the manner that we require statistics indicating the following:

- The cost of its operations;
- The patterns of utilization of its services;
- The availability, accessibility, acceptability of its services;
- Information demonstrating that the PDP sponsor has a fiscally sound operation; and
- Other information that we may require;

This proposed section would also contain proposed provisions for each PDP sponsor to report significant business transactions to us annually, within 120 days of the end of its fiscal year (unless for good cause shown, we authorize an extension of time). The information provided to us, would have to contain a description of significant business transactions as defined in proposed § 423.501 between the PDP sponsor and a party in interest. For those transactions, the PDP sponsor would be required to show that the costs of the transactions do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or if they do exceed, a justification that the higher costs are consistent with prudent

management and fiscal soundness requirements.

For purposes of this proposed section, the PDP sponsor would be required to produce a combined financial statement for itself and a party of interest if 35 percent or more of the costs of operation of the PDP sponsor go to a party in interest or 35 percent or more of the revenue of a party in interest is from the PDP sponsor. We would require the combined financial statements to include the following information:

- The display, in separate columns, of the financial information for the PDP sponsor and each of the parties in interest.
- The elimination of inter-entity transactions in the consolidated column.
- The examination of statements by an independent auditor in accordance with generally accepted accounting principles and include appropriate opinions and notes.

Upon written request from a PDP sponsor showing good cause, we could waive the proposed requirement that the organization's combined financial statement include the financial information discussed above for a particular entity.

In this proposed section, for any employees' health benefits plan that includes a PDP sponsor in its offerings, the PDP sponsor would be required to furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (for the particular PDP sponsor) under the Employee Retirement Income Security Act of 1974 (ERISA). The PDP sponsor would also be required to furnish the information to the employer or the employer's designee, or to the plan administrator, as the term "administrator" is defined in ERISA. This proposed section would also require each PDP sponsor organization to notify us of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities and each PDP sponsor would be required to make the information reported to us under this proposed section available to its enrollees upon reasonable request. These provisions would remain unchanged from the MA regulations.

15. Proposed Prohibition of Midyear Implementation of Significant New Regulatory Requirements

In proposed § 423.516, we propose that we may not implement, other than at the beginning of a calendar year, provisions under this proposed section that would impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

L. Effect of Change of Ownership or Leasing of Facilities During the Term of Contract

(If you choose to comment on issues in this section, please include the caption "Subpart L—Effect of Change of Ownership or Leasing of Facilities During the Term of Contract" at the beginning of your comments.)

1. Overview

Proposed Subpart L of proposed part 423 would describe the impact that a PDP sponsor organization's "change of ownership" (CHOW) or leasing of facilities during the term of its contract would have on the status of the organization's contractual relationship with us, as well as required procedures to be followed by a contracting PDP sponsor to effect a CHOW.

2. Provisions

In developing the proposed provisions for this proposed subpart as it relates to PDP sponsor organizations, we reviewed the experience that MA contractors and we have had under the provisions of subpart L of Part 422. A single set of CHOW requirements for both MA and PDP contractors would simplify management, assure consistency, and reduce administrative burden for those entities that are managing both programs. To that end, as a starting point we are proposing that the requirements in proposed §§ 423.551, 423.552, and 423.553, of this proposed rule, for the PDP sponsor, would be essentially the same as the requirements found in §§ 422.550, 422.552 and 422.553 for the MA program. Those proposed requirements and procedures are summarized in section 3, below.

Since the impact of a change of ownership on a PDP sponsor's contract with us would be similar to its effect on an MA organization's contract, we believe that the two sets of requirements should be similar. However, we are considering the modification of existing change of ownership provisions in both rules in order to reduce the administrative burden of these requirements and to increase the effectiveness of these provisions. We request comments regarding how these provisions could be modified to accomplish these objectives. In particular, we seek comments regarding: the situations which constitute a change of ownership, how these provisions should be applied to large companies with multiple business units, the notification requirements related to a change of ownership, the novation agreement provisions, and the provision related to the leasing of a PDP's facilities.

3. Proposed General Provisions

In proposed § 423.551(a), we would present the three situations that constitute CHOW in the context of proposed subpart L. We would state that—

- The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a CHOW;
- Transfer of substantially all the assets of the sponsor to another party constitutes a change of ownership; and
- The merger of the PDP sponsor's corporation into another corporation, or the consolidation of the PDP sponsor's organization with one or more other corporations, resulting in a new corporate body, constitutes a CHOW.

We note that § 422.551(a)(2) if carried over from the MA rule would provide that a change of ownership occurs whenever there is a "[t]ransfer of title and property to another party * * *" This provision would seem to apply to any transfer no matter how small and, read literally, would include a partial transfer of the employer's assets such as a spin off or the sale of a single facility or operating division of the employer. Combined with the absolute assignment rule of (d), this has the potential to lead to absurd results. Therefore, in our proposed rule, we would change § 423.551(a)(2) to include only asset sales that are essentially transfers of the entire business enterprise. We request comments on situations where a sponsor transfers to another party substantial assets, but less than substantially all of its assets. In such comments, please describe the different scenarios that might develop under such circumstances, especially the extent to which benefits covered by the agreement might reasonably be expected to be provided by the old or new owner and the best approach for either transferring, issuing, or reissuing sponsor agreements."

The proposed exception to the three provisions discussed above would be that a transfer of corporate stock or the merger of another corporation into the PDP sponsor's organization, with the PDP sponsor organization surviving, would not usually constitute a CHOW.

Proposed § 423.551(c) of this proposed section, would require a PDP sponsor that has a Medicare contract in effect under proposed § 423.502 of proposed Subpart K and is considering or negotiating a CHOW, to notify us at least 60 days before the anticipated effective date of the change. The PDP

sponsor would also be required to provide updated financial information and a discussion of the financial and solvency impact of the CHOW on the surviving organization.

In this proposed section we would also state that if the PDP sponsor fails to give us the required notice in a timely manner, it would continue to be liable for payments that we make to it on behalf of Medicare enrollees after the date of the CHOW.

Proposed § 423.551(d) would define a novation agreement, the legal vehicle that we would use to recognize the new owner of a PDP sponsor organization's corporation, as the successor in interest to the Medicare contract. For this proposed rule, a novation agreement would be an agreement among the current owner of the PDP sponsor, the prospective new owner, and us. This agreement would have to be signed by all three parties and, to be effective, contain the proposed provisions at proposed § 423.552. The agreement would also have to allow us to recognize the new owner as the successor in interest to the current owner's Medicare contract. The new owner has to be sure to get adequate data to substantiate claims for reimbursement from the previous owner, because the new owner would be responsible at the time of the reconciliation process.

Proposed § 423.551(e) would detail the consequences of a CHOW that occurs without a novation agreement. Under this proposed section, if there is not a novation agreement, the existing Medicare contract would become invalid and, if the new owner wanted to participate in the Medicare program as a PDP sponsor, it would have to apply for, and enter into a contract in accordance with proposed subpart K of this proposed part.

4. Proposed Novation Agreement Requirements

Proposed § 423.552(a) would provide the three conditions that should be met for our approval of a novation agreement. Consistent with our approach in the MA program, we are proposing that the first condition would be for the PDP sponsor to give us notice, at least 60 days before the effective date of the CHOW. That notice would also include updated financial information and a discussion of the financial and solvency impact of the CHOW on the surviving organization. If notice were not timely, the contractor would continue to be liable for payments that we make to it on behalf of Medicare enrollees after the date of "CHOW" as described in proposed § 423.551(c)(2). The second proposed condition would be that the PDP sponsor would submit three signed copies of the novation agreement that contains the proposed provisions specified in proposed § 423.552(b) to us at least 30 days before the proposed CHOW date, and one copy of other relevant documents required by us. The final condition would be our determination after reviewing a novation agreement concerning the following:

- The proposed new owner is in fact a successor in interest to the contract.
- Recognition of the new owner as a successor in interest of the Medicare program.
- The successor organization meets the requirements to qualify as a PDP sponsor under proposed subpart K.

Proposed § 423.552(b) would identify the four required provisions of a properly constituted novation agreement. In this proposed section, we would require the agreement to state that the new owner would assume all obligations under the Medicare contract and the previous owner would be required to waive its right to reimbursement for covered services furnished during the rest of the current contract period. The previous owner would also be required to guarantee performance of the contract by the new owner during the contract period, or post a performance bond that is satisfactory to us. The last condition would require the previous owner to agree to make its books, records, and other necessary information available to the new owner and to us to permit an accurate determination of costs for the final settlement of the contract period. We would have to be able to recognize the new owner as the successor in interest to the current owner's Medicare contract and the novation agreement would be effective, once signed by all three relevant parties.

5. Effect of Leasing of a PDP Sponsor's Facilities

Proposed § 423.553 would address provisions related to when a PDP sponsor leases its facilities to another party and its PDP sponsor contract with us. Specifically, we are proposing that if a PDP sponsor leases all or part of its facilities to another entity, the other entity would not acquire PDP sponsor status under section 1860D–12(b) of the Act. If a PDP sponsor leases all of its facilities to another entity, its Medicare contract would terminate. If the other entity wants to participate in the Medicare program as a PDP sponsor, it would be required to apply for and enter into a contract in accordance with proposed § 423.502. If the PDP sponsor leases part of its facilities to another entity, its contract with us would remain in effect while we survey the PDP sponsor to determine whether it continues to be in compliance with the applicable proposed requirements and qualifying conditions specified in proposed Subpart K of this part.

M. Grievances, Coverage, Reconsiderations, and Appeals

(If you choose to comment on issues in this section, please include the caption "Subpart M—Grievances, Coverage Determinations, Reconsiderations, and Appeals" at the beginning of your comments.)

1. Introduction

Proposed subpart M of part 423 would implement sections 1860D–4(f), 1860D–4(g), and 1860D–4(h) of the Act, which set forth the procedures PDP sponsors must follow with regard to grievances, coverage determinations, and appeals.

Under section 1860D–4(f) of the Act, a PDP sponsor must provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor provides covered benefits) and enrollees.

Section 1860D–4(g) of the MMA addresses the procedures for coverage determinations and redeterminations of PDP sponsors. In general, the MMA requires that a PDP sponsor's procedures meet the same requirements as those that apply to MA organizations (under paragraphs (1) through (3) of section 1852(g)) of the Act for organization determinations and redeterminations. This includes the same timeframes for making these determinations and redeterminations, including the requirements for expedited procedures when the standard timeframes could seriously jeopardize an enrollee's life, health, or ability to regain maximum function. In addition, section 1860D–4(g)(2) of the Act specifies that if a PDP sponsor has tiered cost sharing for formulary drugs, it must establish an exceptions process. Under the exceptions process, consistent with guidelines established by the Secretary, a nonpreferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual, or both.

Section 1860D–4(h) of the Act addresses appeals of a PDP sponsor's coverage determinations and redeterminations. Here, the MMA requires that the PDP sponsors follow

appeals requirements that are similar to those applicable to MA organizations under paragraphs (4) and (5) of section 1852(g) of the Act (regarding independent review entity (IRE) review and ALJ hearings, respectively). As a result, in our regulations at § 423.612(b), we propose to require a 60-day timeframe for requesting an appeal, which has been a long-standing requirement throughout the entire Medicare managed care appeals process. To the extent the proposed requirements differ from the MA rules, we discuss these differences below. In addition, section 1860D–4(h)(2) of the Act specifies that appeals, involving coverage of a covered part D drug that is not on a PDP's formulary, are permissible only if the prescribing physician determines that all covered Part D drugs, on any tier of the formulary for treatment of the same condition, would not be as effective for the individual as the nonformulary drug, would have adverse effects on the individual, or both. The proposed regulations needed to implement the above provisions are discussed below.

2. General Provisions (§ 423.560 Through § 423.562)

Subpart M begins with proposed § 423.560, which sets forth several definitions for terms used in the subpart. These definitions are generally self-explanatory and mirror those used in subpart M of part 422 for MA, but have been modified to reflect applicability to Part D drug benefits.

Section 423.562, General Provisions, provides an overview of the responsibilities of PDP sponsors and the rights of PDP enrollees with respect to grievances, coverage determinations, and appeals. The responsibilities of PDP sponsors under § 423.562(a) include establishing and maintaining procedures for grievances, coverage determinations, exceptions to tiered cost-sharing formulary structures, requests for formulary exceptions, and appeals. This section would also specify that enrollees receive written information about the grievance and appeal procedures available to them through the PDP sponsor, and about the QIO complaint process available to enrollees. Like under the MA program, the proposed regulations indicate that if a PDP sponsor delegates any of its responsibilities under subpart M to another entity or individual through which the sponsor provides covered drug benefits, the PDP sponsor is ultimately responsible for ensuring that the applicable grievance, coverage determination, and appeal requirements are met.

Section 423.562(b) of our proposed rule explains the basic rights of PDP enrollees in relation to PDP sponsors under subpart M and references the regulations that explain the rights. These include, for example, the right to a timely coverage determination and appeal rights pursuant to that coverage determination.

Section 423.562(c) of our proposed rule specifies that an enrollee has no appeal right when there is no payment liability, or when benefits have been provided by a non-network provider (that is, a non-network pharmacy), except in those situations in which, under subpart C, the PDP is obligated to cover such drugs. Finally, § 423.562(d) explains that, unless otherwise noted, the general Medicare appeals rule under part 422, subpart M, is applicable for appeals to an Administrative Law Judge (ALJ) or the Medicare Appeals Council (MAC).

3. Grievance Procedures (§ 423.564)

As defined in § 423.560 of our proposed rule, a grievance means any complaint or dispute, other than one that constitutes a coverage determination, expressing dissatisfaction with any aspect of a PDP sponsor's operations, activities, or behavior, regardless of whether remedial action is requested. An enrollee might file a grievance, for example, if he or she has a complaint about the timeliness of filling a prescription, or the accuracy of the prescription. As required by section 1860D–4(f) of the MMA, the grievance procedures in this subpart generally mirror those found in part 422, Subpart M, for MA. Thus, our regulations would require that each PDP sponsor have procedures to ensure that grievances are heard and resolved in a timely manner, but they would not include prescriptive details on the procedures. The only exceptions to this approach, under § 423.564(d), involve certain limited situations where a PDP sponsor must respond to a grievance within 24 hours, such as a grievance oyer a PDP sponsor's decision to invoke an extension relating to a coverage determination or redetermination, or a PDP sponsor's refusal to grant an enrollee's request for an expedited coverage determination or redetermination where the enrollee has not yet purchased or received the drug that is in dispute.

Section 423.564(c) of our proposed rule explains the distinction between the grievance procedures of the PDP sponsor and the quality improvement organization (QIO) complaint process. This section further establishes that when an enrollee submits a quality of care complaint to a QIO, the PDP sponsor must cooperate with the QIO in resolving the complaint.

Section 423.564(e) of our proposed rule concludes the grievance procedures by proposing minimum record keeping requirements for a PDP sponsor, which include recording the receipt date of a grievance, its final disposition, and the date the enrollee is notified of the disposition.

4. Coverage Determinations (§ 423.566 Through § 423.576)

These proposed provisions implement the MMA requirement that PDP sponsors establish procedures for making coverage determinations and redeterminations regarding covered drug benefits that are essentially the same as those in effect for MA organizations under part 422, subpart M for MA. Therefore, for the drug benefits under Part D, we have continued standard and expedited requirements for coverage determinations and redeterminations.

Section 423.566(a) of our proposed rule specifies that each PDP sponsor must have a procedure for making timely coverage determinations regarding the drug benefits an enrollee is entitled to receive and the amount, if any, that an enrollee is required to pay for a benefit. The PDP sponsor is required to establish both a standard procedure for making coverage determinations and an expedited procedure for situations in which applying the standard procedure could seriously jeopardize the enrollee's life, health, or ability to regain maximum function.

As proposed in § 423.566(b), actions that would constitute coverage determinations include: a PDP sponsor's failure to provide or pay for a covered Part D drug (including failure to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the sponsor determines that the drug otherwise would be excluded under section 1862(a) of the Act); failure to provide a coverage determination in a timely manner that would adversely affect the health of the enrollee; decisions on the amount of cost sharing; or decisions on whether the preferred drug is appropriate for an enrollee. Section 423.566(c) lists those individuals who can request a standard coverage determination as the enrollee (including his or her authorized representative) and the prescribing physician on behalf of the enrollee. We

note that we have not included the legal representative of a deceased enrollee's estate (as is specified in § 422.566(c)(1)(iii)) since that individual would be considered an authorized representative. Those individuals who can request an expedited determination or an expedited redetermination are similarly an enrollee (including his or her authorized representative), or the prescribing physician on behalf of the enrollee. In these situations we propose that a prescribing physician need not be an appointed representative of the enrollee in order to assist in obtaining either a standard or an expedited coverage determination. We welcome comments on any additional individuals or entities that should be able to request a coverage determination.

The standard timeframes and notice requirements for coverage determinations are proposed in § 423.568. These requirements include a determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after receipt of the request if the request is for prescription drug benefits. An extension of the timeframe by up to 14 calendar days is allowable if the enrollee requests the extension, or if the PDP sponsor can justify how a delay is in the interest of the enrollee. For example, the receipt of additional medical evidence may change the outcome of the decision. An enrollee must be notified of the reasons for the delay, and informed of the right to file an expedited grievance if the enrollee disagrees with the sponsor's decision to invoke an extension. If the request is for payment, the determination must be made no later than 30 calendar days after receipt of the request. Consistent with § 1860D–4(g)(1) of the MMA, the timeframe and notice requirements for requests involving payment are the same as those that apply for clean claims under the Medicare Advantage program. This section also establishes the requirement for written notice for PDP sponsor denials and the form and content of the denial notice, including that the notice must explain the reason for the denial and the availability of appeal rights.

Sections 423.570 and 423.572 propose the requirements regarding expedited coverage determinations, including how an enrollee or an enrollee's prescribing physician can make an oral or written request (§ 423.570(b)), and how the PDP sponsor must process requests (§ 423.570(c)). We clarify in § 423.570(a) that requests for payment of prescription drugs already furnished for an enrollee cannot be expedited.

Section 423.570(b)(2) specifies that a prescribing physician may provide written or oral support for a request for expedition, and under § 423.570(c)(3)(ii), we clarify that when requests for expedition are made or supported by an enrollee's prescribing physician, the PDP sponsor must grant the request if the physician indicates that applying the standard timeframe could seriously jeopardize the enrollee's life or health, or the ability to regain maximum function. Section 423.570(d) proposes actions following a denial of a request and explains that when a sponsor denies a request for an expedited determination that the request automatically be transferred to and processed under the standard determination procedures, which require the determination within 14 calendar days. For accepted requests for expedited determination, § 423.572 proposes that the PDP sponsor must make its expedited determination and notify the enrollee and the prescribing physician, as appropriate, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request. Section 423.572(b) proposes the requirements for extensions, and includes the enrollee's right to file an expedited grievance if the enrollee disagrees with the PDP sponsor's decision to invoke an extension. Proposed § 423.572(c) explains that if the PDP sponsor first notifies an enrollee of an adverse expedited determination orally, then it must mail written confirmation to the enrollee within 3 calendar days. Finally, § 423.572(d) explains the requirements for the content of the expedited determination notice, and § 423.572(e) explains that a failure to provide a timely notice would constitute an adverse coverage determination, which may be appealed. Similar to the expedited requirements for MA under Part C, these sections would require that drug coverage determinations be made as expeditiously as the enrollee's health condition requires. Note that given the requirement that timing of determinations (and redeterminations) be based on an enrollee's health condition, the PDP sponsor has a responsibility to ensure that an enrollee's health situation and needs are fully considered in reviewing any requests (for example, if an enrollee has a chronic condition that has necessitated ongoing use of the drug in question). Again, however, if the enrollee already received the drug and the determination involves who should pay for the drug (or how much), there is generally no need for an expedited determination since the enrollee's health needs have been met.

5. Formulary Exceptions Procedures (§ 423.578)

a. Exceptions to a Plan's Tiered Cost-Sharing Structure

As noted above, section 1860D–4(g)(2) of the Act specifies that an enrollee may request an exception to a plan's tiered cost-sharing structure. Under such an exception, a "nonpreferred drug *could* (emphasis added) be covered under the terms applicable for a preferred drug" under certain conditions. At a minimum, the prescribing physician would have to determine that the preferred drug either would not be as effective for the individual or would have adverse effects for the individual, or both. The statute then requires that each PDP sponsor establish exceptions procedures consistent with guidelines issued by the Secretary for making determinations on such requests. Unfavorable determinations constitute coverage denials that would be subject to all the appeals rights discussed in subpart M of part 423.

How this section of the statute is implemented will have significant consequences for PDP sponsors and Medicare beneficiaries. Although the only specific criterion established by law for assessing exceptions requests is the prescribing physician's determination explained above, we believe that the statute's direction that exceptions be made in accordance with "guidelines established by the Secretary" indicates that PDP sponsors be able to establish additional criteria, subject to the Secretary's guidance. This flexibility raises two key, intertwined questions. First, to what extent should the Secretary limit a plan's discretion in establishing exceptions criteria? And second, how detailed must the criteria be? The absence of detailed criteria, although perhaps desirable for a PDP sponsor, may not afford Part D enrollees the type of drug access intended under the law. However, making tiering exceptions too easy to obtain could eliminate a sponsor's ability to obtain volume pricing discounts, and thus, offer optimal value to beneficiaries.

Based on existing models in the state and private sectors and on Federal managed care models, we believe that PDPs' formularies are likely to include tiered cost sharing; such tiering allows PDP sponsors to obtain better prices on preferred drugs, resulting in savings for both enrollees and the PDPs. Tiering will presumably be particularly critical for stand-alone PDPs (that is, non MA–PD plans), which will not have direct

relationships with doctors and thus will have no clear method of cost/utilization control other than through their pricing structure.

However, it is very difficult to predict exactly how PDP sponsors will design their tiering structures. For example, although the statute refers to "preferred" and "nonpreferred" drugs, actual tiering structures are likely to include three or more classes of drugs (such as "generic," "preferred brand," "non-preferred brand," etc.). We believe that this uncertainty strongly suggests that the proposed regulations not include overly prescriptive requirements with respect to a PDP's exceptions criteria. Instead, we would provide general guidance on the scope of issues that must be addressed under a PDP's exceptions criteria on the procedural elements of that process, but still allow for flexibility and innovation in this regard as we gain experience with the new program.

Thus, we would propose under § 423.578 that a PDP sponsor must establish an exceptions process that addresses each of the following sets of circumstances: (1) The enrollee is using a drug and the applicable tiered cost-sharing structure changes during the year; (2) the enrollee is using a drug and the applicable tiered cost-sharing structure changes at the beginning of a new plan year; and (3) there is no pre-existing use of the drug by the enrollee. For purposes of this subpart, "using a drug" means the enrollee is receiving the drug in the course of treatment, including time off if it is part of the treatment. A PDP's exceptions criteria would not necessarily need to be different under each scenario.

While we thought it necessary to require PDP sponsors to include certain criteria in the exceptions process, we also recognize the need to avoid a situation where a PDP sponsor's cost-sharing rules are effectively driven by the exceptions criteria, rather than the other way around. Thus, in § 423.578(a)(2) we have proposed a limited number of elements that must be included in any sponsor's exception criteria: (1) A description of the process used by the PDP to evaluate the physician's certification; (2) consideration of the cost of the requested drug compared to that of the preferred drug; (3) consideration of whether the formulary includes a drug that is the therapeutic equivalent of the requested drug; and (4) consideration of the number of drugs on the plan's formulary that are in the same class and category as the requested drug.

We also considered including a number of other exceptions criteria such as—(1) requiring PDP sponsors to establish a blanket rule permitting continued access to a drug at a given price when there is a mid-year change in the tiering structure; (2) requiring an enrollee who is using a drug that is subsequently removed from the sponsor's formulary or is no longer designated as the "preferred drug" to try a preferred drug(s), and experience adverse effects, before being permitted to resume using the original drug; (3) requiring a sponsor to establish exceptions criteria that are specific to particular classes of covered Part D drugs, such as cholesterol-lowering drugs; and (4) requiring sponsors to give enrollees an opportunity to request exceptions to a plan's tiered cost-sharing structure other than on a case-by-case basis. Additionally, we contemplated the possibility of establishing criteria for the review process used to evaluate plan formularies and tiering structures, and developing exceptions criteria that are specific to particular classes of covered Part D drugs. Based on public comment and any additional information that is available at the time on the formulary structure, we may add further detail to these criteria or include additional criteria in the final rule.

Consistent with existing MA rules, we are proposing that an enrollee, the enrollee's authorized representative or the prescribing physician may request an exception. The statutory requirement that the prescribing physician determine that the preferred drug either would not be as effective for the individual generally, or would have adverse effects for the individual, would constitute a minimum threshold for approving an exception request. Thus, we are proposing that a PDP sponsor may require a written certification to that effect from the prescribing physician, as well as certain limitations on the content requirements sponsors could impose for these certifications. However, we would permit PDP sponsors flexibility in how this standard is applied. For example, a PDP sponsor could require that a physician certify that the preferred drug would be less effective than the nonpreferred drug, or the PDP sponsor could choose to apply a more stringent standard (such as requiring that the prescribing physician's certification also include the enrollee's patient history or require the enrollee first try the preferred drug, absent medical contraindications).

A PDP's exceptions procedures would also be required to describe how a determination on an exception request would affect the enrollee's cost sharing obligations under the PDP's tiering structure. For example, would a request for a nonpreferred drug result in payment at the preferred brand drug level, or at the generic drug level, if available?

b. Exceptions and Appeals Rules for Non-Formulary Determinations

Section 1860D–4(h)(2) of the Act establishes a limitation on requests for exceptions when a particular drug is not on a plan's formulary at all. The statute specifies that an enrollee may appeal a determination not to provide coverage of a non-formulary drug "only if the prescribing physician determines that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the nonformulary drug, would have adverse effects for the individual, or both." Notably, this limitation is set forth under the "appeals" provisions of the statute, as opposed to under the preceding coverage determination and redetermination provisions that are discussed above for exceptions to tiered cost-sharing rules. Thus, we believe the intent of this provision is to limit appeals to cases where the prescribing physician has made the determination described by the law.

Unlike for the tiering exceptions, the statute does not specifically require that PDP sponsors develop an exceptions process to review requests for exceptions for non-formulary drugs. However, we do not believe that the statute intends to preclude an enrollee from obtaining a coverage determination from a PDP sponsor absent a determination by the prescribing physician, or to require that the physician's determination alone should result in a favorable coverage determination by the PDP. Thus, we propose to require that PDP sponsors also establish exceptions criteria for addressing these situations. Requiring sponsors to use an exceptions process to review requests for coverage of non-formulary drugs will create a more efficient and transparent process and will ensure that enrollees know what standards are to be applied. Additionally, requiring a similar exceptions process for conducting these types of reviews will help ensure that a PDP sponsor's formulary is based on scientific evidence rather than tailored to fit exceptions and appeals rules for formulary drugs.

Under this exceptions process, which we propose at § 423.578(b), a PDP must allow enrollees to request (1) Coverage of covered Part D drugs that are not on a sponsor's formulary; (2) continued coverage of a drug the sponsor has

removed from its formulary; (3) an exception to a sponsor's policy regarding coverage for a step therapy; and (4) an exception to a sponsor's dosing limitation. A PDP's criteria would need to include a description of the criteria it will use to evaluate the prescribing physician's determination, clarify how the plan evaluates the relative safety and efficacy of the requested drug, and describe the cost-sharing scheme that will be applied if coverage is provided. Again, an enrollee, the authorized representative, or prescribing physician could request an exception, and the PDP sponsor may require a written certification from the prescribing physician that the non-covered drug is medically necessary to treat the enrollee's disease or medical condition. An enrollee would have a right to a redetermination by the PDP of any unfavorable coverage determination.

Like for tiering exceptions, we are proposing that enrollees be required to request reconsideration by an independent review entity (IRE), as opposed to having these cases automatically forwarded to the IRE. We welcome comments on both these issues.

c. Treatment of Determinations Regarding Exceptions Requests

From a procedural standpoint, we propose at § 423.578(c)(1) that determinations on exception requests constitute plan coverage determinations under § 423.566 and should be completed in the same timeframes. Enrollees would then have an opportunity to request a plan redetermination. Unfavorable redetermination decisions could then be appealed to the independent review entity. The IRE's review would focus on whether the PDP had properly applied its formulary exceptions criteria for the individual in question. If it determined that the PDP sponsor correctly applied its exceptions criteria, the sponsor's determination would be upheld. Thus, the IRE would not have any discretion with respect to the validity of the plan's exceptions criteria or formulary. (CMS would be responsible for evaluating and approving a PDP's exceptions criteria and formulary as part of the annual plan approval process.) In many instances, however, evaluating whether the criteria for a formulary exception had been satisfied would necessarily involve an element of medical judgment (*e.g.*, would a patient suffer significant adverse effects by using the plan-preferred drug?). In those situations, the IRE's medical staff would be responsible for reviewing the sponsoring plan's determination as to whether the formulary exceptions criteria had been applied properly. Note that part D enrollees could subsequently access higher levels of the appeals process like for any other unfavorable coverage determination, consistent with the statutory reference to section 1852(g)(4) and (5) of the MA provisions.

Although not required by statute, we thought it important to put in place certain safeguards regarding the issuing and effect of a coverage determination made as part of the exceptions process. We believe that these safeguards will help to ensure that the exceptions process is both fair and efficient for enrollees. First, to ensure that enrollees who file exceptions requests for drugs that are being removed from a sponsor's formulary are not disadvantaged by a sponsor's failure to issue a timely decision, we establish in § 423.578(c)(1) and § 423.578(c)(2) that if a sponsor fails to issue a timely decision, the sponsor must continue to provide coverage until a decision is made on the request. Section 423.578(c)(2)(i) allows enrollees to receive up to a one-month supply of the requested drug, but a sponsor could adjust the supply to account for a shorter time frame.

Once a sponsor approves an exceptions request, we believe an enrollee should not have to continue filing exceptions requests for future refills of the drug. Therefore, we provide in § 423.578(C)(3) that once a sponsor approves a drug pursuant to the exceptions process, an enrollee is entitled to continue receiving refills of the drug for as long as the physician continues prescribing the drug and for as long as the drug continues to be considered safe and effective for treatment of the enrollee's disease or medical condition.

The final safeguard implemented under § 423.578 prohibits PDP sponsors from assigning drugs approved under either exceptions process to a special formulary tier, co-payment, or other cost-sharing requirement. In other words, sponsors must employ reasonable criteria (for example, the cost of the requested drug compared to the cost of other similar drugs on the plan's formulary) in determining the co-payments or other cost-sharing requirements of drugs approved for coverage under the exceptions process.

We recognize that these provisions represent a critical component of the new prescription drug benefit, and we particularly welcome suggestions from commenters on these proposals. Our goal is to foster the establishment of exceptions processes that employ criteria designed to maximize available drug benefits for all Medicare beneficiaries, while ensuring that plan sponsors have the flexibility they need to negotiate the best process on behalf of enrollees.

6. Appeals

a. Redeterminations (§ 423.580 Through § 423.590)

Sections 423.580 through § 423.590 explain the right to a redetermination and the requirements that apply to PDP sponsors for both standard and expedited redeterminations. If a decision regarding a coverage determination is unfavorable (in whole or in part) to the enrollee, the enrollee may file an oral or written request with the PDP or MA–PD plan for a redetermination on the decision. Note that, unlike the existing MA regulations, the proposed regulations would not identify Social Security Administration (SSA) field offices as a possible location for filing redetermination requests. Using any filing location other than the plan itself can significantly affect the speed with which the appeal is resolved. Moreover, given that section 931 of the MMA mandates the transfer of responsibility for Medicare appeals from SSA to DHHS by no later than October 1, 2005, we believe that an explicit regulatory reference to SSA field offices would not be appropriate.

For an expedited redetermination, an enrollee or the prescribing physician (acting on behalf of an enrollee) may submit an oral or written request for redetermination. However, requests for payment of drugs already received cannot be expedited. The proposed requirements for making standard redetermination determinations of covered benefits in § 423.590(a) specify that the PDP sponsor must issue its determination as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date of receipt of the request. Under § 423.590(b), for standard redeterminations involving requests for payment, the PDP sponsor must issue its redetermination no later than 60 calendar days from the date of receipt of the request. In the case of expedited redeterminations, § 423.590(d) specifies that a PDP sponsor must complete its redetermination and give the enrollee and the prescribing physician involved, as appropriate, notice of its decision as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request. For both the standard and expedited redetermination for covered benefits, the PDP sponsor may extend the timeframe for making its determination

by up to 14 calendar days if the enrollee requests the extension, or if the sponsor justifies a need for additional information and how the delay is in the interest of the enrollee. An extension would not be provided for redeterminations involving requests for payment.

If the PDP sponsor's redetermination results in an affirmation, in whole or in part, of its original adverse coverage determination, the sponsor must give written notification to the enrollee and advise the enrollee of the right to file an appeal with the IRE that contracts with CMS.

b. Independent Review Entity (IRE) Reconsideration (§ 423.600 Through § 423.604)

The MMA gives the Secretary the flexibility to establish an appeals process similar to that used for the MA appeals process. Thus, the proposed IRE reconsideration process set forth at § 423.600 through § 423.604 is much like that applicable to MA organizations under Part C. Note that when the PDP sponsor's redetermination affirms, in whole or in part, its adverse coverage determination, any issue remaining in dispute may be appealed by the enrollee to the IRE that contracts with CMS. However, unlike under the MA program, PDP sponsor redeterminations involving tiering issues or coverage of a non-formulary drug would not be automatically forwarded to the IRE. Instead, an enrollee would need to request an IRE review. This proposed requirement modifies the MA procedure that affords automatic referral to the IRE whenever the MA organization's original denial is upheld by the organization's redetermination. We believe that this change is appropriate given the statutory limitation that an appeal request be made only if the prescribing physician determines that all covered Part D drugs on the formulary would not be as effective or would have adverse effects. Moreover, many of the drug appeals may involve relatively small monetary amounts, raising doubts about the efficacy of forwarding all such cases to an IRE.

Thus, § 423.600 proposes that an enrollee who is dissatisfied with the PDP sponsor's redetermination may file a written request for reconsideration by the IRE. We also propose that when an enrollee files for an appeal, the IRE is required to solicit the views of the prescribing physician. Also, in order for an enrollee to request a reconsideration of a PDP sponsor's determination not to provide for a covered drug that is not on the PDP formulary, the prescribing physician must determine that all covered part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the nonformulary drug, would have adverse effects for the individual, or both.

Section 423.602 proposes the requirements for the IRE reconsideration determination notice, including the requirement that if the determination is adverse (that is, does not completely reverse the PDP sponsor's adverse coverage determination), the enrollee must be informed of the right to request an ALJ hearing and the procedures that must be followed to obtain the hearing.

Section 423.604 of our proposed rule explains that a reconsideration by the IRE is final and binding on the enrollee and the PDP sponsor, unless the enrollee requests an ALJ hearing.

c. Administrative Law Judge (ALJ) Hearings, Medicare Appeals Council (MAC) Appeals, and Judicial Review (§ 423.610 Through § 423.630)

As stated above, Section 1860D–4(h)(1) of the Act merely requires the Secretary to establish a reconsideration and appeals process that is "similar" (as determined by the Secretary) to the process used for MA organizations under the authority of 1852(g)(4) and (5) of the Act. Although we believe the Congress gave us a good deal of discretion in designing these procedural rules under Part D, we have determined as a policy matter to adopt most of the ALJ, MAC, and judicial review procedures currently used in the MA program.

Section 1852(g)(5) of the Act provides the right to a hearing and to judicial review for an enrollee dissatisfied by reason of the enrollee's failure to receive a covered Part D drug to which he or she believes he or she is entitled, and at no greater charge than he or she believes he or she is required to pay. Section 1852(g)(5) of the Act also specifies the amount in controversy needed to pursue a hearing and judicial review and authorizes representatives to act on behalf of individuals that seek appeals. In general, we would be implementing section 1869 changes that apply to Part D through cross-reference to the appropriate Part 405 regulations.

If the IRE's reconsideration determination is not fully favorable, the enrollee may request a hearing before an ALJ if the amount remaining in controversy meets the threshold requirement established annually by the Secretary. The threshold requirement will be published annually in the **Federal Register.** Although a PDP sponsor generally is not a party to the IRE appeal and may not request a hearing before an ALJ, the sponsor is considered a party to the ALJ hearing for the limited purpose of participation in the hearing. If the ALJ hearing does not result in a fully favorable determination, the enrollee may request MAC review of the ALJ decision.

Following the administrative review process, the enrollee is entitled to judicial review of the final determination if the amount remaining in controversy meets the threshold requirement established annually by the Secretary and published in the **Federal Register.**

7. Effectuation of Reconsideration Determinations (§ 423.636 Through § 423.638)

Sections 423.636 and 423.638 propose the requirements for effectuation of coverage determinations reversed by the PDP sponsor, redeterminations reversed by the independent review entity, or reversals by an ALJ or higher level of appeal. For example, § 423.636(a)(1) requires that for redeterminations of requests for benefits, if the PDP sponsor reverses its determination, it must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the date it receives the request for redetermination. When the PDP sponsor is reversed by the independent review entity, § 423.636(b)(1) requires that it must authorize the benefit under dispute within 72 hours from the date it receives notice reversing the redetermination, or provide the benefit as expeditiously as the enrollee's health requires, but no later than 14 calendar days from the date of the reversal notice. For redeterminations of requests for payment, § 423.636(a)(2) requires that if the PDP sponsor reverses its coverage determination, it must pay for the benefit no later than 60 calendar days after the date it receives the request for reconsideration. Under § 423.636(b)(2) if a sponsor's redetermination is reversed by the independent review entity, it must pay for the benefit no later than 30 calendar days from the date it receives notice reversing the redetermination.

Section 423.638 proposes that for expedited redeterminations reversed by the PDP sponsor or the independent review entity, the PDP sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires but no later than 72 hours after the date it receives the request for redetermination, or in the case of reversal by the independent review entity, from the date it receives the reversal notice.

Finally, for reversals by an ALJ or higher level of appeal, under § 423.636(c) and § 423.638(c) the PDP sponsor must pay for, authorize, or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date it receives notice reversing its determination.

8. Federal Preemption of Grievances and Appeals

We believe that the grievance procedures for the Part D Drug Program under Title I should be the same as those that apply to the MA program under Title II.

Section 232(a) of the MMA amended 1856(b)(3) of the Act so that it now reads: "The standards under this part shall supersede any State law or regulation (other than State licensing laws or State law relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part." Section 1860D–12(g) of the Act then incorporates this preemption rule for PDP sponsors and prescription drug plans. As we discussed earlier in Part I of this preamble, we believe that these preemption provisions would not cause all State laws to be superseded—particularly in areas where we have no authority to regulate. In the context of our grievance and appeals rules, because our regulations provide for doing so, we would continue to defer to state law on the issue of authorized representatives of enrollees in the appeals process. We do not believe that the Congress intended for the Secretary to regulate matters for which the Secretary is not authorized to promulgate standards (for example, spousal rights, powers of attorney, or legal guardianship). Often, authorized representative matters are non-Federal issues. However, because we do have the authority to regulate in the field of grievances, we are concerned that state grievance requirements will now be preempted, and we may need to reexamine our Federal grievance requirements. We request comments on this preemption issue and the specific state grievance requirements that should be incorporated into Federal regulatory requirements at § 423.564.

We also note that tort law, and often contract law, are generally developed based on case law precedents established by courts, rather than by legislators through statutes or by state officials through regulations. In addition, we do not believe we would have the authority under Part D to set specific tort remedies or to govern resolution of private contracting disputes between PDPs and MA–PDs and their subcontractors. We believe that the Congress did not intend for our regulations to supersede each and every State requirement applying to MA–PDs and PDPs—even those for which the Secretary lacks expertise and authority to regulate. Thus, we do not believe, for example, that wrongful death or similar law suits based upon tort law would be superseded by the appeals process established in these regulations. Similarly, State contract law would continue to govern private contract disputes between PDPs or MA–PDs and their subcontractors.

Under principles of Federalism, and Executive Order 13132 on Federalism, which generally require us to construe preemption narrowly, we believe that an enrollee should still have state remedies available in cases in which the legal issue before the court is independent of an issue related to the organization's status as a stand alone PDP or an MA–PD plan.

9. Employer Sponsored Prescription Drug Programs and Appeals

The waiver provisions of section 1857(i) of the Act were incorporated into Part D through section 1860D–22(b) of the Act. When an employer, whether by contracting with MA–PDs or PDPs or otherwise, provides prescription drug benefits in addition to those covered under Part C and Part D of Title XVIII of the Social Security Act to their retirees, such employer may have established a group health plan governed by both Title I of the Employee Retirement Income Security Act of 1974, as amended (ERISA), and State law (to the extent such State law is not preempted by ERISA). In addition, when MA–PDs, PDPs, and programs described in 42 U.S.C. 1395w–132 offer benefits covered under Part D, they also would fall under the requirements of Part 423 of our proposed regulations, with respect to Part D benefits.

In drafting our Part C, MA rules, we consulted the Department of Labor (DOL), employer groups, and the health plan industry in trying to eliminate unnecessary Federal regulation of claims and appeals issues that impact matters within the jurisdiction of both DOL and DHHS. Based on our experience under Part C, we have reason to believe that some Medicare eligible individuals may receive integrated prescription drug benefits, *i.e.*, Part D benefits through an MA–PD, PDP, or program described in 42 U.S.C. 1395w–132 and supplemental benefits through an ERISA-covered plan. For example, an employer-sponsored plan may pay the cost-sharing amount for a prescription drug that is offered by an MA–PD or PDP. Clearly, if the enrollee had a dispute about Part D coverage, he or she could file an appeal with the PDP sponsor. If the enrollee's dispute involved only the amount of cost sharing paid by the employer-sponsored plan, he or she would file an appeal in accordance with the procedures of the ERISA covered plan. In some cases, however, the dispute might involve independent coverage decisions under both Part D and the ERISA plan; possibly necessitating parallel appeal procedures on the same case. In this regard, we are soliciting comments on whether, and to what extent, the application of parallel procedures in this context might be a problem for plans, employers, and/or eligible individuals. We also are soliciting suggestions for addressing problems, if any, resulting from the application of parallel procedures.

N. Medicare Contract Determinations and Appeals

(If you choose to comment on issues in this section, please include the caption "Subpart N—Medicare Contract Determinations and Appeals" at the beginning of your comments.)

1. Overview

Section 1860D–12(b)(3)(F) of the Act directs that the "procedures for termination" in section 1857(h) of the Act be incorporated into contract requirements for PDP sponsors. To enhance the flow of this proposed rule, we have separated the provisions of section 1857(h) of the Act into two portions and addressed the two portions in different subparts of this part.

2. Proposed Provisions of the Subpart

As discussed above, § 423.509 of subpart K of this part implements the provisions of sections 1857(h)(1)(A) and 1857(h)(2) of the Act that address reasons for our termination of contracts, opportunity for PDP sponsors to develop a corrective action plan before termination, and procedures for immediate termination if we identify an imminent and serious health risk to enrollees.

Sections 423.641(b) through 423.669 specifies the procedures outlined in section 1857(h)(1)(B) of the Act. These sections specify that we would provide the organization with reasonable notice and opportunity for hearings (including the right to appeal an initial decision) before termination of its contract. Additionally, the requirements at § 423.641(a) specifies the procedures for making and reviewing our

determination that an entity is not qualified to enter into a contract as a PDP sponsor under this part. Finally, § 423.641(c) identifies procedures for reviewing our decision as specified at § 423.507(b) not to renew a contract with a PDP sponsor.

Section 1860D–12(b)(3) of the Act states that we must apply certain specified provisions of section 1857 of the Act including the procedures for termination in section 1857(h) of the Act in the same manner as they apply to contracts under section 1857(a) of the Act. Therefore, we are proposing that a single set of procedures relating to contract determinations and appeals apply to both MA and PDP sponsor contractors. The requirements at § 423.641 through § 423.669 would mirror the requirements at § 422.641 through § 422.698 for the MA program.

A summary of the specific process and content of the proposed appeals and determination system for PDP sponsors found in this subpart are below.

Sections 423.641 through 423.669 of our regulations detail the specific process and content of the appeals and determinations system, as it relate to PDP sponsors. The topics covered in these sections fall into the following five categories:

(1) *Contract determinations.* Sections 423.641 through 423.643 would describe the types of ccntract determinations, the notice requirements, and the effect of contract determinations on the PDP sponsor contract.

(2) *Reconsideration.* Sections 423.644 through 423.649 would describe when a PDP sponsor organization may request a reconsideration of our contract determination, the procedures for requesting a reconsideration, the internal operation of the reconsideration, the notice requirements for relating the reconsideration determination to all parties, and the impact of this determination on the PDP sponsor's contract.

(3) *Hearing.* Sections 423.650 through 423.667 would discuss in detail the process surrounding a hearing, including when a hearing may be requested by a PDP sponsor and how to make the request, the internal operation of the hearing (for example, designation of participants in the hearing, witnesses and evidence that can be presented, and record of the hearing), and the notice and effect of the hearing decision on the PDP sponsor's contract. If the contractor has submitted a request for a hearing timely, the effective date of the contract determination may have been postponed pending the reconsideration determination. Finally, this section discusses the right for review of the hearing decision by the Administrator and the effect of that review decision.

(4) *Reopening.* Section 423.668 would present the opportunity for reopening of the contract or reconsidered determination of a hearing officer or the Administrator.

O. Intermediate Sanctions

(If you choose to comment on issues in this section, please include the caption "Subpart O'Intermediate Sanctions" at the beginning of your comments.)

1. Overview

Supbart O would implement most of the provisions of section 1860D–12(b)(3)(E) of the Act. This section of the statute provides that the contract requirements at section 1857(g) of the Act that govern "intermediate sanctions" for Medicare Advantage (MA) organizations, with a few exceptions, will apply to contracts for PDP sponsors. Therefore, with two exceptions, the requirements in § 423.750 through § 423.760 would mirror the requirements at § 422.750 through § 422.760. The two changes we are proposing to make to comply with the MA provisions are found below in the section called, "Basis for Imposing Sanctions."

Freezing marketing or enrollments has generally been our first and most frequently used sanction authority. The MMA requires at least two qualified plans, that is a PDP per region. If we were to freeze the enrollment or marketing of a PDP sponsor, that is one of only two plans in a region, beneficiaries would no longer have the level of choice the MMA intended. If we are contemplating sanctioning a plan that is one of only two PDP sponsors in a region, we may have to consider using other remedies including civil monetary penalties to maintain an adequate level of choice for beneficiaries. However, we do not want to discriminate in our treatment of PDPs when imposing sanctions. Our goal would be to have consistent policies and procedures across all regions in regard to sanctions. Therefore, we request comment on whether closing enrollment should be used in any situation or should we generally rely on civil monetary penalties as a sanction for PDPs.

2. Kinds of Sanctions (§ 423.750)

Section 423.750 of our regulations would describe four types of sanctions that we may impose on PDP sponsors, if warranted under § 423.752. These sanctions are identical to those we have imposed on M+C contractors. The range of potential sanctions, and the fact that one or more of them may be imposed at any one time, would permit us to tailor our action to a specific situation.

Three of these sanctions would disrupt the operation of the PDP sponsor in relation to Medicare beneficiaries (that is, suspension of new enrollment (§ 423.750(a)(2), suspension of our payments to the PDP sponsor for enrolled beneficiaries (§ 423.750(a)(3), and suspension of all marketing activities (§ 423.750(a)(4)). We may keep the sanction in force until we are satisfied that the organization has corrected and will not repeat, the deficiency on which the sanction was based.

The fourth sanction that we could impose on an organization is civil monetary penalties ranging from $10,000 to $100,000, depending on the violation. Both the Office of the Inspector General (OIG) (§ 423.756(f)(2)) and CMS (§ 423.756(f)(3)) may impose civil monetary penalties.

3. Basis for Imposing Sanctions (§ 423.752)

Sections 423.752(a) and 423.752(b) of our regulations would list the seven violations for which sanctions may be imposed on a PDP sponsor organization. These violations are the same as those that warrant the imposition of sanctions for MA contractors, with the exception of two deletions we are proposing below. Specifically, sanctions would be imposed if the PDP sponsor engages in any of the following:

(1) Fails to provide required medically necessary services with adverse effect on the enrollee.

(2) Imposes premiums on beneficiaries that are in excess of those permitted in subpart F of part 423 of these proposed regulations.

(3) Expels or will not re-enroll a beneficiary in violation of this part.

(4) Engages in the practice of health screening or "cherry picking."

(5) Misrepresents or falsifies information furnished to CMS, any other entity or individual under the Part D drug benefit program.

(6) Employs or contracts with an individual or entity excluded from participation in the Medicare program as specified under section 1128 or 1128A of the Act (or with an entity that employs or contracts with the individual or entity) for the provision of certain services.

Additionally, as an alternative to the sanctions listed above, we would be able to decline to authorize renewal of the organization's contract (or may elect to terminate the contract entirely in accordance with § 423.509). In addition, § 423.509(a) would provide that a PDP sponsor organization be sanctioned if it

fails to carry out the terms of its contract as specified under this section.

Section 1860D–12(b)(3)(E) of the Act would specifically exclude two of the bases for sanctions at section 1857(g)(1) of the Act for MA contractors from application to PDP sponsor organizations as specified in part 423. Specifically, we would not impose sanctions on a PDP sponsor in the event it fails to enforce the limit on balance billing under a private-fee-for-service plan as required at § 422.216(a)(4), or fails to prohibit interference with practitioners' advice to enrollees, as required at § 422.206, since we do not believe these provisions are applicable in the context of the Part D drug benefit.

4. Procedures for Imposing Sanctions (§ 423.756)

Section 423.756 of our proposed regulations would specify our procedures for conducting the sanction process for PDP sponsor organizations. This process would mirror that used for the MA program. A brief summary of the process is as follows—

- We must send a timely notification of sanction to the PDP sponsor, outlining the nature and basis of the proposed sanction, and copy OIG.
- We must provide the PDP sponsor with an 15 or 30 day extension, to respond. If requested, an uninvolved CMS official will conduct an informal reconsideration of the determination with a written decision.
- Non-monetary sanctions would be effective 15 days from the organization's receipt of a final notice of sanction and remain in effect until we determine that the violation is corrected. CMS or the OIG, depending on the basis for the sanction, may impose civil monetary penalties.

5. Maximum Amount of Civil Money Penalties Imposed by CMS (§ 423.758)

Section 423.758 of our proposed regulations would provide that we be given discretion, as we have been in the M+C program, to determine the amount of monetary penalty to impose on a PDP sponsor within the limits specified at § 423.758. Three situations where monetary penalty limits are listed are as follows—

(1) If the deficiency in which the determination was based has adversely affected the health of an enrollee (or has substantial probability of doing so), the penalty may be $25,000 per determination.

(2) We may apply a monetary penalty for each week that a deficiency remains uncorrected after the organization receives our notice of sanction or notice of reconsideration determination, up to $10,000 per week.

(3) If we determine that a PDP sponsor has terminated its contract without following the process required in subpart K at § 423.510, the penalty imposed may be either $250 per Medicare beneficiary enrolled in the organization at the time the PDP sponsor terminated its contract, or $100,000, whichever is greater.

6. Other Applicable Provisions (§ 423.760)

Section 423.760 of our proposed regulation provides that the provisions of section 1128A of the Act (except subsections (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A of the Act.

P. Premiums and Cost-Sharing Subsidies for Low-Income Individuals

Section 1860D–14 of the Act establishes a program to provide subsidies for assistance with premium and cost-sharing amounts for Part D eligible individuals with lower income and resources. The proposed regulations in this subpart and in regulations published by the Social Security Administration (SSA) adding a subpart D to a new part 418 of title 20 of the Code of Federal Regulations implement section 1860D–14 of the Act.

The statute divides subsidy eligible individuals into two different groups based on income and resources: (1) Full subsidy eligible individuals; and (2) other low-income subsidy eligible individuals. The different groups are entitled to different amounts of subsidy assistance. In this proposed regulation, we are defining the eligibility criteria and the amounts of subsidy assistance provided.

1. Eligibility for the Low-Income Subsidy (§ 423.773)

In order to qualify for a full subsidy, an individual must live in one of the fifty States or the District of Columbia and have countable income below 135 percent of the Federal poverty level for the individual's family size. For purposes of this section, "federal poverty line" (FPL) has the meaning given that term in section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)), including any revision required by that section.

In addition, an individual must have resources that do not exceed three times the resource limit under section 1613 for applicants for Supplemental Security Income (SSI) under title XVI, which in 2006 is $6,000 if single, or $9,000 if married. Thereafter, this resource limit will be increased annually by the percentage increase in the Consumer Price Index (all items, U.S. city average) as of September for the year before, rounded to the nearest multiple of $10.

Individuals not eligible for the full subsidy may be eligible for the partial subsidy if they live in one of the fifty States or the District of Columbia and have income below 150 percent of the FPL for their family size, and have resources in 2006 that do not exceed $10,000 if single, or $20,000 if married. Beginning in 2007 and for each subsequent year, the resource limit will be increased annually by the percentage increase in the Consumer Price Index (all items, U.S. city average) as of September for the year before, rounded to the nearest multiple of $10.

Low-income Part D eligible individuals who reside in the territories are not eligible to receive premium and cost-sharing subsidies under this subpart. Subpart S of this proposed rule addresses the provision of covered Part D drugs to low-income individuals residing in the territories.

In making income and resource determinations for the low-income subsidy for Part D, the statute refers to certain sections of the SSI program rules. For example, the MMA refers to income being determined in the same manner as for Qualified Medicare Beneficiaries (QMBs) under the Medicaid program, without use of the more liberal methodologies that States are permitted to use. The QMB provisions reference the SSI rules (specifically, section 1612 of the Act, which are the rules of the SSI program for determining income). Our proposed definition of income is consistent with the MMA in that it references SSI rules.

The MMA provides that we will compare the individual's income to the appropriate FPL applicable to "the family of the size involved." As there is no reference in the MMA statute to using previous definitions of family size, we propose to define family size to include the applicant, his or her spouse who lives in the same residence, and the number of individuals related to the applicant who live in the same residence and who depend on the applicant or the applicant's spouse for at least one-half of their financial support.

We considered limiting family size to 1 or 2 individuals to more closely resemble the SSI rules where family size is not actually defined but where benefits are paid on the basis of an eligible individual or eligible couple. This is the definition we propose to use

in determining eligibility for Transitional Assistance under the drug card. The decision to limit family size under the drug card was based on the short duration of that program (18 months), the limited benefit ($600 a year), and the fact that we would have to rely entirely on a computer and systems-based process for determining Transitional Assistance eligibility and verifying income and other information from applicants. However, we do not believe it was the intent of the Congress to similarly limit the definition for purposes of determining eligibility for subsidies under the Part D program. Unlike the provisions authorizing the Medicare-approved drug discount card program, there are no provisions with respect to the low-income subsidy program that give the Secretary specific authority to define family size. Instead, we are interpreting the term "family of the size involved." We believe that this term implies a definition that is greater than an individual or couple and that includes other dependent relatives residing in the applicant's household. In addition, in order for the term "family size" to have meaning in the context of subsidy determinations, the notion of dependency needs to take into account the impact of a dependent on the relative need of the applicant or the applicant's spouse in attaining the subsidy. Accordingly, we have specified that dependents included in the calculation of family size are only those relatives residing in the residence who are financially dependent on the applicant or the applicant's spouse for one-half of their support.

In determining the income to be compared to the FPL for the size of the family involved, we would include income of the Medicare beneficiary and spouse, if any. Thus, if a married individual applies, both the income of the applicant and his or her spouse who lives in the same residence, regardless of whether the spouse is also an applicant, is counted and measured against the appropriate standard for the low-income subsidy. In our view, this best comports with the statutory reference to determining income in the manner described in section 1905(p)(1)(B) of the Act (for QMBs). In making a standard QMB income determination, States will consider the income of one spouse as available to the other spouse. Moreover, since both spouses will be considered in the family size determination, it would be counterintuitive to count a spouse's presence while not including that spouse's income. Other members who meet the one-half support test will be counted in the family size calculation, but income of these dependents will be ignored in the eligibility determination. The one-half support test ensures that a family member with sizable income is not erroneously counted as a dependent while that person's income is ignored.

The MMA (at section 1860D–14(a)(3)(D)) provides that resources will be determined according to section 1613 of the Act. The resource standard depends upon whether the applicant is a single individual or a member of a married couple and whether the resources will be measured against the basic or alternative resources standards. See section 1860D–14(a)(3)(D) and (E) and H.R. Conference Report No. 108–391 at 470. However, that section does not define resources, it defines what are not resources. The MMA also provides for the development of a simplified application in which applicants attest to their level of resources and submit only minimal documentation. The implication of this provision is that the Congress envisioned a simple process. In order to keep the process simple and minimize administrative cost, we intend to only consider liquid resources (that is, those that could be converted to cash within twenty days) and real estate that is not an applicant's primary residence as resources that are available to the applicant to pay for the Part D premiums, deductibles and copayments. Thus, we will not consider other non-liquid resources (for example, a second car) to be available to the applicant for this purpose.

We do not believe this policy will have a significant impact on program costs. We believe any such program costs associated with not counting non-liquid resources other than countable real estate would be offset by the administrative savings resulting from a more simplified program. As we indicate further in this section, we are working with SSA on a quality assurance strategy that will strike an appropriate balance between administrative costs and program goals and objectives.

Section 1860D–14(a)(3)(B)(v)(I) of the Act requires that full-benefit dual eligibles (as defined under section 1935(c)(6) of the Act) and individual receiving benefits under the SSI program be treated as full subsidy eligible individuals with respect to premium assistance, elimination of the deductible, continuation of coverage above the initial coverage limit, and elimination of cost-sharing above the annual out-of-pocket threshold. However, copayment subsidies for these individuals will vary depending on whether the individual is in an institution or has income below or above 100 percent of the FPL. Full benefit dual eligible individuals with income above 100 percent of the FPL will have copayments not to exceed $2 for a generic or a preferred multiple source drug or $5 for an other drug.

Under Medicaid, the term "dual eligibles" generally refers to low-income Medicare beneficiaries who qualify for some level of medical assistance. Those entitled to full benefits under Medicaid generally have most of their health care expenses, including prescription drugs, paid for by a combination of Medicare and Medicaid. However, Federal law also specifies several groups of dual eligibles who, while not entitled to full Medicaid benefits, are entitled to more limited medical assistance, specifically payment of Medicare Part A or Part B premiums and/or cost sharing, such as payment of Medicare deductibles and coinsurance. These groups are certain QMBs, specified low-income Medicare beneficiaries (SLMBs), qualified disabled and working individuals (QDWIs), and certain qualifying individuals (QIs).

For purposes of the low-income subsidy under Part D, we propose to define the term "full benefit dual eligible individual" as an individual who for any month has coverage under a PDP or MA–PD and is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. Comprehensive benefits referred to in this section do not include those benefits received under section 1115 Pharmacy Plus demonstrations. For individuals who become medically needy by spending down excess medical expenses, the individual is not eligible as medically needy until he or she satisfies their spenddown obligation. This requirement is reflected in the proposed regulations at § 423.772.

Section 1860D–14(a)(3)(B)(v)(II) of the Act authorizes the Secretary to treat QMBs, SLMBs, and QIs who are not full benefit dual eligible individuals as full subsidy eligible individuals. This authority does not apply to QDWIs. As indicated in the proposed regulations at § 423.773(c), the Secretary proposes to elect to exercise this authority and treat these individuals as being eligible for full subsidy assistance. This decision is based on the fact that nearly all QMBs, SLMBs, and QIs, by definition, will likely meet the requirements to be considered a full subsidy individual. Generally, QMB, SLMB, and QI individuals have income below 135

percent of the FPL and resources that do not exceed twice the SSI limit. The exception will be in the few States that have more liberalized income and asset rules for these groups under section 1902(r)(2) of the Act. We do not believe that treating these groups as subsidy eligible will have a large cost impact. Further, we believe that it will ease the administrative burden of having to educate these individuals on the need to apply for the subsidy.

Section 1860D–14(a)(1) distinguishes between noninstitutionalized full benefit dual eligible individuals with incomes at or below 100 percent of the FPL and other non-institutionalized individuals covered as full subsidy eligibles. This distinction is made solely for purposes of the reduction in cost-sharing below the out of pocket threshold. Therefore, full benefit dual eligibles (and, as proposed above, at the Secretary's election QMBs, SLMBs, and QIs) receive a full premium subsidy, have no annual deductible, and have coverage above the initial coverage limit. However, with respect to cost-sharing below the out-of-pocket threshold, these individuals have a two-tiered system depending upon whether their incomes are at or below 100 percent of the FPL or above 100 percent of the FPL. For those noninstitutionalized full benefit dual eligible individuals below 100 percent of the FPL, a copayment is imposed that does not exceed the lesser of $1 for a generic or a preferred multiple source drug or $3 for any other drug, or the amount charged to other individuals with income below 135 percent of the FPL who meet the resource standard based on three times the SSI standard. For individuals in this group above 100 percent of the FPL, a copayment not exceeding $2 for a generic or a preferred multiple source drug is imposed, or $5 for an other drug.

Finally, the statute gives the Secretary the option to permit a State to make subsidy eligibility determinations by using the methodology it uses under section 1905(p) of the Act if the Secretary determines that this would not result in any significant difference in the number of individuals who are made eligible for the subsidy. This would permit a State to use the same resource methodologies that it uses to determine Medicaid eligibility for QMBs, SLMBs, and QIs if the Secretary determines that the use of those methodologies would not result in any significant differences in the number of individuals who are made eligible for a subsidy. This includes the less restrictive methodologies the State uses under section 1902(r)(2) of the Act to determine eligibility for QMBs, SLMBs, and QIs. At this time, the Secretary proposes not to exercise this option.

This means that when making eligibility determinations for other low-income subsidy eligibles, all States will use the same resource methodologies across the country. The rationale for not electing this authority is twofold. First, uniformity in the application process is a desired goal and having alternative resource methodologies that would vary among States would detract from that goal. Second, based on the administrative burden and complexity that would be involved in administering this alternative process, we see very little benefit in terms of the number of individuals who would be determined subsidy eligible.

2. Eligibility Determinations, Redeterminations and Applications (§ 423.774)

In accordance with section 1860D–14(a)(3)(B)(i) of the Act, an application for subsidy assistance may be filed with either a State's Medicaid program office or SSA. Inquiries made by individuals to PDPs or MA–PDs concerning application or eligibility for the low-income subsidy should be referred to State agencies or SSA. Eligibility determinations would then be made by the State for applications filed with the State Medicaid agency or by the Commissioner of Social Security for those filed with SSA. The Congress believes that more beneficiaries would enroll in the new Part D benefit if given the option to apply at the Social Security office as well as State Medicaid offices. While our goal is to provide a single application and determination process for the low-income subsidy, we recognize that the statute provides that redeterminations and appeals of eligibility determinations are to be made in the same manner as for medical assistance for those individuals who are determined eligible by the State Medicaid agency. Similarly, the Commissioner will decide how to conduct redeterminations and appeals for those subsidy determinations made by Social Security. We invite comments on State Medicaid agency procedures how to best implement the redetermination and appeal process that we believe would best be accomplished if the two separate processes produce the same outcome.

We note that eligibility determinations for low-income subsidies would be effective beginning with the first day of the month in which the individual applies for a subsidy, but no earlier than January 1, 2006, provided the applicant meets the requirements for eligibility when he or she applies and has enrolled with a prescription drug coverage provider or MA plan with prescription drug coverage. Initial eligibility determinations would remain in effect for a period not to exceed 1 year.

Because States and Social Security offices would be performing subsidy determinations, States and SSA would need to share data with CMS. We will then use the data to notify the PDP sponsor or MA organization of the individual's eligibility. We will also use the data to provide information on income so that PDP sponsors and MA organizations may determine the amount of Part D premiums and copayments that may be charged to an individual eligible for the low-income subsidy as discussed later in this preamble.

Section 1860D–14(a)(3)(E)(ii) of the Act directs the Secretary and the Commissioner of SSA to develop a model simplified application form for the determination and verification of Part D eligible individual's assets or resources for the other low-income subsidy provision. We believe it is important to develop a simplified application for income as well as resources and to develop an application that will address both the full and the other low-income subsidy provisions. Therefore, we are working with SSA to develop a model application form to be used to determine eligibility for all subsidies. The application will reflect the definitions of income and resources discussed earlier in this subpart.

With regard to the method and degree to which income and resources will be verified, our general policy is to not spend more on verification than the expected return in terms of benefit savings. Therefore, we intend to use the most efficient and cost-effective process that will balance the need for program integrity with the goal of reducing paperwork burden and cost.

We envision a process based on an operations research strategy whereby States and SSA will build on existing verification processes used for other programs. We plan on maximizing the use of automated data matches for verification of income and certain liquid resources (which minimize both paperwork burden and cost), and relying on specific targeting or profiling criteria derived from a database that would identify a subset of applications for purposes of in-depth verification. This in-depth verification process will enable SSA and States to focus on elements attested to by the applicant that do not lend themselves to verification by electronic means (that is,

countable real estate). By developing a targeted approach, we believe we can strike an appropriate balance between administrative costs and program goals and objectives. We request comments on this approach.

In developing a simplified application, we also considered a number of other issues in order to streamline the application process. For example, the proposed rules permit a personal representative to assist in the application process. We are proposing to define personal representative as an individual who is authorized to act on behalf of the applicant, an individual acting responsibly on behalf of an applicant who is incapacitated or incompetent, or an individual of the applicant's choice who is requested by the applicant to act as his or her representative in the application process.

In addition, we would permit the use of a proxy signature process to allow applications to be taken over the phone or by an Internet process. Under a proxy signature process, an individual attests to the accuracy of the information provided under penalty of perjury prior to submitting the information for processing. Our proposed requirements specify that the individual applying for the low-income subsidy, or a personal representative on his or her behalf complete the application for the low-income subsidy, and certify as to the accuracy of the information provided.

Section 1860D–14(a)(3)(E)(iii)(II) of the Act provides that statements from financial institutions shall accompany applications in support of the information provided therein. As previously discussed, we believe States and SSA will be able to verify information through data matches. As a result, we would reduce an applicant's burden in producing financial statements by not requiring paper copies except when specifically requested. For example, SSA and States may verify some resources for the low-income subsidy through data matches with 1099 files from the IRS, which show the annual amount of interest earned on interest bearing accounts. If the data from the 1099 files indicates the applicant's interest is below a threshold amount relating to the resource limit and the applicant has no countable real estate, the State or SSA could decide that no further information is needed from the applicant relating to certain types of resources. When the threshold is exceeded, additional information may be requested of the individual to support the application. Use of this process would ease the burden on individuals preparing to file an application and will reduce the administrative burden on States and SSA in handling paper verification. Accordingly, § 423.774(d) requires the submission of statements from financial institutions only if requested by the State or SSA.

3. Premium Subsidy (§ 423.780) and Cost-Sharing Subsidy (§ 423.782)

In accordance with section 1860D–14 of the Act, the proposed regulations specify the Part D premium subsidy and the Part D cost-sharing subsidy amounts available to subsidy eligible individuals, with the specific subsidy amounts varying depending upon the individual's income and resources/assets level. Table P–2 below shows the premium and cost-sharing subsidy amounts for the different groups of eligible individuals.

a. Full Subsidy Eligible Individuals

In accordance with section 1860D–14(a)(1)(A) of the Act, full subsidy eligible individuals are entitled to a full premium subsidy equal to 100 percent of the "premium subsidy amount," not to exceed the basic premium for coverage under the prescription drug plan selected by the beneficiary.

Under section 1860D–14(b)(2) of the Act, the premium subsidy amount is equal to the greater of the low-income benchmark premium or the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the region. The premium subsidy determined would apply regardless of whether the individual enrolls in a PDP or MA–PD. However, in the event the low-income benchmark premium is less than the lowest monthly beneficiary premium for basic prescription drug coverage offered by a PDP sponsor in a PDP region, in accordance with section 1860D–14(b)(3) of the Act, the premium subsidy will be equal to the monthly beneficiary premium for basic prescription drug coverage offered by a PDP sponsor in the PDP region.

Under section 1860D–14(b)(2) of the Act, the low-income benchmark premium amount for a PDP region equals either the weighted average of the monthly beneficiary premiums for all basic prescription drug plans (if all prescription drug plans in the PDP region are offered by the same PDP sponsor), or the weighted average of monthly beneficiary premiums for basic prescription drug coverage and the monthly beneficiary premiums attributable to basic prescription drug coverage for alternative prescription drug coverage for both PDP and MA-PD plans. Because section 1860D–14(b)(2)(A)(ii) of the Act references section 1851(a)(2)(a)(i) of the Act, the premiums of cost plans under section 1876 of the Act, PACE plans, specialized MA plans for special needs individuals and private fee-for-service plans are excluded for purposes of determining the weighted average in the region. This is because section 1851(a)(2)(a)(i) of the Act refers only to MA coordinated care plans. We interpret the calculation of the "weighted average" as described in the regulations at § 423.279(b) of this proposed rule.

Table P–1 below is an illustration of the premium subsidy determination.

TABLE P–1.—DETERMINATION OF THE PREMIUM SUBSIDY

Plan options in region		Low-income premium subsidy (full)		
Plans	Monthly beneficiary premium [1]	Percentage of part D enrollees in each plan [2] (percent)	Premium times percentage (weighted average)	Maximum premium subsidy for eligible individual enrolling in plan
PDP 1 Offered by Sponsor A	40.00	15	6.00	36.00
MA–PD Plan 1	38.00	5	1.90	36.00
PDP 2 Offered by Sponsor B	36.00	40	14.40	36.00
MA–PD Plan 2	20.00	15	3.00	20.00
MA–PD Plan 3	0.00	25	0.00	0.00

TABLE P–1.—DETERMINATION OF THE PREMIUM SUBSIDY—Continued

Plan options in region		Low-income premium subsidy (full)		
Plans	Monthly beneficiary premium [1]	Percentage of part D enrollees in each plan [2] (percent)	Premium times percentage (weighted average)	Maximum premium subsidy for eligible individual enrolling in plan
Weighted Average Basic Premium in Region = ...	.....	.....	25.30	.....

The greater of the Low Income Premium Benchmark Amount (25.30) or the lowest PDP premium in the region (36.00) equals 36.00, so the maximum premium subsidy is the lower of 36.00 or the actual plan premium for basic coverage.
[1] Assumes no supplemental premium or late enrollment penalties.
[2] Assumes enrollment weights from the prior year's reference month (not first year of program).

Table P–1 illustrates the determination of the premium subsidy amount in a hypothetical region in which there are 2 PDPs, each offered by different sponsors, and 3 MA–PD plans. Because there are PDPs offered by more than one sponsor, the maximum premium subsidy amount is the greater of 2 amounts: the low-income premium benchmark amount or the lowest PDP premium in the region. The former is calculated by summing the products of the plan (basic) premium and the plan percentage of Part D enrollment in the region, and equals $25.30. The lowest PDP premium in the region, however, is $36.00. Therefore, in this exhibit, the full premium subsidy amount for the region is determined to be $36.00. Consequently, a Part D eligible individual meeting the requirements for a full premium subsidy would have a choice of 3 zero-premium plans in which to enroll (PDP 2, MA–PD 2, and MA–PD 3), because the maximum premium subsidy amount equals or exceeds the premiums for these plans. However, if this individual chose to enroll in PDP 1 or MA–PD 1 for some reason, he or she would be obligated to pay the difference between the plan premium and the premium subsidy amount ($4 or $2, respectively) each month.

We anticipate that fallback plan premiums would be treated the same as those for risk-bid plans in the calculation of the low-income benchmark premium amount.

In accordance with section 1860D–14(b)(2) of the Act, the low-income benchmark premium amounts are determined without the addition of any amounts attributable to late enrollment penalties.

Individuals eligible for the full premium subsidy who are subject to late enrollment penalties under proposed § 423.46 would also be entitled to a subsidy equal to 80 percent of any late enrollment penalty for the first 60 months in which the penalties are imposed, and 100 percent of any penalties in any subsequent month, in accordance with section 1860D–14(a)(1)(A)(ii) of the Act and proposed § 423.780(c).

Section 423.782 of the proposed rule incorporates the provisions of section 1860D–14(a)(1)(B), 1860D–14(a)(1)(C), 1860D–14(a)(1)(D), and 1860D–14(a)(1)(E) of the Act relating to the elimination of the deductible, continuation of coverage above the initial coverage limit (that is, no coverage gap), and reductions in cost-sharing. Specifically, full subsidy eligible individuals have no deductible. In addition, these individuals have continuation of coverage from the initial coverage limit (under paragraph (3) of section 1860D–2(b) of the Act and § 423.104(e)(3)) through the out-of-pocket threshold (under paragraph (5) of the same section). In other words, there is no coverage gap, or "donut hole," for these individuals.

In accordance with section 1860D–14(a)(1)(D)(i) of the Act, institutionalized full-benefit dual eligible individuals have no cost-sharing below the out-of-pocket threshold. We are proposing to define "institutionalized individual" for this subpart as a full-benefit dual eligible individual who is an institutionalized individual as defined in section 1902(q)(1)(B) of the Act.

Under section 1860D–14(a)(1)(D)(ii) of the Act, full-benefit dual eligibles in 2006 with incomes that do not exceed 100 percent of the poverty line for their family size will pay no more than $1 for generic drugs or preferred multiple source drug (as defined in section 1927(k)(7)(A)(i) of the Act). In addition, they would pay $3 for any other drug, or, if less, the amount charged to other individuals with income below 135 percent of poverty who meet the three times the SSI resource standard test, for costs below the out-of-pocket threshold. These $1 and $3 copayment amounts are increased beginning in 2007 by the percentage increase in the CPI (all items, U.S. city average), rounded to the nearest multiple of 5 cents. The cost-sharing subsidies would count toward the application of the out-of-pocket threshold.

After the out-of-pocket threshold is reached, cost-sharing would be eliminated for all full subsidy individuals and full benefit dual eligible individuals. In accordance with section 1860D–14(a)(1)(D)(iii) of the Act, all other full subsidy eligible individuals and full benefit dual eligibles with income above 100 percent of the FPL in 2006 will pay copayment amounts of $2 for a generic drug or preferred multiple source (as defined in section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug, for costs up to the out-of-pocket threshold. In accordance with section 1860D–2(b)(4) and 1860D–2(b)(6) of the Act, these copayments are indexed based on an annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents (see § 423.104(e)(5) of this proposed rule). Also, all other full subsidy eligible individuals and full benefit dual eligible individuals have continuation of coverage from the initial coverage limit (under paragraph (3) of section 1860D–2(b) of the Act and § 423.104(e)(3)) through the out-of-pocket threshold (as specified under paragraph (4) of the section), with limited cost-sharing.

After the catastrophic threshold is reached, cost-sharing would be eliminated for all full benefit dual eligible individuals.

b. Other Low-Income Subsidy Eligible Individuals

In accordance with section 1860D–14(a)(2)(A) of the Act, for other low-income subsidy eligible individuals who do not qualify for the full subsidy or as full benefit dual eligible individuals, their premium subsidy would be on a sliding linear scale basis. The sliding scale premium subsidy would range from 100 percent of the beneficiary base subsidy (as discussed earlier, equal to the greater of the low-income benchmark premium or the lowest monthly beneficiary premium for

a prescription drug plan that offers basic prescription drug coverage in the PDP region), for individuals at or below 135 percent of the FPL for their family size, to no subsidy for individuals at 150 percent of the FPL for their family size. In contrast to full subsidy eligible individuals or full benefit dual eligible individuals, other subsidy eligible individuals subject to the late enrollment penalties under § 423.46 would be responsible for 100 percent of the penalties. We welcome comments concerning the manner in which the sliding scale premium subsidy is calculated for individuals with income from 135 percent up to 150 percent of the FPL. For ease of administration, we could set a scale in a stepped fashion, for example, a set decrease in the subsidy amount for every 5 percent increase in income level.

Other subsidy eligible individuals would have their annual deductible reduced from $250 to $50. This $50 is indexed in accordance with section 1860D–2(b)(6) of the Act beginning in 2007 based on the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of $1. Other subsidy eligible individuals would have continuation of coverage from the initial coverage limit (under paragraph (3) of section 1860D–2(b) of the Act) through the out-of-pocket threshold (under paragraph (4) of that section), meaning no coverage gap or "donut hole." For coverage through the out-of-pocket threshold, these individuals would pay 15 percent coinsurance, substituting for the higher beneficiary coinsurance described in section 1860D–2(b)(2) of the Act (*see* § 423.104(e)(2) of this proposed rule). The cost-sharing subsidies would count toward the application of the out-of-pocket threshold. After the out-of-pocket threshold is reached, these individuals' cost-sharing would be limited to the copayment or coinsurance amount specified under section 1860D–2(b)(4)(A)(i)(I) of the Act (*see* § 423.104(e)(5) of these proposed rules), which, in 2006, means co-payment amounts of $2 for a generic drug or preferred multiple source (as defined in section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug. In accordance with section 1860D–2(b)(4) and 1860D–2(b)(6) of the Act, the $2 and $5 copayments would be indexed based on an annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents.

A question has been raised concerning whether an MA–PD plan could choose to reduce or eliminate copayments for dual eligible individuals. We believe that specialized MA plans (under section 231 of the MMA, as defined in proposed regulations at 42 CFR 422.2) offering benefits only to dual eligible individuals could choose to reduce or eliminate copayments for their members as a supplemental benefit. Otherwise, the Part D copayments stipulated by the MMA for low-income individuals cannot be reduced or eliminated. This is because any reduction of the copayments must apply to all plan members under the uniformity of benefits provisions, set forth in § 423.265(c). Accordingly, MA–PD plans other than special MA–PD plans for dual eligibles may not offer their members who are dual eligible lower co-payments or co-insurance than those paid by its other plan members.

BILLING CODE 4120–01–P

Table P-2
Premium and Cost-Sharing Subsidy Amounts for Various Subsidy Eligible Groups, in 2006

FPL & Assets*	Percentage of Premium Subsidy	Deductible	Copayment up to out-of-pocket limit	Copayment above out-of-pocket limit
Full benefit dual eligibles	100%	$0	1. Institutionalized individuals-$0. 2. <=100% FPL—The lesser of $1-generic/preferred multiple source or $3-other drugs or, the amount charged to other individuals with income below 135% FPL with assets <=$6,000/<=$9,000. 3. All other full benefit dual eligibles-- $2-generic/preferred multiple source- $5-other drugs.	
<=100% FPL <=$6,000 <=$9,000	100%	$0	$0 institutionalized individuals. For all others, the lesser of $1-generic/preferred multiple source or $3-other drugs or, the amount charged to other individuals with income below 135% FPL with assets <=$6,000/<=$9,000.	None
>100% <135% FPL <=$6,000 <=$9,000	100%	$0	$2-generic/preferred multiple source- $5-other drugs.	None
<135% FPL >$6,000- <=$10,000 >$9,000- <=$20,000	100%	$50	15 percent coinsurance	No more than $2 for a generic or preferred multiple source drug or $5 for other drugs
>=135%- <150% <=$10,000 <=$20,000	Sliding Scale Premium Subsidy (100%-0%)	$50	15 percent coinsurance	No more than $2 for a generic or preferred multiple source drug or $5 for other drugs

* 2006 assets figures are shown for individuals first, and then couples.
** The premium subsidy is equal to the percentage shown in the above table of the greater of the low-income benchmark premium amount or the lowest basic PDP premium in the region. It also cannot exceed the basic premium for drug coverage under the prescription drug plan selected.

BILLING CODE 4120–01–C

4. Administration of Subsidy Program (§ 423.800)

We would be establishing a process to notify the PDP sponsor or MA organization that an individual is both eligible for the subsidy and the amount of the subsidy. Because CMS has not yet developed such a process, comments are welcome concerning notification to the PDP sponsor or MA organization that an individual is eligible for a subsidy and the amount of the subsidy. Similarly, we request comments on the proposed requirement that the PDP sponsor or MA organization notify CMS that premiums or cost-sharing have been reduced and the amount of the reduction. We are also considering the process for reimbursing the sponsor or organization for the amount of the premium or cost-sharing reductions. Any individually identifiable information must be kept confidential. Finally, we are requesting comments on how to best reimburse subsidy eligible individuals with respect to out-of-pocket costs relating to excess premiums and cost-sharing incurred before the date the individual was notified of subsidy eligibility but after the effective date the individual became subsidy eligible.

Similarly, we are requesting comments on how to deal with premiums and cost sharing paid by charities or other programs, for example, the Ryan White program or State Pharmacy Assistance programs, on behalf of an individual during a period when he or she is determined to be subsidy eligible. We are specifically requesting comments on whether Medicare should treat these programs for purposes of premium or cost sharing reimbursement as we would other employer-sponsored insurance programs in which Medicare is a primary payer for purposes of coordination of benefits. In addition, we are requesting comments on whether beneficiaries should be responsible for reimbursing any cost sharing or premiums paid on their behalf by another program or charity.

In accordance with section 1860D–14(c)(2) of the Act, reimbursement to PDPs or MA–PDs may be computed on a capitated basis, taking into account the actuarial value of the subsidies and with appropriate adjustments to reflect differences in the risks actually involved. (Refer to Subpart G of this proposed rule for a discussion of interim payments and final reconciliation payments.)

Subsidy amounts under section 1860D–14 of the Act are counted toward the counting of the out-of-pocket threshold at section 1860D–2(b)(4)(C)(ii) of the Act. Prescription drug plans and MA–PDs would be responsible for tracking the application of the low-income subsidy amounts as described in § 423.100 of these proposed rules.

Q. Guaranteeing Access to a Choice of Coverage (Qualifying Plans and Fallback Plans)

(If you choose to comment on issues in this section, please include the caption "Subpart Q"' Guaranteeing Access to A Choice of Coverage Qualifying Plans and Fallback Plans" at the beginning of your comments.)

1. Overview (§ 423.851)

Subpart Q would implement the provisions of sections 1860D–3, 1860D–11(g), 1860D–12(b)(2), 1860D–13(c)(3) and 1860D–15(g) of the Act. In this section, we address a beneficiary's right to have access to a choice of at least two plans; the requirements and limitations on the bid submission; review and approval of fallback prescription drug plans; contract requirements specific to fallback plans; and the determination of enrollee premium and our payments for those plans.

2. Terminology (§ 423.855)

a. Eligible Fallback Entity

As provided under section 1860D–11(g)(2) of the Act, an "eligible fallback entity" for a particular contract period is defined as an entity that meets all the requirements to be a PDP sponsor (except that it does not have to be capable of withstanding potential financial losses as a licensed risk-bearing entity) and does not submit a bid under the risk bidding process for any PDP region for the first year of that contract period. An entity would be treated as submitting a bid under the competitive bidding process, and thus not be an eligible fallback entity, if the entity was acting as a subcontractor for an integral part of the drug benefit management activities of a PDP sponsor that is submitting a bid for a prescription drug plan. An entity would not, however, be treated as submitting a bid if it is a subcontractor of an MA organization, unless that organization is acting as a PDP sponsor with respect to a prescription drug plan, rather than offering an MA–PD plan. We anticipate that some eligible fallback entities may contract with other entities for the performance of some required pharmacy benefit management functions.

As the result of this restriction in bidding, eligible fallback entities would have decided not to submit either a full-risk or limited risk bid in any region (either as a direct contractor, or as a subcontractor for a PDP sponsor) in order to be eligible to submit a fallback prescription drug bid in any region. Section 1860D–11(g)(2)(B) of the Act applies this restriction to the first year of a contract period. We interpret this to mean that an entity that submitted a risk bid in any region in the first year of a three-year contract cycle would not be permitted to be a fallback plan in the second and third year of the same contract cycle for any region. Taken together with the limitations in § 423.265(a)(2) on qualifying as a risk-bearing PDP, these requirements will force organizations to choose either the fallback process or the at-risk process. If an organization wins the fallback bidding, it is effectively barred under § 423.265(a)(2) from bidding as a risk plan in that region for 4 years—for the 3-year contract term, it is barred everywhere, and in the 4th year, it is barred from bidding as a risk plan in that region. We believe that the intent of this restriction was to maximize participation in the competitive bidding program and to limit the attractiveness of participating as a fallback plan for those plans that could participate on an at-risk basis. One of our objectives is to design our bidding process so that fallback plans are not required at all, that is, to support full-risk plans and to provide for limited-risk plans in a particular region if full-risk plans are not available. To the extent that any fallback plans may be required, we are required to submit an annual report to the Congress on the application of the fallback plan provisions and on further recommendations for limiting the need for such plans and maximizing participation by limited risk plans.

We could consider an alternative interpretation of what it means to "offer a fallback plan" in a region for purposes of section 1860D–12(b)(2)(C) of the Act. The alternatives would be—

1. Having a contract with us to be a fallback provider; or

2. Actually offering prescription drug benefits to enrollees when and if the fallback service area is "activated."

With the second interpretation, a fallback entity may not necessarily be barred from the at-risk bidding for 4 years. If the fallback contract was not activated and no plan was offered during year 3, the entity could be eligible to bid at risk for year 4. Interpretation 2 seems reasonable and consistent with the conference negotiations, since the policy goal would be to prevent plans from converting their enrollment under a fallback contract to enrollment under an

at-risk plan. If a fallback contract were not activated, there would be no enrollment and no risk of conversion. This interpretation would be appropriate in the case of an Indefinite Delivery type of contract in which bidders are approved as potential contractors and orders may or may not later be placed against the contracts. However, there are a variety of contracting vehicles available, and we are not prepared to limit the type of contract used at this time. We are requesting comments on this interpretation of "offer a fallback plan," and on the advantages and disadvantages of this type of contracting for eligible fallback entities.

b. Fallback Prescription Drug Plan

As provided under section 1860D–11(g)(4) of the Act, a fallback prescription drug plan is defined as a prescription drug plan offered by an eligible fallback entity that—

- Provides only actuarially equivalent standard prescription drug coverage (without supplemental benefits) as defined in § 423.100;
- Provides access to negotiated prices, including discounts from manufacturers;
- Meets the requirements for PDP sponsors except as otherwise indicated; and
- Meets other requirements as specified by us.

We would require that fallback plans offer actuarially equivalent standard coverage as defined in § 423.100 in order to ensure the incorporation of industry standard cost and utilization containment methods, such as tiered coinsurance structures. We would welcome comments on other requirements, or exceptions from requirements, that should be considered relative to fallback plans.

c. Qualifying Plan

Under § 423.855 of our proposed rule, a qualifying plan is defined as either a full-risk or limited risk prescription drug plan (PDP) or an MA–PD plan that provides basic coverage, or an MA–PD plan that provides supplemental coverage for no additional charge to the beneficiary. Specifically, if the MA–PD plan coverage includes supplemental prescription drug coverage, then in order to meet the definition of a "qualified plan" the MA–PD must be able to apply a premium rebate under Part C of Medicare as a credit against the supplemental coverage premium, leaving no cost to the beneficiary for the supplemental coverage. MA–PD plans must also be open for enrollment and not operating under a capacity waiver in order to be counted as a qualifying plan in an area.

3. Assuring Access to a Choice of Coverage (§ 423.859)

a. Access Standards

As provided under section 1860D–3(a) of the Act and codified in our proposed regulations at § 423.859(a), we are required to ensure that each Part D eligible individual has available a choice of enrollment in at least two qualifying plans offered by different entities in the geographic area in which he or she resides. Therefore, beneficiaries in an area must have a choice of two plans that provide basic coverage (or an MA–PD plan that provides supplemental coverage for no additional charge to the beneficiary). However, to meet the access test, different sponsors must offer the two qualifying plans, and at least one of the plans must be a PDP.

b. Fallback Service Area

As provided in section 1860D–11(g)(3) of the Act, before the start of a contract year, we would determine if Part D eligible individuals in a PDP region have available a choice of enrollment in a minimum of two qualified plans offered by different entities, at least one of which is a prescription drug plan. In the event that we determine that beneficiaries within a PDP region or some portion of the PDP region do not have a choice of two qualified plans, we would establish a "fallback service area." Thus, a fallback service area is any area within a PDP region in which we have determined that Part D eligible individuals do not have available a choice of enrollment in two qualified plans, at least one of which is a prescription drug plan. Three examples of the application of a fallback service area follow:

Example 1—We would establish a fallback service area in an area where an MA regional PPO plan is offered but no PDP is offered in the region. Since beneficiaries in the region would only have the choice of a MA–PD and not a stand-alone PDP, we would define the area as a fallback service area.

Example 2—A fallback service area would also be designated if only one PDP is offered in a region, but in some or all parts of the region neither a regional (PPO) MA–PD plan nor a local MA–PD plan are available to beneficiaries. Since beneficiaries would not have a choice of two qualifying plans, we would define the areas within the region that only have access to the PDP, and not an MA–PD plan, as fallback service areas. As a result, it would be possible for only certain areas (counties) within a region to be designated as fallback service areas.

Example 3—A fallback service area would also be designated in any area in which only one entity offered all qualifying plans, even if that sponsor offered two PDPs, or one PDP and one MA–PD plan with basic coverage, covering the entire region.

In order to meet the requirement that two qualifying plans be available to beneficiaries in each service area, we could, as provided under section 1860D–11(f) of the Act and § 423.272(c) of these regulations, approve limited risk plans. If two qualifying plans were not approved in any particular service area even after our consideration of limited risk plan applications from entities applying to become PDP sponsors, beneficiaries in that service area would be provided with the opportunity to enroll in a fallback plan.

c. Waivers for Territories

Section 423.859(c) of our proposed regulations would make Medicare beneficiaries residing in the U.S. territories—which include American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands—eligible to enroll in Part D. As provided under section 1860D–42(a) of the Act, we would have the authority to waive any Part D requirements, including the requirement that access to two qualifying plans be assured in each service area, as necessary to assure access to qualified prescription drug coverage for Part D eligible individuals residing in the U.S. territories. For instance, if no fallback plans responded to our RFP for offering Part D coverage in a territory, but one PDP plan did, we might consider such a waiver as being in the interest of those beneficiaries. In addition, entities wishing to become prescription drug plans in the territories may request waivers or modifications of Part D requirements that facilitate their operation in those areas. We will publish in operational guidance a list of acceptable waivers and modifications of Part D requirements for entities that wish to operate prescription drug plans in the territories.

We will consider waiving the following requirements in order to assure sufficient access to qualified prescription drug coverage for Part D eligible individuals residing in the U.S. territories—

The proposed requirement set forth in section 1860D–3(a)(1) of the Act and § 423.859(a) of our proposed regulations that we ensure access to at least 2 qualifying plans offering standard

prescription drug coverage in each service area.

The proposed pharmacy access standard under section 1860D–4(b)(1) of the Act and § 423.120 of our proposed regulations, and the service area requirement set forth in § 423.112.

The proposed requirement set forth in section 1860D–4(k) of the Act and § 423.132 of our proposed regulations that PDP sponsors offering a prescription drug plan ensure that pharmacies inform Part D enrollees of any differential between the price of the covered drug to the enrollee and the price of the lowest priced generic drug that is therapeutically equivalent and bioequivalent and available at that pharmacy. This waiver mirrors language in the subpart C preamble regarding § 423.132 (public disclosure of pharmaceutical prices for equivalent drugs). There, we indicate that we will consider waiving this requirement for pharmacies under certain circumstances—including if the pharmacy is located in one of the U.S. territories. We propose replicating the waiver that is provided in the drug card regulation regarding public disclosure of prices for equivalent drugs. The rationale for this waiver in the drug card regulation was that few discount drug cards currently have contractual relationships with retail pharmacies in the territories; waiver of the requirement was meant to reduce the administrative complexity of endorsed card sponsors' contracts with participating retail pharmacies in the territories and, thus, encourage entities to apply to offer a discount card in the territories.

We request comments on the appropriateness of these proposed waivers of Part D requirements. In addition, we request comments regarding any additional waivers of Part D requirements we may wish to consider in order to assure access to qualified prescription drug coverage for Part D eligible individuals residing in the U.S. territories.

4. Submission and Approval of Bids (§ 423.863)

As provided in section 1860D–11(g)(1)(A) of the Act, we would establish a separate bidding process for fallback plans from the process addressed in § 423.265 of our regulations. We anticipate that we would "pre-qualify" bidders from eligible fallback entities in the first half of 2005 for the offering of fallback prescription drug plans in one or more regions in 2006. While formal awards would be made, the services of a fallback plan would only be used if at least two full-risk or limited-risk plans (one of which could be an MA–PD plan) were unavailable. It is quite possible—and it is our policy objective—that we would never use the services of a fallback contractor because there would be at least two risk-bearing plans offered in every region of the country. We would re-solicit bids every three years thereafter in accordance with the three-year contracting cycle provided under 1860D–11(g)(7)(B) of the Act, or annually thereafter as needed to replace contractors between contracting cycles. However, a fallback prescription drug plan may be offered for any year within the contract period only if that area is a fallback service area for that year. We will provide additional guidance on the form and manner in which such fallback bids would be submitted. In general, we would enter into contracts with fallback plans using federal acquisition rules on a timetable ensuring that such contracts were in place at the same time as prescription drug plans would otherwise be offered. In the event that fallback contracts are required, we expect to award (only) two fallback contracts, through a competitive process factoring in price (discounts) and administrative costs.

As discussed in earlier sections of this preamble, section 1860D–11(i) of the Act specifies that we may not interfere with negotiations between drug manufacturers and pharmacies and PDP sponsors, and may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs. However, the revenue requirements standard in 5 U.S.C. 8902(i), discussed in subpart F of this preamble, requires us to ascertain that the bid "reasonably and accurately reflects the revenue requirements for benefits provided under that plan." Therefore, while we will not set the price of any particular drug, or require an average discount in the aggregate on any group of drugs (such as single-source brand-name drugs, multiple-source brand name drugs, or generic drugs), we will evaluate whether the bid is reasonably justified. As specified in 5 U.S.C. 8902(i), we will take steps to ensure that benefits are "consistent with the group health benefit plans issued to large employers," to ensure that the bid amounts submitted are comparable to those available on the private market. For example, if the price reference points appear to be particularly high (or low), we may request an explanation of the bidders' pricing structure, and the nature of their arrangements with manufacturers. We would also ensure that there is no conflict of interest leading to higher bids. In addition to evaluating the reasonableness of the bid amounts submitted by fallback plans, we also propose to negotiate price-related performance targets with fallback plans, consistent with current market practices in which plan sponsors negotiate price-related reference points with PBMs. Additionally, we would also consider potential contractors based on what they bid for administrative functions like claims processing.

Unlike plans that contract on a risk basis, fallback entities are paid on the basis of cost, and thus these entities will have less of an incentive to negotiate low drug prices. Consequently, because the statute directs us to pay management fees that are tied to performance measures, and directs that there must be a measure for costs, we are contemplating tying the performance payments of fallback entities to the average discounts they are able to negotiate, including discounts from manufacturers. To the extent possible, we would like the concept of discount to reflect a broad measure of lower per member spending, this may be accomplished by greater reliance on generics or use of step therapy. Thus, for example, if a performance incentive was based on whether the plan was able to maintain an average discount of 20 percent below the Average Wholesale Price (AWP) of a drug (referred to as "AWP minus (−) 20 percent"), and if the plan averaged less of a discount, it might lose some of its performance incentive payments. If the plan was able to maintain an average discount greater than AWP–20 percent, it could qualify for additional incentive payments. Other potential targets might include average cost per prescription, average anticipated (or guaranteed) rebate per prescription, average dispensing fee per (type of) prescription, or average administrative fee per prescription.

We understand that this type of incentive contracting is found in the pharmacy benefit management market today, and believe that pursuing this type of approach will incentivize fallback plans to secure the best possible prices for beneficiaries and the Medicare program. However, we are aware that using a floating target such as AWP as a reference point may be counterproductive to our goal of minimizing costs, since the AWP can easily be raised to keep prices stable. Therefore, we are interested in identifying other potential reference points that would be less subject to manipulation, such as a relationship to average sales price, or to the prior year's negotiated and delivered prices. We considered whether this approach could

be viewed as a violation of the noninterference provisions of section 1860D–11(i) of the Act. We believe that section 1860D–11(g)(5)(B)(i) of the Act makes clear that the Congress contemplated taking prices into account in calculating incentive payments for fallback entities. Moreover, even though the performance measures will be defined in advance, the determination of incentive payments will be made at the end of the contract period, and thus does not represent interference in the bidding process. Therefore, we are proposing to place performance clauses in the contracts with fallback entities that would tie performance payments to the fallback plan's ability to negotiate certain levels of discounts on drug prices that will be passed on to beneficiaries and us as costs. We would also like to receive comments on alternative reference points or alternative methodologies that could promote competitive pricing.

Except as provided below, in section 6, all of the provisions of § 423.272 of our regulations regarding the review and approval of prescription drug plans apply to the approval or disapproval of fallback prescription drug plans. As indicated in § 423.265(d)(4), and discussed in subpart F of this preamble, all risk bids would be submitted as either full-risk or limited risk. After we evaluate all full-risk and limited risk bids, we will determine whether the region is, in whole or in part, a fallback service area and enter into (or activate) fallback plan contracts. In accordance with section 1860D–11(g)(1)(B)(ii) and section 1860D–11(g)(1)(B)(v) of the Act, only one fallback prescription drug plan would be approved to serve all fallback service areas in any one region, and we would not enter into a contract with just one fallback entity to offer all of the fallback plans throughout the United States.

As with risk bids, we believe we have the authority to negotiate with respect to fallback plans in four broad areas: administrative costs, aggregate costs, benefit structure, and plan management. We would evaluate administrative costs for reasonableness in comparison to other bidders. We would examine aggregate costs to determine whether the revenue requirements for actuarially equivalent standard prescription drug coverage as defined in § 423.100 are reasonable and equitable. We would be interested in steps that the plan is taking to control costs, such as through measures to encourage use of generic drugs, therapeutic interchange to preferred brand-name drugs, and formulary compliance. We would be interested in reviewing the formulary to ensure that it is appropriate for a region in which beneficiaries do not have alternative plans from which to choose. We would examine and discuss any proposed benefit structures or changes to benefits, particularly with regard to any potentially discriminatory features. Finally, we would discuss indicators and any identified issues with regard to plan management, such as customer service.

5. Rules Regarding Premiums (§ 423.867)

Except as provided with regard to any enrollment penalty or low-income assistance, or employer group waivers under sections 1857(i) and 1860D–22(b) of the Act (§ 423.462(a) in subpart J), the monthly beneficiary premium charged under a fallback prescription drug plan offered in all fallback service areas in a PDP region must be uniform. It must equal 25.5 percent of an amount equal to our estimate of the average monthly per capita actuarial cost, including administrative expenses, under the fallback prescription drug plan of providing coverage in the region. In calculating administrative expenses, we would use a factor based on similar expenses of prescription drug plans that are not fallback prescription drug plans. We would like to receive comments suggesting the kinds of costs fallback plans might have that PDPs would not (for example, the cost of gearing up systems quickly, less ability to negotiate pharmacy network discounts) and what costs they would not have (for example, marketing).

Fallback plans would not receive a portion of any applicable late enrollment penalties since they do not bear risk for increased expenses attributable to individuals to whom the penalty applies. Monthly beneficiary premiums for enrollees in fallback prescription drug plans would be deducted from Social Security benefits (as provided in § 422.262(f)(1)) or in any other manner provided under section 1840 of the Act.

6. Contract Terms and Conditions (§ 423.871)

In general, the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans would be the same as the terms and conditions of contracts for prescription drug plans, with the following exceptions:

- The contract term for a fallback prescription drug plan would be for a period of 3 years (except as may be renewed after a subsequent bidding process). However, a fallback prescription drug plan may be offered for any year within the contract period only if that area is a fallback service area for that year.
- An eligible fallback entity with a contract under this part may not engage in any marketing or branding of a fallback prescription drug plan. This refers to marketing activities promoting the plan and its sponsor to Part D eligible beneficiaries as addressed in § 423.50 of this proposed rule, and not to required dissemination of information on approved plan characteristics to enrollees as required in § 423.128 of our proposed rule. Beneficiary education and outreach to employers potentially interested in providing supplemental coverage will remain solely our responsibility.
- We would establish performance measures for fallback prescription drug plans as discussed elsewhere in this subpart.
- Payment terms would include payment for actual costs (taking into account price concessions) of covered Part D drugs provided to Part D eligible individuals enrolled in the plan, and management fees tied to the performance measures that we establish.
- Each contract for a fallback prescription drug plan would require an eligible fallback entity offering a fallback prescription drug plan to provide us with the information that we determine is necessary to carry out the fallback plan payment provisions, and calculate accurate payments, including, but not limited to, all documentation relating to including 100 percent of drug claims, costs, rebates and discounts, and disclosure of all direct and indirect remuneration as offsets to the claim costs.
- We could amend the contract at any time, as needed, to reflect the exact regions or counties to be included in the fallback service area(s).

Other contract terms will be specified during the bid solicitation process. Competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5)) will be used in fallback plan contracting.

As discussed above, as part of the payment process for fallback plans authorized by section 1860D–11(g)(5) of the Act, we would assess the performance of plans with regard to specific performance measures and tie this performance to an incentive payment. These measures would include at least measures for cost containment, quality programs, customer service, and benefit administration (including claims adjudication). "Cost containment" refers to processes in place to ensure that costs

to the Medicare Prescription Drug Account and to enrollees are minimized through mechanisms such as generic substitution and price discounts. The term "quality programs" refers to drug utilization review processes in place to avoid adverse drug reactions and drug over utilization and to reduce medical errors. The term "customer service" refers to processes in place to ensure that the entity provides timely and accurate filling of prescriptions and delivery of pharmacy and beneficiary support services. We would be interested in surveying enrollees of fallback plans to assess customer satisfaction with plan services. The terms "benefit administration and claims adjudication" refer to processes in place to ensure that the entity provides efficient and effective benefit administration and claims adjudication, such as accurately programming and updating its benefit administration information systems, and providing timely and accurate claims adjudication.

7. Payment to Fallback Plans (§ 423.875)

The amount payable under approved fallback prescription drug contracts would be the amount determined under the specific contract negotiated for each such plan. In general, all such contracts would provide for payment for the allowable and allocable costs (taking into account negotiated price concessions) of covered Part D drugs provided to Part D eligible individuals enrolled in the plan and payment of management fees that are tied to the performance measures we established for the management, administration, and delivery of the benefits under the contract.

In contrast to PDP sponsors offering prescription drug plans and MA organizations offering MA–PD plans, eligible fallback entities are not required to bear any of the risk associated with the provision of the prescription drug benefit. They may, however, bear administrative cost risk related to the achievement of specified performance measures. In other words, they would receive reimbursement for the full contracted cost attributable to delivering the drug benefit, including management fees and administrative costs, but may not receive the full measure of available incentive payments tied to performance measures unless specified targets have been met.

We are considering alternatives for the fallback plan payment process. Under one proposal, we would establish an account against which the claims costs and management fees would be debited. This means that the entity offering the fallback plan would debit the prescription drug claim costs and their negotiated administrative fees against this account in a manner to which we agree and would then be subject to certain cost reporting and settlement requirements, as, for instance, with regard to rebate allocation. An alternative approach would be to establish an estimated monthly payment per enrollee as a prospective payment for the fallback plan. Initially, that amount could change monthly to reflect differences between the costs of enrollees in a fallback plan versus payments to the plan under the prospective system. The objectives of this approach would be to provide the correct amount of money to the fallback plan to reflect their actual costs. We request comment on payment methodologies, particularly in regard to prospective or retrospective rebate allocation.

R. Payments to Sponsors of Retiree Prescription Drug Plans

1. Overview

Subpart R would implement section 1860D–22 of the Act, which provides for making subsidy payments to sponsors of qualified retiree prescription drug plans. Section 1201 of the MMA amends the Internal Revenue Code of 1986 to provide that these subsidy payments will be exempt from Federal tax. Further guidance on the Federal tax treatment of the subsidy will be under the auspices of the U.S. Department of the Treasury.

a. Options for Sponsors of Retiree Prescription Drug Programs

The enactment of Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) on December 8, 2003, has provided sponsors of retiree prescription drug plans with multiple options for providing drug coverage to their retirees. We believe the availability of these various options will encourage employers and unions to continue to assist their retirees in having access to prescription drug coverage.

Generally, employers and unions who offer drug benefits to their retirees (and their spouses and dependents) who are also eligible for Medicare Part D could—

(1) Provide prescription drug coverage through employment-based retiree health coverage. If employment-based retiree health coverage were at least actuarially equivalent to the standard prescription drug coverage under Medicare Part D, the sponsor would be eligible for a special Federal subsidy for each individual enrolled in the sponsor's plan who is also eligible for Medicare Part D, but who nevertheless elects not to enroll in Medicare Part D;

(2) Contract with a PDP sponsor or Medicare Advantage (MA) organization to enroll Medicare beneficiaries covered under the retiree plan into a prescription drug plan (PDP) or Medicare Advantage-prescription drug (MA–PD) plan. Alternatively, the sponsor itself could apply to be a PDP sponsor or MA organization and offer a PDP or MA–PD plan to its retirees. That plan could consist of "enhanced alternative coverage" (as defined under § 423.4 of our proposed rule), that is, drug coverage that is more generous than that offered under the standard prescription drug coverage under Medicare Part D (as defined under § 423.4 of our proposed rule). Medicare would subsidize the cost of such coverage through direct and reinsurance subsidies. At its option, the sponsor could elect to subsidize the monthly beneficiary premium (as calculated under § 423.286 of the Drug Benefit);

(3) Provide prescription drug coverage that supplements, or "wraps-around," the coverage offered under the PDP or MA–PD plans in which their retirees (and retirees' spouse and dependents) enroll.

The first option is the subject of this subpart of our proposed rule. The latter options, all of which involve employers' or unions' retirees (and their spouses and dependents) enrolling in Part D, are discussed in detail in the preamble to subpart J. We note that employers also have the option of subsidizing the monthly beneficiary premium for the PDP or MA–PD plan in which the employer or union's retirees (and their spouses and dependents) elect to enroll.

If employers or unions elect to sponsor either an enhanced alternative plan covered under Medicare Part D or supplemental coverage that "wraps around" Medicare Part D, either election will have an impact as to when their retirees (and retirees' dependents) will be eligible for catastrophic drug coverage, with important consequences for participants, sponsors, the plans, and the Medicare program. By delaying the provision of government-financed catastrophic coverage, these plans would lower the cost of Part D to the Federal government by lowering our reinsurance payments while preventing beneficiaries from facing any gaps in coverage. As discussed in subpart C of this preamble, individuals enrolled in a PDP or MA–PD plan would be eligible for catastrophic drug coverage after they have incurred out-of-pocket drug costs in the amount specified under § 423.104(e)(iii)(A) of our proposed rule. Under the reinsurance provisions,

Medicare would reimburse PDP sponsors and MA organizations offering MA–PD plans 80 percent of their gross costs for providing catastrophic coverage (excluding administrative costs and net of discounts, rebates, and similar price concessions). Only drug costs paid by a Part D enrollee, or on behalf of a Part D enrollee by another person, would count toward the annual out-of-pocket threshold. Amounts reimbursed by insurance or otherwise, by a group health plan, or by another third-party payment arrangement would not count toward the threshold. We refer to those drug expenditures that count toward the out-of-pocket threshold as "true out-of-pocket expenditures" (TrOOP).

Under these rules, sponsors who provide retirees (and retirees' spouses and dependents) enhanced alternative coverage would, in effect, delay the total drug spending that would trigger catastrophic coverage, because plan participants would have lower cost sharing, and thus, have lower out-of-pocket costs. Similarly, employers or unions who would sponsor supplemental coverage that would "wrap-around" Medicare Part D coverage would raise the total drug spending that would trigger government-financed catastrophic coverage, since drug costs paid for by those plans would reduce beneficiary costs and would not count toward the true out-of-pocket annual limit.

When an employer or union elects to contract with a PDP sponsor or MA–PD organization, the PDP sponsor, under § 423.458(c) of our proposed rule, or the MA organization, under § 422.106(c), may submit written requests to us for permission to waive requirements under Part D that hinder the design or offering of PDP or MA–PD plans to employers. We believe these waivers would facilitate efficient administration and integration of their enhanced Part D coverage with other retiree health benefits offered by the sponsor, as another subsidized option for employers to offer enhanced coverage instead of using Medicare's alternative retiree drug subsidy. For example, the PDP sponsor or MA organization could request permission to restrict enrollment in its PDP or MA–PD plan to the sponsor's retirees (and their spouses and dependents) and offer a benefit that resembles or enhances the sponsor's existing coverage. Similarly, should the plan sponsor wish to enroll its retirees (and their spouses and dependents) in its own plan, with enrollment limited to those individuals, the sponsor could apply to be a PDP sponsor or MA organization offering a MA–PD plan and request such waivers as necessary.

We encourage plan sponsors to carefully review each option and determine which one is most beneficial to the sponsor and its retirees. We believe that the variety of options will encourage sponsors to retain drug coverage for their retirees (and their spouses and dependents), and we seek comment on how we can use all of these subsidized options to maximize enhancements in retiree coverage.

b. The Retiree Drug Subsidy Provision

During the past 15 years, the availability and generosity of employment-related retiree health coverage has been eroding due to rising health care costs, increasing numbers of retirees (who may be more costly to cover than younger active workers), and the impact of changes in accounting rules. For example, in 1988 approximately 66 percent of the nation's private sector firms with 200 or more workers that offered health benefits to active workers also offered retiree health benefits to any of their retirees, including both the pre-65 and the ages 65 and older populations, but by 2003 only 38 percent of these firms were offering retiree health coverage. Most employers that offer retiree health benefits also provide retiree prescription drug coverage. A more detailed discussion of the trends in retiree coverage, as well as the limitations in the data available on these trends is provided in the impact analysis section of this proposed rule.

By providing heavily subsidized insurance coverage of prescription drug expenditures incurred by, or on behalf of, Medicare beneficiaries, the MMA would significantly reduce the cost of existing retiree beneficiary drug coverage. For retiree-beneficiaries who enroll in Part D, Medicare would become the primary insurer. MMA would then lower the sponsor's cost of drug coverage by having the sponsor's plan become a secondary payer of retiree drug coverage. However, plan sponsors may benefit from the greater flexibility and fewer prescriptive requirements of the alternative retiree drug subsidy.

The retiree drug subsidy is designed to accommodate plan sponsors seeking greater flexibility and less regulation. In addition, while the expenses associated with providing retiree drug coverage continue to be deductible expenses for Federal tax purposes, the payments associated with the retiree drug subsidy are not counted as taxable income for employers. As discussed in the Regulatory Impact Analysis of this preamble, the after-tax nature of the retiree drug subsidy payments effectively increases the value of these payments for employers that are subject to the corporate income tax. For example, the tax-free $611 average retiree drug subsidy amount would be equivalent to about $940 of taxable income for employers with a marginal tax rate of 35 percent. As discussed further in the impact analysis, we believe that the tax treatment of the retiree drug subsidy payments will provide an additional incentive for employers to participate in the retiree drug subsidy program.

The intent of the MMA retiree prescription drug subsidy provisions is to slow the decline in employer-sponsored retiree insurance. By providing a special subsidy payment to sponsors of qualifying plans, the MMA provides employers with extra incentives and flexibility to maintain prescription drug coverage for their retirees. Our intention is to make these subsidy payments as reasonably available to plan sponsors as possible. We wish to take into account as much as possible the needs and concerns of plan sponsors, consistent with necessary assurances that Federal payments are accurate and in accordance with statutory requirements, that the interests of retiree-beneficiaries are protected, and that employers do not receive "windfalls" consisting of subsidy payments that are not passed on to beneficiaries.

We plan to conduct outreach to plan sponsors, retirees and retiree associations, and other interested parties on all aspects of the MMA. We encourage their input on the feasibility and advisability of the approaches we have identified, as well as any other issues presented by the new statute, or additional options beyond those we have identified. We look forward to employer, union, and other public comments on all aspects of this proposed regulation. We particularly seek comments on the sections noted in the preamble.

2. Definitions (§ 423.882)

The Act contains a number of definitions that are critical to understanding how the retiree drug subsidy functions. To make it easier to understand how these definitions work together to establish the subsidy amount, we first provide an overview of the structure of the subsidy program and then provide a description of the key concepts. As noted above, a significant portion of the Medicare population receives prescription drug coverage through employer and/or union

sponsored retiree health benefits. The Act provides for Medicare payment to plan sponsors who choose to provide prescription drug coverage that is at least as generous as the standard prescription drug benefit under Medicare Part D. The Congress intended for the subsidy to encourage as many sponsors as possible to retain this coverage for their retirees (and their spouses and dependents). The subsidy payment made to a sponsor of a qualified retiree prescription drug plan would be based on actual drug spending by individuals enrolled in the plan and not premium payments. The subsidy is 28 percent of certain costs that are incurred for certain prescription drugs for individuals covered under the qualified retiree prescription drug plan who are eligible for the Medicare Part D drug benefit but who are not enrolled in Medicare Part D. The statute defines a number of terms in order to distinguish between costs that are to be considered in determining the subsidy payment amount, and costs that may not be considered in determining the subsidy payment amount.

Only group health plans that provide health coverage to Part D eligible individuals based on their status as retiree participants (or spouses or dependents of retiree participants) may qualify as a retiree prescription drug plan. The term "group health plan" is defined later below. Additionally, to be considered a qualified retiree prescription drug plan, the sponsor's group health plan must be at least actuarially equivalent to the standard drug coverage under Medicare Part D (in accordance with section 1860D–22(a)(2)(A) of the Act and as discussed below in section 3(b) of this subpart). As required under section 1860D–22(a)(2)(A) of the Act, the sponsor must submit an actuarial attestation that its plan is at least actuarially equivalent to the standard Medicare Part D prescription drug benefit for the plan to be a "qualified retiree prescription drug plan." In addition to meeting tests of actuarial equivalence, the plan must be a group health plan that provides prescription drug benefits to Medicare Part D eligible individuals, as defined in § 423.882, based on their status either as retirees or as spouses and dependents of those retirees.

The next step is to identify the "qualifying covered retirees" (that is, those Medicare beneficiaries eligible to enroll in Medicare Part D who are enrolled in the retiree plan, but who are not enrolled in the Medicare Part D benefit) and determine the "gross covered retiree plan-related prescription drug costs" (gross costs) under the plan for these individuals for the year. Gross costs refer to the costs directly associated with the dispensing of a prescription drug. (In the prescription drug industry, gross costs are frequently referred to as the "ingredient costs" (the cost of the drug itself) and the "dispensing fee" (the pharmacy charge for dispensing the drug to a patient)). The statute, however, specifically excludes the retiree health plan's administrative costs from gross costs. Having established that gross costs are the base upon which the subsidy payment is to be determined, the statute then specifies that the payment may be made only for those costs that fall between the "cost threshold" and the "cost limit". For 2006, the cost threshold is $250 and the cost limit is $5,000. In other words, the first $250 in prescription drug costs for an individual during a year and any prescription drug costs for that year that exceed $5,000 is disregarded. The dollar values for the cost threshold and cost limit are adjusted annually.

The statute then specifies that the amount of gross costs that fall between the cost threshold and cost limit must be reduced by any discounts, chargebacks, rebates, and other price concessions. These net costs actually paid by the sponsor or by or on behalf of the retiree are referred to as the "allowable retiree costs." The intent of this provision is to ensure that Medicare subsidy payments take into account the pricing adjustments and discounts that actually occur in the market today. Some pricing adjustments, such as manufacturer rebates, typically occur well after payment is made to the pharmacy. Since the ingredient costs and dispensing fees found in the claims data do not include the lower "prices" achieved as a result of manufacturer rebates and other price concessions, further adjustment is needed to account for these other pricing related factors when determining the costs under the plan that will be "allowable" for purposes of the Medicare subsidy payment amount.

To summarize, the statute provides that the retiree drug subsidy payment amount equals 28 percent of the allowable costs attributable to the portion of the gross costs that fall between the cost threshold and cost limit. The definitions below further articulate the meaning of the key terms involved in determining the subsidy payment amount. The definitions are organized to first describe the Medicare Part D eligible individuals, then terminology related to retiree plans, and finally, terminology related to the subsidy payment amount and the basis upon which the payment is determined.

Part D Eligible Individual

Section 423.4 of our proposed rule defines a Part D eligible individual as an individual who is entitled to or enrolled in benefits under Medicare Part A or who is enrolled under Medicare Part B.

Qualifying Covered Retiree

Section 1860D–22(a)(4) of the Act defines a qualifying covered retiree as a Part D eligible individual who is not enrolled in a Part D prescription drug plan (PDP) or Medicare Advantage-Prescription Drug (MA–PD) plan but who is covered under a qualified retiree prescription drug plan. We note that the qualifying covered retiree is not necessarily the retired employee who is the participant under the plan; it also includes coverage of a Part D eligible individual who is covered under the plan as a spouse or dependent of a participant. (Under ERISA, an employee or former employee who is covered under an employment-related plan is referred to as the "participant." Dependents of the participant are referred to as "beneficiaries," but to avoid confusion with "Medicare beneficiaries," we will refer to the beneficiaries under the health plan as "spouses and dependents.")

Employment-Based Retiree Health Coverage

Section 1860D–22 (c)(1) of the Act defines employment-based retiree health coverage. Employment-based retiree health coverage means coverage of health care costs under a group health plan based on an individual's status as a retired participant in the plan or as the spouse or dependent of a retired participant. The term includes coverage provided by voluntary insurance coverage or pursuant to statutory or contractual obligation.

Group Health Plan

The term "group health plan" has the same meaning as defined in section 607(1) of ERISA, 29 U.S.C. 1167(1). Section 1860D–22(c)(3) of the Act specifies that the definition of a group health plan includes plans maintained for their employees by the Federal government (including the Federal Employee Health Benefits Program (FEHBP) and the TRICARE program); plans maintained by State or local government; and church plans exempt from Federal taxes under section 501 of the Internal Revenue Code of 1986 (despite the fact that those types of group health plans are not generally subject to ERISA requirements).

Qualified Retiree Prescription Drug Plan

A qualified retiree prescription drug plan means employment-based retiree health coverage that meets the requirements set forth in § 423.884(a) through § 423.884(d) for a Part D eligible individual who is a participant or the spouse or dependent of a participant under the coverage.

Sponsor

Sponsor means plan sponsor as defined in section 3(16)(B) of ERISA, 29 U.S.C. 1002(16)(B). This term means an employer, an employee organization (generally a trade union) or a combination of employers and employee organizations. Section 1860D–22(c)(2) of the Act, however, modifies this definition in the case of a plan maintained jointly by one employer and an employee organization and for which the employer is the primary source of financing, in which case the term "sponsor" means the employer.

Covered Part D Drug

Covered Part D drug has the meaning given in § 423.4 of our proposed rule and as discussed in subpart C of this preamble.

Retiree Drug Subsidy Amount

The retiree drug subsidy amount is defined as 28 percent of the allowable retiree costs for each qualifying covered retiree. Section 1860D–22(a)(3) of the Act describes the subsidy payment to be made to the sponsor of a qualified retiree prescription drug plan with respect to each qualifying covered retiree who is covered under the plan.

Gross Covered Retiree Plan-Related Prescription Drug Costs

Section 1860D–22(a)(3)(C)(ii) of the Act defines gross covered retiree plan-related prescription drug costs to mean specified costs incurred for a qualifying covered retiree enrolled in a qualified retiree prescription drug plan "during a coverage year." (For ease of reference, we use the term "gross retiree costs" interchangeably with the defined term.) We explain below in the preamble discussion related to § 423.888, that we have tentatively determined that the subsidy should be based on calendar year data. For purposes of this definition, we simply use the term "year;" in the final regulation, we will clarify whether it is a plan year or a calendar year.

In accordance with section 1860D–22(a)(3)(C)(ii) of the Act, we define the term, gross covered retiree plan-related prescription drug costs, (gross retiree costs) to mean the costs incurred under a qualified retiree prescription drug plan for a qualifying covered retiree that are directly related to the dispensing of covered Part D drugs during the year (other than administrative costs), whether they are paid under the plan or by the retiree. Costs for covered Part D drugs incurred under the plan that are paid for by the retiree include all retiree cost sharing under the plan (for example, deductibles or copayments). Costs for non-covered Part D drugs are not considered gross retiree costs, even if paid for under the plan.

As discussed above, dispensing fees are included in gross retiree costs, but administrative costs are excluded. Therefore, we expect to monitor dispensing fees carefully through our audit activities in order to ensure that other administrative costs are not improperly included in the dispensing fees.

Allowable Retiree Costs

In accordance with section 1860D–22(a)(3)(C)(i) of the Act, allowable retiree costs means gross covered retiree plan-related prescription drug costs between the cost threshold and cost limit that are actually paid by either the qualified retiree prescription drug plan or the qualifying covered retiree (or on the retiree's behalf), net of any manufacturer or pharmacy discounts, chargebacks, rebates, and similar price concessions. For the purposes of determining the subsidy payment, allowable retiree costs include cost sharing paid "on behalf of" the qualifying covered retiree by any person or entity. This would include amounts paid by family members and charitable organizations to assist the retiree in his or her cost-sharing obligations. Amounts paid by other group health plans and insurers, such as under a spouse's plan that provides secondary coverage towards the cost sharing, would also be considered allowable retiree costs.

We note that the rules for calculating allowable costs under the subsidy provisions of section 1860D–22 of the Act must not be confused with the rules that pertain to the amount of cost sharing that must be paid by beneficiaries who enroll in Medicare Part D. Under section 1860D–2 of the Act (§ 423.466(b) of our proposed rule), beneficiary cost sharing under the PDP or MA–PD plan only counts toward reaching the annual "out of pocket threshold" that triggers catastrophic coverage if it is paid by the beneficiary or by another person such as a family member. In general, beneficiary cost sharing for which the beneficiary is reimbursed through insurance, a group health plan, or other third-party payment arrangement will not count toward the annual out-of-pocket threshold. The employer/union subsidy provisions contain no similar limitation. Thus, beneficiary cost sharing is an allowable cost regardless of who pays the cost sharing.

Because allowable retiree costs exclude gross retiree costs below the cost threshold, a plan sponsor will be entitled to a subsidy payment for a qualifying covered retiree only if that individual's gross retiree costs, or total drug spending under the plan for a year, exceed the cost threshold for that year.

As noted above, allowable retiree costs are drug costs that are *actually paid* by either the qualified retiree prescription drug plan or the qualifying covered retiree (or on the retiree's behalf), and therefore net of any drug discounts, chargebacks, rebates, and any other similar price concessions passed through to the plan or retiree. (For purposes of this discussion, we will refer to all of the immediately preceding terms as "rebates"; that is, discounts, chargebacks, rebates, and similar price concessions). We understand that much of the rebate accounting is not applied in the context of point of sale claims data, but rather in periodic accounting adjustments, and that rebates are frequently reported along with administrative fees paid by the manufacturer. We are aware and concerned that, in some cases, plan sponsors may accept lower administrative costs or receive services at or below fair market value in lieu of some or all of the rebates. We are concerned that this practice may result in improper shifting of costs in order to inappropriately maximize subsidy amounts. We intend to monitor these arrangements closely to ensure that allowable retiree costs are not improperly inflated. We are also concerned that these accounting and business practices would be incompatible with the requirement to disclose all price concessions for purposes of determining allowable retiree costs and we, therefore, are proposing to require that the true cost of rebates be segregated in all records. We require that all rebates passed through to the plan sponsor and retiree in any form be subtracted when calculating allowable retiree costs.

Due to the nature and timing of rebate accounting, we believe that this will require a form of step-down cost reporting in which rebates received at the aggregate level may be apportioned down to the level of plan enrollees incurring allowable retire costs on a reasonable basis. Since Medicare beneficiaries would be expected to have higher per capita prescription drug

utilization than other populations, we believe it would generally be appropriate to allocate rebates (and other similar price concessions) on the basis of percentage of dollars spent rather than of covered lives. The method of apportioning and applying rebates will be influenced by the payment methodology that is implemented for the retiree drug subsidy (see discussion in section 5 of this subpart). For example, in a one-time annual retroactive payment system, where payment of the subsidy is made after the close of the year, it should not be too difficult to factor in the rebates credited to the sponsor (or plan) for the period in question since the subsidy payment may occur after the rebates have been credited. Conversely, under a monthly payment system, factoring in the rebates would require a process to reflect the rebates as they are realized, because they are not likely to be determined and known until after some subsidy payments occur.

We believe either approach would require a form of cost reporting in which rebates received at the aggregate plan level would be apportioned to plan enrollees. One approach would be to reduce the subsidy payments by a certain percentage calculated to equal the assumed size of the rebates expected to occur. After 2006, the amount of reduction could be based upon the rebates received in prior years. Once the actual rebates were credited for the year in which the subsidy payments were made, the payments could be reconciled. Alternatively, rebates could be accounted for and paid in the month in which they are received. We also briefly discuss how rebates could be applied to different payment methodologies in section 5(b) of this subpart.

In any case, plans must require and keep accurate records on all price concessions and ensure that these are distinctly accounted for separately from administrative fees. We are considering how to best account for all of the price concessions and rebates. We welcome comments on the nature and scope of price concessions in this industry, and on the various forms these arrangements may take, as well as on the pass-through issue. We also welcome comments on how rebates and other forms of remuneration can be most accurately applied to the cost data to efficiently satisfy the requirement that all rebates must be netted out of allowable retiree costs, while minimizing the burden on sponsors. All cost reporting would be subject to inspection and audit (including periodic audits) by CMS and the OIG. As discussed later, to the extent either CMS or the OIG discover that a sponsor was overpaid for the retiree drug subsidy (that is, the records do not support the payments made, or there is insufficient documentation to determine whether the payments are correct), we may recoup the overpayments or take other appropriate action. The reopening and overpayment provisions are discussed in section 6 of this subpart R.

Dispensing Fees

For purposes of consistency, we plan to use the same definition that will be applied to PDP and MA–PD plans. See the discussion of dispensing fees in subpart C of the preamble to our proposed rule, which discusses possible definitions.

3. Requirements to Apply for the Retiree Subsidy (§ 423.884)

a. General Requirements

This section outlines the general requirements related to applying for the subsidy payment described in this proposed rule. First, in order to be considered a qualified retiree prescription drug plan, a plan must meet the definition of employment-based retiree health coverage as defined in § 423.882 of our proposed rule, and must also comply with the requirements proposed in § 423.884 and discussed in this section of the preamble. Additionally, a plan sponsor that wishes to be paid the Medicare subsidy must apply annually for the subsidy. In paragraph b, below, we describe the actuarial attestation that must be submitted with the subsidy application; in paragraph c, we describe the application process, including the information that must be submitted to establish that the sponsor qualifies for a subsidy; and in paragraph d, we describe the disclosure notices that plan sponsors are required to provide to beneficiaries. Finally, the sponsor must meet the requirements of proposed § 423.888(d) with regard to maintenance and access to records for purposes of audit, as discussed in section 5 of this subpart, below.

We intend to conduct outreach to plan sponsors, including State and local governments, who would be prospective applicants for these subsidy payments in order to encourage communication, better understand the needs of the employer community, and provide information on the retiree drug subsidy program, as well as to solicit suggestions on how we can best implement this program. We invite comments on the most effective methods of conducting outreach, as well as prospective venues for conducting that outreach.

b. Attestation of Actuarial Value Amount

1. Attestation Requirements

In § 423.884(a) of our proposed rule we would require that the sponsor submit an attestation to us that the actuarial value of the prescription drug coverage under its retiree plan or plans is at least equal to the actuarial value of standard Medicare Part D prescription drug coverage. (A more complete discussion of actuarial equivalency follows, below.) In § 423.884(a)(1) of our proposed rule, we would require that the attestation be submitted annually after year 2006, but no later than 90 days prior to the earlier of the start of the calendar year or plan year. (Our tentative decision is to use a calendar year.) For purposes of the initial application for the subsidy for 2006, the attestation must be submitted by September 30, 2005. Additionally, we would require that an updated attestation be submitted when mid-year changes to the drug coverage materially affect the drug coverage's actuarial value. (A material change means any change that potentially causes a plan to no longer meet the actuarial equivalence test.) These submissions would not be required when non-material changes are made to the coverage (for example, when there are changes in the period of open enrollment). We would require that the attestation be submitted 90 days prior to the effective date of any material changes. If the impending changes result in the plan either no longer being a qualified retiree prescription drug plan or no longer providing creditable coverage because its benefits are no longer actuarially equivalent to Medicare Part D coverage for purposes of either actuarial test, we would require that beneficiaries be notified of this change 90 days prior to the change taking effect and informed regarding opportunities to enroll in Medicare Part D. (*See* subsequent discussion regarding disclosure notices.)

We believe that requiring attestation on an annual basis and 90 days prior to material changes in coverage, with a 90 day notice to beneficiaries when necessary, should provide sufficient assurance to beneficiaries and CMS that the plan meets requirements concerning actuarial equivalency and affords beneficiaries time to enroll in Medicare Part D without incurring a late enrollment penalty as provided for in § 423.56 of our proposed rule. We would also require that the attestation, which must be signed by an authorized

representative of the plan sponsor (or a plan administrator designated by the sponsor), include a certification, signed under penalty of perjury, that indicates that the information contained in the attestation is true and accurate to the best of the attester's knowledge and which acknowledges that the information is being provided to obtain Federal funds. We welcome comments on whether these proposals provide sufficient protection for beneficiaries and whether these proposals would be operationally feasible without creating an undue burden for sponsors.

2. Establishing Actuarial Equivalency

Section 1860D–11(c) of the Act provides the Secretary with the authority to determine the standards and methods for determining actuarial equivalence. In developing standards for actuarial equivalence, our intent is to consider how to maximize coverage for retirees while limiting costs for the government, and the retiree drug subsidy is one important option for achieving this objective. The MMA provisions creating Part D provide multiple options for plan sponsors, ranging from participating in the retiree drug subsidy to various mechanisms for enrolling retirees in Part D prescription drug plans while offering enhanced benefits. Our goal is not only to protect, but also to enhance coverage offered to retirees. As discussed elsewhere, prior to enactment of the MMA, employers have been systematically restricting drug coverage for future retirees. Taken together, these legal and behavioral factors introduce substantial uncertainty about how plan sponsors will assess their options and react to the new Part D benefit.

Congress has clearly and repeatedly articulated four key policy objectives for the Medicare retiree drug subsidy program. The first goal involves maximizing the number of retirees retaining employer-based drug coverage through the retiree drug subsidy program created by Section 1860D–22 of the Act. The second goal entails not creating windfalls, whereby retirees might receive a smaller subsidy from sponsors of their retiree drug plans than Medicare would pay on their behalf. The third goal is to minimize the administrative burdens on beneficiaries, employers and unions. The final goal is to minimize costs to the government of providing retiree drug subsidies (and not exceed the budget estimates). While the first, third and fourth goals received extensive discussion during the creation of MMA, the second goal has emerged largely in response to the possibility that the MMA might have created an unintended windfall.

We believe the Secretary has authority to achieve these goals based on the requirements that plans qualifying for the retiree drug subsidy must offer at least actuarially equivalent benefits to those offered by standard Part D prescription drug plans (PDPs). Our proposed regulation reflects our attempt to accomplish the four objectives of maximizing the number of retirees benefiting from the retiree drug subsidy, avoiding windfalls, minimizing administrative burden and not exceeding budget estimates. In doing so, we are considering a range of potential options, each of which may have an impact on achieving the key objectives. We seek comments on how best to accomplish these goals, recognizing both that there may be tradeoffs, and that our implementation must be consistent with the statutory authority provided the Secretary.

The definition of actuarial equivalence in this context may have an impact on our policy objectives. One possible definition would stipulate that plans must meet the same test as for "creditable coverage." The test for creditable coverage requires that, on average, the total or "gross" value of the benefit package offered by the employer at least equal that of the standard Part D benefit offered by PDPs, without regard to the financing of this benefit package. As we discuss in subpart B of this preamble, the main concern in establishing creditable coverage is in determining the level of health benefit coverage the beneficiary has had, and not on how it was financed, since no payments are involved. However, when applying this gross value (of plan payout) test in the context of the retiree drug subsidy, we must be concerned with whether our subsidy payments to sponsors will exceed the costs that sponsors actually incur in sponsoring the coverage. This one test, or "single prong" approach, to defining actuarial equivalence could not by itself preclude the existence of windfall payments. This is because, without considering financing, an employer theoretically could impose the full cost of the benefit package on the employee through employee premiums, and still be eligible for a subsidy payment if the package the employee was buying met the actuarial equivalence test. Or, the employer could contribute a smaller amount toward the financing of the package than it would receive in a subsidy payment. We seek comments on whether additional steps associated with this approach could ever preclude windfalls. In particular, some observers have argued that the forces in a competitive labor market, collectively bargained contracts, and constraints on changing state, local and other public sector retiree health plans obviate the likelihood of windfalls. We have serious reservations about the adequacy of such forces in precluding the existence of any windfalls without significant additional monitoring by Medicare or others to assure that benefit subsidy payments are passed on to augment benefits received by retirees. Such approaches may create excessive administrative burdens on retirees, employers, and unions, and thus alternative approaches to precluding windfalls are likely to be preferable.

Another possible policy option would be to use the "one prong" approach to determining actuarial equivalency, but to also limit the amount of the retiree drug subsidy so that it could not exceed the amount paid by plan sponsors on behalf their retirees. This would assure the elimination of windfalls. However, while this approach would be simple both to describe and operationalize, we have questions about the adequacy of the legal basis underpinning such a policy.

A third approach, which could be implemented in a variety of ways, would establish a "two-prong" test of actuarial equivalence: A "gross" test would assure the total value of benefits, and a "net" test would reflect only the value of benefits not financed by beneficiaries. This third approach is structured specifically to preclude windfalls. The first prong of the actuarial equivalency would again be a test based strictly on plan design. This test would evaluate whether the expected amount of paid claims (or "plan payout") under the retiree prescription drug coverage is at least equal to the expected amount of paid claims under the standard Medicare Part D benefit. The second prong of the actuarial equivalency test would be a "net value" test in which the gross value of the plan design would be reduced to account for the level of benefits financed solely by the beneficiary. For instance, the net value of the coverage could be calculated by subtracting the retiree premium from the expected amount of paid claims under the retiree drug program. In order to qualify for the subsidy, a sponsor's plan would have to meet both prongs of the actuarial equivalence standard.

The "net" prong of the two-prong test of actuarial equivalence could have several variants. While each variant of the two-prong test would preclude windfalls, each would present a different balance among potentially

competing objectives. At a minimum, we believe that the net value of the creditable coverage should as a policy matter at least equal the average per capita amount that Medicare would expect to pay as the retiree drug subsidy. (We estimate this value at $611 in 2006.) While there may be policy advantages to this approach, we have questions about the adequacy of the legal basis underpinning such a policy. We specifically invite comment on the question of whether the statutory language could reasonably be interpreted to support this approach. Alternatively, a higher threshold could be required. For instance, we could require that this value be more closely related to the net value of the standard Medicare Part D benefit (which is the expected amount of paid claims under Medicare Part D less the monthly beneficiary Medicare Part D premium under § 423.286 of our proposed rule). However, as the threshold was raised, it would be more difficult for retiree plans to qualify, that is, to (1) not provide windfalls and (2) offer coverage that is at least as generous in overall actuarial value as the Medicare subsidy.

Another alternative benchmark value for the net test could be the after-tax value of the expected average per capita retiree drug subsidy. (There is special tax treatment available for the retiree drug subsidy. Plan sponsors get to deduct all the associated expenses but the value of the subsidy payments is not recognized as income for tax purposes.) Unfortunately, determining the appropriate amounts to use for this benchmark would pose significant problems because of the heterogeneity of the plan sponsors. For example, we estimate that at least 60 percent of retirees that are age 65 and older receive retiree health benefits from entities that are exempt from taxation (including both public and nonprofit entities, based on data from the 2001 Medical Expenditure Panel Survey); for those plan sponsors subject to taxation, their rates of taxation vary markedly. In addition, as mentioned above, we have questions about the adequacy of the legal basis underpinning this approach.

As noted above, adopting a two-prong test with the higher value for the net test could arguably provide greater protection to beneficiaries, but might drive plan sponsors out of participating in the retiree drug subsidy and toward using the Part D-based options for supporting and enhancing drug coverage. Conversely, adopting a lower value for the net test might qualify more plan sponsors to participate in the retiree drug subsidy, but it might also discourage some employers and unions from increasing their contributions to reach the higher threshold level, and thereby increasing generosity of coverage. Public comment would help limit uncertainty by clarifying the likely responses of plan sponsors to these different approaches. In addition, we solicit comments not only on the desirability of the different options, but also (as noted above) on the legal bases for possible options.

In any case, the actuarial equivalence test(s) established by CMS must be applied to each sponsor's retiree prescription drug plan in order to determine if it is a qualified retiree prescription drug plan for purposes of qualifying for a subsidy. In considering the point of reference for a "plan," we recognize that there is tremendous diversity and complexity in prescription drug coverage options among employers and unions for retirees. There may be either different employer/union contribution levels or benefit designs within a single plan for various segments of retirees (referred to as "tiered cost sharing"). A qualified retiree prescription drug plan is defined with reference to the definition of a "group health plan" which section 1860D–22(c)(3) of the Act specifies is to be the definition of that term in section 607(1) of ERISA. That definition states that the term "means an employee welfare benefit plan providing medical care * * * to participants or beneficiaries directly through insurance, reimbursement, or otherwise * * *." Section 3(1) of ERISA in turn defines an employee welfare benefit plan as "any plan, fund, or program [which is] established or maintained by an employer or by an employee organization, or by both, to the extent that the plan, fund, or program was established or is maintained for the purpose of providing for its participants or their beneficiaries, through the purchase of insurance, or otherwise, * * * medical, surgical, or hospital care or benefits * * *."

Section 1860D–22(a)(2)(A) of the Act clearly indicates that a plan must meet the actuarial equivalence test in order to qualify for a subsidy. We propose to apply the ERISA definition in a way that is appropriate in the context of section 1860D–22 of the Act, and recognizes the diversity in retiree drug coverage among employers and unions. Our proposal is modeled on the approach adopted by the Department of Treasury at 26 CFR § 54.4980(B)(2), in the context of a different definition of "group health plan." In the Questions and Answers that relate to that section, Q–6 and A–6 take the position that all health benefits provided by a sponsor are presumed to be under a single plan unless it is clear from the plan instruments and instrumental operation that the plans are separate plan arrangements. We believe this proposed approach is familiar to plan sponsors, is appropriately flexible, and protects retiree-beneficiaries. We welcome comments on how best to apply the statutory definition of a "plan" within this context, especially to sponsors that offer a multiple choice of retiree plans with various levels of sponsor contributions.

We believe we have discretion as to whether to require that the sponsor demonstrate that the value of the retiree coverage under the group health plan is actuarially equivalent to standard prescription drug coverage under Part D for each individual based on: (1) the benefit package received by the individual, or (2) on average across all participants and beneficiaries receiving coverage under the sponsor's group health plan. We propose to require sponsors to apply the actuarial equivalence test to each group health plan as a whole, with the standard met if *on average* the actuarial value of retiree drug coverage under the plan is at least equal to the value of standard prescription drug coverage under Part D. We believe that this approach would be less burdensome for sponsors.

As previously noted in subpart F of this preamble, we will provide additional information in the future on the processes for determining actuarial valuation, including that of retiree prescription drug coverage. We are currently considering the following guidelines—

- We anticipate that we would specify, as either recommended or required in further guidance, data sources, methodologies, assumptions, and other techniques in accordance with generally accepted actuarial principles. We would require that the actuarial attestation be provided to us and we would verify that the attestation was signed by a qualified actuary. In addition, we may select a random sample of attestations for which we would require additional information to provide a quality control review. Also, we expect that a detailed review of the actuarial attestation would be included in the auditing process.
- Section 1860D–11(c)(3)(B) of the Act specifies that PDP sponsors or MA organizations offering MA–PD plans may use qualified independent actuaries in developing bids. We believe it is appropriate to adopt this model with respect to this proposed rule, allowing retiree plan sponsors to use outside actuaries in their processes. We would

specify that a qualified actuary is an individual who is a member of the American Academy of Actuaries, because members of the Academy must meet not only educational and experience requirements, but also a code of professional conduct and standards of practice. These standards create a common ground for actuarial analysis. Furthermore, a member of the Academy is subject to its disciplinary action for violations of the code and standards. This same requirement is specified in the SCHIP legislation at section 2103(c)(4)(A) of the Act.

c. Sponsor Application for Subsidy Payment and Required Information

A plan sponsor who wishes to be paid the retiree drug subsidy must apply annually for the subsidy. We will provide the technical details (including important systems issues) to sponsors and other interested parties in the very near future in order to facilitate our developing appropriate guidance, which will, in turn, encourage sponsor participation and minimize the burden to sponsors to the maximum extent possible. We intend to actively seek comments from sponsors and to release guidance to sponsors in 2005. In order for plan sponsors to receive a subsidy payment for 2006, we would require that all plan sponsors apply for the subsidy payment no later than September 30, 2005. For future years, as described above in the discussion of attestation, we would require that plan sponsors apply for the subsidy no later than September 30 of the previous year. Table R–1, containing the key dates involved in the sponsor application process, is included at the end of this section.

We request comment on this approach, including how such a deadline might interfere with a sponsor's open season, and whether or not sponsors will already know, as early as 90 days prior to the start of the year, which plan option a beneficiary has enrolled in. For sponsors that institute retiree prescription drug coverage after September 30, 2005, we would require that these sponsors apply at least 150 days prior to the start of the new plan for the first plan year.

We would require that sponsors (or an administrator of the plan designated by the sponsor) provide all of the following information as part of the application for special subsidy payment—

- Employer Tax ID Number (if applicable);
- Sponsor name;
- Sponsor address;
- Contact name, job title and email address;
- Actuarial attestation and supporting documentation for each qualified retiree prescription drug plan for which the sponsor will be seeking subsidy payments;
- Identifying information for each of the separate plans.

Additionally, the following information must also be submitted for each plan—

- Full names of each qualifying covered retiree (as defined previously) enrolled in the sponsor's prescription drug plan (including spouses and dependents if Medicare-eligible), and the following information—
- Health Insurance Claim (HIC) number (when available);
- Date of birth;
- Sex;
- Social Security number; and
- Relationship to the retired employee.

(Nothing in this data collection discussion should be construed as limiting OIG authority to conduct any audits and evaluations necessary for carrying out our proposed regulations.)

Since we will be dealing with individually identifiable health information, we provide elsewhere in this preamble a separate discussion of privacy issues related to the submission of this information. We note that, in most cases, the plan sponsor would not have access to claims information or similarly protected health information regarding retirees. Therefore, throughout this preamble where we refer to information provided by the plan sponsor, we may in fact mean by the plan administrator, insurer, or group health plan on behalf of the plan sponsor. In addition, we are aware that sponsors may not have information on Medicare Part D eligible individuals who receive benefits under the employer-sponsored plan as spouses or dependents of a plan participant. We are also aware that many employers do not currently collect information about dependents, but plan administrators may maintain that information about dependents. Moreover, we are also aware that all plans do not consistently collect Medicare Health Insurance Claim (HIC) and Social Security numbers. Therefore, in order to be able to make and/or audit subsidy payments, we need a process to be able to identify the Medicare beneficiaries on whose behalf the subsidy payments would be made. We welcome comments on the proposed information list.

We encourage sponsors who plan to request a subsidy payment from Medicare to begin to evaluate the availability of this information and to plan for the creation of a file with this type of information contained in it. Technical systems specifications for the file would be included in guidance to sponsors from CMS. We actively seek input from employers, plan sponsors, plan administrators, and other interested parties to facilitate our developing the most appropriate, efficient, and effective guidance.

We have worked with many employers and other insurers in the context of Medicare Secondary payer requirements, and we believe that this will help facilitate the identification process. We welcome the opportunity to work with employers and insurance companies in this regard. Additionally, we launched a "Voluntary Data Sharing" initiative in 2000 that allows CMS and employers to electronically exchange employee group health coverage information and Medicare entitlement information on a current basis. This process can, for example, identify whether a retiree or spouse is a Medicare beneficiary and the date of entitlement to Medicare. More information about the CMS Employer Voluntary Data Sharing initiative can be found at: *http://www.cms.hhs.gov/medicare/cob/employers/emp_vdsa.asp.*

Finally, an authorized representative of the requesting sponsor must sign the completed application. The application will specify the terms and conditions of eligibility to receive a subsidy payment. The application would require the sponsor to comply with all Federal laws and regulations, as well as the terms and conditions of eligibility for a subsidy payment, including auditing of claims for subsidy payment and combating fraud and abuse, any further certification that CMS may require. The sponsor would be required to acknowledge that the information is being provided to obtain Federal funds. The signed application would constitute an agreement between the sponsor and CMS and would be referred to as the "sponsor agreement." The sponsor would be required to include in all subcontracts with third party administrators and other subcontractors performing functions in connection with the sponsor retiree drug benefit an acknowledgement that the subcontractor knows and understands that all information provided in connection with the contract will be used for purposes of obtaining Federal reimbursement.

Once the full application for subsidy payment is submitted, we would match the names and identification numbers of retirees submitted by the sponsor with the Medicare Data Base (MDB) to determine which individuals are both eligible for Medicare Part D (that is,

individuals who are entitled to benefits under Medicare Part A or who are enrolled under Medicare Part B) but who are not enrolled in Medicare Part D. We would then provide to the sponsor (or to a plan administrator designated by a sponsor) the names and other necessary identifying information, if any, of the sponsor's qualifying covered retirees.

We recognize that there would be a need to update information from sponsors on a routine basis in order to incorporate newly eligible retiree-beneficiaries and to prevent overpayments and underpayments as qualifying covered retirees make switche between Medicare Part D and the retiree drug plan. We are considering options for this enrollment update process. One possibility is to use a complete enumeration file submitted as part of the annual application process, with subsequent, periodic updating. We would appreciate public comments on this issue.

We are also considering and seek comment on whether to require a surety bond type of instrument or preferred creditor status " as part of the enrollment process—in order to address situations related to businesses that may terminate or experience bankruptcy prior to completion of a final reconciliation.

TABLE R–1.—PROPOSED KEY DATES

Publication of final rule	Early 2005
Application for Subsidy Due Date for All Sponsors, regardless of whether they operate on a calendar or plan.	No later than September 30, year 2005.
Attestation of Actuarial Equivalence Due Date for all Sponsors	No later than September 30, 2005.
Retiree drug subsidy Program Begins	January 1, 2006.
Application for Subsidy Due Date for plans operating on a plan year basis.	September 30, 2006 (for 2007) and each September 30 thereafter for subsequent years.
Application for Subsidy and Attestation of Actuarial Value Due Date for plans operating on a calendar year basis.	September 30, 2006 (for 2007) and each September 30 thereafter for subsequent years.
Application for Sponsors that institute coverage after September 30, 2005.	150 days prior to the start of the new plan.
Notice to CMS of mid-year plan changes that materially affect actuarial valuation.	90 days prior to the plan change.
Notice to enrollees of plan changes that result in the plan no longer being a qualified retiree prescription drug plan.	90 days prior to the plan change.

d. Creditable Coverage and Notification

Section 1860D–22(a)(2)(c) of the Act specifies that in order for a sponsor's plan to meet the definition of a qualified retiree prescription drug plan, the sponsor must provide for disclosure of whether coverage is "creditable coverage" in accordance with the proposed requirements set forth under proposed § 423.56 of our proposed rule. The actuarial equivalence standard for creditable coverage is the same as one of the tests proposed for the actuarial equivalence standard for qualified retiree prescription drug plans in order to qualify for a retiree drug subsidy. The actuarial equivalence standard for creditable coverage is the "gross value" test (that is, whether the expected amount of paid claims (or "plan payout") under the retiree prescription drug coverage is at least equal to the expected amount of paid claims under the standard Medicare Part D benefit), which is the so-called first prong of the actuarial equivalence test for purposes of qualifying for the retiree drug subsidy.

As explained in subpart B of the preamble of our proposed rule, if a Medicare Part D eligible individual fails to enroll in Medicare Part D upon first becoming eligible for Medicare Part D, the individual would be subject to the late enrollment penalty if the individual elects to enroll in Medicare Part D at a later date. However, the late enrollment penalty would be waived if the beneficiary had creditable prescription drug coverage during the time he or she was not enrolled in Part D.

Proposed § 423.56 of our proposed rule would require certain entities providing drug coverage, including group health plans, to disclose to Part D eligible individuals and CMS whether that coverage is considered "creditable coverage" as described in proposed § 423.56(a) of our proposed rule, or whether the value of the coverage to the individual is at least actuarially equivalent to standard prescription drug coverage under Medicare Part D. Consequently, plan sponsors under this proposed rule would be subject to the requirements in proposed § 423.56 of our proposed rule governing disclosure of creditable coverage.

As discussed in subpart B of our proposed rule and discussed below, we intend to describe the proposed process for providing this disclosure notice, including guidance on its content, placement, and timing of notice. The content of the disclosure notice and its timely receipt would be important components in the decision making process for beneficiaries, because the creditable status of the retiree's drug coverage would have a direct impact on the assessment of late enrollment penalties associated with Medicare Part D premiums. Notifying the retiree of any subsequent changes in their creditable coverage status is equally important. Because retirees would have a limited time in which to make decisions about their Medicare Part D coverage without facing a penalty; it would be important that the notification of creditable status be provided in a timely and conspicuous manner. However, we are also concerned about the potential administrative burden imposed by this proposed requirement and therefore, we are soliciting comments on the format, placement, and timing of this notice.

We have considered several approaches to implementing this requirement. One possible approach would be to provide the sponsors with standard language that could be incorporated into the required disclosure materials the sponsors routinely disseminate to their enrollees in their retiree drug plans. (We could provide standard language to be inserted into these materials.) We are soliciting comments regarding the types of materials that could provide an appropriate vehicle for this purpose, as well as ways to ensure that the notice is conspicuous and readily identified by recipients, particularly in those instances where the coverage is not creditable.

Another possible approach would be to require each sponsor to issue a separate notice to each Part D eligible enrollee in their retiree drug plan. This

type of notice would be the most conspicuous and would subsequently increase the likelihood that beneficiaries are made aware of the creditable coverage status of their prescription drug coverage. Because retirees are subject to financial penalties for the failure to maintain creditable coverage when they enroll in Medicare Part D after the initial enrollment period, a separate notice may better inform beneficiaries and ensure that they take appropriate action to avoid the penalties. The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 101–93, requires entities that offer health insurance coverage to inform their members, in writing, of the type and duration of "creditable coverage." Implementing regulations at 62 FR 16901 (April 8, 1997) provided a "Certification of Creditable Coverage" that must be produced and disseminated to individuals when their coverage ends. We considered requiring that information about the creditable status of prescription drug coverage be included in this certification. However, since the certification required under HIPAA is not provided until after the coverage has ended, it would arrive too late to assist beneficiaries in deciding whether to enroll in Part D. However, the HIPAA certification may serve as a useful model, and we invite your comments about the administrative burden associated with producing and disseminating a similar notice of creditable status to beneficiaries.

The timing and frequency of these notices would also be a key consideration. The initial notice of creditable status would have to be coordinated with the first "Annual Coordinated Enrollment Period for Part D," which begins November 15, 2005, to ensure that retirees have this information when making their decisions regarding Part D coverage. Retirees would also need to know about any change in the creditable status of existing coverage before this change becomes effective so that they have sufficient time to decide whether to obtain Part D coverage. If a retiree's creditable drug coverage ends or is changed to the extent that it is no longer creditable, the retiree has a "Special Enrollment Period" during which he or she can enroll in Part D without financial penalty. Thus, we believe that this notice should be provided, at a minimum of these two important times, and also upon request by the beneficiary.

We view this process as an important one, and invite comments on how best to ensure that retirees receive timely and adequate notice of the creditable status of their prescription drug coverage without imposing a significant administrative burden on sponsors that provide the coverage. We also note that section 1860D–22(a)(2)(C) of the Act requires sponsors to disclose the creditable status of this coverage to us, and we invite your comments on the possible methods of providing this disclosure.

4. Retiree Drug Subsidy Amounts (§ 423.886)

As explained previously, § 423.886 governs the subsidy amount a sponsor of a qualifying retiree prescription drug plan receives for each qualifying covered retiree that is enrolled with the sponsor in a year. The sponsor is eligible to receive a subsidy payment for each qualifying covered retiree whose gross covered retiree plan-related prescription drug costs exceed the cost threshold. The amount of the subsidy would be 28 percent of the allowable retiree costs attributable to the gross retiree costs that are above the threshold and do not exceed the cost limit. For plan years ending in 2006, the cost threshold is $250 and the cost limit is $5000.

The cost threshold and cost limit for a plan year that ends after 2006 would be adjusted in the same manner that the annual Part D deductible and the annual Part D out-of-pocket threshold are adjusted annually under § 423.104(e)(1)(ii) and § 423.104(e)(4)(iii)(B) of our proposed rule, respectively. Accordingly, beginning in 2007, we will adjust the cost limit and cost threshold based on the annual percentage increase or decrease in average per capita expenditures for covered Part D drugs in the United States for Part D eligible individuals for the 12 month period ending in July of the previous year, with the cost threshold rounded to the nearest multiple of $5 and the cost limit rounded to the nearest multiple of $50.

CMS claims that are generated by an overpayment of the subsidy to a sponsor, including collection of interest, administrative costs, and late payment penalties would be governed by regulations at 45 CFR Part 30, subpart B.

5. Payment Methods, Including Provision of Necessary Information (§ 423.888)

a. Plan Year Versus Coverage (Calendar) Year

Under section 1860D–22(a)(3)(B) of the Act, the cost threshold and cost limits that determine the amount of the subsidy are calculated for "plan years that end in" 2006 and subsequent calendar years. However, section 1860D–22(a)(3)(A) of the Act refers to the subsidy amount for a qualifying covered retiree for a "coverage year," that is defined as calendar year. Thus, we believe that, in the context of section 1860D–22 of the Act, the reference to retirees enrolled in a qualified plan "during a coverage year" can be read to mean that the retiree must be enrolled during either a calendar year or plan year that ends in the specified calendar year. As explained below, we would prefer a strict calendar year basis and believe our proposed requirements would permit sponsors with non-calendar plan years to comply with reasonable modifications. We are interested in receiving comments on whether we should maintain our initial policy based on the calendar year or whether we should consider a plan year as the basis for the subsidy.

While a calendar year approach is more straightforward from the perspective of Federal administration of the subsidy program, use of "plan year" may better conform to the accounting systems of the plans and the sponsors. However, we note that the Federal subsidy is related to drug spending, not plan coverage. If we do elect to use a "plan year" as the basis for payment, we would use the definition of a "plan year" in section 3(39) of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1002(39), which includes, for a plan, the calendar, policy, or fiscal year on which the records of a plan are kept. If we do elect to use a "plan year," the statute makes clear that the cost threshold and the cost limit will apply based on the calendar year in which the "plan year" ends. For example, in the case of a July 1, 2006–June 30, 2007, "plan year," the cost threshold and the cost limit applicable in general in 2007 would also apply for this "plan year." Because the actuarial attestation would be due no later than April 1, 2006 (90 days in advance of the plan year), it is quite possible that the cost threshold and cost limits for 2007 would not yet have been calculated at that time.

Another issue that is unique to the use of a "plan year" as a basis for the subsidy payment that arises in the first year of the program is how to handle plan years that begin in 2005. For example, if a plan year ends on June 30, 2006, only six months of that plan year accrued after January 1, 2006. The following are at least three options for addressing this problem:

(1) The first option is to start counting gross costs for prescriptions filled after January 1, 2006. That is, even though

the plan year in this example began on July 1, 2005, gross costs of qualifying covered retirees would only take into account prescriptions filled beginning with January 1, 2006. These gross costs would have to exceed $250 before their associated allowable costs would be subsidy eligible. Since subsidy payments are not authorized prior to the start of the Part D program, this option represents the strictest reading of the statute, in that gross costs and, therefore, allowable costs, are calculated without regard to the portion of the plan year that falls before January 1, 2006. It would, however, disadvantage plans that choose to use plan year instead of calendar year, since total subsidy payments for calendar 2006 would be lower than they would have been if calendar year had been used since the cost threshold must be met a second time in calendar 2006.

(2) The second option is to determine a subsidy amount as if the sponsor were authorized to receive subsidy payments for the entire "plan year" and then to prorate this amount based on the number of "plan year" months that fall in 2006. First, gross costs would be determined for the entire "plan year". Allowable costs and the subsidy amount would be derived based on the proportion of the gross costs that exceed the cost threshold but are less than the cost limit. Finally, the subsidy amount for the plan year would be prorated by the number of months of the plan year that fall in 2006. In our example of a July 1–June 30 plan year, six months would fall in 2006 so the annual subsidy amount would be cut in half. This option, while still consistent with the statute, would provide a larger payment than the first option.

(3) The third option would determine subsidy amounts on monthly basis as if the sponsor were authorized to receive subsidy payments for the entire "plan year", but would then pay only the amounts for the "plan year" months that fall in 2006. The process for determining the subsidy is similar to that described in option two, but rather than calculating an annual subsidy amount, one would determine the subsidy payments applicable to costs incurred for each month of the plan year. The sponsor would then receive the subsidy payments for the months in the plan year that fell in 2006 (that is, January 1 through June 30, 2006). This option would require that the sponsor determine the month in which costs are incurred. Therefore, it adds some complexity to the calculation of the subsidy. However, since subsidy eligible expenditures are weighted more toward the latter part of the plan year, this option would produce a stream of subsidy dollars that would parallel the actual flow of the sponsor's plan expenditures.

We would like to receive your comments on these options or other possible approaches, as well as on the threshold issue of whether we should rely only on calendar years, as explained below. We again note that relying on calendar years avoids the complications discussed above.

b. Payment Methodology

Section 1860D–22(a)(5) of the Act specifies that payments to plan sponsors are to be made "in a manner similar to" the payment rules in section 1860D–15(d) of the Act, which apply to payments made to PDP sponsors and MA organizations under Part D. We believe that section 1860D–15(d) of the Act gives us broad discretion to determine a payment method. We wish to develop a payment methodology that is beneficial to the sponsors, and is cost efficient. Some of the factors to consider in developing a system that will pay subsidies are whether it is technologically feasible and what it would cost. Another issue is that pharmaceutical rebates, which must be excluded from allowable retiree costs, are generally not factored into the payments at the point of sale but instead not until much later in the process. We also recognize that highly automated insurance carriers or pharmacy benefit managers (PBMs) are used by almost all the sponsors for collection of the claims data that will be key elements of the data required for the payment of the subsidy.

Our proposed policy is predicated on the assumption that plan sponsors utilize the services of sophisticated point-of-sale claims payment agents such as PBMs. We further understand that PBMs (or comparable administrative entities) routinely adjudicate prescription drug claims on a real-time basis and have very limited claims (sometimes referred to as incurred, but not received) or payment lags. As a result, actual monthly expenditures are routinely known shortly after the close of a month. We outline below our proposed approach to calculating and paying the alternative subsidy to qualified retiree prescription drug plans in 2006 (using an actuarial attestation based on a plan year, but with the alternative subsidy computed on a calendar year basis):

- For each month starting with January 2006, the plan sponsor would certify by the 15th of the following month (that is, February, 2006 for January, 2006) the total amount by which actual retiree-beneficiary gross drug spending exceeded the cost threshold yet remained below the cost limit. Medicare would pay 28 percent of the certified amount to the sponsor by the 30th of that month. Not later than 45 days after the end of the calendar year, the plan sponsor would submit a final reconciliation (but for outstanding rebates) to us for payment by or, if applicable, to us. (We recognize that plan sponsors may not receive some rebates until after the close of the their plan year.)
- In the month in which they are received (or recognized), the appropriate share of any discounts, rebates, or other price concessions, along with any adjustments to the actual expenditures for prior months, are reflected. Any amounts owed the government would offset the subsidy payment for that month, to the extent that the amount owed to the government would exceed any applicable monthly payment, the plan sponsor would pay this amount to us.
- Plan sponsors (or more likely, plan administrators, insurers or group health plans on their behalf) would maintain detailed records of claims payment and other matters. The specifics of the data retention, data submission, audit and financial requirements would be determined in future instructions.

We note that, due to our need for monthly coverage and spending data, this system could work equally well for plans whether their plan year is coterminous with or is different than the calendar year. Because the special subsidy is based on allowable gross drug spending, without regard to the relationship of this spending to plan coverage or reimbursement, we believe the amount of drug spending for each eligible retiree-beneficiary can be easily be extracted from the insurance coverage provided in a "plan year". We believe months, as opposed to a daily, weekly, or annual basis, constitute the appropriate unit for computing the special subsidy. We note that more detailed, disaggregated data would be needed for purposes of audits and annual reconciliations.

Actual monthly payments could be adjusted by the actual amounts received in that month for discounts, chargebacks and rebates appropriately attributed to allowable gross costs (as defined for purposes of claiming the special subsidy). Under this approach, payments would be based on actual drug spending and discount, chargeback or rebate payments. While arguably more data intensive, we believe this to be the most straightforward option, minimizing reliance on projections and

actuarial representations. It also would facilitate expeditiously paying sponsors full subsidy amounts to which they would be entitled. Any underpayment or overpayment would generally be dealt with through an adjustment to subsequent periodic payments. This option would provide a payment stream, which comes closest to subsidizing actual plan expenditures as they occur.

The following items would be three possible alternative options to our proposed methodology discussed above and the broad outline of the process for receiving subsidy payments. Under all three alternative options, sponsors would have to meet the specified filing deadlines in order to receive subsidy payments:

(1) The first alternative option would be to make a single payment after the close of the year. Under this option, by the start of the fourth month after the close of the plan or calendar year, sponsors whose attestation of actuarial equivalence had been approved for that year would submit to us the number of months of coverage for each qualifying covered retiree and their gross and allowable costs. (Partial years of coverage would result from individuals becoming qualifying covered retirees during the course of the year and also from decedents who die during the course of the year. In the case of new qualifying covered retirees, only their expenses from the month of their status change forward can be included in their gross and allowable costs, which would have to exceed the cost threshold in order for a payment to be made.) Gross and allowable costs would be derived directly from claims payments and retiree cost sharing for prescriptions dispensed during the plan year offset by appropriate rebate cost reporting (as discussed in section 2 of this subpart with respect to allowable retiree costs). The portion of gross costs that exceeded the cost threshold but were less than the cost limit would be derived. Discounts, chargebacks, and rebates, which already would have been factored for the year, would be removed from these gross costs to calculate allowable costs and the subsidy amount. We would review this submission and make a payment for the year by the end of the following month. This alternative option would be the simplest to administer and would obviate the need for interaction between CMS and sponsors other than during the review process. From the perspective of sponsors, however, this option may be less desirable since payment would not be received until after the close of the year.

(2) The second alternative option would be to make interim payments throughout the year with a settlement after the end of plan or calendar year. Under this alternative option, sponsors desiring to receive subsidy payments would develop an estimate of per capita subsidy payments based on the plan's claims history and the rebates or discounts received in the prior period. Sponsors would submit the estimate, as well as the basis for the estimate, at the same time that they submit their attestation of actuarial equivalence (which we have proposed in section 3(b) of the preamble to be three months prior to the start of the plan year). If the sponsor files on a timely basis and we agree that the sponsor offers a qualified retiree prescription drug plan, we would review the estimate and the documentation and determine an interim monthly per capita amount. Plans would be paid a percentage (70 percent for 2006 and 2007, 90 percent for subsequent years) of this interim payment level on a periodic basis for each qualifying covered retiree based on the sponsor's enrollment information which would be matched against Medicare records to verify qualifying status. We would pay less than 100 percent of this amount to minimize the possibility of having to recoup large amounts of money at the time of settlement. We are proposing to pay 70 percent in 2006 and 2007 given the significant uncertainty that will exist in estimating subsidy payments. We request comments on whether estimating techniques as to qualifying covered retirees and as to levels of drug spending during the year are reliable enough to justify a higher percentage. By the start of the fourth month after the close of the plan or calendar year, the sponsor would submit documentation on gross claim costs and rebates, as described in option 1, above. We would review the documentation and settle for the year by making an additional payment if more payment were due to the sponsor or by reducing subsequent interim payments to reflect any overpayment. This alternative option is more administratively complex than the first alternative option because it entails developing an interim payment amount and making those payments. It would, however, provide subsidy funding to sponsors during the plan or calendar year.

(3) The third alternative option would be to make lagged payments based mainly on actual experience on a periodic basis throughout the year with a settlement after the end of the year limited to reconciling estimated versus actual discounts, chargebacks, and rebates. By the 15th of the month following the close of the payment period, sponsors whose attestation of actuarial equivalence had been approved would submit information to us on gross and allowable costs for the previous payment period for each qualifying covered retiree whose gross costs, coverage (that is, calendar) year to date, exceeded the cost threshold, but were not in excess of the cost limit. The information submission would be based on actual claims experience. Actual monthly payments could then be adjusted on a percentage basis for estimated discounts, chargebacks, and rebates (the sponsor would submit a justification, which we would approve, for the percentage used). By the 15th of the following month, we would review the submission and make payment. By the start of the fourth month after the close of the plan or calendar year, the sponsor would submit documentation on actual discounts, chargebacks, and rebates received for the plan compared to those estimated. Any under payment or overpayment would be dealt with through an adjustment to subsequent periodic payments.

We would like your comments on the operational aspects of the proposed policy, as well as the broad alternative options, and on their desirability from the perspective of plan sponsors.

In addition to the question of payment methodology, there is the issue of the periodicity of the subsidy payments. While this is not an issue with regard to an annual retroactive payment, the question of periodicity does arise with regard to the ongoing payment alternatives. We would like your comments on the use of bi-annual, quarterly or monthly payment periods under these approaches. We also considered a variable payment option in which the frequency of payment would vary in accordance with the size of the sponsor's plan. For example, a sponsor with 10,000 or more qualifying covered retirees would receive monthly payments while sponsors with less than 10,000 qualifying covered retirees would receive quarterly payments. We are concerned that this alternative may be inequitable in terms of cash flow and overly administratively complex to implement. Again we are asking for your comments, particularly with regard to the balance between timeliness versus administrative burden posed by monthly or quarterly payments versus annual payments. We are also asking for your comments on whether to use more than one of the payment alternatives described above based upon the size of

the sponsor's plan. For example, in order to minimize administrative burden on small businesses, sponsors with less than 100 qualifying retirees could receive an annual retroactive payment. We solicit comments, in particular on the issue of whether less frequent payments might be preferable for small employers because it would minimize their reporting burden.

Our understanding is that PBMs and other entities currently involved in the administration of claims are highly automated and capable of efficiently and effectively providing the necessary information at low (incremental) cost in a timely manner. We are particularly interested in your comments about the capabilities of the service providers and their views, as well as the views of the plan sponsors and others, on the most appropriate arrangement, as well as your comments on the feasibility of the proposed approach and proposed alternative options.

c. Data Collection

Regardless of what payment methodology is ultimately chosen for the subsidy, we would need certain data from the sponsors of the plans (or the plan administrators, insurers or group health plans designated by the sponsors) in order to accurately calculate the amount of the subsidy to which the sponsor is entitled. This data would include updating of the information that was provided during the application process such as the names of the qualifying covered retirees enrolled in the plan, including the spouses and the dependents, the Health Insurance Claim (HIC) numbers (when available), social security numbers, dates of birth, sex, and relationship to the retired employees. We would also require an affirmation that the Medicare benefits of each qualifying covered retiree are not secondary to the sponsor's retiree health coverage (if the Medicare benefits are secondary to the sponsor group health plan, that would indicate that the participant is not in retiree status and, thus, is not a qualifying covered retiree except in certain situations in which the retiree qualifies for Medicare based on ERSD status), and dates of enrollment in the sponsor's retiree plan.

The plan sponsor (or the designated administrator, insurer, or group health plan) would be required to submit cost data for each qualifying covered retiree. The timing of the submission and the relevant time period of the cost data is contingent on the payment methodology that is adopted in the final rule for the subsidy. A separate issue, however, is the level of detail of the cost data. There are two options, and a combination of the two, to be considered:

(1) First, we could require that the sponsor (or the plan administrator, insurer, or group health plan designated by the sponsor) submit the aggregate total of all allowable drug costs of all of the qualifying covered retirees in the plan for the time period in question. This would be the cost incurred between the cost threshold and cost limit with an appropriate adjustment for rebates. This aggregate cost would not be broken down to each qualifying covered retiree. The sponsor (or administrator, insurer, or group health plan) would have to maintain the claims data to support its submission for audit purposes. While this option would probably be easier for the sponsors and would be the most protective of the individual's privacy, it may be the most problematic in terms of assuring the accuracy of the subsidy payment.

(2) A second option would be for the sponsor (or the plan administrator, insurer, or group health plan) to submit the aggregate allowable costs for each qualifying covered retiree for the time period in question. This would be more complex for the sponsor and would raise some privacy questions but would provide more assurance with regard to the accuracy of the subsidy payment.

(3) A third option would be to combine various elements of the first two options. For example, the sponsor (or the administrator, insurer, or group health plan) would be required to submit information with the specificity outlined in the second option for each of the first two years of the subsidy's availability. In the third and fourth years, however, the sponsor (or the administrator, insurer, or group health plan) would submit its claims data in accordance with the first option.

(4) A fourth potential option that we considered and subsequently ruled out would have been for the sponsor (or the plan administrator, insurer, or group health plan) to submit the actual claims data for each qualifying covered retiree. This option, however, would have been the most complex in terms of administering the subsidy program and the most problematic in terms of privacy. In addition, the benefits of this option would not have outweighed the higher costs associated with submitting actual claims data for each qualifying covered retiree.

As discussed in the next section, we would require the creation and retention of detailed, individual records reflecting both claims and financial data. In assessing the merits of the two options, it is important to understand our plans for vigorous implementation of our audit authority. We believe that a vigorous audit program is consistent with permitting the reporting of more aggregated data. For example, plan sponsors could report the aggregate total of gross allowable drug costs for all qualifying covered retiree-beneficiaries incurred in a month, adjusted to reflect discounts, chargebacks and rebates (we discuss the issue of adjustments based upon rebates and other price concessions in section 2 of this subpart in connection with the discussion of allowable retiree costs). In the end-of-year report, CMS could require more detailed information on eligibility, drug spending, and discounts, rebates and chargebacks. Finally, we might require the retention of detailed enrollee records for audit or other analytical purposes. We believe that by requiring different levels of detail for data and records, depending on the purpose for which they are to be used, provides sponsors and plan administrators, insurers, or group health plans with a minimum amount of burden and a maximum amount of flexibility and time in which to produce the required records. We welcome your comments on these options or your proposals for other options. Regardless of what option is chosen, we would require that the data include the period of time when the cost was incurred, the period of Medicare eligibility for each qualifying covered retiree, and the period of enrollment in the sponsor's retiree plan for each qualifying covered retiree. This is because, as mandated by section 1860D–22 of the Act, only costs incurred while the Medicare beneficiary is enrolled in the sponsor's drug plan and not in Part D can be considered allowable retiree costs.

This proposed rule also specifies, as required by section 1860D–15(d) of the Act, that all information obtained pursuant to this subpart may be used by the officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this subpart R of part 423.

d. Audits

At § 423.888(d), we propose that the sponsor of the plan (or the plan administrator, insurer, or group health plan designated by the sponsor) would be required to maintain and provide access to sufficient records for our audits or audits of the OIG to assure the accuracy of the attestation regarding actuarial value and the accuracy of subsidy payments made under this subpart. This proposed rule specifies that the working documents and reports of the actuaries conducting the analyses

that serve as the basis for the attestation, and all documentation of the costs incurred and utilization for the amount of the subsidy payment, including the underlying claims data, would be made available for audit inspection. All records would be maintained for at least 6 years after the end of the plan year in which the costs were incurred. We believe that 6 years is a sufficient length of time to preserve our right to conduct follow-up audits and would not be too burdensome on the sponsors. Six years is also the length of time certain other Medicare records are required to be retained. In the event of an ongoing investigation, litigation or negotiation, we or the OIG may extend the 6-year retention period. We invite your comments on the appropriateness of this level of documentation, and any unique operational issues it may raise. We may conduct audits in a manner similar to the audits of financial records of PDP sponsors and MA organizations, as outlined in § 423.504(d)(2) of our proposed rule.

6. Appeals (§ 423.890)

Although the statute does not contain provisions for administrative appeals of the retiree drug subsidy amount, and although we do not believe there is a constitutional property interest in the retiree drug subsidy (*See American Manufacturers Mutual Insurance Co.* v. *Sullivan*, 526 U.S. 40 (1999) (individual did not have a property right in the receipt of payment of a bill for medical services before an agency determined that the services were reasonable and necessary); *Giese* v. *Barnhart*, 55 Fed. Appx. 799, 2002 WL 31856 (9th Cir. 2002) (there is no "termination" of benefits warranting due process when the individual never qualified for benefits in the first place), we believe that it is prudent policy to allow an opportunity for review of certain agency decisions issued in relation to this subpart. Examples of these decisions are as follows—

- A retiree prescription drug plan is determined not to be actuarially equivalent.
- An enrollee in a retiree prescription drug plan is determined not to be a qualifying covered retiree.
- A determination of the subsidy amount to be paid to a sponsor.

We propose using a three step process for review of subsidy determinations.

(1) In the first step, the sponsor could request an informal written reconsideration by us of the subsidy determination. Initial subsidy determinations would be final and binding unless the sponsor requested reconsideration in a timely manner or we reopened the determination in accordance with the procedures discussed below. The request for reconsideration would have to be filed within 15 days of the date of the notice of the adverse determination. We believe a short time frame is necessary in order to ensure that subsidy amounts can be finalized in as expeditious a manner as possible. We note that the 15-day time frame is used in MA contract termination appeals (see § 422.650) and we believe employers are similar to MA organizations in their level of sophistication. We expect that sponsors possess adequate resources to meet the time line and pursue the appeals in the proper manner. The written reconsideration would be entirely on the papers. Sponsors would be able to submit a position paper and any additional evidence they wished us to consider. We would make its informal reconsideration determination on these papers and inform the sponsor of its decision. We could inform the sponsor of its determination orally (over the telephone) or in writing (by electronic mail or by post); however, on a sponsor's request, we would put our decision in writing. We expect that when we make a reconsideration determination wholly favorable to the sponsor, a written decision will not be requested. Our reconsideration determination would be final and binding, unless the sponsor further appealed the determination or if we reopened the reconsideration determination in accordance with the reopening provisions discussed below.

(2) The second step of the appeals process would be an informal hearing before our hearing officer (who was not a party to the initial decision). Requests for a hearing would need to be made within 15 days of the date the sponsor received our reconsideration decision. If there is a dispute as to the date of receipt, unless there was evidence to the contrary, we would assume that the sponsor received the decision at least 5 days from the date on the written reconsideration decision. Because we expect that we would deliver only favorable decisions orally, we do not expect receipt of an orally communicated decision would be an issue in determining whether a party has met the deadline for requesting a hearing of an adverse determination. The hearing officer's decision would be final and binding, unless further appealed to our Administrator. We have also proposed that the hearing officer appointed by the Administrator would be limited to a review of the record that was before us in making its initial or review determination and no new evidence could be presented at the hearing stage. The hearing officer's scope of authority would be limited to determining whether we applied our own policies in accordance with the facts that were before us. Our hearing officer would have to render the decision in an as expeditious manner as possible.

(3) The third step of the appeals process would be a review by our Administrator. A sponsor could request an Administrator review or the Administrator, on his or her own motion, could take review, but in either case this review would have to be requested (or taken) within 15 days of the hearing officer's decision. Again, we would expect that sponsors received the hearing officer's decision within 5 days of the date on this decision.

We believe a three-step appeals process allowing an opportunity for informal written review, followed by an oral hearing would conserve both agency and sponsor resources and ensure that a more formal hearing process is not invoked unless necessary. However, we also have considered other options, including having at the second level of appeal a telephone hearing with a CMS hearing officer instead of an in-person hearing. Another option is for a hearing on the record with the Hearing Officer, but without the opportunity for oral testimony. Although we believe these rules are procedural rules not subject to notice and comment rulemaking, in the case of this new benefit, we would welcome comments on the sufficiency of these rules and the other options discussed above.

In addition to the appeals process, we have included provisions for reopening and revising an initial or reconsidered determination. We believe the authority to reopen retiree drug subsidy determinations would be in keeping with our authority in section 1860D–22(a)(2)(B) of the Act to "perform audits and other oversight activities necessary to ensure * * * accuracy of payments," since this audit authority would not be meaningful if we could not reopen payment determinations we later determined to be erroneous. In addition, we believe that sections 1870 and 1871 of the Act provide us with the authority to reopen final determinations of the retiree drug subsidy to such employers. Therefore, in this proposed rule we would include reopening provisions based on those used in Medicare claims reopening, and found in part 405 of the Code of Federal Regulations (subparts G and H). Including reopening provisions would allow us to ensure that any overpayments or underpayments

discovered as a result of oversight or audit could be rectified. Under our proposed provisions, reopening could occur for any reason within one year of the final determination of payment, within four years for good cause, or at any time when the initial, reconsidered, or revised determination was procured by fraud or similar fault. We could initiate a reopening on its own, or an employer could request reopening, but these requests would be at our discretion. The Supreme Court has determined that in the context of reopening cost reports, a fiscal intermediary's decision not to reopen a final determination is not subject to judicial review, (*See Your Home Visiting Nurse Services, Inc.* v. *Shalala*, 525 U.S. 449, 456 (1999)), and we believe the same reasoning would apply in the context of Part D.

Good cause would be interpreted in the same manner as in Part 405 and as further clarified in the Medicare Carriers Manual (MCM), section 12100. Thus, good cause would exist, if—(a) new and material evidence, not readily available at the time of the determination, is uncovered; (b) there is an error on the face of the evidence on which such determination or decision is based; or, (c) there is a clerical error in determination. In order to meet the standard under (a), the evidence could not have been available at the time the determination was made. A clerical error constitutes such errors as computational mistakes. An error on the face of the evidence exists if it is clear, based upon the evidence that was before us when we reached our initial determination, that the initial determination is erroneous. For example, good cause would exist in cases where it is clear from the files that rebates or administrative costs were not appropriately accounted for, where computation errors had been made, where an employer included non-Part D drugs in their calculations, where individuals not enrolled in the plan were included in calculating payment, and in similar situations. Reopening could occur at any time if the underlying decision was obtained through fraud or similar fault—such as if an employer sponsor—or its subcontractor—knew or should have known that it was claiming erroneous subsidies. We believe it would be necessary to include subcontractors in this standard, since we expect many sponsors will contract with benefit administrators to manage the benefit, and these administrators will be providing data to CMS. We have not included provisions for reopening hearing officer or Administrator decisions, but are considering allowing for the reopenings as well. We request comments on this issue.

7. Privacy

The HIPAA Privacy Rule at 45 CFR part 160 and subparts A and E of part 164 ("Privacy Rule") applies to "covered entities," which include group health plans and health insurance issuers, as defined in 45 CFR 160.103. Third party administrators would be business associates, as defined in 45 CFR 160.103, of group health plans. Sponsors would not become covered entities by sponsoring a plan and do not have access to claims information or similar Protected Health Information necessary to support the subsidy payment. Much of the data that we would need to support the subsidy payment outlined above would be protected health information held by group health plans, insurers, and "third party administrators" on behalf of self-funded group health plans.

Covered entities may only use or disclose protected health information as permitted or required by the Privacy Rule. A business associate contract generally must limit the business associate's uses or disclosures of protected health information to those the covered entity could make. Permitted uses and disclosures include those for treatment, payment, and health care operations as well as those for public priority purposes, such as those uses and disclosures required by law (45 CFR 164.512(a)).

Section 423.888(b) would require the plan (or the third party administrator on behalf of the plan, as applicable) or the insurer of the plan to disclose certain data to CMS that is related to the retiree drug subsidy when directed by the plan sponsor to do so. We believe we have the authority to mandate the disclosure of this data to CMS pursuant to our oversight authority under section 1860D–22(a)(2)(B) of the Act, which provides that the Secretary shall have the access to such records as necessary to ensure the adequacy of subsidy payments made to sponsors. A sponsor applying for the subsidy can direct the plans that it sponsors (or the third party administrators or the insurers, as applicable) to disclose the protected health information to us, and disclosure will be permitted under the Privacy Rule because the disclosure is required by law, that is, by this regulation. In order to protect the privacy of the information, the protected health information would be provided directly to CMS and would not be shared with the sponsor. (CMS would disclose the information on the enrollees' Part D eligibility to the sponsors or the plan under § 423.884(b)(6).) We invite comment on the impact this will have on sponsors of retiree plans and on the group health plans, issuers, and third-party administrators of these plans.

8. Change of Ownership (§ 423.892)

Sponsors who apply for a subsidy payment would be required to comply with change of ownership requirements, similar to those set forth in proposed § 423.551 for the MA–PD and PDP plans. However, for purposes of the retiree drug subsidy, we are proposing slightly different change of ownership provisions than those proposed in § 423.551 for PDPs. We request comments regarding how these provisions could be modified to accomplish these objectives. In particular, we seek comments regarding: the situations which constitute a change of ownership, how these provisions should be applied to large companies with multiple business units, the notification requirements related to a change of ownership, and whether sponsors should be subject to novation agreement and facility leasing provisions similar to those proposed in § 423.551.

In § 423.892, we would carry over the three situations that constitute change of ownership (CHOW) in § 423.551 of our proposed rule. We would state that a CHOW includes the following—

- The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law;
- A transfer of substantially all of the assets of the sponsor to another party; or
- The merger of the sponsor's corporation into another corporation, or the consolidation of the sponsor's organization with one or more other corporations, resulting in a new corporate body.

The proposed exception to the three provisions discussed above would be that a transfer of corporate stock or the merger of another corporation into the sponsor's organization, with the sponsor organization surviving, would not usually constitute a CHOW.

We would require a sponsor that has a sponsor agreement in effect and who is considering or negotiating a CHOW, to notify us at least 60 days before the anticipated effective date of the change. In addition, we would also require that when there is a CHOW, and this results in a transfer of the liability for prescription drug costs, the existing subsidy agreement would automatically be assigned to the new owner. We would also require that the new owner

to whom a sponsor agreement is assigned be subject to all applicable statutes and regulations and to the terms and conditions of the subsidy agreement.

We welcome comments on any aspect of the proposed section on change of ownership. We are particularly interested in comments on situations in which a sponsor transfers substantial assets, but substantially less than all of its assets, to another party. Please describe the different scenarios that might develop under such circumstances, especially the extent to which benefits covered by the sponsor agreement might reasonably be expected to be provided by the old or new owner and the best approach for either transferring, issuing or reissuing sponsor agreements. We would also like to receive comments on scenarios that might develop if more than one entity retains or acquires liability for prescription drug costs as the result of the terms of a change in ownership.

9. Construction (§ 423.894)

Sections 423.890(a) through § 423.890(d) are based on section 1860D–22(a)(6) of the Act. It provides that nothing in section 1860D–22 of the Act must be interpreted as preventing—

- An individual who is eligible for Medicare Part D and who is covered under employment-based retiree health coverage from enrolling in a prescription drug plan or in a MA–PD plan;
- The sponsor of employment-based retiree health coverage or an employer or other person from paying all or any part of any premium required for coverage under a prescription drug plan or MA–PD plan on behalf of an individual;
- Employment-based retiree health coverage from providing coverage that is supplemental to the benefits provided under a prescription drug plan or a MA–PD plan, including benefits to retirees who are not covered under a qualified retiree prescription drug plan, but who are enrolled in a PDP or MA–PD plan;
- Employment-based retiree health coverage from providing coverage that is better than the standard prescription drug coverage (as defined in § 423.104(e)) to retirees who are covered under a qualified retiree prescription drug plan; and
- Sponsors from providing for flexibility in benefit design and pharmacy access provisions, without regard to the requirements for basic Medicare Part D drug coverage, as long as the actuarial equivalence requirement (as defined in § 423.884(a)) is met.

S. Special Rules for States—Eligibility Determinations for Low-Income Subsidies, and General Payment Provisions

1. Eligibility Determinations (§ 423.904)

The MMA added a new section 1935 to the Act, "Special Provisions Relating to Medicare Prescription Drug Benefit," which specifies the requirements for States regarding low-income subsidies under the new part D benefit. In accordance with the statute, our proposed regulations at § 423.904(a) and (b) would require States to make initial eligibility determinations for premium and cost sharing subsidies based on applications filed with the States, to conduct periodic redeterminations consistent with the manner and frequency that redeterminations are conducted under Medicaid, and to notify us of eligibility determinations and redeterminations once they are made.

In § 423.904(c), States would be directed to identify individuals who apply for the low-income subsidy who may also be eligible for programs under Medicaid that provide assistance with Medicare cost sharing and to offer enrollment in these programs. This requirement is consistent with existing obligations imposed on States when they make eligibility determinations for Medicaid. We also specify that States notify deemed subsidy eligibles of their subsidy eligibility.

In section § 423.904(d), we would require States to begin accepting application forms for the low-income subsidy no later than July 1, 2005. Our rationale for requiring States to take applications earlier than the open enrollment period for PDP and MA–PD plans would be to allow more time to process the large number of expected subsidy applications at the beginning of the program.

In section § 423.904(d), we would also require States to make available application forms, provide information on the nature of and requirements for the subsidy program, and provide assistance in completing subsidy applications. States also would be required to ensure that applicants or personal representatives attest to the accuracy of the information provided. In verifying application information, we would specify that States may require the submission of statements from financial institutions and may require that information on the application be subject to verification in a manner the State determines to be most cost-effective and efficient. As we discuss under subpart P, we envision a process that will balance the need for program integrity with the goal of reducing paperwork burden and cost.

In addition, § 423.904(d) would direct States to provide us with necessary information to carry out implementation of the Part D program. This will include information such as income levels for other low-income subsidy eligible individuals under § 423.773 needed to permit PDPs and MA–PDs to determine the amount of sliding scale premium subsidy that a person will receive under § 423.780(b).

In developing this proposed rule, we worked with the Social Security Administration (SSA) on a simplified application form and process for the low-income subsidy program. As a result, we developed uniform criteria for determining resources, income, and family size under the subsidy, which are reflected in the proposed definitions at § 423.772, and the proposed eligibility requirements at § 423.773.

We are considering a number of options to ease the burden on States and to ensure, to the degree permissible under the MMA, a consistent eligibility determination process. We invite comments from States on this issue.

2. General Payment Provisions (§ 423.906)

We specify in § 423.906(a) that States could receive the regular Federal match for administrative costs in determining subsidy eligibility.

Section 1935(d) of the Act contains provisions on Medicaid coordination with Medicare prescription drug benefits. The proposed regulations specify in § 423.906(b) that, in the case of a person who is eligible for Part D and also eligible for full Medicaid benefits, medical assistance is not available for Medicaid covered drugs that could be covered under Part D or for cost sharing related to such drugs. In these cases Medicare is the primary payer. The provision of Part D covered drugs is no longer considered a benefit under the Medicaid program for full benefit dual eligibles, even if such individuals have not enrolled in a Part D plan. Therefore, no payment should be made under Medicaid for covered Part D prescription drugs for full benefit dual individuals.

Also, in our proposed regulations in § 423.906(c), we specify that for individuals enrolled in a drug plan under Part D or in an MA–PD States may elect to cover under Medicaid outpatient drugs, other than Part D covered drugs, in a manner as otherwise provided in their State Plan for individuals who are not full-benefit dual eligible individuals or through

arrangements with the PDP sponsor or MA–PD.

3. Treatment of Territories (§ 423.907)

Low-income Part D eligible individuals residing in the territories are not eligible for premium and cost-sharing subsidies. However, in accordance with section 1935(e) of the Act, territories may submit a plan to the Secretary under which medical assistance is to be provided to low-income individuals for covered Part D drugs. Territories with approved plans will receive increased grants under sections 1108(f) and 1108(g) of the Act. Section 423.907 contains the provisions explaining the territories submittal of plans and the grant funding.

4. State Contribution to Drug Benefit Costs Assumed by Medicare (§ 423.908 through § 423.910)

Medicare will subsidize prescription drug costs for full-benefit dual eligible individuals. However, in accordance with section 1935(c) of the Act, States and the District of Columbia will be responsible for making monthly payments to the Federal government beginning in January 2006 to defray a portion of the Medicare drug expenditures for these individuals. The statute directs, and we would specify, in § 423.910(b)(2) that State payments would be made in a manner similar to the mechanism through which States pay Medicare Part B premiums on behalf of low-income individuals who are eligible for both Medicare and Medicaid, except that those payments will be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

As we are proposing to specify in § 423.908 through § 423.910, to calculate the monthly State contributions, we would first calculate an amount we refer to as the projected monthly per capita drug payment. This amount is based in part on a State's Medicaid per capita expenditures for covered Part D drugs for Medicare beneficiaries eligible for full benefits under Medicaid for 2003, which is equal to the weighted average of gross per capita Medicaid expenditures for prescription drugs for 2003 for Medicaid recipients not receiving drugs through a managed care plan and the estimated actuarial value of prescription drugs benefits provided under a capitated managed care plan for these individuals in 2003. The weighted average would be based on the proportion of individuals who, in 2003, did and did not receive medical assistance for covered outpatient drugs through a Medicaid managed care plan.

The gross per capita Medicaid expenditures for prescription drugs for 2003 is equal to the average (mean) per person expenditures (including dispensing fees) for a State during 2003 for covered Part D drugs provided to Medicare beneficiaries receiving full benefits under Medicaid who are not receiving medical assistance for drugs through a Medicaid managed care plan, based on data from the Medicaid Statistical Information System (MSIS) and other available data, as adjusted by an adjustment factor.

We would apply an adjustment factor to the gross per capita Medicaid expenditures for prescription drugs. The adjustment factor for a State would have to equal the ratio of the aggregate payments to the State in 2003 under rebate agreements under section 1927 of the Act to a State's 2003 gross expenditures for covered Part D drugs not received through a Medicaid managed care plan, based on data contained in the CMS–64 Medicaid expenditure report. We propose to define 2003 as CY 2003 (January 1, 2003, through December 31, 2003). The gross per capita Medicaid expenditures for prescription drugs for 2003 will be reduced by this adjustment factor ratio.

The projected monthly per capita drug payment for a month would be equal to 1/12 of the product of the State's Medicaid per capita expenditures for covered Part D drugs for Medicare beneficiaries eligible for full benefits under Medicaid for 2003 and a proportion equal to 100 percent minus the Federal medical assistance percentage (as defined in section 1905(b) of the Act) applicable to the State for the year for the month at issue. This amount would be increased by the growth factor for each year beginning in 2004 through the year for the month at issue. The growth factor for years 2004, 2005, and 2006 would be the average percent change from the previous year of the per capita amount of prescription drug expenditures (determined using the most recent National Health Expenditure projections). The growth factor for 2007 and succeeding years would equal the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals for the 12-month period ending in July of the previous year.

The monthly State contributions for each year, beginning in January of 2006, would be the product of the projected monthly per capita drug payment, the total number of full benefit dual eligible individuals for the State in the applicable month, and the applicable ten year phased-down factor for the year (*see* Table S–1). As illustrated in Table S–1, State contributions would decline each year until 2015, at which time the applicable 10 year phased-down factor for each year will be fixed at 75 percent.

As specified in § 423.910(b)(3), failure on the part of a State to pay these State contribution amounts would result in interest accruing on those payments at the rate provided under section 1903(d)(5) of the Act, in accordance with section 1935(c)(1)(C) of the Act. In addition, as required by the statute, we would immediately offset unpaid amounts and accrued interest against Federal Medicaid matching payments due to the State under section 1903(a) of the Act. As we specify in § 423.910(e), we would perform periodic data matches to identify full-benefit dual eligibles for purposes of computing State contributions. As we specify in § 423.910(d), States would be required to provide data on full benefit dual eligible enrollees in order to conduct the data match required under section 1935(c)(1)(D) of the Act.

States would make contributions only on behalf of Medicare beneficiaries who would otherwise be eligible for outpatient prescription drug benefits under Medicaid. States would not make contributions on behalf of individuals such as those QMBs who are not otherwise eligible for Medicaid, SLMBs, and QIs for whom the State will pay only Part B premiums or Medicare cost sharing on their behalf. In order to give meaning to the term full benefit dual eligible for purposes of the baseline calculation, we needed to define it in a manner that would permit the baseline calculation to operate. Therefore, we are proposing that Medicaid eligible individuals who receive comprehensive benefits including drug coverage under Medicaid and are also covered under Medicare Part A or Part B to be full benefit dual eligibles for purposes of calculating the baseline. This definition of full benefit dual eligibles excludes Medicare beneficiaries who receive Medicaid drug coverage under a section 1115 Pharmacy Plus demonstration.

As we specify in § 423.910(g), to assist States in their budget planning, we must notify States by October 15 each year of the projected monthly per capita drug payment calculation for the next calendar year.

The ten-year phased-down State contribution factors are identified below in Table S–1.

TABLE S–1.—ANNUAL PHASED–DOWN PERCENTAGES OF STATE CONTRIBUTIONS TO MEDICARE PART D DRUG BENEFIT COSTS

Year	State Percentage
2006	90
2007	88⅓
2008	86⅔
2009	85
2010	83⅓
2011	81⅔
2012	80
2013	78⅓
2014	76⅔
2015 and thereafter	75

T–Part D Provisions Affecting Physician Self-Referral, Cost-Based HMO, PACE, and Medigap Requirements

(If you choose to comment on issues in this section, please include the caption "T–Part D Provisions Affecting Self-Referral, Cost-Based HMO, PACE, and Medigap Requirements" at the beginning of your comments.)

Subpart T includes discussion of several other regulatory areas that would be affected by the proposed provisions implementing the Medicare prescription drug benefit. In the discussion that follows, we specify the revised requirements for physician self-referral prohibition, cost-based HMOs, PACE organizations, and Medigap policies. Any corresponding regulation text appears before or after the section 423 rules in subpart A of our proposed rules.

1. Definition of Outpatient Prescription Drugs for Purposes of Physician Self-Referral Prohibition (§ 411.351)

Section 1877 of the Act, also known as the physician self-referral law, prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which the physician (or an immediate family member) has a financial relationship (ownership or compensation) unless an exception applies. Section 1877 of the Act also prohibits the DHS entity from submitting claims to Medicare for DHS furnished as a result of a prohibited referral.

"Outpatient prescription drugs" are a designated health service under section 1877 of the Act. We have defined in regulation "outpatient prescription drugs" for purposes of the physician self-referral prohibition as "all prescription drugs covered by Medicare Part B" (§ 411.351). However, effective January 1, 2006, additional outpatient drugs will be covered under Medicare Part D. These additional covered Part D drugs are defined elsewhere in this preamble in II.C.1 of Subpart J, and in regulations text at § 423.100.

As a result of the proposed Medicare prescription drug benefit provisions, we propose to amend the physician self-referral definition of "outpatient prescription drugs" at § 411.351 to include the additional outpatient drugs covered under the new Part D benefit. Specifically, we propose to define "outpatient prescription drugs" for purposes of the physician self-referral prohibition as "all drugs covered under Medicare Part B and Part D." We believe that referrals for Part D drugs are subject to the same risk of overutilization and anti-competitive behavior as referrals for Part B drugs when a financial relationship exists between the referring physician and the entity furnishing the drugs. We are soliciting comments on this proposed definition.

2. Cost-Based HMOs and CMPS offering Part D coverage (§ 417.440 and § 417.534)

Section 1860D–21(e) of the Act provides that Part D rules will generally apply to reasonable cost reimbursement HMOs and CMPs (Competitive Medical Plans) that contract under section 1876 of the Act and that offer qualified prescription drug coverage to Part D eligible enrollees in the same manner as such rules apply to local MA–PD plans (described in section 1851(a)(2)(A)(i) of the Act). As a result, 42 CFR part 417 must be revised to reflect the treatment of an HMO or CMP as a local MA–PD plan. To codify these changes in regulation we are revising § 417.440(b) specifying that an HMO or CMP may offer qualified prescription drug coverage. In new § 417.534(b)(4), we specify that to the extent that a cost HMO or CMP chooses to participate in the Part D program by offering qualified prescription drug coverage to its members, any costs associated with the offering of Part D benefits may not be claimed on its Medicare cost report.

Section 1860D–21(e)(2) of the Act reinforces the fact that section 1876 reasonable cost contracts that offer Part D of Medicare may do so only as MA–PD plans. This section of the statute stipulates that section 1876 reasonable cost contracts may only offer Part D coverage to individuals also enrolled for Medicare in the reasonable cost contract. In other words, section 1876 reasonable cost HMOs and CMPs are not permitted to operate as "free standing" PDPs.

Section 1860D–21(e)(3) of the Act provides that the Part D bids of section 1876 reasonable cost contracts will not be included in the computation of the national average monthly bid amount and the low-income benchmark premium amount. We discuss the national average monthly bid amount in the subpart F preamble and the low-income benchmark premium amount in the subpart P preamble.

The waiver authority provided in section 1860D–21(c) of the Act would be available to section 1876 reasonable cost HMOs and CMPs in the same manner as it is available to MA–PD plans. We discuss section 1860D–21(c) of the Act and the waiver authority it provides in the subpart J preamble. To the extent that a Part D requirement is in conflict with or duplicative of a section 1876 requirement, or to the extent that a waiver would promote coordination of Part A and Part B benefits with Part D benefits, waiver would also be available to section 1876 reasonable cost HMOs and CMPs. We invite comment on whether there are any Part D requirements otherwise applicable to MA–PD plans that would be uniquely problematic to implement for section 1876 reasonable cost HMOs and CMPs.

3. PACE Organizations Offering Part D Coverage

a. Overview

Section 1860D–1(a)(1) of the Act provides that in general each Part D eligible individual is entitled to obtain qualified prescription drug coverage as a fee-for-service enrollee or a MA enrollee. Although PACE enrollees are neither fee-for-service nor MA beneficiaries, those entitled to benefits under Part A or enrolled under Part B will be Part D eligible individuals. Section 1860D–21(f)(1) of the Act further specifies that a PACE program may elect to provide qualified prescription drug coverage to its Part D eligible enrollees.

Currently, sections 1894 and 1934 of the Act require PACE organizations to provide enrollees with all medically necessary prescription drugs. Drugs covered under Medicare Parts A and B are included in the monthly Medicare capitation rate paid to PACE organizations for Medicare beneficiaries, while outpatient prescription drugs are included as a portion of the monthly Medicaid capitation rate paid to PACE organizations for Medicaid recipients or the Medicaid premium paid by non-Medicaid recipients. The MMA alters the payment structure for covered Part D drugs for PACE organizations by shifting the payer source for PACE enrollees who are full benefit dual eligibles (as defined under section

1935(b)(6) of the Act) from Medicaid to Medicare, and in part from the beneficiary to Medicare in the case of non-full benefit dual eligibles who elect to enroll in Part D. Prescription drug coverage for PACE enrollees enrolled in Medicaid who are not Medicare beneficiaries would continue to be funded by the State through their monthly capitation payment to the PACE organization.

As discussed in proposed § 423.34(d), in accordance with section 1935(d)(1) of the Act, full benefit dual eligibles will no longer be eligible for medical assistance for covered Part D drugs under Medicaid; rather, such individuals may only receive coverage for covered Part D drugs under Part D of Medicare. Consequently, in order for PACE organizations to continue to meet the statutory requirement to provide prescription drug coverage to their enrollees, and ensure that they receive adequate payment for the provision of covered Part D drugs, PACE organizations will need to offer qualified prescription drug coverage to their Part D eligible enrollees.

The MMA provides little specific guidance for implementing the prescription drug benefit for Part D eligible PACE enrollees. Section 1860D–21(f) of the Act indicates that to the extent a PACE program elects to provide qualified prescription drug coverage to Part D eligible individuals, Part D requirements apply to the provisions of such coverage in a manner that is similar to that of MA–PD local plans. Furthermore, the PACE organization may be deemed as an MA–PD local plan.

We believe that Congress did not intend to alter the way in which PACE services, including outpatient prescription drugs, are currently being provided to enrollees. Therefore, we are proposing that PACE organizations not be deemed as MA–PD local plans. Rather, PACE organizations would be treated in a manner that is similar to an MA–PD local plan for purposes of payment under Part D. This approach is consistent with section 1894(d)(1) of the Act that provides that payments will be made to PACE organizations in the same manner and from the same sources as payments are made to a Medicare+Choice (now MA) organization.

In order to account for the shift in payer source for dual eligible and Medicare-only PACE enrollees, we believe that PACE organizations would elect to provide Part D coverage to their enrollees in order to receive payment for prescription drugs. We view the Part D requirements that are associated with payment as most directly relevant to PACE organizations. However, because all Part D requirements applicable to MA–PD local plans apply in a similar manner to PACE organizations, we also discuss a limited set of non-payment related Part D provisions that would be directly relevant to PACE.

A background of the PACE model is provided below followed by a discussion of Part D requirements as they relate to PACE programs offering qualified prescription drug coverage.

b. Background

Sections 4801 through 4803 of the Balanced Budget Act of 1997 (Pub. L. 105–33) established PACE as a Medicare benefit category and a State plan option under Medicaid. PACE organizations provide services to frail, elderly individuals as an alternative to nursing home placement. The PACE benefit includes all Medicare benefits under Parts A and B, all services in the Medicaid State plan, and any other service(s) deemed necessary by the PACE interdisciplinary team. The PACE benefit currently includes outpatient prescription drugs as well as over-the-counter medications that are indicated by the participant's care plan. Thus, all PACE organizations have been providing the equivalent of qualified prescription drug coverage as described in proposed part 423.

Similar to institutionalized individuals, PACE participants do not acquire their prescription drugs directly from pharmacies, except in unusual circumstances such as when a participant is away from the PACE organization's service area and requires urgent care. Rather, the PACE organization either dispenses prescription drugs directly to participants from its own in-house pharmacy or obtains prescription drugs from a contracted pharmacy that delivers the medications to PACE participants.

PACE organizations are risk-bearing entities that receive a capitated monthly rate from Medicare for Medicare-covered services and from Medicaid for Medicaid-covered services. As required by sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act, the PACE organization pools payments received from all sources in order to provide all services needed by its enrollees, including services covered by neither Medicare nor Medicaid. Most PACE enrollees are dually eligible for Medicare and Medicaid; however, participants may be eligible for Medicare only or Medicaid only. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act require the PACE organization to provide all covered services to enrollees regardless of source of payment. PACE statutory language further clarifies that deductibles, co-payments, coinsurance, or other cost-sharing responsibilities do not apply for PACE participants. Consequently, a PACE organization may not charge its participants any cost-sharing. We note that payment of premiums is permitted under the PACE statutory language.

The PACE Medicare and Medicaid regulations are located in part 460 of title 42 of the CFR. As directed by sections 1894 and 1934 of the Act, these regulatory requirements are a blend of Medicare Advantage (MA) and Medicaid managed care requirements as well as requirements from the PACE Protocol that was created by On Lok, Inc. under a demonstration with the Secretary. Thus, although certain PACE requirements are the same or similar to the proposed MA requirements, most are unique to PACE.

c. Payment Related Requirements for MA–PD Plans and PACE Organizations

i. Part D Bids for Basic Prescription Drug Coverage

Section 1860D–11(b) of the Act requires entities seeking to offer qualified prescription drug coverage under Part D, including MA–PD plans, PDPs, 1876 cost plans, and PACE organizations to participate in a bidding process. As discussed in § 423.279 of the proposed rule, these bids would serve as the basis for establishing a national average monthly bid amount under § 423.780 of our proposed rule that would be applicable to all plans, including PACE organizations. However, section 1860D–21(f)(3) of the Act specifies that the bids of certain plans, including PACE organizations, would not be included in the computation of the national average benchmark amount as well as the low-income benchmark premium amount under § 423.780(a).

In accordance with proposed subpart F, we are proposing that each PACE organization would submit a Part D bid that would reflect its average monthly revenue requirements to provide qualified prescription drug coverage, including enhanced alternative prescription drug coverage, for a Part D eligible individual with a national average risk profile. This bidding process would occur in a similar manner as for MA–PD plans and PDPs. In accordance with § 423.265(c)(3) of our proposed rule, the Part D bids would be prepared according to CMS guidelines on actuarial valuation and actuarially certified.

Plans would use qualified actuaries to prepare their bids in accordance with these principles. However, we are concerned that requiring small PACE organizations to independently contract with actuaries would be costly and burdensome. In order to minimize their cost, PACE organizations may choose to collectively contract with an outside actuary to develop the methodology for establishing a bid, however, each bid would need to be actuarily certified. We note that although each PACE organization's bid would not necessarily be the same, all would follow the same methodology in that they would be required to include the cost of providing basic drug coverage.

Since PACE organizations are required to enroll Medicare-only individuals who meet PACE eligibility requirements, all PACE organization bids would also be required to include the portion of the bid attributable to the cost of providing the enhanced alternative prescription drug coverage discussed later in this section.

ii. Part D Premiums for Prescription Drug Coverage

As stated previously, PACE organizations are required to provide uniform benefits to all enrollees regardless of source of payment. We have reviewed the proposed Title I regulation in conjunction with the PACE regulation and have identified that there would be 3 primary categories of PACE enrollees under the MMA: (1) Individuals enrolled in Medicaid, but not Medicare (Medicaid-only); (2) Individuals enrolled in Medicare and Medicaid (Dual eligibles); and (3) Individuals enrolled in Medicare, but not Medicaid (Medicare-only). Within the Medicare-only category of enrollees would be 3 subcategories: (a) Those individuals with income below 135 percent of the Federal poverty line (FPL) and resources below three times the maximum amount of resources an individual may have and still be eligible for supplemental security income under Title XVI of the Act, (b) those individuals with income below 150 percent of the FPL and resources in 2006 that do not exceed $10,000 if single, or $20,000 if married as set forth under proposed § 423.773(d) and, (c) those individuals with income above 150 percent FPL or resources that exceed the amounts set forth under § 423.773(b)(2) or (d)(2).

To ensure that PACE organizations receive payment for the Part D benefit that is consistent with the MMA and PACE statutory requirements, we are proposing policies to address these categories of PACE enrollees. We note that Medicaid-only PACE enrollees are ineligible for Part D prescription drug coverage. Prescription drug coverage offered by the State would be funded through the Medicaid portion of the monthly capitation rate paid to the PACE organization.

Since section 1894 of the Act precludes cost sharing for PACE enrollees, our only option is to require PACE organizations to offer qualified prescription drug coverage without cost-sharing obligations. Therefore, for dual eligible and Medicare-only PACE enrollees, we are proposing that PACE organizations offer enhanced alternative prescription drug packages with no enrollee cost-sharing. For both dual eligibles and Medicare-only enrollees, CMS would pay PACE organizations a direct subsidy, as calculated under § 423.329(a)(1). In addition, the PACE organization would receive low-income premium and cost sharing subsidy payments or partial subsidy payments for those enrollees who qualify for the low-income subsidy. We note that dual eligible beneficiaries are deemed eligible for the full low-income subsidy under § 423.773(c), which includes a premium subsidy up to the low-income benchmark premium amount under § 423.780(a) or, if greater, the lowest beneficiary premium amount for a PDP offering basic prescription drug coverage in the PDP region where the beneficiary resides. We believe that as compared to larger PDPs and MA–PD plans, PACE organizations may lack the purchasing power to obtain significant discounts and other price concessions for covered Part D drugs. We, therefore, expect that some PACE organizations will submit bids under Part D that on average are higher than those submitted by other Part D plans. Consequently, because the low-income premium subsidy payments are based on regional bid averages, the premium subsidy payments received by PACE organizations might be lower than their Part D basic beneficiary premiums, and thus might not cover the full costs of providing dual eligible beneficiaries coverage for covered Part D drugs. (Section 1860D–13(a)(1) of the Act requires that the enrollee's premium would be increased to cover this discrepancy between the plan bid and the national average monthly bid amount as described under § 423.286(d)(1)).

We are concerned about the impact on low-income PACE enrollees and request public comment on other approaches to handling this premium differential. We note also that Medicare-only beneficiaries who do not qualify for the low-income subsidy or only qualify for the partial low-income subsidy under § 423.780(b) would also be responsible for paying the difference between the low-income premium subsidy and the plan's beneficiary premium.

The enhanced alternative prescription drug premium amount would be established by the PACE organization during the bidding process and would take into account the additional cost of providing a prescription drug package to enrollees without the application of cost-sharing. Premium amounts actually paid by PACE enrollees would vary for dual eligibles and for Medicare-only PACE enrollees depending on whether the enrollee qualifies for the low-income premium subsidy.

Section 423.104(g)(2) of our proposed rule specifies that a plan may not offer enhanced alternative prescription drug coverage unless it also offers basic prescription drug coverage. In this instance, PACE organizations vary from MA–PD plans in that their enrollees are exempt from cost-sharing. It would be impractical to offer basic prescription drug coverage to PACE enrollees because stand-alone basic prescription drug coverage assumes beneficiary cost-sharing. As codified in § 423.458(d) of our proposed rule, section 1860D–21(c)(2) of the Act establishes authority for CMS to waive Part D provisions for PACE organizations that: (1) Conflict with PACE provisions (2) duplicate PACE requirements; or (3) improve the coordination of benefits between Part D and PACE. Under this authority we are proposing to waive § 423.104(g)(2) for PACE organizations in order to promote coordination of benefits between Part D and PACE.

Section 423.265(b) of our proposed rule specifies that each potential PDP sponsor or MA organization planning to offer an MA–PD plan must submit Part D bids and supplemental information not later than the first Monday in June for each prescription drug or MA–PD plan it intends to offer in the subsequent calendar year.

The start-up of a new PACE organization may take from 2.5–3 years to develop the capacity to offer PACE services, including capital expenditures associated with constructing or renovating space for a PACE Center. In addition, as required by sections 1894 and 1934 of the Act, many activities associated with PACE involve the States. For example, PACE applications are submitted to the State for review prior to CMS review and the PACE program agreement is a 3-party contract; CMS, the State in which the potential PACE program is located, and the PACE organization. We do not believe it would be appropriate for a potential

PACE organization to miss the deadline for submission of bids because of logistical issues associated with PACE. For these reasons, we are proposing to waive our proposed § 423.265(b).

iii. Risk Corridor Payments

Proposed §§ 423.308 and 423.336 define allowable risk corridor costs and outline the risk corridor payment methodology. As stated previously, risk corridor payments allow plans to transition from administratively set payment rates to market based payment rates by limiting some of the risk of bidding. Their purpose is to adjust for significant differences in the projected cost and actual cost of providing basic prescription drug benefits. We have reviewed Part D risk corridor payment provisions and have determined that they do not conflict with the PACE requirement of full financial risk in §§ 1894(f)(2)(B)(v) and 1934(f)(2)(B)(v) of the Act. Therefore, we are proposing that PACE organizations would be eligible to participate in the Part D risk corridor provision.

In accordance with proposed § 423.308, PACE organizations would be required to track allowable risk corridor costs for all Part D eligible PACE enrollees for purposes of risk corridor payments. We note that the costs for Medicare only enrollees (who would be purchasing enhanced alternative prescription drug coverage) must be adjusted not only to exclude any costs attributable to benefits beyond basic coverage, but also to exclude any basic coverage costs determined to be attributable to increased utilization over the standard benefit as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

iv. Reinsurance Payments

Part D reinsurance payments are available to Part D plans for allowable reinsurance costs above the annual out-of-pocket threshold. As discussed in Subpart C, only certain out-of-pocket costs, or true out-of-pocket expenditures (TrOOP), actually incurred by the beneficiary, another person, an SPAP, or paid for by CMS in the form of the low-income cost sharing subsidy count toward the annual out-of-pocket threshold. Because PACE organizations are precluded from imposing cost-sharing on their enrollees, PACE enrollees will not incur any direct cost-sharing that would count toward TrOOP. However, for dual eligibles and other Medicare-only enrollees who qualify for the low-income subsidy, the low-income subsidy amounts received by the PACE programs will count toward the annual out-of-pocket threshold. Consequently, for enrollees with high drug costs that qualify for the low-income subsidy, PACE programs will be eligible for reinsurance payments. In accordance with proposed § 423.800 PACE organizations would be required to track the application of low-income cost sharing subsidies to be applied to the out-of-pocket threshold for purposes of reinsurance payments. In contrast, PACE organization will not receive any reinsurance payments for Medicare-only enrollees who do not qualify for the low-income subsidy, since these individuals will have no incurred costs that count toward the out-of-pocket threshold.

We request public comment concerning the impact of these rules on PACE organizations. We are particularly interested in receiving drug utilization information from PACE organizations. We also request public comments identifying additional alternatives for providing comparable prescription drug benefits to PACE enrollees.

d. Application of Additional MA–PD Plan Requirements to PACE Organizations

As discussed previously, § 423.458(d) establishes regulatory authority for CMS to waive Part D provisions for PACE organizations. Section 423.458(d) states that PACE organizations may request waivers from CMS. Initially, CMS will identify Part D provisions on behalf of PACE organizations that we believe require waivers. We have identified the non-payment related Part D provisions listed below to waive on behalf of PACE organizations. The provisions identified below do not represent an exhaustive list of all necessary waivers. We request public comment identifying any additional Part D requirements that meet the criteria of section 1860D–21(c)(2) of the Act. We plan to provide this more comprehensive listing of Part D provisions that CMS would waive on behalf of PACE organizations.

i. Requirements for Providing Information About Part D

Sections 423.48 and 423.128 of the proposed regulation specify requirements for providing information about Part D and for the dissemination of plan information. Plans would be required to provide information to CMS regarding benefits, formularies, premiums, cost sharing, and enrollee satisfaction. This information would be published in Medicare's comparative plan brochures and provide key information for beneficiaries to use in making informed decisions about Part D prescription drug coverage.

We believe that the differences between MA–PD plans/PDPs and PACE would complicate comparison and confuse beneficiaries. In addition to specific eligibility requirements for enrollment in PACE, PACE organizations exist only in those States that elect to include PACE in their Medicaid State plan. We are concerned that including PACE information in the comparative plan brochure would be misleading and specifically request public comment on the advantages and disadvantages of including PACE in the MA–PD/PDP comparative brochure. We are proposing that PACE organizations receive a waiver of this requirement in order to promote better coordination of the benefits under PACE and Part D.

ii. Negotiated Prices

Section 423.104(g) of the proposed rule would require MA–PD plans and PDPs to provide enrollees with access to negotiated drug prices. Since PACE enrollees receive the vast majority of their prescription drugs directly from the PACE organization with no cost sharing applied, the negotiated price requirement is already accounted for under part 460. Therefore, we are proposing a waiver of § 423.104(g) in order to promote better coordination of benefits between Part D and PACE.

iii. Access to Pharmacy Networks

Section 423.120(a)(1) of the proposed rule would require that a plan's contracted pharmacy network be located within specified distances from enrollees. Because PACE enrollees receive their prescription drugs directly from their PACE organization as opposed to through a pharmacy, the distance between the enrollee and a network pharmacy is irrelevant. We believe that requiring a PACE organization to set up a pharmacy network would be burdensome, costly, and unnecessary and diverts funds from patient care. Thus, we are proposing to waive this requirement in order to promote better coordination of benefits between PACE and Part D.

iv. Single Card, Standardized Technology

Section 423.120(c) of the proposed rule would require plans to employ the use of a card or other type of standardized technology to assist enrollees in accessing negotiated prices for Part D drugs. Since PACE participants do not routinely acquire their prescription drugs directly from pharmacies, requiring PACE organizations to develop standardized technology would be burdensome, costly, and unnecessary and diverts

funds away from patient care. Therefore, we are proposing to waive proposed § 423.120(c) under the authority of 1860D–21(c)(2) of the Act for PACE organizations to promote better coordination of benefits between Part D and PACE.

v. Out-of-Network Pharmacies

Section 423.124 of the proposed rule specifies access requirements for drugs obtained through out-of-network pharmacies. These provisions would ensure that enrollees residing in long term care facilities have access to drugs in an out-of-network long term care pharmacy and AI/AN enrollees have access to an out-of-network I/T/U pharmacy. Enrollees who obtain their Part D covered drugs from these out-of-network pharmacies would be financially responsible for deductibles or cost-sharing applicable under network pharmacies.

Under the current PACE regulations in §§ 460.90(a) and 460.100, PACE organizations are responsible for all prescription drugs, including those provided to any participants residing in long term care facilities, AI/AN, and those associated with an emergency health event or an approved urgent care need. As noted previously, PACE participants are not responsible for deductibles, co-payments, coinsurance, or other cost sharing associated with prescription drugs. In the PACE program, when participants are out of the service area and need prescription drugs, the PACE organization would arrange payment in full with the pharmacy.

As noted previously, PACE organizations are required to provide all PACE enrollees with prescription drug coverage. Therefore, we view the out of network pharmacy requirements as duplicative of PACE regulations. Thus, we are proposing to waive § 423.124 of the proposed rule for the reasons noted above.

vi. Disclosure of Price Difference Between Part D Drug and Generic Equivalent

Public disclosure requirements in proposed § 423.132 provide that a PDP or MA–PD plan must ensure that its pharmacies inform enrollees of any differential between the negotiated price for a covered Part D drug and the lowest priced generic equivalent. This requirement is inconsistent with the PACE model. PACE participants or their caregivers work with the PACE interdisciplinary team in making care planning decisions and have input into all aspects of their care, including prescription drug use. For this reason, we are proposing a waiver of the public disclosure requirement in proposed § 423.132 under the authority of section 1860D–21(c)(2) of the Act for PACE organizations in order to promote better coordination of benefits between Part D and PACE.

vii. Privacy, Confidentiality, and Accuracy of Records Requirements

Requirements associated with privacy, confidentiality, and accuracy of enrollees' records under Part D are included in proposed § 423.136. We view these requirements as duplicative of § 460.200(e) of the PACE regulation. We believe that the PACE regulations are providing the same protections as would be provided under proposed § 423.136. For the reasons noted above, we are proposing to waive § 423.136.

viii. Medication Therapy Management Program

The medication therapy management program requirements in proposed § 423.150 would require MA–PDs and PDPs to employ pharmacists to counsel beneficiaries who have chronic conditions and use multiple drugs to ensure they are taking safe combinations of prescription drugs and using the drugs properly. PACE enrollees typically suffer from multiple health conditions that necessitate close monitoring by their interdisciplinary team. Currently, PACE organizations have pharmacists on staff or under contract, working with PACE primary care physicians as they develop the participants' care plans and monitor their drug regimens. In addition, the PACE interdisciplinary team, through its daily interactions with PACE participants and their caregivers, provides counseling to ensure that medication regimens are followed. We believe that the existing PACE regulations satisfy or exceed the medication therapy management program requirements in proposed § 423.150. For the reasons noted above, we are proposing to waive proposed § 423.150 for PACE organizations.

ix. Licensing

Proposed § 423.401 specifies licensing requirements for PDPs. A PDP must be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan. A similar requirement exists for MA–PDs. Organizations that are not licensed under State law would obtain certification from the State that the organization meets financial solvency and other standards required by the State for it to operate.

We view these requirements as duplicative of PACE requirements. First, sections 1894(e)(2)(iv) and 1943(e)(2)(iv) of the Act require PACE organizations to meet applicable State and local laws and requirements. In addition, sections 1894(f)(2)(B)(v) and 1934(f)(2)(B)(v) of the Act require PACE organizations to be at full financial risk. Therefore, we believe PACE organizations are meeting the intent of these MA requirements. For the reasons noted above, we are proposing to waive § 423.401 for PACE because we believe they are duplicative of PACE requirements.

x. Determinations and Appeals Processes

Proposed process requirements for grievances, coverage determinations, reconsiderations, and appeals under Part D are discussed in Subpart M. We believe the PACE grievance and appeals processes under §§ 460.120 and 460.122 meet the intent of the MMA since they would accommodate complaints regarding prescription drug coverage. Therefore, we are proposing to waive §§ 423.560–423.638 for PACE organizations because we believe they are duplicative of PACE requirements.

xi. Application Process

Subpart K of proposed part 423 includes requirements governing the application process, contracts with PDP sponsors, and reporting requirements. Sections 1894 and 1934 of the Act, as well as PACE regulations in subparts B and C specify application and contract (called a program agreement in accordance with sections 1894 and 1934 of the Act) requirements for PACE that duplicate requirements in subpart K. For this reason, we are proposing to waive the sections in proposed subpart K that address the application process and contract requirements.

We invite comments on the MMA requirements we have proposed to be waived for PACE organizations and ask for comment on additional waivers that may be needed to integrate the Medicare prescription drug benefit and the PACE benefit.

4. Medicare Supplemental Policies

a. Overview and Background

In this proposed rule, we are including two provisions related to Medicare supplemental (Medigap) policies. As required under section 1882(v), as added by section 104 of MMA, we are setting forth standards for the written disclosure notice that Medigap insurers must provide to their

policyholders who have drug coverage. In addition, in order to reflect the addition of the Medicare drug benefit by MMA, we are proposing to revise the definition of a Medigap policy.

i. Medicare Supplemental Policies

A Medicare supplemental (Medigap) policy is a health insurance policy sold by private insurance companies to fill the "gaps" in original Medicare plan coverage. A Medigap policy typically provides coverage for some or all of the deductible and coinsurance amounts applicable to Medicare-covered services and sometimes covers items and services that are not covered by Medicare. Under section 1882 of the Social Security Act (Act), Medigap policies generally may not be sold unless they conform to one of the 10 standardized benefit packages that have been defined, and designated as plans "A" through "J," by the National Association of Insurance Commissioners (NAIC). Three States (Massachusetts, Minnesota, and Wisconsin) have different standardized Medigap plans and are sometimes referred to in this context as the "waiver" States.

Three of the 10 standardized Medigap plans (Plans H, I, and J) contain coverage for outpatient prescription drugs. In addition, there are Medigap policies issued before the standardization requirements went into effect ("prestandardized" Medigap plans) that cover drugs, as well as Medigap policies in the waiver States, some of which have varying levels of coverage for outpatient prescription drugs.

ii. Legislative Authority and Background

In connection with the addition of a prescription drug benefit to Medicare, the MMA also prescribes changes to the law applicable to Medigap policies. Among other requirements, section 1882(v) of the Social Security Act, as added by section 104 of the MMA, requires Medigap issuers to provide a written disclosure notice to individuals who currently have a policy with prescription drug coverage. (Section 1882(v)(6)(A) specifies that this is to be called a "Medicare Rx policy.") The MMA also requires that the Secretary establish standards for this disclosure notice in consultation with the National Association of Insurance Commissioners (NAIC).

The purpose of this disclosure notice is to inform an individual who has a Medigap Rx policy about his or her Medigap choices once the new Medicare Prescription Drug Benefit Program (Medicare Part D) goes into effect on January 1, 2006. Specifically, effective on that date, section 1882(v) will prohibit the sale of new Medigap Rx policies, and require the elimination of drug coverage from Medigap Rx policies held by beneficiaries who enroll under Part D. The statute permits the renewal of Medigap Rx policies if the policy was purchased prior to January 1, 2006, and the individual does not enroll in Part D.

In addition, beneficiaries who do not enroll in Part D during the Initial Enrollment Period, and choose to enroll later, will be charged higher Part D premiums unless they can establish that they had creditable prescription drug coverage prior to enrolling in Part D. Under section 1860D–13(b)(4)(F) of the Act, and § 423.56(a) of this proposed rule, Medigap policies meet the definition of creditable prescription drug coverage if they also meet actuarial equivalence requirements.

Issuers of Medigap insurance policies are required to provide disclosure notices to policyholders with Medigap Rx policies that inform them of their options under the new legislation, as well as informing them whether or not their policies constitute "creditable prescription drug coverage." As explained in the preamble to Subpart B of this proposed rule, to be considered creditable prescription drug coverage, the coverage must be determined (in a manner specified by the Secretary) to provide prescription drug coverage the actuarial value of which (as defined by the Secretary) equals or exceeds the actuarial value of standard prescription drug coverage under Medicare Part D. Subparts B and F of this proposed rule provide additional detail on creditable coverage and actuarial equivalence.

b. Definition of Medicare Supplemental Policy

Because of the importance of these disclosure notices to beneficiaries, we believe it is necessary to clarify what comes within the scope of a Medigap Rx policy. We are proposing to revise and clarify the definition of a Medicare supplement (Medigap) policy, currently codified at 42 CFR 403.205, to reflect the addition of the Medicare drug benefit by MMA. There was some ambiguity in the past about whether a policy that covered only prescription drugs, either as a separate, "stand-alone" policy or as a rider to another policy, met the definition of a Medigap policy. The ambiguity was created by the fact that there was no Medicare drug benefit to supplement, and has been resolved with the enactment of the Medicare drug benefit. There has also been some confusion about whether a rider attached to a Medigap policy is considered to be part of the policy, and therefore subject to Medigap requirements.

Accordingly, we propose to revise the definition of a Medigap policy, effective January 1, 2006, to include any insurance policies or riders that contain a prescription drug benefit, and that are primarily designed for, or are primarily marketed and sold to Medicare beneficiaries. We are also proposing to clarify that any rider attached to a Medigap policy is an integral part of the policy. All the requirements that apply to the base policy, such as guaranteed renewability or disclosure requirements, would apply to the rider. Thus, for instance, if an insurer offers an optional prescription drug rider that can be added to any other policies, addition of the rider would make the entire policy a Medigap prescription drug policy (Medigap Rx policy) subject to the disclosure requirements for these policies in section 1882(v) of the Act.

Moreover, any stand-alone drug policies that were not previously considered to meet the definition of a Medigap policy, will meet that definition as of January 1, 2006, when the prescription drug benefit takes effect, and new sales of these policies would be prohibited after that date.

c. Standards for the Disclosure Notice That Medicare Supplemental (Medigap) Issuers Are Required To Provide Current Policy Holders With Drug Coverage

i. General

We believe that the statute is quite clear about the choices that need to be made by beneficiaries who hold Medigap Rx policies. Therefore, we propose to establish standards for the disclosure notice in the form of a required notice that sets forth those choices. The proposed notice is set forth below.

ii. Timing and Content of the Disclosure Notice

The statute requires Medigap issuers to send a written disclosure notice to each individual who is a policyholder or certificate holder of a Medigap Rx policy at the most recent available address of that individual. The issuers must send the disclosure notice during the 60-day period immediately preceding the initial Medicare Part D enrollment period. The initial enrollment period (IEP) for Medicare Part D runs from November 15, 2005 through May 15, 2006. Accordingly, Medigap issuers must send the written disclosure notice between September 16, 2005 and November 15, 2005.

The written disclosure notice must inform the individual of his or her Medigap options if the individual does or does not enroll in Medicare Part D. These include the following:

- If the individual does enroll in Part D, he or she can keep the Medigap policy but the drug coverage must be eliminated.
- If the individual enrolls in a Medicare Part D Prescription Drug Plan (PDP) during the initial enrollment period (IEP), the individual also has the right to buy another Medigap plan, from the same issuer, that does not include drug coverage. The individual has a guaranteed right to buy Plan A, B, C, or F (including the high deductible Plan F) or one of the new Medigap benefit packages mandated by section 104(b) of the MMA (which are expected to be designated K and L), if these plans are offered by the issuer and available to new enrollees. The issuer may also offer other Medigap plans on a guaranteed issue basis.
- If the individual does not enroll in Part D, he or she has the option of keeping the Medigap policy with drug coverage.
- If the individual does not enroll in Part D during the IEP, the individual may continue enrollment in his or her current Medigap plan without change, but the individual will lose the right to buy another Medigap plan on a guaranteed issue basis. In addition, if the current Medigap plan does not provide creditable prescription drug coverage, there are limitations on the periods in a year in which the individual may enroll in Medicare Part D and any such enrollment may be subject to a late enrollment penalty (increased premium) if the current Medigap plan does not provide creditable prescription drug coverage. We also propose to require that the disclosure notice contain information on the potential impact of an individual's election on his or her Medigap premiums.

It is important to note that the disclosure requirement in section 104 of the MMA that applies to Medigap issuers is separate from the disclosure requirement contained in section 101 of the MMA (section 1860D–13 of the Act). The disclosure requirement in section 104 of the MMA applies exclusively to issuers of Medigap policies and contains very specific statutory criteria for the disclosure notice. The disclosure requirement in section 101 of the MMA applies to various forms of prescription drug coverage, including Medigap. *See* Subpart B.

The MMA requires that these entities, including Medigap issuers, disclose to the Secretary, as well as to the Part D eligible individuals, whether the coverage they provide currently meets the actuarial equivalence requirement for creditable coverage. The entities must also notify the individuals if the coverage changes so that it no longer meets the actuarial equivalence requirement. Section 101 of the MMA directs the Secretary to establish procedures for the documentation of creditable prescription drug coverage by these entities. We are developing procedures for the disclosure requirements in section 101 of the MMA. In Subpart B of this proposed rule, we provide a discussion of the disclosure provisions in section 101 of the MMA.

iii. Medigap Policies as Creditable Coverage

Medigap issuers will be responsible for determining whether the drug coverage under their policies is creditable drug coverage in accordance with the final rule implementing the Part D drug benefit. However, The CMS actuaries have determined that, if the final Part D regulations were to reflect the definition of creditable prescription drug coverage in this proposed rule, drug coverage in standardized Medigap Plans H and I would not meet such a standard. Since actuarial equivalence can be demonstrated using a group's experience, it is possible to have a specific group for which the drug coverage in standardized Medigap Plan J would be creditable prescription drug coverage. However, based on the distributions of drug utilization that the actuaries have seen so far, they believe that drug coverage in standardized Medigap Plan J would be unlikely to meet the definition of creditable prescription drug coverage based on this proposed rule. We caution, however, that whether or not coverage is creditable cannot be determined until we have issued a final rule implementing the new Part D drug benefit.

iv. Required Disclosure Notice

The disclosure notice set forth below contains the basic language that would be required to be included in all disclosure notices sent by Medigap issuers. It also proposes specific language to be included for policies that do not provide creditable coverage. We propose to use the same basic model for policies that do provide creditable coverage, but we are not proposing exact language at this time. We are instead inviting comments on how the draft notice could be adapted for the types of policies that might provide creditable coverage. As noted above, it is highly unlikely, though theoretically possible, that a standardized Plan J could be found to provide creditable coverage. In addition, some pre-standardized policies with drug coverage, as well as policies sold in any of the three "waiver" states of Massachusetts, Minnesota and Wisconsin might qualify. We would, however, note that we expect to require that the notice informing policyholders that they do have creditable coverage must advise them that they may be subject to late enrollment penalties under Part D if they eventually enroll in a Part D plan and have not maintained the creditable drug coverage they have under their Medigap policies.

In addition, we plan to work with the waiver States so that in the event the coverage offered in those States meets the definition of creditable coverage, there will be a required disclosure notice appropriate for use in those States. We are also soliciting comments on what to include in these potential model disclosure notices.

The following is a proposed disclosure notice for Medigap issuers to use for Medigap policies that do not have creditable drug coverage. As stated above, this group likely will include standardized Medigap Plans H, I, and J, as well as prestandardized Medigap plans, or plans sold in waiver states, that do not provide creditable drug coverage. The information shown in brackets represents text that may be modified by the Medigap issuer based on State law or the issuer's own policies. For example, if the Medigap issuer wishes to offer additional plans on a guaranteed issue basis if the individual enrolls in Medicare Part D during the IEP and wants to buy a Medigap plan without drug coverage, the issuer may tailor the required language to add that guaranteed issue offering.

This draft disclosure notice reflects consultation with the NAIC. We provided the NAIC with an earlier draft of the disclosure notice. After having an opportunity to review our disclosure notice, the NAIC's Senior Issues Task Force prepared its own version of the draft disclosure notice. We participated in lengthy discussions of these draft versions of the disclosure notice at NAIC meetings and during conference calls. The disclosure notice largely reflects the disclosure notice developed by the NAIC's Senior Issues Task Force. We have, however, made some changes to ensure that the draft fully complies with the statutory requirements and we will consult further with the NAIC.

The draft model disclosure notice text follows:

Important Notice to Medicare Supplement Policyholders Who Have Prescription Drug Benefits

You have a Medicare Supplement (Medigap) policy from [name of company] that includes an outpatient prescription drug benefit. Please read this entire notice about your Medigap policy and the new Medicare Prescription Drug Program (Medicare Part D). The coverage options that will be available to you under Part D beginning January 1, 2006 will provide greater value than your current coverage. It is important to know this because it will affect the important choices you have to make about your drug coverage.

You can enroll in the new Medicare Prescription Drug Program (Medicare Part D) from November 15, 2005 to May 15, 2006. Medicare Part D is voluntary; you can choose to enroll or not to enroll. There are two ways to enroll in Medicare Part D. If you want to stay in Original Medicare with a Medigap policy, you can enroll in a Prescription Drug Plan (PDP). Or you may choose to enroll in a Medicare Advantage (MA) plan that covers prescription drugs. If you enroll in a Medicare Advantage plan that covers prescription drugs, you will get all your Medicare benefits from that plan and you may get little benefit from a Medigap policy. Call 1–800-MEDICARE (1–800–633–4227) or visit *www.medicare.gov* on the web for more information about Medicare Advantage or Medicare Part D.

If You Do Not Enroll in Part D

If you decide not to enroll in the new Medicare Prescription Drug Program (Medicare Part D), you can keep your current Medigap policy without changes and you do not need to do anything in reply to this notice. However, because the outpatient prescription drug benefit in your policy is not equal in value to the Medicare Part D benefit, you should keep in mind that you will probably be charged higher Part D premiums if you want to enroll in Medicare Part D after May 15, 2006. Make sure you read the section called "If You Enroll in Medicare Part D After May 15, 2006."

If You Enroll in Part D By May 15, 2006

If you enroll in the new Medicare Prescription Drug Program (Medicare Part D) through a PDP on or before May 15, 2006 and you want to keep a Medigap policy, you have the following options:

You can keep your current Medigap policy, but Federal law requires us to remove the prescription drug coverage, and adjust your premium. [In your case, the new premium will be [issuer insert dollar amount of premium]]; If you choose this option, you must notify us promptly of the effective date of your Part D enrollment so that we can remove the drug coverage from your policy as of that date. [Insert options for notifying issuer]

or

You can cancel your existing policy and enroll in one of our other plans that does not contain outpatient prescription drug coverage [Plans A, B, C, F (including the high deductible Plan F), and the plans likely to be designated K or L] [issuer insert plans from above list that you currently offer or any others you may want to offer], regardless of your health. [Descriptions of these plans and their current premiums are enclosed—OR—If you would like information about one or more of these plans, please contact us at 1–800–000–0000 or www.issuer.com]. [If you want a new Medigap policy, you must apply for it within 63 days of your enrollment in the new Medicare Prescription Drug Program (Medicare Part D)]. You must notify us promptly of the date your Part D enrollment will begin so that we can start your new policy without drug coverage as of that date.

If you enroll in Part D and you do not apply for a different Medigap policy, you can keep your current Medigap policy but the drug coverage will be removed from the policy, as described in Option #1.

If You Enroll in Medicare Part D After May 15, 2006

If you do not enroll in the Medicare Prescription Drug Program (Medicare Part D) during the initial Medicare Part D enrollment period, but want to do so after May 15, 2006, you need to know [three] things.

1. There are limitations on when you can enroll in Medicare Part D. Generally, you will only be able to enroll between November 15th and December 31st each year.

2. Because you will be enrolling after May 15, 2006, you will have to pay a higher monthly premium for Medicare Part D than if you enrolled by May 15, 2006, unless you have other coverage that qualifies you to enroll without a late enrollment penalty. You will pay this higher premium for as long as you have Part D coverage. Also, the longer you wait to join Part D, the higher your premium will be.

3. You may not be able to enroll in another Medigap policy with our company, as you could have if you had enrolled in Medicare Part D by May 15, 2006. You will be able to keep your current policy with the drug benefit removed.

If you enroll in Medicare Part D after May 15, 2006, please let us know as soon as possible. Federal law requires us to remove the prescription drug benefit from your Medigap policy and adjust your premium.

Effect on Premiums

In making your decision about what to do, please keep in mind that the law requires us to make changes to our plans. These changes, and the decisions that policyholders like you will make, will have an effect on future premiums. Please contact us so we can discuss the likely differences in premiums, depending on which choices you make now and how those premiums may change over time.

Assistance

If you need help understanding your choices, please contact us at 1–800–000–0000 or *www.issuer.com* for more information [insert issuer phone number and website address].

Your State Health Insurance Assistance Program (SHIP) can help you with information about your Medigap policy and the new Medicare Prescription Drug Program (Medicare Part D). You can reach the SHIP Program [at insert SHIP number—OR by finding your State's Program number on the next page].

For more information about Medicare Part D, call 1–800–MEDICARE (1–800–633–4227). Information is also available at *www.medicare.gov* on the web.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether OMB should approve an information collection, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Below is a summary of the proposed information collection requirements outlined in this regulation. We are soliciting comment on these proposed requirements, before they are submitted to OMB for PRA approval.

Subpart A—General Provisions

Subpart A does not contain any requirements subject to the PRA.

Subpart B—Eligibility and Enrollment

Section 423.34 Enrollment process

(b) A Part D eligible individual seeking to enroll in a PDP must complete and submit the PDP's enrollment form to the PDP prior to enrollment.

The burden associated with this requirement is the time and effort necessary for an individual to submit the required enrollment application to a PDP sponsor. We estimate that it will take 30 minutes to complete and submit the required application to the PDP. During the first Part D initial enrollment period, it is estimated that 24 million individuals will complete and submit these applications. This estimate is based on preliminary estimates of the number of individuals who will enroll in PDPs in 2006. In 2007, and beyond,

the number of enrollments will be substantially less, since an individual will generally be limited to changing PDPs during the annual coordinated election period, therefore, it is estimated 6 million individuals may change their PDPs annually and that 2 million new beneficiaries will be making first time elections into PDPs.

(c) A PDP sponsor must provide each individual with prompt notice of acceptance or denial of the individual's enrollment request.

The burden associated with this requirement is the time and effort necessary for a PDP sponsor to disclose to an individual notice of acceptance or denial of the individual's enrollment request. Although we have no basis at this time for estimating either the number of regions or the number of participating plans, a rough estimate is that during the first Part D initial enrollment period a total of 24 million notices will be disclosed, affecting approximately 100 PDPs (based upon an estimate of 2 PDPs per 50 states, if each state were to be a region, or alternatively, 4 PDPs for each of 25 regions). Given that each PDP will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that it will take each PDP approximately 8 hours to produce each notice—either an acceptance or a denial notice must be provided. We further estimate that on average, it will take each PDP sponsor 1 minute to assemble and disseminate each notice. We further estimate that on average, it will take each sponsor 4,000 hours to disclose 240,000 notices during this first year. In 2007, and beyond, we estimate that 60,000 notices will be disclosed annually at 1,000 hours per sponsor. This assumption is based on that fact that once the notices have been standardized, a PDP sponsor will mass-produce and mail the required notices.

Section 423.36 Enrollment Periods

(c) An individual is eligible to enroll in a Part D plan, enroll in a PDP, or disenroll from a PDP and enroll in another PDP, if the individual demonstrates to CMS, in accordance with guidelines CMS issues, that the PDP sponsor offering the PDP substantially violated a material provision of its contract under this part that meets the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for an individual to submit the required materials to CMS demonstrating that a PDP substantially violated a material provision of its contract. Based on our experience with the current Medicare+Choice program, we would expect that few, if any, individuals will avail themselves of this option. Generally, in those instances where CMS has found that an M+C organization has substantially violated a material provision of its contract, CMS has taken the necessary action on behalf of these individuals. Thus, we do not estimate any burden on individuals under this provision.

Section 423.42 Coordination of Enrollment and Disenrollment Through PDPs.

(a) An individual may enroll in, or disenroll from a PDP during the enrollment periods specified in § 423.36, by filing the appropriate enrollment form with the PDP sponsor or through other mechanisms CMS determines appropriate.

The burden associated with this is discussed above in §§ 423.34 and 423.36 of the PRA section.

(c) Each PDP sponsor must submit every disenrollment notice to CMS within timeframes CMS specifies. The PDP sponsor must also provide each enrollee with a notice of disenrollment and file and retain disenrollment requests for the period specified in CMS instructions.

The burden associated with these requirements is the time and effort necessary for a PDP sponsor to disclose the disenrollment notice to each enrollee and CMS, and file/retain disenrollment requests for the period specified in CMS instructions. We estimate that on an annual basis there will be approximately 24,000 disenrollments per PDP sponsor. Given that each sponsor will be creating a standardized disclosure notice for mass mailings, we are proposing the following burden estimates. We estimate that it will take each PDP sponsor approximately 8 hours to produce the standardized notice. We further estimate that on average, it will take each PDP sponsor 1 minute to disclose each notice and that on average each PDP sponsor will be required to disclose 24,000 notices on an annual basis for an annual burden of 400 hours. Once the notice has been disclosed to the enrollee the PDP sponsor will forward a copy of the notice to CMS on a batch basis. We estimate that it will require each PDP sponsor 52 hours on an annual basis to send the batch files of disenrollment notices to CMS on an annual basis. In regard to the record retention requirement we estimate that it will require each of the PDP sponsors 52 hours on an annual basis to maintain the required documentation. While this estimate may appear low, we believe the retention of the documentation will most likely be an automated process.

Section 423.44 Disenrollment by the PDP.

(c) If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i), or (b)(iv) of this section, the PDP sponsor must give the individual timely notice of the disenrollment, that meets the requirements set forth in this section, with an explanation of why the PDP is planning to disenroll the individual.

The burden associated with this requirement is the time and effort necessary for a PDP sponsor to disclose to an individual notice of disenrollment. We estimate that on an annual basis it will require a total of 576,100 notices, affecting each PDP sponsors to some degree, as described below. Given that each PDP sponsor will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that it will take each PDP sponsor approximately 8 hours to produce the standardized notice. We further estimate that on average, it will take each PDP 1 minute to disclose each notice. Burden estimates for these disenrollments are provided below.

(d) A PDP sponsor may disenroll an individual from the PDP for failure to pay any monthly premium if the PDP sponsor can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount.

The burden associated with this requirement is the time and effort necessary for a PDP sponsor to submit the required materials to CMS demonstrating that the PDP sponsor made reasonable efforts to collect the unpaid premium amount and the time and effort necessary for a PDP sponsor to disclose to an individual the notice of disenrollment. We estimate that it will take a PDP 5 minutes to submit the required documentation to CMS for each occurrence and that each of the PDP sponsors will be required to submit the necessary documentation to CMS 960 times on an annual basis. We estimate that on an annual basis 96,000 individuals will be disenrolled for failure to pay premiums, and it will take each PDP 1 minute to disclose each notice and that each PDP will be required to disclose 960 notices on an annual basis for a annual burden of 16 hours.

To disenroll an individual from its PDP, based on an individual's behavior, the PDP sponsor must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraphs (d)(2)(i) through (d)(2)(iii) of

this section and any extenuating circumstances.

The burden associated with this requirement is the time and effort necessary for a PDP to document and retain the documentation that meets the requirements set forth in this section. We estimate that it will take a PDP 3 hours to capture and retain the required documentation for each occurrence and that each PDP will have 1 occurrence on an annual basis.

The PDP sponsor must disenroll an individual when the individual no longer resides in the PDP's service area. We estimate that on an annual basis 240,000 individuals will be disenrolled for moving out of the service area, and it will take each PDP 1 minute to disclose each notice. It is estimated that each PDP will disclose 24,000 notices on an annual basis for a annual burden of 400 hours.

When a PDP contract terminates as provided in § 423.507 through 423.510 as the PDP sponsor must send a notice to the enrollee before the effective date of the plan termination or area reduction. The notice must provide an effective date of the plan termination and a description of alternatives for obtaining benefits under Part D.

The burden associated with this requirement is the time and effort necessary for a PDP sponsor to disclose to an individual the notice of disenrollment. We estimate that on an annual basis it will require a total of 240,000 notices, affecting approximately 10 PDPs. Given that each PDP will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that it will take each PDP sponsor approximately 8 hours to produce the standardized notice. We further estimate that on average, it will take each PDP 1 minute to disclose each notice and that each PDP will be required to disclose 24,000 notices on an annual basis for a annual burden of 400 hours.

Section 423.48 Information About Part D.

Each PDP and MA–PD plan must provide, on an annual basis, and in a format and using standard terminology that CMS may specify in guidance, the information necessary to enable CMS to provide to current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage.

The burden associated with this requirement is the time and effort necessary for a PDP to submit the required materials to CMS. We estimate that on an annual basis it will take 100 PDP sponsors 2 hours to submit the required documentation to CMS.

Section 423.50 Approval of Marketing Materials and Enrollment Forms

(a) At least 45 days (or 10 days if using marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution, the PDP sponsor must submit the its marketing materials and forms, as defined in paragraph (b) of this section, to CMS for review.

The burden associated with this requirement is the time and effort necessary for a PDP to submit the required materials to CMS. We estimate that on an annual basis it will take 100 PDP sponsors 2 hours to submit the required documentation to CMS.

Section 423.56 Procedures To Document Creditable Status of Prescription Drug Coverage

(b) Each entity or State that offers prescription drug coverage under any of the types described in § 423.4 must disclose, to all Part D eligible individuals whether such coverage meets the requirements of actuarial equivalence set forth in § 423.265.

The burden associated with this requirement is the time and effort necessary for each of these entities and States to disclose to an individual notice of coverage. We estimate that on an annual basis it will require a total of 5,800,000 notices, affecting slightly over 440,000 entities, including 440,000 employer and union-sponsored group health plans with Medicare-eligible workers, and fewer than 200 other entities including over 100 Medigap plans, State Pharmaceutical Assistance Programs, and a handful of State Pharmacy Plus programs. [Note: A discussion of the costs of the disclosure notices for public and private employer and union sponsored qualified prescription drug plans is in the impact analysis section on payments to sponsors of retiree prescription drug plans.] Given that each entity and State will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that it will take each entity or State approximately 8 hours to produce the standardized notice. We further estimate that on average, it will take each entity 1 minute to disclose each notice. It is estimated that the burden per entity will be as follows:

—On average, the 4 State Pharmacy Plus programs will provide 169,118 notices for an annual burden of 2819 hours (these notices are required in 2005 even though, as discussed elsewhere in this preamble, these States may decide to lower their costs while maintaining equivalent benefits by replacing or reforming these programs).
—On average each of the 440,000 group health plans will provide 4.5 notices for an annual burden of .075 hours.
—On average each of the 20 State Pharmaceutical Assistance Programs will provide 60,000 notices for an annual burden of 1000 hours.
—On average each of an estimated 120 Medigap issuers will provide 15,833 notices for an annual burden of 264 hours.

(c) Each entity must disclose their creditable coverage status to CMS in a form and manner described by CMS.

The burden associated with this requirement is the time and effort necessary for each entity to submit the required creditable coverage status materials to CMS. We estimate that on an annual basis it will take each entity 1 hour to submit the required documentation to CMS.

Subpart C—Benefits and Beneficiary Protections.

(h) A PDP sponsor or an MA organization offering qualified prescription drug coverage is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers and passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies, prices, and/or monthly beneficiary prescription drug premiums, in the manner and frequency specified by CMS.

The burden associated with this requirement is the time and effort necessary for PDP sponsor or an MA organization to disclose to CMS the aggregated negotiated price data on concessions to CMS. We estimate that on an annual basis it will take 100 PDPs and 350 organizations 10 hours to submit the required documentation to CMS for total annual burden of 4,500 hours.

Section 423.120 Access to Covered Part D Drugs

(b) A PDP sponsor or MA organization's formulary must be reviewed by a pharmacy and therapeutic committee that committee must maintain written documentation of its decisions regarding formulary development and revision.

The burden associated with this requirement is the time and effort necessary for a PDP or MA committee to document and retain the documentation that meets the requirements set forth in this section.

We estimate that it will take 100 PDPs and 350 providers PDP or MA entity 1 hour each to capture and retain the required documentation on an annual basis for total annual burden of 450 hours.

A PDP sponsor or MA organization offering an MA–PD plan must provide notice of at least 30 days to CMS, affected enrollees, authorized prescribers, pharmacies, and pharmacists prior to removing a covered Part D drug from its formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug.

The burden associated with this requirement is the time and effort necessary for an entity offering an MA–PD PDP plan to provide notice of at least 30 days to CMS, affected enrollees, authorized prescribers, pharmacies, and pharmacists of the removal of a covered Part D drug from its formulary.

Given that each entity will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that on an annual basis it will take each entity approximately 1 hour to produce the standardized notice. We further estimate that on average, it will take 100 PDP's and 350 MA organizations 40 hours to disclose the required notice for a total annual burden of 18,450 hours.

(c) A PDP sponsor or MA organization offering an MA–PD plan must issue and reissue, as necessary, a card or other type of technology to its enrollees to use to access negotiated prices for covered Part D drugs.

The burden associated with this requirement is the time and effort necessary for an entity to provide each enrollee a card. The burden associated with this requirement is reflected in section 423.128.

Section 423.128 Dissemination of Plan Information

(a) A PDP sponsor or MA organization offering an MA–PD plan must disclose its plans information as required by this section to each enrollee of a prescription drug plan offered by the sponsor under this part and to Part D eligible individuals.

The burden associated with this requirement is the time and effort necessary for a PDP sponsor or MA organization offering an MA–PD plan to disclose its plans information. We estimate that it will require 100 PDP sponsors and 350 MA organizations 80 hours on an annual basis to prepare the plan materials. We further estimate that on an annual basis, on average, it will require each entity 120 hours on an annual basis to disclose the required materials to enrollees and eligible individuals for a total annual burden of 90,000 hours.

(e) A PDP sponsor or MA organization offering qualified prescription drug coverage must furnish to enrollees, an explanation of benefits when prescription drug benefits are provided under qualified prescription drug coverage that meets the requirements et forth in this section.

The burden associated with this requirement is the time and effort necessary for 100 PDP sponsors and 350 MA organizations offering an MA–PD plan must disclose an explanation of benefits when prescription drug benefits to enrollees. We estimate that it will require each entity 160 hours on an annual basis disseminate the required materials for total annual burden of 56,000 hours.

Subpart D—Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

Section 423.153 Cost and Utilization Management, Quality Assurance, Medication Therapy Management Programs, and Programs To Control Fraud, Abuse, and Waste

(d) To become a PDP sponsor an applicant must disclose to CMS and others upon request, the amount of the management and dispensing fees and the portion paid for medication therapy management services to pharmacists.

The burden associated with this requirement is the time and effort necessary for an applicant to submit the required information to CMS upon request. We estimate that is will require 100 applicants, 30 minutes each to provide the required material to CMS for consideration for a total annual burden of 50 hours.

Section 423.168 Accreditation Organizations

(c) An accreditation organization approved by CMS must provide to CMS in written form and on a monthly basis all of the following required by this part.

Since CMS expects to contract with less then 10 organizations on an annual basis, this requirement is not subject to the PRA.

Section 423.171 Procedures for Approval of Accreditation as a Basis for Deeming Compliance

(a) A private, national accreditation organization applying for approval must furnish to CMS all of the information and materials set forth in this part.

Since CMS expects to less then 10 applicants on an annual basis, this requirement is not subject to the PRA.

Subpart F—Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

Section 423.265 Submission of Bids and Related Information

(a) An applicant may submit a bid that meets the requirements set forth in this section, to become a PDP sponsor or to become an MA organization offering an MA–PD plan.

The burden associated with this requirement is the time and effort necessary for an entity to submit the required materials to CMS. We estimate we will receive 100 PDP and 350 MA applications on an annual basis and that it will requires each entity 80 hours to submit the required documentation to CMS for total annual burden of 26,000 hours.

Subpart G—Payments to PDP Sponsors and MA–PD Plans for All Medicare Beneficiaries for Qualified Prescription Drug Coverage

Section 423.329 Determination of Payment

(b) PDP sponsors must submit data regarding drug claims to CMS that can be linked at the individual level to Part A and Part B data in a form and manner similar to the process provided under § 422.310 and other information as CMS determines necessary.

The burden associated with this requirement is the time and effort necessary for PDP sponsors submit the required claims data to CMS. We estimate that on an annual basis it will take 100 PDPs 52 hours to submit the required documentation to CMS for total annual burden of 5,200 hours.

Section 423.336 Risksharing Arrangements

(a) A PDP sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (b) of this section.

The burden associated with this requirement is the time and effort necessary for PDP sponsors submit the required bid materials to CMS. We estimate that on an annual basis it will take 10 PDPs 20 hours to submit the required documentation to CMS for total annual burden of 300 hours.

(c) Within 6 months of the end of a coverage year, the PDP sponsor or MA organization offering a MA–PD plan sponsor must provide to CMS the cost data requirements set forth in the paragraph.

The burden associated with this requirement is the time and effort

necessary for PDP sponsors submit the required cost data to CMS. We estimate that on an annual basis it will take 100 PDP sponsors and 350 MA organizations 10 hours to submit the required documentation to CMS for total annual burden of 45,000 hours.

Section 423.343 Retroactive Adjustments and Reconciliations

(c) Within 6 months after the end of a coverage year, the PDP sponsor or MA organization offering a MA–PD plan must provide CMS must provide to CMS the data requirements set forth in the paragraph.

The burden associated with this requirement is the time and effort necessary for PDP sponsors and MA organizations to submit the required data to CMS. We estimate that on an annual basis it will take 100 PDP sponsors and 350 MA organizations 10 hours to submit the required documentation to CMS for total annual burden of 4,500 hours.

(d) Within 6 months after the end of a coverage year, the PDP sponsor or MA organization offering a MA–PD plan must provide CMS the cost data requirements set forth in the paragraph.

The burden associated with this requirement is the time and effort necessary for PDP sponsors and MA organizations to submit the required cost data to CMS. We estimate that on an annual basis it will take 100 PDP sponsors and 350 MA organizations 10 hours to submit the required documentation to CMS for total annual burden of 4,500 hours.

Subpart I—Organization Compliance With State Law and Preemption by Federal Law

Section 423.410 Waiver of Certain Requirements To Expand Choice

(f) Under this section a prospective prescription drug plan (PDP) applicant may submit a waiver application to CMS to waive certain state licensure and fiscal solvency requirements in order to contract with CMS.

The burden associated with this requirement is the time and effort necessary for a PDP applicant to submit a waiver application that meets the requirements of this section. We estimate that on an annual basis it will take 100 applicants 10 hours to submit the required waiver documentation to CMS for total annual burden of 1000 hours.

Subpart J—Special Part D Rules for Organizations Offering MA Plans and Coordination under the Part D Program

Section 423.458 Application of Part D Rules to MA–PD plans on and After January 1, 2006

(c) Organizations offering or seeking to offer a Medicare Advantage-Prescription Drug plan may request from CMS in writing waiver or modification of those requirements under Part D of Medicare that are duplicative of, or that are in conflict with provisions otherwise applicable to the plan under Part C of Medicare.

The burden associated with this requirement is the time and effort necessary for an organization to submit the required waiver information to CMS for consideration. We estimate we will receive 10 waiver applicants, 20 hours to provide the required material to CMS for consideration for a total annual burden of 200 hours.

Section 423.462 Additional Part D Waiver Authority for Prescription Drug Plans

(a) Prescription drug plans may request, in writing, a waiver or modification of those requirements under Part D of Medicare that hinder the design of, the offering of, or the enrollment in, prescription drug plans under contracts between prescription drug plans and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations to furnish benefits to the entity's employees, former employees, or members or former members of labor organizations.

The burden associated with this requirement is the time and effort necessary for an organization to submit the required waiver information to CMS for consideration. We estimate we will receive 10 waiver applicants, 20 hours to provide the required material to CMS for consideration for a total annual burden of 200 hours.

Subpart K—Application Procedures and Contracts With PDP Sponsors

Section 423.502 Application Requirements

(b) In order to become a PDP sponsor, an entity, or an individual authorized to act for the entity (the applicant), must complete and submit a certified application in the form and manner required by CMS that meets the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for PDP sponsors and MA organizations to submit the required application materials to CMS. We estimate that on an annual basis it will take 100 PDP sponsors and 350 MA organizations 10 hours to submit the required documentation to CMS for total annual burden of 4,500 hours.

Section 423.505 Contract Provisions

(d) The PDP sponsor agrees must maintain for 6 years books, records, documents, and other evidence of accounting procedures and practices that are sufficient to meet the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for PDP sponsors and MA organizations to maintain the required documentation outlined in this section. We estimate that on an annual basis it will take 100 PDP sponsors and 350 MA organizations 52 hours to maintain the required documentation on an annual basis, for total annual burden of 23,400 hours.

(f) The PDP sponsor must submit to CMS certified financial information that must include the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for PDP sponsors and MA organizations to submit the required certified data to CMS. We estimate that on an annual basis it will take 100 PDP sponsors and 350 MA organizations 8 hours to submit the required documentation to CMS for total annual burden of 3,600 hours.

(g) PDP sponsors must inform all related entities, contractors and subcontractors that payments they receive are, in whole or in part, from Federal funds.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to all related entities. We estimate that it will require each of the 100 PDP sponsors 8 hour on an annual basis to disclose the information for a total annual burden of 800 hours.

(j) As a condition for receiving a monthly payment under subpart G of this part, the PDP sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority must request payment under the contract on a document that certifies the accuracy, completeness, and truthfulness of all data related to payment, as stipulated in this section.

The burden associated with this requirement is the time and effort necessary for 100 PDP sponsors to submit the required certified document that meets all of the certification

requirements referenced in this section to CMS. We estimate that on an annual basis it will take 100 PDP sponsors 8 hours to submit the required documentation to CMS for total annual burden of 800 hours.

Section 423.507 Nonrenewal of Contract

(a) If a PDP sponsor does not intend to renew its contract, it must notify CMS in writing by the first Monday of June in the year in which the contract ends and notify, in an manner that meets the requirements of this section, each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective.

The burden associated with this requirement is the time and effort necessary for a PDP sponsor to submit a notice of nonrenewal to CMS. We estimate that on an annual basis it will take 10 PDP sponsors 1 hour to submit the required documentation to CMS for total annual burden of 10 hours.

Section 423.508 Modification or Termination of Contract by Mutual Consent

(b) If the contract is terminated by mutual consent, the PDP sponsor must provide notice to its Medicare enrollees and the general public as provided in paragraph (c) of this section.

Based on our experience with the M+C program CMS does not anticipate that more then 9 of these terminations will occur on an annual basis.

Section 423.509 Termination of Contract by CMS

(b) If CMS notifies the PDP sponsor in writing 90 days before the intended date of their termination the PDP sponsor must notify its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

The PDP sponsor must also notify the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area.

Based on our experience with the M+C program CMS does not anticipate that more than 9 of these terminations will occur on an annual basis.

Section 423.510 Termination of Contract by the PDP Sponsor

(a) If a PDP sponsor terminates its contract because CMS fails to substantially carry out the terms of the contract the PDP sponsor must give advance notice to CMS, its Medicare enrollees, and the general public in a manner that meets the requirements set forth in the section.

Based on our experience with the M+C program CMS does not anticipate that more than 9 of these terminations will occur on an annual basis.

Section 423.514 Reporting Requirements

(b) Each PDP sponsor must report to CMS or other Federal agencies, on an annual basis the information necessary to meet the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for 100 PDP sponsors to submit the required document that meets all of the requirements referenced in this section to CMS or other federal agencies. We estimate that on an annual basis it will take 100 PDP sponsors 40 hours to submit the required documentation, for total annual burden of 4,000 hours.

(f) Each PDP sponsor must make the information reported to CMS under this section available to its enrollees upon reasonable request.

The burden associated with this requirement is the time and effort necessary for PDP sponsors to disclose the required materials that meet all of the requirements referenced in this section to the public upon request. We estimate that on an annual basis it will take 100 PDP sponsors 20 hours to submit the required documentation, for total annual burden of 2,000 hours.

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

Section 423.551 General Provisions

Paragraph (c) states that a PDP sponsor that has a Medicare contract in effect under § 423.502 of this part and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The PDP sponsor must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

The burden associated with this requirement is the time and effort of the PDP sponsor considering or negotiating a change in ownership, to notify CMS and provide the information specified in this section. While this requirement is subject to the PRA, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.4.

Section 423.552 Novation Agreement Requirements

Paragraph (a) discusses the conditions for CMS approval of a novation agreement. This paragraph requires the PDP sponsor to notify CMS at least 60 days before the date of the proposed change of ownership and requires them to provide CMS with updated financial information and a discussion of the financial solvency impact of the change of ownership on the surviving organization.

The burden associated with this requirement is discussed above in § 423.551 of the PRA section.

This paragraph also requires the PDP sponsor to submit to CMS, at least 30 days before the proposed change of ownership date, 3 signed copies of the novation agreement containing the provisions specified in this section, and 1 copy of other relevant documents required by CMS.

The burden associated with this requirement is time and effort of the PDP sponsor to provide CMS with the required documentation. While this requirement is subject to the PRA, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.4.

Subpart M—Grievances, Coverage Determinations, and Appeals

Section 423.562 General Provisions

Paragraph (a). A PDP sponsor must ensure that all enrollees receive written information about the Grievance and appeal procedures that are available to them through the PDP sponsor and that meet the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 8 hours on an annual basis to disclose the information for a total annual burden of 800 hours.

Section 423.564 Grievance Procedures

Paragraph (e). The PDP sponsor must maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the PDP sponsor notified the enrollee of the disposition.

The burden associated with this requirement is the time and effort necessary for PDP sponsors to maintain the required documentation outlined in this section. We estimate that on an

annual basis it will take 100 PDP sponsors 52 hours to maintain the required documentation on an annual basis, for total annual burden of 5,200 hours.

Section 423.568 Standard Timeframe and Notice Requirements for Coverage Determinations

Paragraph (a). When a party makes a request for a drug benefit, the PDP sponsor must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after receipt of the request.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 8 hours on an annual basis to disclose the information for a total annual burden of 800 hours.

If the PDP sponsor extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the sponsor's decision to invoke an extension.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 4 hours on an annual basis to disclose the information for a total annual burden of 400 hours.

Paragraph (b). If a PDP sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 4 hours on an annual basis to disclose the information for a total annual burden of 400 hours.

Section 423.570 Expediting Certain Coverage Determinations

Paragraph (c). The PDP sponsor must document all oral requests in writing and maintain the documentation in the case file.

The burden associated with this requirement is the time and effort necessary for PDP sponsors to maintain the required documentation outlined in this section. We estimate that on an annual basis it will take 100 PDP sponsors 26 hours to maintain the required documentation on an annual basis, for total annual burden of 2,600 hours.

Paragraph (d). If a PDP sponsor denies a request for expedited determination, it must give the enrollee prompt oral notice of the denial and subsequently deliver, within 3 calendar days, a written letter that explains the notice requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 4 hours on an annual basis to disclose the information for a total annual burden of 400 hours.

Section 423.572 Timeframes and Notice Requirements for Expedited Coverage Determinations

Paragraph (a). Except as provided in paragraph (b) of this section, a PDP sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee and prescribing physician involved. We estimate that it will require each of the 100 PDP sponsors 4 hours on an annual basis to disclose the information for a total annual burden of 400 hours.

(b) When the PDP sponsor extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the sponsor's decision to invoke an extension.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 4 hours on an annual basis to disclose the information for a total annual burden of 400 hours.

(c) If the PDP sponsor first notifies an enrollee of an adverse expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 4 hours on an annual basis to disclose the information for a total annual burden of 400 hours.

§ 423.578 Exceptions process.

Paragraph (a). An enrollee, the enrollee's authorized representative, or the enrollee's prescribing physician may file a request for an exception.

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for exception. We estimate it will require an individual 30 minutes to provide the request and that each of the 100 PDP sponsors will receive 20 requests on an annual basis. Therefore, we estimate a total annual burden of 1000 hours.

Paragraph (b). An enrollee, the enrollee's authorized representative, or the prescribing physician (on behalf of the enrollee) may file an exception request.

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for exception. We estimate it will require an individual 30 minutes to provide the request and that that each of the 100 PDP sponsors will receive 20 requests on an annual basis. Therefore, we estimate a total annual burden of 1000 hours.

A PDP sponsor may require a written certification from the enrollee's prescribing physician that the requested prescription drug is medically necessary to treat the enrollee's disease or medical condition.

The burden associated with this requirement is the time and effort necessary for a prescribing physician to submit the required documentation to the PDP sponsor. We estimate it will require a prescribing physician 30 minutes to provide the request and that that each of the 100 PDP sponsors will make 10 requests on an annual basis. Therefore, we estimate a total annual burden of 500 hours.

Section 423.582 Request for a Standard Redetermination

Paragraph (a) An enrollee must ask for a redetermination by making an oral or written request with a PDP sponsor that made the coverage determination or a SSA office.

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for redetermination. We estimate it will require an individual 30 minutes to provide the request and that each of the 100 PDP sponsors will receive 20 requests on an annual basis.

Therefore, we estimate a total annual burden of 1000 hours.

(c) If the 60-day period in which to file a request for a redetermination has expired, an enrollee may file a request for redetermination and extension of time frame with the PDP sponsor.

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for extension of redetermination. We estimate it will require an individual 15 minutes to provide the request and that each of the 100 PDP sponsors will receive 10 requests on an annual basis. Therefore, we estimate a total annual burden of 250 hours.

Paragraph (d) The person who files a request for redetermination may withdraw it by filing a written request for withdrawal at one of the places listed in paragraph (a) of this section.

The burden associated with this requirement is the time and effort necessary for an individual to submit a withdraw request. We estimate it will require an individual 15 minutes to provide the request and that each of the 100 PDP sponsors will receive 10 requests on an annual basis. Therefore, we estimate a total annual burden of 250 hours.

Section 423.584 Expediting Certain Redeterminations

Paragraph (c) The PDP sponsor must document all oral requests in writing, and maintain the documentation in the case file.

The burden associated with this requirement is the time and effort necessary for PDP sponsors to maintain the required documentation outlined in this section. We estimate that on an annual basis it will take 100 PDP sponsors 8 hours to maintain the required documentation on an annual basis, for total annual burden of 800 hours.

(d) If a PDP sponsor denies a request for expedited redetermination, it must give the enrollee prompt oral notice, and subsequently deliver, within 3 calendar days, a written letter that explains the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 2 hours on an annual basis to disclose the information for a total annual burden of 200 hours.

Section 423.590 Timeframes and Responsibility for Making Redeterminations

Paragraph (a) When the PDP sponsor extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the PDP sponsor's decision to invoke an extension.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 2 hours on an annual basis to disclose the information for a total annual burden of 200 hours.

(d) The PDP sponsor must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 2 hours on an annual basis to disclose the information for a total annual burden of 200 hours.

Subpart N—Medicare Contract Determinations and Appeals

This Subpart deals with Contract Determinations and Appeals; therefore, the information collection requirements referenced in this Subpart are exempt from the PRA in accordance with 5 CFR 1320.4(a)(2) during the conduct of an administrative action, investigation, and/or audit.

Subpart O—Intermediate Sanctions

Section 423.756 Procedures for Imposing Sanctions

(a) Before imposing the intermediate sanctions specified in this section, CMS will allow the PDP sponsor to provide evidence that it has not committed an act or failed to comply with the requirements as described. In addition, CMS may allow additional time for the PDP sponsor to provide the evidence if the PDP sponsor sends a written request providing a credible explanation of why additional time is necessary.

These information collection requirements are exempt from the PRA in accordance with 5 CFR 1320.4(a)(2) during the conduct of an administrative action, investigation, and/or audit.

Subpart P—Premiums and Cost-Sharing Subsidies for Low-Income Individuals

Section 423.774 Eligibility Determinations, Redeterminations and Applications

Paragraph (d) of this section discusses the application requirements for individuals applying for low-income subsidy. This paragraph states that individuals applying for low-income subsidy, or a personal representative applying on the individual's behalf, must complete all required elements of the application, provide any statements from financial institutions, as requested, to support information in the application, and certify, as to the accuracy of the information provided on the application form.

The burden associated with this requirement is the time and effort for the individual or personal representative applying on the individual's behalf, to complete the low-income subsidy application, provide financial statements as requested and to certify that the information provided is accurate. These collection requirements are subject to the PRA; however, the burden associated with these requirements is currently approved under OMB# 0938–0467 with a current expiration date of October 31, 2005. We will revise this currently approved PRA package to incorporate the burden being imposed on new enrollees. We estimate that this requirement will impose a burden on 4.5 new enrollees for a total additional burden of 750,000 hours annually (4.5 × 10 minutes).

Section 423.800 Administration of Subsidy Program

Paragraph (b) of this section requires the PDP sponsor offering the PDP, or the MA organization offering the MA–PD plan, to reduce the individual's premiums and cost-sharing as applicable and provide information to CMS on the amount of such reductions, in a manner determined by CMS. This paragraph also requires the PDP sponsor and MD–PD organization to maintain documentation to track the application of the low-income cost-sharing subsidies to be applied to the out-of-pocket threshold.

The burden associated with these requirements is the time and effort for the PDP sponsor or the MA organization to provide information to CMS and to maintain documentation. We estimate that it will take each of the 100 PDP sponsors and each of the 350 MA organizations approximately 52 hours on an annual basis to provide the information to CMS. We also estimate

that it will take approximately 26 hours for each entity to maintain the information for tracking purposes. Therefore, we estimate that it will take approximately 35,100 total hours annually to comply with these requirements.

Subpart Q—Guaranteeing Access to a Choice of Coverage

Section 423.859 Assuring Access to a Choice of Coverage

Paragraph (c) states that CMS may waive or modify the requirements of this part if an entity seeking to become a prescription drug plan in a State other than the 50 States or the District of Columbia requests waiver or modification of any Part D in order to provide qualified prescription drug coverage in a State other than the 50 States or the District of Columbia.

The burden associated with this requirement is the time and effort for the PDP to make a request of waiver or modification to CMS. We estimate that approximately 2 PDPs will request a waiver or modification on an annual basis. Since this requirement affects less than 10, it is exempt from the PRA in accordance with 5 CFR 1320.3.

Section 423.863 Submission and Approval of Bids

Paragraph (a) discusses the process CMS uses for the solicitation and approval of bids. CMS solicits bids from eligible fallback entities for the offering in all fallback service areas in one or more PDP regions of a fallback prescription drug plan. CMS specifies the form and manner in which fallback bids are submitted in separate guidance to bidders.

The burden associated with this requirement is the time and effort for the fallback entities to prepare and submit a bid.

We estimate as an upper limit that approximately 20 fallback entities will submit a bid every three years. We also estimate that it will take each fallback entity approximately 80 hours to complete and submit the bid to CMS. Therefore, we estimate it will take a total of (5 * 80) /3 = 133.33 hours on an annual basis to comply with this requirement.

Paragraph (b) discusses the procedures CMS uses to enter into contracts. CMS solicits bids from eligible fallback entities and uses competitive procedures to enter into contracts.

The burden associated with this requirement is the time and effort for the fallback entities to enter into a contract with CMS.

We estimate, again as an upper limit, that approximately 5 fallback entities will enter into a contract with CMS on an annual basis. Since this requirement affects less than 10, it is exempt from the PRA in accordance with 5 CFR 1320.4.

Section 423.871 Contract Terms and Conditions

Paragraph (f) states that each contract for a fallback prescription drug plan requires an eligible fallback entity offering a fallback prescription drug plan to provide CMS with the information CMS determines is necessary to carry out the requirements of this section.

The burden associated with this requirement is the time required of the fallback prescription drug plan to provide CMS with the information CMS determines necessary. We estimate that approximately 5 fallback prescription drug plans will enter into a contract with CMS. Since this requirement affects less than 10, it is exempt from the PRA in accordance with 5 CFR 1320.4.

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

Section 423.884 Requirements for Qualified Retiree Prescription Drug Plans

(a) and (b) In order to qualify for the retiree drug subsidy, the employer or union sponsor shall file an annual application with CMS for each qualified prescription drug plan maintained, including an attestation as to actuarial value. For convenience, these applications may be packaged together.

The burden associated with this requirement is the time and effort necessary for an entity to submit the application to CMS. The requirements of this part state that an application must provide sponsor and plan identification information, together with an actuarially-certified attestation that the actuarial value of the prescription drug coverage in each such plan is at least equal to the actuarial value of standard Medicare Part D prescription drug coverage in accordance with actuarial guidelines established by CMS in accordance with generally accepted actuarial principles. If there is a change during the year that materially affects the actuarial value of their drug coverage, sponsors will need to submit an updated attestation. Sponsors will also be required to collect identifying information on their qualifying covered retirees.

For each entity we estimate an average of 2 hours administrative work to assemble the application, 31 hours for systems changes to extract identifying information on qualifying covered retirees and about 17 hours for preparation of the actuarial attestations, for a total of approximately 50 hours, for each prescription drug plan. The 17-hour estimate for preparation of actuarial attestations is a weighted average. See the economic impact section of this proposed regulation for the analysis pertaining to the range of time needed for sponsors of various sizes and numbers of plans.

For the number of entities applying for the subsidy, we have used 50,000, our estimate of the total number of public, private, and union sponsors projected to offer retiree prescription drug coverage in 2005. We have estimated on the basis of this figure in order to calculate the highest potential burden.

The total burden for preparation and filing of the 2005 applications for 50,000 sponsors is 2,500,000 hours. We also estimate that 5 percent of the initial applications may have to be refiled due to mid-year changes to drug coverage that materially affect actuarial value. We estimate 125,000 hours for this activity.

If CMS determines that a sponsor of a retiree prescription drug program meets all of the requirements of this section, it will send to the sponsor a written notice of that determination along with two copies of the sponsor agreement outlining the conditions for obtaining a subsidy payment. If the sponsor wishes to participate in the subsidy program, it must return both copies of the agreement, signed by an authorized representative, to CMS.

The burden associated with this requirement is the time and effort necessary for an entity to submit the required signed agreements to CMS. We estimate that on an annual basis it will take 50,000 entities 30 minutes to submit the required agreements to CMS, for a total of 25,000 hours.

(c) Each entity must disclose the creditable coverage status for each prescription drug plan to CMS in a form and manner described by CMS. We estimate this activity to take about 1 hour each for a total of approximately 50,000 hours.

In addition, each entity must notify each Part D eligible individual of the plan's creditable coverage status in a form and manner prescribed by CMS. The burden associated with the sponsor notices is required by § 423.56 of the proposed regulation, as discussed earlier in this analysis.

For the sponsors of retiree drug coverage, we estimate that it will take 50,000 entities approximately 8 hours

each to produce a standardized notice for a total of 400,000 burden hours.

Given that each entity will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that it will take each of them 4 hours to disclose, on average, 240 (rounded) notices (or 1 minute per notice), for a total burden of 200,000 hours. This estimate is based on that assumption that once the notices have been standardized, each entity will mass-produce and mail the required notices.

If an individual establishes to CMS that he or she was not adequately informed that he or she no longer had creditable prescription drug coverage or the coverage is involuntarily reduced, the individual may apply to CMS to have the coverage treated as creditable coverage so as to not be subject to the late enrollment fee described in § 423.46. The burden associated with this requirement is the time and effort necessary for an individual to apply to CMS to have such coverage treated as creditable coverage. While we have no way of determining how many individuals will apply to CMS, for the purpose of providing an upper bound estimate for public comment we estimate that on an annual basis it will take 100,000 individuals 15 minutes to apply to CMS, for a total of 25,000 hours.

(d) The employer or union sponsor of the plan must maintain the records outlined in this section for 6 years after the expiration of the plan year in which the costs were incurred.

The burden associated with this requirement is the time and effort necessary for an entity to maintain the required documentation for six years. We estimate that on an annual basis it will take 50,000 entities 20 hours to retain the required documentation, for a total of 1,000,000 burden hours.

Section 423.890 Appeals

The information collection requirements set forth in this section are exempt from the PRA as stipulated in 5 CFR 1320.4.

Section 423.892 Change in Ownership

A sponsor who is contemplating or negotiating a change of ownership must notify CMS. We estimate that approximately 5 percent of sponsors will fall into this category in a given year.

The burden associated with this requirement is the time and effort necessary for a sponsoring entity to submit the required notification to CMS. On an annual basis it will take 2,500 entities (5 percent of 50,000) about 30 minutes to submit the required notification to CMS, for a total of approximately 1,250 burden hours.

Subpart S—Special Rules for States—Eligibility Determinations for Subsidies and General Payment Provisions

Section 423.904 Eligibility Determinations for Low-Income Subsidies

Paragraph (b) of this section states the State agency must inform CMS of cases where eligibility is established or redetermined.

The burden associated with the requirement on State agencies to inform CMS of cases where eligibility is established or redetermined is estimated to total approximately 11,220 annual hours. We estimate that there will be approximately 600,000 of these cases on an annual basis. We also estimate that it will take approximately 10 hours per month for the State agency to inform CMS of these cases.

Paragraph (d) of this section requires States to make available—low-income subsidy application forms, information on the nature of, and eligibility requirements for the subsidies under this section, and offer assistance with the completion of the application forms. States must require an individual or personal representative applying for the low-income subsidy to complete all required elements, provide documents as necessary, and certify as to the accuracy of the information provided. In addition, States must provide CMS with other information as specified by CMS that may be needed to carry out the requirements of the Part D prescription drug benefit.

The burden associated with the requirement on States to make available the information specified in this section is subject to the PRA; however, we believe the burden for this requirement to be a reasonable and customary business practice; therefore, imposes no additional burden on the States.

The burden associated with the requirement on States to require the applicant of the low-income subsidy to complete all required elements, to provide documents, and to certify as to the accuracy of the information is subject to the PRA; however, the burden associated with this requirement is discussed in § 423.774 above.

The burden associated with the requirement on States to provide CMS with other information as specified by CMS is estimated to total approximately 1,020 annual hours. Since it is difficult to determine at this time the volume of information CMS will request, we are estimating that it will take on average 20 hours per State on an annual basis to provide CMS with the specified information.

Section 423.907 Treatment of Territories

Paragraph (a) of this section discusses the requirements on territories to submit plans for approval by the Secretary to receive increased grants. This paragraph states that a territory may submit a plan to the Secretary under which medical assistance is to be provided to low-income individuals for the provision of covered Part D drugs. Paragraph (b) of this section describes what a plan must include.

The burden associated with this requirement is the time and effort of territories to prepare and submit a plan for approval. While this requirement is subject to the PRA, we estimate that this requirement would affect only 5 territories; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.4.

Section 423.908 Phased-Down State Contribution to Drug Benefit Costs Assumed by Medicare

Paragraph (d) of this section discusses the requirements on States to submit MSIS data. This paragraph requires States to provide accurate and complete coding to identify the numbers and types of Medicaid and Medicare dual eligibles in their MSIS data submittals.

The burden associated with the requirement on States to provide accurate and complete coding in their MSIS data submittals is subject to the PRA; however, this requirement is already approved under OMB #0938–0502 with a current expiration date of January 31, 2006.

Paragraph (e) of section requires States to submit an electronic file, in a manner specified by the Secretary, identifying each full benefit dual eligible enrolled in the State for each month with Part D drug coverage who is also determined to be full benefit eligible by the State for full Medicaid benefits.

The burden associated with the requirement on States to submit an electronic file identifying each full benefit dual eligible enrolled in the State for each month with Part D drug coverage is estimated to total approximately 120 hours per State on an annual basis. We estimate that it will take approximately 10 hours for each State to submit an electronic file on a monthly basis. Therefore, we estimate a total burden of 6,120 hours on an annual basis. Startup development effort is estimated at 100 hours per State for a total of 5,100 hours.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Attn: John Burke (CMS–4068–P), Room C5–13–28, 7500 Security Boulevard, Baltimore, MD 21244–1850;

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Christopher Martin, CMS Desk Officer (CMS–4068–P), *christopher_martin@omb.eop.gov*. Fax (202) 395–6974.

IV. Regulatory Impact Statement

A. Overall Impact

[If you choose to comment on issues in this section, please include the caption "Impact Analysis" at the beginning of your comments.]

We have examined the impacts of this proposed rulemaking under Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impact and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). Our estimate is that this rulemaking is "economically significant" as measured by the $100 million standard, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a regulatory impact analysis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amends Title XVIII of the Social Security Act (the Act) to create a voluntary prescription drug benefit within the Medicare program beginning in 2006. The Medicare prescription drug benefit will make prescription drugs more affordable for beneficiaries by offering subsidized Medicare prescription drug coverage to all beneficiaries, with even more generous assistance available to low-income beneficiaries. We believe that this is an important step in modernizing the Medicare program to better meet beneficiaries' needs. We anticipate that by giving beneficiaries access to affordable insurance coverage that helps them to pay for their outpatient prescription drugs—which have become a critical component in the delivery of comprehensive, quality health care services—the Medicare prescription drug benefit will help beneficiaries to lead healthier, more productive lives, while also helping to improve the effectiveness of the Medicare program.

The MMA also authorizes Medicare to make retiree drug subsidy payments to employers and unions that provide qualified retiree prescription drug coverage to beneficiaries who do not enroll in a Part D plan. This alternative retiree drug subsidy provides special tax-favored payments to the qualified retiree health plans. The retiree drug subsidy program has highly flexible rules that permit employers and unions to continue providing drug coverage to their Medicare-eligible retirees while retaining their current plan designs that are at least equivalent to the standard Part D benefit and using the drug subsidy to reduce the cost of providing generous coverage.

With the trend toward declining retiree health insurance coverage that has occurred over the past decade, the Medicare alternative retiree drug subsidy is intended to "help employers [to] retain and enhance their prescription drug coverage so that the current erosion in coverage would plateau or even improve" (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report, p. 53).

Medicare Part D also offers employers a variety of other options for continuing to assist their Medicare retirees. They can also choose to provide enhanced drug coverage to their Medicare-eligible retirees through or in coordination with Part D by encouraging their Medicare-eligible retirees to enroll in Part D (with Medicare subsidizing the costs of their standard Part D benefits), and providing enhanced coverage over and above the standard Part D benefit. This can be achieved by either providing separate supplemental drug coverage that wraps around a Part D plan (similar to policies that wrap around Medicare benefits under Part A and Part B), arranging for a Part D plan (that is, a prescription drug plan (PDP) or Medicare Advantage Prescription Drug Plan (MA–PD)) to provide enhanced benefits to their retirees, or choosing to become a Part D plan that offers enhanced benefits to their retirees. In all of these cases, financial support from the new Medicare drug subsidy can augment contributions by employers to provide a more generous and less costly drug benefit for retirees than is possible through employer support alone.

We believe that the implementation of Medicare Part D, including the Medicare retiree drug subsidy and the other opportunities it affords employers for providing continued prescription drug assistance to their Medicare retirees, will result in combined aggregate payments by employers and Medicare for drug coverage on behalf of retirees generally being greater—and frequently significantly greater—than they otherwise would have been without the enactment of the MMA. Furthermore, the Medicare prescription drug benefit and retiree drug subsidy represent a particularly important strengthening of health care coverage for future Medicare-eligible retirees, given the erosion in the availability and generosity of employer-sponsored retiree coverage for future Medicare beneficiaries that has already been taking place, as is discussed in further detail subsequently in this impact analysis.

We estimate that in calendar year (CY) 2006 about 41 million Medicare beneficiaries will receive drug coverage either through a Medicare Part D plan (that is, by enrolling in a PDP or MA–PD), including beneficiaries who receive supplemental premium subsidies and enhanced drug coverage as a new retiree benefit, or through an employer or union sponsored retiree plan that is sufficiently generous to qualify for the Medicare retiree drug subsidy. By CY 2010, due to growth in the overall Medicare population, we estimate that nearly 45 million Medicare beneficiaries will be receiving such coverage.

The Medicare drug benefit, including the retiree drug subsidy, will lead to an increase in Federal spending on Medicare benefits and a decrease in Federal spending on Medicaid benefits (as dual eligibles' drug coverage is shifted from Medicaid to Medicare). The net effect of these changes on Federal outlays is estimated to be $48 billion in CY 2006 and $67 billion in CY 2010, with the total effect estimated to be $287 billion over the period from CY 2006–2010. The vast majority of this Federal spending is on Medicare subsidies that defray the cost of the Medicare drug benefit for beneficiaries, that provide substantial additional cost-sharing and premium assistance to low-income beneficiaries, and that make it more

affordable for employers to continue to provide and support high quality retiree drug coverage. We also anticipate that States will save money due to the Medicare drug benefit, as responsibility for drug coverage for full-benefit dual eligibles is shifted from Medicaid to Medicare and as State spending on State prescription drug assistance programs is likely to be at least partly displaced by the Medicare drug benefit. We also estimate that many more eligible low-income beneficiaries will take up Medicaid and other low-income benefits, in addition to the comprehensive Medicare drug benefit, as a result of the additional value of the drug benefit and unprecedented beneficiary outreach activities. Taking all of these considerations together, we estimate that the Medicare drug benefit will lead to net State budgetary savings of about $500 million in CY 2006 and $3.0 billion in CY 2010, with total net savings of about $8.2 billion over the period from CY 2006–2010.

As discussed in more detail in section L of the impact analysis, from both an economic and budgetary accounting perspective, Federal spending on the Medicare drug benefit largely represents transfers of Federal budget revenue from taxpayers to Medicare beneficiaries and retiree plans sponsored by private and public sector employers and unions. Also, from an economic perspective, there is effectively a transfer of Federal budget revenues from taxpayers to State governments, as Medicare pays for some of the costs of drug coverage for full-benefit dual eligibles that had been previously paid for by States and as the Medicare drug benefit displaces some State spending on prescription drug assistance programs. In addition, a portion of the Federal spending on Medicare Part D is for administrative costs incurred by PDPs and MA–PDs to administer the benefit.

B. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule (and subsequent final rule) that includes any Federal mandate that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. We anticipate that this rule would not impose costs above the $110 million UMRA threshold on State, local, or tribal governments. With the exception of the electronic prescribing provisions (for which we are unable to develop a cost estimate because standards are still to be developed), we have determined that this rule would not impose costs on the private sector exceeding $110 million.

1. Private Sector

There are two provisions of the MMA that are reflected in this notice of proposed rulemaking that represent mandates on the private sector as defined by the UMRA: Provisions related to disclosure notices of creditable coverage and electronic prescribing.

As discussed elsewhere in this document, certain private sector entities—Medigap plans and private sector employer or union sponsored health plans that provide drug coverage to Medicare beneficiaries who are retired or who are active workers—are required to provide at certain times disclosure notices on whether the coverage provided equals or exceeds the actuarial value of defined standard Part D coverage. Later in the impact analysis we provide a discussion of the costs expected to be borne in providing such notices, including the costs associated with performing the actuarial valuation of the drug benefits. The largest cost for providing these notices is expected to occur in the months preceding the implementation of the drug benefit in January 2006 when the largest volume of notices need to be provided. Following receipt of these notices, beneficiaries will be making choices regarding where they receive their drug coverage.

For private sector employers that provide retiree drug coverage, the implementation of Medicare Part D, including the Medicare retiree drug subsidy program, is expected to produce net savings that far exceed the costs of the disclosure notices. This is true both for employers that choose to obtain the retiree drug subsidy, and for employers and unions that decide to restructure their prescription drug coverage to provide continued assistance by paying Medicare Part D premiums and/or supplementing the Medicare prescription drug benefit.

For those private entities that will not achieve savings—Medigap insurers and group health plans that offer coverage only to beneficiaries who are active workers, not retirees—the cost of providing disclosure notices is estimated to be approximately $69 million in 2005 (which translates into an average of roughly $154 per employer that offers drug coverage to Medicare beneficiaries who are active workers and about $11,050 per Medigap insurer). Thus, the costs associated with the notice requirements are not expected to reach the $110 million UMRA threshold.

Another private sector mandate in the MMA is that no later than April 1, 2009, prescriptions for covered Part D drugs for Medicare beneficiaries that are transmitted electronically will have to comply with certain standards. The proposed rule describes the process that will be used to develop these standards, but the actual standards are not yet specified. Moreover, we are seeking comment on a set of approaches to speed the adoption and reduce the cost of more rapid adoption of electronic prescribing, and to maximize the benefits of electronic prescribing on reducing costs and inappropriate care involving the drug benefit. Consequently, at this time it is not possible to estimate the impact. An impact statement on the actual standards will be prepared separately.

We also note that Section 104 of the MMA, which prohibits the sale of new Medigap policies with drug coverage or the renewal of existing Medigap policies that contain drug coverage for Medicare drug benefit enrollees, is not an unfunded mandate as defined by UMRA. This statutory Medigap prohibition does not result in the "expenditure" of funds by the private sector, one part of the statutory test for an unfunded mandate. Moreover, the MMA itself directly restructures the role of Medigap insurance, and it is not the "promulgation of any rule" on our part, the other factor in the statutory test for an unfunded mandate. For a discussion of the effect on Medigap insurers of the MMA prohibition, see section J of the impact analysis.

2. States, Local and Tribal Governments

While States will incur direct costs as a result of this proposed rule, as discussed in greater detail in section H on State impacts, States will achieve net savings under this proposed rulemaking, as now Medicare will be paying for prescription drug costs previously funded under Medicaid, State Pharmacy Assistance Programs (SPAPs), and State sponsored retiree health insurance, or will be providing subsidies for State sponsored qualified retiree prescription drug coverage. There are several sources of the direct costs States will incur. As described below, several of these, taken alone and without consideration of offsetting gains, would reach or exceed the threshold level in UMRA.

In order to defray a portion of the Medicare drug expenditures for full-benefit dual eligibles, States will be responsible for making monthly payments to the Federal government

beginning in January 2006. These payments are estimated to be $8.5 billion in CY 2006, reaching $11.1 billion by CY 2010. These payments represent the largest direct cost to States. States will also incur costs associated with assisting in eligibility determinations for the Medicare Part D low-income subsidies. In addition to giving responsibility for eligibility determinations to the Social Security Administration, the MMA also gives States, as a condition of receipt of any Federal financial assistance under Title XIX, responsibility for conducting determinations for eligibility for low-income premium and cost-sharing subsidies under Part D, and as part of those determinations also make determinations related to medical assistance for Medicare cost-sharing under Medicare Parts A and B. Federal matching payments will be available to assist in paying for these administrative costs. Prior to enactment of the MMA, we roughly estimated that the State share of Medicaid administrative costs that might be associated with these low-income eligibility determinations was approximately $100 million a year, beginning in FY 2005. However, we are undertaking new collaborations with the Social Security Administration, the State Health Insurance Assistance Programs (SHIPs), and other groups to assist in outreach and enrollment, and to help avoid any new administrative burdens for States. We plan to develop an updated estimate of State administrative costs for eligibility determination activities once the operational processes for the eligibility determinations are more fully developed. We also note that there are likely to be some additional costs to States arising from this activity, as discussed in section H of this impact analysis, due to the Medicare Part D low-income eligibility determinations process raising awareness of other benefits available to low-income Medicare beneficiaries through Medicaid and leading to higher enrollment in that program. As noted earlier, however, we believe that overall costs to the States will be reduced due to implementation of the new Medicare drug benefit.

In addition, States will also have revenue losses associated with the MMA prohibition on States imposing taxes on premiums related to Part D coverage. As a result of the shift of beneficiaries from prescription drug coverage subject to State premium taxes to Part D coverage, we estimate that the loss in premium tax revenue to States will be about $111 million in CY 2006, and $129 million by CY 2010, totaling $598 million over this period.

States will also incur direct costs attributable to required disclosure notices for creditable coverage. Similar to the requirement for private sector employers, State governments that offer retiree health insurance benefits with drug coverage will need to provide disclosure notices to Medicare beneficiaries enrolled in their employer sponsored plans related to that coverage. States will also need to provide disclosure notices to Medicare beneficiaries who receive drug coverage through State Medicaid programs, State Pharmacy Plus programs, and State Pharmacy Assistance Programs. As noted elsewhere in this document, the costs of providing such notices are small and are far more than offset by the savings achieved from receiving the Medicare retiree drug subsidy (because States may also qualify for this subsidy) or through the enrollment of beneficiaries in the Part D benefit.

As discussed in the States section of the impact analysis, the direct and indirect costs and revenue losses to States are more than offset by savings States will achieve as a result of the implementation of the Medicare Part D prescription drug benefit. As noted in that section, the net savings to States increase over time, as the share of drug coverage costs for full-benefit dual eligibles for which States are required to compensate Medicare declines.

Local governments that offer retiree health insurance benefits that include coverage for prescription drugs also will need to provide disclosure notices to Medicare beneficiaries enrolled in their employer sponsored plans related to that coverage. As noted previously, the costs of providing such notices are small, and are far more than offset by the savings achieved either from receiving the Medicare retiree drug subsidy (because local governments may also qualify for this subsidy) or through the enrollment of beneficiaries in the Part D benefit.

We have determined that this proposed rule does not mandate any requirements for Tribal governments.

C. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications.

As discussed previously, the MMA and this proposed rule have implications for States. In addition to the provisions addressed in the UMRA discussion, the statute includes specific provisions prohibiting State regulation of PDP plans, except for licensure and solvency, and permitting the Secretary to waive even State licensure and solvency requirements. The majority of these waivers, however, are temporary and may not exceed 36 months, except in the case of a State that does not have a licensing process for PDP sponsors. As specified in the MMA, we will consult with the National Association of Insurance Commissioners (NAIC) on establishing the financial solvency and capital adequacy standards that will be used in the waiver process.

Because of the national nature of the Medicare Part D benefit, the statute includes provisions that supercede State law relative to the Secretary's final electronic prescribing standards applicable to covered Part D drugs for Part D eligible individuals, and also prohibits States from limiting the amount that a PDP sponsor can recover from liable third parties under Medicare Secondary Payer provisions.

CMS has started routine consultations with States regarding the numerous provisions related to the Medicare prescription drug benefit that have implications for States. Among these, CMS' Center for Medicaid and State Operations has regular meetings with State Medicaid Directors and has used these opportunities to provide our State partners with information about MMA. For example, in March 2004, CMS held conference calls with State representatives to provide them with an overview of the MMA and information on what to expect during implementation, to discuss the provisions in the statute dealing with State payments to the Federal government under Section 103 of the MMA, and to allow States to raise issues about the implementation process. In April and May 2004, CMS held conference calls with State representatives to discuss the calculation of State phased-down contribution, definition of "full-benefit dual eligibles", excluded drugs, enhanced FMAP on family planning drugs, and related State payment issues. CMS is currently working with State Medicaid Directors, State Pharmaceutical Assistance Program staff, and State Health Insurance Assistance Program (SHIP) counseling staff to raise awareness of the Medicare prescription drug discount card program, and we expect to have similar efforts for the implementation of the Medicare Part D prescription drug benefit. We have also consulted with the NAIC on Medigap issues.

The Medicare retiree drug subsidy is an optional program that public or private employers may choose to participate in if they offer qualified retiree prescription drug coverage. Like other employers, State and local governments that offer qualified retiree prescription drug coverage and wish to receive Medicare retiree drug subsidy payments will need to comply with the reporting requirements of this proposed rule, such as attestation of actuarial equivalence and certain data reporting necessary for calculating the retiree drug subsidy payment amount. However, these are not requirements because no public or private employer need apply for Medicare retiree drug subsidy payments. Thus, we have determined that the retiree drug subsidy provisions of this proposed rule would not impose direct costs on State and local governments. As discussed earlier in the preamble, we intend to conduct outreach to prospective applicants for Medicare retiree drug subsidy payments, including State and local governments that sponsor retiree health plans, in an effort to better understand the needs of this segment of the employer community, share information about the Medicare retiree drug subsidy program, and solicit suggestions about how we can best implement the program.

D. Limitations of the Analysis

The following analyses present projected effects of this proposed rule on Medicare beneficiaries, the Federal budget, States, private sector organizations that provide drug coverage to Medicare beneficiaries, and small entities. These impact estimates are generally consistent with the President's fiscal year 2005 budget. Unless otherwise noted, all estimates in this impact analysis are net budgetary spending based on calendar year data.

Because 2006 will be the first year of the Medicare prescription drug benefit and retiree drug subsidy program, we do not have program experience from prior years. In estimating the impact of a completely new program, there are limited data and much greater uncertainty than would be the case with modifications to existing programs. Additionally, there are further policy and administrative issues under consideration in the context of the rule making process. We have explored a wide variety of potential approaches. We believe that these estimates provide a reasonable representation of the likely effects of the policies and potential options discussed. Our analysis generally reflects the broad range of options we have explored and represents a "mid-range" estimate of the projected possible impacts of the Medicare drug benefit and retiree drug subsidy. We are continuing to work to examine the effects of the issues under consideration and to refine our understanding of the impacts. We would welcome comments on any aspect of the approach, methodology, or assumptions used to develop the estimates presented in this impact analysis.

In addition, we note that analyses in the 2004 Medicare Trustees Report can provide a sense of the range of uncertainty inherent in these types of estimates. Because the methodology used in our estimates is fairly similar to the one used by the Medicare Trustees, we believe that the Trustees Report provides relevant information on the potential range of uncertainty in these types of estimates (see the "2004 Annual Report of the Boards of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds" available on the CMS Web site).

E. Enrollment Estimates

1. Summary

We estimate that in CY 2006 about 41 million Medicare beneficiaries will receive drug coverage either through a Medicare Part D plan (that is, by enrolling in a PDP or MA-PD) or through an employer or union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy. By CY 2010, as a result of growth in the overall Medicare population, we estimate that nearly 45 million Medicare beneficiaries will be receiving such coverage.

As mentioned previously, Medicare Part D offers additional assistance with Medicare drug benefit cost-sharing and premiums to low-income beneficiaries who meet certain income and assets requirements. We estimate that about 10.9 million beneficiaries would enroll in the Medicare Part D low-income subsidy program in CY 2006. Among low-income subsidy participants, we estimate that about 6.4 million would be full-benefit dual eligibles.

2. Projection Assumptions

We project that there will be 43.3 million beneficiaries entitled to or enrolled in Medicare Part A or enrolled in Medicare Part B in 2006 who will be eligible for Medicare Part D. We estimate that roughly 95 percent of these beneficiaries, 41.2 million, will receive drug coverage either through a Medicare Part D plan (that is, a PDP or MA–PD) or through an employer sponsored retiree plan that is eligible for the Medicare retiree drug subsidy.

First, we assume that Medicare beneficiaries who are active workers and who have employer-sponsored insurance as their primary payer with Medicare as a secondary payer (MSP), will not participate in Medicare Part D at this time. Since these beneficiaries are active workers, not retirees, they would be ineligible for the Medicare retiree drug subsidy. In addition, we believe that it is unlikely that these beneficiaries will enroll in the Medicare drug benefit at this time. These beneficiaries are likely to already have creditable drug coverage from their employer and that coverage would be the primary payer regardless of enrollment in the Medicare drug benefit. In the future, when Medicare becomes the primary payer for these beneficiaries, they will have an opportunity to enroll in Medicare Part D without a late enrollment penalty as long as they had creditable drug coverage from their previous primary insurer.

Second, we assume that all beneficiaries who are full-benefit dual eligibles will enroll in the Medicare drug benefit. As discussed in the preamble, there will be automatic processes put in place to ensure that any beneficiary who is a full-benefit dual eligible who does not enroll in the Medicare drug benefit will be automatically enrolled in a Medicare Part D plan.

Third, among all other eligible beneficiaries, we assume that roughly 99 percent receive prescription drug coverage either through a Medicare Part D plan (that is, a PDP or MA–PD) or through an employer or union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy. This assumption is based in part on the experience of high participation rates in Medicare Part B, but on other factors as well. The standard Medicare Part D benefit shares several similar features with Medicare Part B that encourage enrollment. Both are subsidized benefits, where the beneficiary premium is set at roughly 25 percent of the cost of the insurance, with the government providing a subsidy to cover the remaining 75 percent.

In addition, under both Part B and Part D, beneficiaries face a late enrollment penalty or surcharge (in the form of higher premiums) unless they enroll within the initial enrollment period, have met creditable coverage requirements in the case of Medicare Part D, or have met certain other requirements that occur in a limited number of circumstances. We believe

that the late enrollment penalty is a strong incentive for beneficiary enrollment. The statute provides that the penalty is the greater of either 1 percent of the base beneficiary premium for each month of late enrollment or an amount that CMS determines is actuarially sound for each month of late enrollment that is subject to the penalty (that is, when the beneficiary did not have other creditable coverage). As discussed elsewhere in the preamble, during the first several years of the program, we currently expect that we would specify a penalty amount of 1 percent of the base beneficiary premium per month of late enrollment. In future years once we have sufficient data and experience under the program, we anticipate being able to determine the appropriate penalty amount (that is, either one percent or a greater amount that is actuarially sound). This late enrollment penalty begins after the close of the open enrollment period in May 2006 for those beneficiaries without other creditable coverage. Prescription drug costs are a major concern for Medicare beneficiaries. There will be extensive educational and outreach efforts prior to implementation of Medicare Part D to educate beneficiaries about the coverage available to them through the Medicare drug benefit and about enrollment processes, including the presence of the late enrollment penalty. We think that beneficiaries' concern about current prescription drug costs and the likelihood that as an elderly or disabled individual they will have even greater need for prescription drugs as they age, in combination with the substantial late enrollment penalty, will result in high initial enrollment in the Medicare drug benefit.

We also note that we believe it is likely that some beneficiaries who have not enrolled in Medicare Part B will choose to enroll in the Medicare prescription drug benefit. Many beneficiaries who currently have not enrolled in Part B would face a late enrollment surcharge should they want to enroll in Part B at this time. These same beneficiaries would not face a late enrollment penalty if they chose to enroll in the Medicare Part D drug benefit during the initial enrollment period, and we believe their experience with the Part B late enrollment surcharge may influence their decision-making regarding Part D.

Other features of the Medicare drug benefit are also likely to encourage high enrollment. In addition to the Federal subsidy of the beneficiary premium (which is a part of the standard benefit), a subset of beneficiaries, specifically those who meet certain income and assets requirements, are eligible for additional low-income subsidies. We expect that States over the next 18 months will also be doing aggressive outreach particularly related to the lower income population. For example, many States have been working with CMS to facilitate enrollment (including for some States auto-enrollment arrangements) of beneficiaries participating in State Pharmaceutical Assistance Programs into the Medicare drug discount card program. In addition, as discussed elsewhere in the preamble, the MMA also provides for transitional grants to States with Pharmaceutical Assistance Programs in each of fiscal years 2005 and 2006, to among other things, help facilitate enrollment in Part D.

Also, in the months preceding the implementation of the Part D benefit, the approximately 76 percent of beneficiaries who have drug coverage (based on 2001 Medicare Current Beneficiary Survey data) will receive separate specific disclosure notices from the entities from which they get that coverage regarding enrollment in the Medicare prescription drug benefit and the applicability of the late enrollment penalty. These notices from other sources are in addition to the extensive outreach efforts that CMS and SSA will conduct over the next 18 months. We also expect that Medicare Advantage plans will work with their members to facilitate enrollment into MA–PD plans.

Another feature of the Medicare Part D program that factors into our expectations regarding participation is the availability of the Medicare retiree drug subsidy. The Medicare retiree drug subsidy lowers the cost of providing drug benefits for employers that sponsor qualified retiree plans, making it more affordable for employers to provide this coverage. We anticipate that most beneficiaries with employer or union sponsored retiree drug coverage will receive their prescription drug coverage through an employer or union plan that is eligible for the Medicare retiree drug subsidy.

It is important to note, though, that in addition to the ability to obtain Medicare retiree drug subsidy payments, Medicare Part D also gives employers a variety of other options for providing their retirees with assistance with prescription drug costs. Employers can choose to provide enhanced drug coverage to their Medicare-eligible retirees through or in coordination with Part D by encouraging their retirees to enroll in Part D (with Medicare subsidizing the costs of their standard Part D benefits), and providing enhanced coverage over and above the standard Part D benefit. This can be achieved by either arranging for a PDP or MA–PD Part D plan to provide enhanced benefits to their retirees, choosing to become a Part D plan that offers enhanced benefits to their retirees, or providing separate supplemental drug coverage that wraps around a Part D plan (similar to policies that wrap around Medicare benefits under Parts A and B). Thus, some beneficiaries with employer sponsored drug coverage are likely to receive enhanced prescription drug benefits by enrolling in Part D and receiving employer sponsored enhanced Part D benefits or wraparound coverage and/or premium assistance.

The advantages and disadvantages to employers of choosing among the various options for providing employer prescription drug assistance (for example, taking the Medicare retiree drug subsidy versus offering enhanced prescription drug benefits through a Part D plan) will in many cases be influenced by a number of factors, including current benefit design, employer and retiree contributions and other financial considerations, tax status, labor relations, and contractual agreements. Because of these factors and because employers have several options that are advantageous to their retirees and to them in terms of both costs and labor relations, it is difficult to accurately predict which specific choices they will make in many cases. We expect that some employers will choose to provide prescription drug assistance in the form of enhanced benefit packages through Part D plans or separate wraparound coverage. Employers commonly do this relative to Medicare Part A and Part B coverage, either through separate supplemental policies or through arrangements with Medicare Advantage plans. In fact, the Medicare retiree drug subsidy represents a new type of arrangement for employers relative to the interaction of their retiree coverage with Medicare. Thus, we expect that some employers may prefer to interface with the new Medicare prescription drug benefit in a manner similar to their supplementation of the basic Medicare Part A and Part B benefits. In addition, we anticipate that providing enhanced Part D benefits or separate wraparound coverage may be an attractive option to those employers that may not be eligible for the Medicare retiree drug subsidy because their retiree drug benefits, as currently structured, are not as generous as the standard Medicare Part D benefit.

Regardless of whether employers seek the Medicare retiree drug subsidy or provide drug coverage to retirees by

encouraging them to participate directly in the Medicare prescription drug benefit and providing enhanced benefits or wraparound coverage, Medicare Part D is estimated to significantly lower employers' cost of providing drug coverage, thus making the provision of that coverage much more affordable and thus more likely. The variety of choices available to employers means that there is some uncertainty around specific choices on the part of employers. An example of the complexity of the issues surrounding employer decision making related to the Medicare retiree drug subsidy is the tax-advantaged status of the 28 percent subsidy. This provides a substantially different incentive to three groups of employers: (a) Those for-profit employers paying 35 percent on the margin in corporate income tax rates, (b) those for-profit employers paying far lower rates for a variety of reasons (including not earning a profit), and (c) governmental and non-profit sponsors who do not pay corporate income taxes to begin with. These different incentives, in turn, could affect whether plan sponsors choose the alternative Medicare retiree drug subsidy or choose to enhance benefits provided through Part D.

A fourth participation assumption concerns enrollment in the low-income subsidy portion of the program. We estimate that approximately 14.5 million beneficiaries will be eligible for the low-income subsidy in 2006. We assume that a portion of beneficiaries who are eligible for the low-income subsidy (while receiving prescription drug coverage under Part D) will not take up the low-income assistance. While we assume 100 percent uptake among full-benefit dual eligibles (as discussed previously), we assume that roughly 56 percent of other beneficiaries who are eligible for the low-income subsidy will choose to enroll in it. We assume less than full uptake of the low-income subsidy among these beneficiaries based on experience with other means tested programs such as Medicaid and Medicare Savings (QMB/SLMB) programs, which suggests that full take up does not generally occur.

There are several limitations inherent in the assumptions to predict the specific impacts of a major new program like the Medicare drug benefit. For example, it can be difficult to project enrollment rates in this entirely new program, and there is uncertainty about how employers will respond to the multiple approaches available to augment Medicare prescription drug coverage including the retiree drug subsidy. The assumptions discussed previously reflect our current best estimates, considering the structure of the program, the wide variety of new efforts to educate beneficiaries and facilitate enrollment, and information about participation rates in other types of similar programs where available. In addition, the estimates do not take into account the possibility that some beneficiaries may have creditable drug coverage through pre-standardized Medigap plans. To the extent that such situations exist and beneficiaries choose to remain in such coverage, our estimates for Medicare Part D may be slightly overstated.

F. Anticipated Effect of Medicare Part D on Beneficiaries

Included in the following section are discussions of: the anticipated positive effects of the Medicare prescription drug benefit on beneficiaries, a recap of the Medicare drug benefit's structure, estimates of the average amount of drug spending covered by the Medicare drug benefit and average beneficiary premiums, and a discussion of the benefits of the Medicare retiree drug subsidy and the other opportunities Medicare Part D affords employers for providing continued prescription drug assistance to retirees.

1. Qualitative Discussion of Positive Effects of the Medicare Drug Benefit

The purpose of the Medicare prescription drug benefit is to provide all of the nation's Medicare beneficiaries with the opportunity to enroll in a prescription drug benefit that is subsidized by the Medicare program. Outpatient prescription drugs have become an integral component in the delivery of comprehensive, high-quality health care services. Giving beneficiaries access to affordable drug coverage that helps them to pay for their outpatient prescription drugs and helps beneficiaries and their health professionals use prescription drugs more effectively as part of their overall health care, will enable beneficiaries to lead healthier, more productive lives, while improving the effectiveness of the Medicare program.

a. Enhancement of the Medicare Benefit Package

When the Medicare program was first enacted, outpatient prescription drug coverage was generally not included in private sector health benefit packages. However, over the last two decades, prescription drugs have played an increasingly critical role in health care delivery. For example, currently, at least one medication is ordered, provided, or continued in approximately 65 percent of all visits to office-based physicians by persons 65 years and over (2001 National Ambulatory Medical Care Survey, National Center for Health Statistics). Prescription drugs have significantly improved the treatment and management of many major conditions—including life-threatening diseases such as stroke (anticoagulant or clot-blocking therapy), heart disease and coronary artery disease (antihypertensive medications, cholesterol-lowering drugs), and cancer (targeted biologics and other agents that modify the course of illness and can be taken orally), as well as disorders that have fundamental impacts on quality of life like psychiatric illnesses (antipsychotics and antidepressants), osteoporosis (bone-strengthening drugs), and arthritis (anti-inflammatory drugs and other disease-modifying agents)—thereby contributing to longer and healthier lives as well as reductions in other types of medical expenditures such as inpatient admissions and lengths of stay ("The Price of Progress: Prescription Drugs in the Health Care Market," J.D. Kleinke, *Health Affairs* 20:5, September/October 2001, available at *http://www.healthaffairs.org*). Many other significant diseases have seen improvements in treatment and management and thus in patient health as a result of new medications. Examples include: AIDS/HIV, complex infections, diabetes, asthma and chronic lung diseases, Parkinson's disease, and many less common but serious disorders. With more new medicines in development than ever before, potential future health benefits from better drug therapies are even greater. Medicare Part D will augment the Medicare program benefit package by making drug coverage, which is currently offered in most private sector health plans, available to all beneficiaries. This represents an important step in modernizing the Medicare program to better meet beneficiaries' needs and respond to changes in health care delivery.

b. Access to Subsidized Prescription Drug Coverage

The Medicare prescription drug benefit will make subsidized prescription drug coverage available to the estimated 24 percent of Medicare beneficiaries that currently do not have any prescription drug coverage at all (based on 2001 Medicare Current Beneficiary Survey data). Additionally, the Medicare prescription drug benefit will make subsidized coverage available to many other beneficiaries who may have less generous, costly drug coverage—including those who currently receive drug coverage through

Medigap policies or through "access-only" group health plans (group health plans that are available through their former employers which require retirees to pay the premiums for such coverage), and those retirees who may currently be paying a large share of the cost of their retiree coverage.

By providing a substantial subsidy to defray the cost of Medicare drug coverage, including new subsidies for the retiree coverage and Medicare Advantage coverage that many beneficiaries receive today, the Medicare prescription drug benefit will make prescription drug coverage more accessible and affordable for many beneficiaries. As discussed in more detail elsewhere in the preamble, the Medicare program will make payments to PDPs and MA–PDs (through a direct subsidy and government reinsurance payments) that will amount to roughly 75 percent of the total cost of the Medicare Part D prescription drug benefit for all beneficiaries. Medicare Part D will also offer low-income beneficiaries additional assistance by reducing or eliminating beneficiary premiums and by providing very low cost-sharing requirements.

c. Improved Compliance With Treatment Regimens

Available data suggest that not having drug coverage, combined with high drug expenses, may cause some beneficiaries to either not have their prescriptions filled or have them filled less often because they are not financially able to purchase outpatient prescription drugs. Because the Medicare prescription drug benefit will reduce affordability barriers associated with obtaining outpatient prescription drugs by reducing both the costs of drug treatment and beneficiaries' payments, we believe it will help to improve beneficiaries' compliance with their drug treatment regimens.

There is evidence that some beneficiaries, particularly those without drug coverage, do not fill some prescriptions ordered by their physicians and skip doses to make their drugs last longer due to cost concerns. For example, a study of Medicare beneficiaries in eight States found that among those without drug coverage, 25 percent reported not filling a prescription due to cost, while 27 percent reported skipping doses to make drugs last longer. These rates of "noncompliance" with physician prescribing orders were more than double the rates reported among beneficiaries with drug coverage (Dana G. Safran, *et. al.*, "Prescription Drug Coverage And Seniors: How Well Are States Closing the Gap?" *Health Affairs* Web Exclusive W253, July 2002, *http://content.healthaffairs.org/cgi/reprint/hlthaff.w2.253v1.pdf*).

Furthermore, analysis of data from the 2001 Medicare Current Beneficiary Survey (MCBS), a nationally representative sample of Medicare beneficiaries shows that Medicare beneficiaries without drug coverage fill fewer prescriptions than those with drug coverage. Overall, beneficiaries without drug coverage, on average, self-report filling 37 percent fewer prescriptions (18) than those with drug coverage (29). While some of this difference in utilization likely reflects differences in health status and other beneficiary characteristics, this phenomenon holds true even among groups of beneficiaries with large numbers of chronic conditions. For beneficiaries with five or more chronic conditions, those without drug coverage self-report, on average, filling approximately 38 prescriptions a year compared to beneficiaries with drug coverage, who self-report filling, on average, 50 prescriptions.

Finally, a study in the December 2001 issue of the *Journal of General Internal Medicine* found that certain characteristics, such as minority ethnicity, and low income (defined as income less than $10,000) significantly increase the risk that individuals without drug coverage will restrict their use of medications by, for example, skipping doses or avoiding taking medication altogether. For example, the odds of medication restriction in minority subjects were higher among those with no drug coverage than among those with full drug coverage. Similarly, the odds of medication restriction were higher in low-income subjects with no drug coverage than in those with full drug coverage. (Michael A. Steinman, *et al.*, "Self-restriction of Medications Due to Cost in Seniors without Prescription Coverage," 16 *Journal of General Internal Medicine* 793–799, Dec. 2001). Thus, comprehensive coverage is particularly likely to have an impact on prescription drug use among disadvantaged populations.

d. Improved Health and Reduction of Adverse Health Effects

Not filling prescriptions, skipping doses, or cutting pills in half are referred to in the medical literature as "medication noncompliance," and can have adverse health effects. We believe that by reducing financial barriers associated with obtaining outpatient prescription drugs and encouraging beneficiary compliance with their drug treatment regimens, the Medicare prescription drug benefit will reduce the occurrence of adverse health events and lead to overall improvements in beneficiaries' health.

Medication noncompliance can lead to worsening health problems and the need for additional health care services. For example, a study of prescription drug noncompliance among disabled adults found that about half of the individuals reporting medication noncompliance due to cost reported experiencing one or more health problems as a result, including pain, discomfort, disorientation, change in blood pressure or other vital signs, having to go to a doctor or emergency room, or being hospitalized. (Jae Kennedy and Christopher Erb, "Prescription Noncompliance Due to Costs Among Adults with Disabilities in the United States," *American Journal of Public Health*, July 2002). This same study cited other research indicating that medication noncompliance is a clinical problem, particularly related to chronic illnesses such as hypertension, and has been found to be a predictor of hospital admissions and emergency room visits in other studies.

Similarly, another study found that limiting access to medications among low-income, elderly Medicaid patients increased rates of admission to nursing homes. The study analyzed Medicaid recipients aged 60 years or older who took three or more medications per month and at least one maintenance drug for chronic diseases. Limiting affordable access to prescription drugs for this population (through a reimbursement cap on medications) increased rates of admission to nursing homes. The authors concluded that for the sicker patients in the study, the limitation on medication more than "double[d] the rate" of admission in comparison to a group whose medications were not limited. (Stephen B. Soumerai *et al.*, "Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes," 325 *New England Journal of Medicine* 1072, 1074, 1991).

There is also evidence suggesting that the use of specific drugs may reduce adverse health events, utilization of other health care services, and related costs for certain groups of patients. For example, a recent study found that the use of statins in cholesterol-lowering drug therapy reduced the incidence of coronary disease-related deaths by 24 percent in elderly men and women (ages 70 to 82) with a history of, or risk factors for, vascular disease, and also reduced the incidence of non-fatal heart attacks and fatal or non-fatal strokes in these patients ("Pravastatin in Elderly

Individuals at Risk of Vascular Disease (PROSPER): A Randomised Controlled Trial," *Lancet* 2002, 360:9346, 1623–1630).

Similarly, the Heart Outcomes Prevention Evaluation (HOPE) study has found that antihypertensive drug therapy reduced the combined risk of cardiovascular death, heart attack and stroke by 22 percent in approximately 9,000 high-risk middle-aged and elderly patients (ages 55 and older), with $871,000 in net estimated savings over 4 years, and also significantly reduced the risk of adverse cardiovascular outcomes by 25 to 30 percent in a broad range of high-risk middle-aged and elderly patients with diabetes mellitus (See "Drug Therapy and Heart Failure Prevention," Editorial, Jennifer V. Linseman, PhD, and Michael R. Bristow, MD PhD, *Circulation* 107:1234, American Heart Association, 2003; "Economic Impact of Ramipril on Hospitalization of High-Risk Cardiovascular Patients, Cathryn A. Carroll, PhD MA MBA BSPharm, *The Annals of Pharmacotherapy*, Volume 37, No. 3, pp. 327–331; and "Effects of Ramipril on Cardiovascular and Microvascular Outcomes in People With Diabetes Mellitus: Results of the HOPE Study and MICRO-HOPE Substudy, Evaluation (HOPE) Study Investigators, *Lancet* 355 (9200):253–259, 2000).

While there is evidence that the use of certain prescription drugs may be cost-effective for specific groups of patients (in the sense that they result in net health care cost savings or produce health improvements at relatively low cost), thus far it has been difficult to generalize the results of these drug-specific studies more broadly to estimate the potential health care cost savings or morbidity or mortality reductions in the context of an overall Medicare prescription drug benefit. First, the findings from available cost-effectiveness analyses in the literature suggest that while some prescription drugs may lead to short-term or long-term reductions in net health care costs, other prescription drugs may lead to net increases in health costs. Second, the Medicare prescription drug benefit will improve access to prescription drugs for a broader patient population than is typically included in the available studies in the literature, which may affect the potential cost-effectiveness of certain drugs. For example, while the literature suggests that the use of statin drugs for lowering blood cholesterol levels in patients with existing heart disease is relatively cost-effective, using these drugs to preventively lower blood cholesterol levels in patients that do not have heart disease may be less cost-effective (see "Are Pharmaceuticals Cost-Effective? A Review Of The Evidence," Peter J. Neumann, Eileen A. Sandberg, Chaim M. Bell, Patricia W. Stone, and Richard H. Chapman, *Health Affairs* 19:2, November/December 2000; and "The Price of Progress: Prescription Drugs in the Health Care Market," J. D. Kleinke, *Health Affairs* 20:5, September/October 2001 available at *http://www.healthaffairs.org)*.

In addition to the anticipated reductions in adverse health events associated with anticipated improvements in prescription drug compliance, we believe that many elements of the Medicare prescription drug benefit—including quality assurance, electronic prescribing, better beneficiary information on drug costs and ways to reduce drug costs (for example, through generic substitution), and medication therapy management which are designed to improve medication use and reduce the risk of adverse events, including adverse drug interactions—will also improve beneficiaries' health outcomes. We believe that these improvements will occur through enhanced beneficiary education, health literacy and compliance programs; improved prescription drug-related quality and disease management efforts; and ongoing improvements in the information systems that are used to detect various kinds of prescribing errors—including duplicate prescriptions; drug-drug, drug-allergy and drug-food interactions; incorrect dosage calculations, and problems relating to coordination between pharmacies and health providers. We also believe that additional reductions in errors and additional improvements in prescription choices based on the latest available evidence will occur over time as the electronic prescribing provisions of the MMA are implemented (*To Err is Human: Building A Safer Health System*, Institute of Medicine of the National Academies, 1999, pp. 191–193, *http://www.iom.edu* or *http://www.nap.edu*).

Ultimately, we believe that the evidence supports our conclusion that making prescription drugs more available and affordable will help beneficiaries to live healthier, more productive lives. We also believe that expanding prescription drug coverage will reduce adverse health events and Medicare program spending on more costly services for some beneficiaries, and will be particularly important for beneficiaries with limited means who are more likely to forego beneficial prescription drugs when they do not have coverage. However, the effect on aggregate Medicare program spending across all beneficiaries is difficult to ascertain. At this time, there have not been studies that have found evidence that expansions of drug coverage across a large population, as will occur under the Medicare drug benefit, yields aggregate health care cost savings. Furthermore, there have been mixed results on the impact of coverage on the cost-effectiveness of care involving certain individual drugs in general, and in differing patient populations. Thus, the extent to which the Medicare drug benefit may lead to reductions in Medicare spending for other health care services in the aggregate across all beneficiaries is difficult to predict. Additional research will be needed to further examine and quantify these potential effects. For example, we are currently conducting a demonstration study on the extent to which coverage of oral medicines reduces the use of professionally-delivered medicines and the associated physician and health care services that are currently covered in Part B. We are very interested in developing further evidence on the best ways to encourage outcome improvements and overall health care cost reductions through drug coverage, and would welcome comments in this area and how this can be incorporated into the implementation of the drug benefit. For example, CMS is currently collaborating with AHRQ and other experts to identify priorities for developing better evidence and increasing value in the use of outpatient medications, and intends to develop further evidence as part of the implementation of the drug benefit.

2. Recap of the Structure of the Medicare Part D Drug Benefit

As discussed in more detail elsewhere in the preamble, standard prescription drug coverage under Medicare Part D for 2006 consists of a $250 deductible, 25 percent cost-sharing (or an actuarially equivalent cost-sharing structure) up to an initial coverage limit of $2,250, 100 percent cost-sharing after the initial coverage limit until an out-of-pocket threshold of $3,600 is reached, and nominal cost-sharing for expenditures beyond the out-of-pocket threshold (that is, the greater of 5 percent coinsurance or a copayment of $2 for a generic or preferred multiple source drug and $5 for any other drug in 2006, or an actuarial equivalent cost-sharing structure). For each year after 2006, the deductible, initial coverage limit, out-of-pocket threshold, and nominal copayment amounts are indexed to per capita growth in prescription drug expenditures for Part D enrollees, as

described in more detail in the preamble.

While we model all of our impact estimates on the defined standard benefit structure, we note that PDP and MA–PD plans have the option of offering actuarially equivalent standard or alternative coverage. In addition, plans may offer enhanced alternative coverage where for an additional premium they offer supplemental drug coverage such as coverage for benefits above the initial coverage limit (that is, coverage of the so-called "doughnut hole"), and we anticipate that some plans will offer this coverage.

Beneficiaries who meet certain income and assets requirements qualify for low-income subsidy assistance with cost-sharing and premiums. While the out-of-pocket threshold level is the same for all enrollees, the beneficiary cost-sharing liability covered by the low-income subsidy counts towards the Part D out-of-pocket threshold. Therefore, subsidy-eligible individuals will pay substantially less than all other enrollees before the catastrophic coverage begins. Institutionalized full-benefit dual eligibles pay no cost-sharing. Other full-benefit dual eligibles with income not in excess of 100 percent of the Federal Poverty Level (FPL) face no deductible, have nominal cost sharing of $1 for generic drugs or preferred multiple source drugs and $3 for any other drug up to the out-of-pocket threshold, and receive full coverage for drug costs beyond the out-of-pocket threshold. Other full-benefit dual eligibles with income above 100 percent of FPL and beneficiaries who are not full benefit dual eligibles, but who have income less than 135 percent of FPL and assets up to $6,000 per individual (or $9,000 per couple) in 2006, face no deductible, have nominal cost sharing of $2 and $5 for the respective drugs up to the out-of-pocket threshold, and receive full coverage for costs beyond the out-of-pocket threshold. For other beneficiaries with income less than 150 percent of FPL and assets up to $10,000 per individual (or $20,000 per couple) in 2006, there is a reduced deductible of $50, cost-sharing of 15 percent for costs up to the out-of-pocket threshold, and nominal cost sharing of $2 and $5 for the respective drugs for costs beyond the out-of-pocket threshold. For years after 2006, all aspects of the benefit structure related to the low-income subsidy are indexed to growth in per capita drug spending, except for the nominal copayment amounts for full-benefit dual eligibles with income not in excess of 100 percent of FPL and the low-incomes assets tests, which are indexed to the Consumer Price Index.

The low-income subsidy also offers beneficiaries substantial help with premiums. Many beneficiaries who receive the low-income subsidy will pay no premium for Medicare drug coverage. Full-benefit dual eligibles and beneficiaries who have incomes up to 135 percent of FPL and who meet the assets test receive a full Federal subsidy of the beneficiary premium—that is, beneficiaries pay no premium as long as they select a PDP or MA–PD that has a premium that does not exceed the greater of the low-income benchmark premium or the lowest PDP premium for basic coverage for the region and as long as they sign up for Medicare Part D within the initial enrollment period or have met creditable coverage requirements. Other beneficiaries receiving a low-income subsidy—those with income between 135 percent and 150 percent of FPL and meeting asset requirements—would face a sliding scale premium based on income.

Medicare Part D also has implications for beneficiaries enrolled in the Program of All Inclusive Care for the Elderly (PACE). PACE programs already provide a comprehensive drug benefit to dual eligible enrollees and to enrollees who only have Medicare coverage. For the dual eligible enrollees, PACE programs will now be receiving funding for prescription drugs through Medicare Part D instead of through the State Medicaid program. PACE enrollees who only have Medicare coverage are today paying the full cost of their drug coverage. As a result of the Federal subsidization of Part D coverage, they will receive substantial premium relief. This lowering of premiums for beneficiaries who only have Medicare coverage may lead to an increase in enrollment in PACE organizations.

3. Estimated Total Drug Spending, Spending Paid by the Medicare Drug Benefit, and Premiums

a. Summary

Table V–1 presents estimates for Medicare Part D enrollees of average total drug spending, average drug spending paid for by the Medicare drug benefit, and the average premium associated with Medicare Part D drug coverage. Since beneficiaries who are eligible for the low-income subsidy receive additional assistance with cost-sharing and premiums, we present estimates separately for beneficiaries who do and do not receive the low-income subsidy.

For Medicare Part D enrollees who do not receive the low-income subsidy, we estimate that average per capita drug spending in CY 2006 would be $2,936. This projection of drug spending includes cost-management savings discussed in the next subsection, such as price concessions and generic substitution, or utilization effects resulting from the Medicare drug benefit. The Medicare drug benefit would be expected to pay for on average about $1,437 of prescription drug costs, or on average nearly half of total beneficiary drug spending in CY 2006.[3] Beneficiary premiums for defined standard coverage will vary across PDPs and MA–PDs. We estimate that the beneficiary premium to obtain defined standard coverage would be on average about $428 per year in CY 2006. Thus, we estimate that the average monthly premiums would be in the range of about $35. A beneficiary may pay more or less depending upon which PDP or MA–PD the beneficiary selects. For these non-low-income beneficiaries, the government is estimated to contribute $1,231 of the $1,659 total cost of the standard Medicare Part D benefit (including PDP and MA–PD administrative costs). In CY 2010, drug spending for Part D enrollees who do not receive the low-income subsidy is projected to be $3,852 on average, with the Medicare drug benefit paying for on average $1,890 of prescription drug costs. The average premium in CY 2010 for these beneficiaries is projected to be $564 per year or roughly $47 per month for defined standard coverage.

For enrollees who receive the low-income subsidy, we estimate that average per capita drug spending in 2006 would be $3,649.[4] We estimate that on average the Medicare drug benefit would be expected to pay for about $3,476 of prescription drug costs, or approximately 95 percent of total drug spending. In 2010, these beneficiaries would be expected to spend on average $4,794 per capita on prescription drugs, with the Medicare

[3] We note that $1,437 reflects the average payout of the Medicare drug benefit for non-low-income beneficiaries in 2006. This is different from what the payout would be for a beneficiary with total drug spending equal to average total drug spending for all enrollees. For example, standard coverage under Medicare Part D would payout $1500 for a beneficiary with total spending of $2936. The difference between the average payout versus the payout for a beneficiary with average total drug spending is due to the interaction between the distribution of drug spending and the deductible and cost-sharing structure of the Medicare drug benefit.

[4] Average drug spending for enrollees eligible for the low-income subsidy is higher than for enrollees not eligible for the subsidy because a substantial portion of those eligible for the low-income subsidy are full-benefit dual eligibles, who on average tend to be sicker.

drug benefit paying for on average about $4,518 of those drug costs. As discussed in the preamble, the low-income cost-sharing amounts vary depending upon a beneficiary's income and assets. Consequently, the share of drug spending paid for by the Medicare drug benefit would vary by subsidy eligibility category, ranging from an average of about 85 percent for the highest-resource subsidy eligibility category (that is, those beneficiaries who qualify for the subsidy under the criteria that they have income less than 150 percent of FPL and assets up to $10,000 per individual (or $20,000 per couple) in CY 2006) to more than 95 percent for the most generous subsidy category (that is, full-benefit dual eligibles with income not in excess of 100 percent of FPL). As discussed in the following methodology section, these estimates do not take into account the waiver of cost sharing for institutionalized full-benefit dual eligibles, which further enhances the drug subsidy for this category of beneficiaries.

As noted previously, many beneficiaries who receive the low-income subsidy receive a full Federal subsidy of the beneficiary premium (that is, the beneficiary pays no premium at all), as long as they enroll in a PDP or MA–PD with a premium that does not exceed the greater of the low-income benchmark premium or the lowest PDP premium for basic coverage for the region and as long as they enroll during the initial enrollment period or have met creditable coverage requirements. For low-income enrollees with income between 135 percent and 150 percent of FPL who face a sliding scale premium based on income, we estimate that the premium will average $214 per year or roughly $18 per month in 2006, and $282 per year or roughly $24 per month in 2010.[5] The government contribution to the cost of Medicare Part D prescription drug coverage for low-income subsidy enrollees is estimated to average almost $3,500 in CY 2006.

b. Methodology and Assumptions Underlying Estimates

To estimate beneficiary drug spending for the period CY 2006–2010, we use drug spending data from the Medicare Current Beneficiary Survey (MCBS) adjusted for underreporting and trended forward based on projected growth in per capita drug spending based on the National Health Expenditures projections.

In projecting drug spending for enrollees in Medicare Part D, we assume that PDPs and MA–PDs will achieve a certain level of savings due to cost management activities such as negotiation of manufacturer rebates and discounts and other price concessions, and promotion of generic substitution. We assume discounts and cost-management savings of 15 percent in 2006, 17 percent in 2007, 19 percent in 2008, 21 percent in 2009, and 23 percent in 2010. To take into account that some enrollees in the Medicare Part D drug benefit are likely to have had previous drug coverage from other sources and received some level of discounts and cost-management savings through that coverage, we adjusted the MCBS spending data upward to reflect the full retail price by backing out any assumed discounts and cost management savings and then applied the Part D savings factor. We note that some beneficiaries without drug coverage are currently receiving discounts through the Medicare-approved drug card program. Conceptually, those discounts should also be backed out of drug spending before applying the Part D savings factor; however, because the drug spending data on which our projections are based predate the Medicare-approved drug card program, such an adjustment was not necessary.

Our assumptions related to the cost management savings take into account several factors. Insured products generally obtain lower drug prices than those available to cash paying customers. For example, an April 2000 study prepared by HHS entitled, "A Report to the President: Prescription Drug Coverage, Spending, Utilization and Prices," indicated a significant price differential between individuals paying cash for prescriptions at a retail pharmacy versus individuals with insurance. This difference held true for both the Medicare and non-Medicare populations. According to the study, in 1999 the price paid by cash customers was nearly 15 percent more than the total price paid under prescription drug insurance, including the enrollee cost sharing. For 25 percent of the most commonly prescribed drugs, this price difference was higher—over 20 percent. Such price concessions are envisioned to be an important part of the Medicare drug benefit, as the statute specifically requires PDPs and MA–PDs to provide beneficiaries with access to negotiated prices, which would reflect manufacturer rebates and discounts and other price concessions. Besides these types of price concessions, we also anticipate that PDPs and MA–PDs will achieve savings as a result of other cost management activities such as promotion of generic substitution, which Medicare will help support as well through providing information on opportunities for cost savings to beneficiaries and their health providers. As discussed elsewhere in the preamble, the statute requires PDPs and MA–PDs to put in place a cost-effective drug utilization management program that would include incentives to reduce costs when medically appropriate. We believe that these various efforts are likely to increase use of generics relative to brand-name drugs among Medicare Part D enrollees.

Furthermore, in developing our cost management savings assumptions, we also considered the nature of the drug price negotiations occurring under the Medicare prescription drug benefit. We expect that the private price negotiations between PDP sponsors and drug manufacturers would achieve comparable or better savings than direct price negotiation between the government and manufacturers, as well as coverage options that better reflect beneficiary preferences. This expectation reflects the strong incentives to obtain low prices and pass on the savings to beneficiaries resulting from competition, relevant price and quality information, Medicare oversight, and beneficiary assistance in choosing a drug plan that meets their needs. This is similar to the conclusion of other analyses, for example, CBO's recent statement that "Most single-source drugs face competition from other drugs that are therapeutic alternatives. CBO believes that there is little, if any, potential savings from negotiations involving those single-source drugs. We expect that risk-bearing private plans will have strong incentives to negotiate price discounts for such drugs and that the Secretary would not be able to negotiate prices that further reduce federal spending to a significant degree." It also reflects Medicare's recent experience with drug price regulation for currently-covered drugs, in which regulated prices for many drugs have significantly exceeded market averages.

In addition, our drug spending projections assume that changes in beneficiary out-of-pocket costs resulting from the Medicare drug benefit would affect beneficiaries' utilization of drugs. For example, as discussed previously, beneficiaries without drug coverage fill fewer prescriptions and spend less in total on prescription drugs than beneficiaries with drug coverage. Under

[5] We note that to estimate the average sliding scale premium we assume a uniform distribution of income between 135 percent and 150 percent of FPL. If the income distribution is not uniform, the average sliding scale premium could differ somewhat from our estimates.

the Medicare drug benefit, we would expect that drug utilization and spending would increase for beneficiaries without prior drug coverage. Our estimates assume that aggregate beneficiary drug spending (that is, total drug spending for all beneficiaries including those with and without drug coverage prior to 2006) would be 10.6 percent greater in CY 2006 than it otherwise would be, due to reduced out-of-pocket costs resulting from the Medicare drug benefit.

Using our estimates of projected drug spending for enrollees in Medicare Part D, we estimate the amount of drug spending that would be paid for by the Medicare drug benefit, separately for enrollees who would and would not receive the low-income subsidy. For enrollees who receive the low-income subsidy, these estimates take into account the differential cost-sharing by income and assets within the low-income group. However, due to data limitations, our estimates do not take into account the fact that beneficiary cost-sharing is waived entirely for institutionalized full-benefit dual eligibles.

For the purposes of this impact analysis, those beneficiaries who are assumed to enroll in Medicare Part D are assumed to do so within their initial enrollment period and face no late enrollment penalty. We also assume that all low-income beneficiaries with income under 135 percent of FPL select PDP and MA–PD plans with a premium that does not exceed the greater of the low-income benchmark premium or the lowest PDP premium for basic coverage for the region, and thus face no beneficiary premium.

TABLE V–1.—ESTIMATED AVERAGE ENROLLEE TOTAL DRUG SPENDING, DRUG SPENDING PAID FOR BY MEDICARE DRUG BENEFIT, AND DRUG BENEFIT PREMIUM, CY 2006 AND CY 2010

	Estimated average annual drug spending	Estimated average annual drug spending paid for by the medicare drug benefit*	Estimated average annual premium
2006:			
Enrollees Not Receiving Low-Income Subsidy	$2,936	$1,437	$428.
Enrollees Receiving Low-Income Subsidy	3,649	3,476	0 or $214**.
2010:			
Enrollees Not Receiving Low-Income Subsidy	3,852	1,890	$564.
Enrollees Receiving Low-Income Subsidy	4,794	4,518	0 or $282**.

* Average annual drug spending paid for by the Medicare drug benefit reflects on average how much the Medicare drug benefit will payout per beneficiary. This is different from the amount of drug costs the Medicare drug benefit would payout for a beneficiary with average total drug spending, due to the interaction between the distribution of drug spending and the deductible and cost-sharing structure of the Medicare drug benefit. We also note that the average drug spending paid for by the Medicare Part D plan reflects drug costs reimbursed by the plan and does not include PDP or MA–PD administrative costs.

** Low-income subsidy enrollees with income between 135 percent and 150 percent of FPL face a sliding scale premium based on income, which is estimated to average $214 per year in 2006 ($282 in 2010). Other enrollees in the low-income subsidy pay no beneficiary premium at all, as long as they select a PDP or MA–PD with a premium that does not exceed the greater of the low-income benchmark premium or the lowest PDP premium for basic coverage for the region and as long as they enroll within the initial enrollment period or have met creditable coverage requirements.

4. Positive Effects of the Medicare Retiree Drug Subsidy and Other Employer Options for Providing Prescription Drug Assistance

The Medicare prescription drug benefit and retiree drug subsidy represent additional funding sources that can help employers and unions continue to provide high quality drug coverage for their retirees. We anticipate that these new sources of support will have many important positive benefits for the quality and security of drug coverage for retirees. In this section, we describe the Medicare retiree drug subsidy and several other ways that Medicare Part D offers financial assistance with retiree prescription drug costs to employers and unions.

a. Overview of the Medicare Retiree Drug Subsidy

The positive benefits for retiree coverage from the new retiree drug subsidy are the result of the subsidy itself, the special tax-favored status of the subsidy payments to the qualified retiree health plans, and the flexibility in using the subsidy to support retiree coverage. The retiree drug subsidy program has highly flexible rules and stands as an additional option that permits employers and unions to continue providing drug coverage to their Medicare-eligible retirees while retaining their current plan designs that are at least equivalent to the standard Part D benefit, and receiving a Federal subsidy that reduces the cost of providing this coverage. Employers retain the option of delivering regular supplementation to Medicare Part A and Part B benefits through arrangements with Medicare Advantage organizations offering a MA only plan without the Part D benefit, but then still participate in the retiree drug subsidy program and through a separate private contract with the MA organization arrange for an employer-sponsored retiree drug benefit.

The intent of the Medicare retiree drug subsidy is to offer qualified retiree prescription drug plans financial assistance with a portion of their prescription drug costs and thereby "help employers [to] retain and enhance their prescription drug coverage so that the current erosion in coverage would plateau or even improve" (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report, p. 53). By making a tax-free subsidy for 28 percent of allowable prescription drug costs (that is, drug spending between $250 and $5,000 for 2006) available to qualified retiree prescription drug plans, the Medicare retiree drug subsidy significantly reduces financial liabilities associated with employers' retiree drug coverage and encourages employers to continue assisting their retirees with prescription drug coverage.

To provide a rough estimate of the per capita retiree drug subsidy, we used MCBS data on prescription drug spending for retirees with employer-sponsored coverage, adjusted for under-reporting, and trended these data forward based on the projected growth rate in prescription drug spending from the National Health Expenditures projections. We then applied 28 percent

to annual allowable costs between the cost threshold and cost limit ($250 and $5,000, respectively, in 2006). This calculation yielded an estimated per capita retiree drug subsidy amount of $611 in 2006. The per capita subsidy amount was calculated across all beneficiaries in qualified retiree prescription drug plans, including both those who do and do not have spending high enough to qualify for a Medicare retiree drug subsidy payment. We are aware that there are other sources of information on the value of current and projected retiree coverage, and we seek comment on the completeness and accuracy of our MCBS-based projections for valuing the retiree subsidy.

The Medicare retiree drug subsidy is excluded from the taxable income of the employer (just as the Medicare subsidy provided to beneficiaries through the Medicare prescription drug benefit is excluded from the taxable income of the beneficiary). The tax-free nature of the Medicare retiree drug subsidy generally increases its value to employers. As indicators of the value of this tax subsidy, we provide some estimates of the equivalent values of a taxable subsidy for employers at several corporate income tax rates. For corporations with taxable incomes, marginal tax rates generally range from 15 percent to 35 percent. According to estimates by the Congressional Research Service, the weighted average effective tax rate for corporations that pay taxes is approximately 28.5 percent. Combining this tax rate and the estimated $611 average per capita subsidy amount for 2006, we estimate that the $611 tax-free retiree drug subsidy amount would be equivalent to a taxable subsidy of $855 for employers subject to taxation. The equivalent taxable subsidy for any particular employer with taxable income would, of course, vary depending on its specific marginal tax rate. For example, the tax-free $611 average retiree drug subsidy amount would be equivalent to about $815 of taxable income for employers with a marginal tax rate of 25 percent and about $940 of taxable income for employers with a marginal tax rate of 35 percent. We request comments on the effect of the tax-favored treatment of the subsidy payments for employers and retirees, including further evidence on the distribution of marginal tax rates among employers offering or likely to offer retiree coverage.

Another important factor in whether employers or unions will use the retiree subsidy is whether their contribution to the retiree coverage is sufficient to qualify for coverage, and if it is not currently sufficient, whether they will increase the generosity of their contribution in order to receive the cash and tax value of the subsidy. As we note below, we intend to implement the retiree drug subsidy in a manner that avoids "windfalls" to employers that are not making contributions to retiree coverage that reflect the value of the retiree subsidy. Because some employers appear to contribute less than the value of the retiree subsidy to the coverage they provide now, we seek comment on the current levels and trends of such limited employer contributions, and on how the new Medicare payments may affect decisions by firms to increase the generosity of their retiree health contributions. Such increased contributions are likely to be in the financial interest of some employers, because they could qualify for the value of the full subsidy by making an additional incremental contribution of less than the full value of the subsidy, thereby achieving net savings.

b. Additional Options Available to Employers Through Medicare Part D

As indicated earlier, in addition to the ability to obtain Medicare retiree drug subsidy payments for sufficiently generous drug coverage, Medicare Part D also gives employers a variety of other options for continuing to assist their Medicare-eligible retirees in obtaining more generous drug coverage. For example, employers that are supporting retiree coverage now could also choose to provide enhanced drug coverage by using the new Medicare Part D subsidy directly (that is, encouraging their retirees to enroll in an enhanced Medicare Part D plan which includes a 75 percent government subsidy for the standard benefit) and employers providing enhanced coverage over and above the standard Part D benefit that maintains or exceeds the generosity of their current benefit designs. This can be achieved by either arranging for a PDP or MA–PD Part D plan to provide enhanced benefits to their retirees, choosing to become a Part D plan that offers enhanced benefits to their retirees, or providing separate supplemental drug coverage that wraps around a Part D plan (similar to the typical employer and union policies that wrap around Medicare benefits under Part A and Part B).

Based on published employer surveys, reports from employers and benefit consultants, and other sources of evidence including the fact that some employers are not making contributions to coverage sufficient to qualify for the retiree drug subsidy, we expect that some employers will choose to provide prescription drug assistance to their Medicare-eligible retirees in the form of enhanced benefit packages through Part D plans or separate wraparound coverage. In both cases, the employer contributions would augment the Medicare's subsidized coverage under Part D. Employers currently do this relative to Medicare Part A and Part B coverage, either through separate supplemental policies or through arrangements with Medicare Advantage plans. In fact, the Medicare retiree drug subsidy represents a new type of arrangement for employers relative to the interaction of their retiree coverage with Medicare. Thus, some employers may prefer to interface with the new Medicare prescription drug benefit in a manner similar to their supplementation of the basic Medicare Part A and Part B benefits. In addition, we anticipate that providing enhanced Part D benefits or separate wraparound coverage may be an attractive option to those employers that may not be eligible for the Medicare retiree drug subsidy because their retiree drug benefits, as currently structured, are not actuarially equivalent to the standard Medicare Part D drug benefit. We also expect that many of the employers and unions that choose to provide drug coverage through or in coordination with Part D will also choose to pay some or all of their retirees' Part D premiums. Since the Medicare Part D drug benefit includes a direct Federal subsidy, these approaches would allow employers to continue to provide a benefit package of similar or greater generosity compared to their existing arrangements while potentially lowering their prescription drug costs.

Although the Medicare prescription drug benefit and retiree drug subsidy represent additional funding sources for employer-sponsored retiree drug coverage that can help employers to retain drug coverage for their retirees, there are also a number of economic forces unrelated to Medicare that play a role in employers' decision making regarding both the availability and the generosity of employer-sponsored retiree health coverage. Many of the economic forces behind the ongoing erosion of retiree health benefits that are discussed subsequently in this impact analysis may continue to give employers a financial incentive to reduce the costs associated with providing retiree health coverage. The Employee Benefit Research Institute (EBRI) has estimated that additional declines in retiree drug coverage could potentially continue to occur, particularly for future retirees, "due to existing business, accounting,

and cost trends," regardless of changes in the Medicare program ("EBRI Special Analysis: How Many Medicare Beneficiaries Will Lose Employment-Based Retiree Health Benefits if Medicare Covers Outpatient Prescription Drugs?" Dallas L. Salisbury and Paul Fronstin, Employee Benefit Research Institute, July 18, 2003, available at *http://www.ebri.org*).

c. Anticipated Effects of the Medicare Retiree Drug Subsidy Program and Part D Assistance for Retirees

While there is considerable uncertainty about the choices that employers will make regarding the form of prescription drug assistance that they may choose to provide for their Medicare-eligible retirees, we believe that employers will generally continue to provide prescription drug assistance to their retirees and that Medicare Part D will make it more affordable for them to do so.

First, with the decline over the years in the number of employers offering retiree health insurance coverage, the remaining employers who continue to offer such coverage directly are likely those employers who have a contractual commitment or other interest in maintaining that coverage.

Second, although employers' responses to Medicare Part D and the retiree drug subsidy are expected to play out over the next few years, initial signals suggest that there has been a positive response to the Medicare retiree drug subsidy. Several major employer associations, including the Employers' Coalition on Medicare, American Benefits Council, and the U.S. Chamber of Commerce, have praised the MMA for giving businesses flexibility in deciding how their retiree health plans will interact with the Medicare prescription drug benefit, and for offering employers a 28 percent Medicare retiree drug subsidy payment that would not be taxed for employers who continue to provide high-quality retiree coverage ("ECOM Applauds Historic Passage of Medicare Reform Legislation," Employers' Coalition on Medicare press release, November 25, 2003, *http://www.employersandmedicare.org;* "Senate Passes Medicare, Prescription Drug Reform Bill," press release, American Benefits Council, November 25, 2003, *http://www.americanbenefitscouncil.org,* "Chamber Praises Congressional Action on Medicare Reforms," U.S. Chamber of Commerce, November 25, 2003, *http://www.uschamber.com*).

Additionally, several major corporations have recently issued 2003 annual reports that include estimates of the reduction in their accumulated benefits obligation that will occur over time due to the Medicare subsidy payments they anticipate receiving under the Medicare retiree drug subsidy program. Eighteen companies have estimated that they would collectively save $11.8 billion in long-term postretirement benefit costs, which are expected to be amortized over the full working life of the employees that are eligible for these benefits ("Expected Cost Savings From Medicare Act May Top $11.8 Billion", Lingling Wei, Dow Jones Newswires, The Wall Street Journal, March 22, 2004, available at *http://www.wsj.com*). However, we are aware that some of these companies may need to revise their initial estimates to reflect: (1) The Financial Accounting Standards Board's (FASB) recently-issued Final Staff Position on accounting for the effects of the Medicare retiree drug subsidy payments, which is effective for financial statements for periods beginning after June 15, 2004 ("FASB Staff Position Number FAS 106–2, Accounting and Disclosure Requirements Related to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003," posted May 19, 2004, available at *http://www.fasb.org/fasb_staff_positions/fsp_fas106-2.pdf*), and (2) the regulations for the retiree drug subsidy.

Although most publicly traded companies have chosen to defer recognizing the effects of the Medicare retiree drug subsidy payments pending receipt of additional accounting and regulatory guidance, these sources suggest that numerous large companies that offer employment-based retiree prescription drug coverage anticipate continuing to provide this coverage and accepting the Medicare retiree drug subsidy payments. However, some employers have not yet decided whether they will apply for the Medicare retiree drug subsidy, and are considering the various other options that are available for providing prescription drug assistance to their Medicare-eligible retirees (See Press Releases and Statements, Press Room of the Employers' Coalition on Medicare, available at *http://www.employersandmedicare.org*).

Overall, we believe that the implementation of Medicare Part D, including the Medicare retiree drug subsidy and the other opportunities it affords employers for providing continued prescription drug assistance to their Medicare retirees, will result in combined aggregate payments by employers and Medicare for drug coverage on behalf of retirees generally being greater—and frequently significantly greater—than they otherwise would have been without the enactment of the MMA. Furthermore, we believe that the Medicare prescription drug benefit and retiree drug subsidy represent a particularly important strengthening of health care coverage for future Medicare-eligible retirees, given the erosion in the availability and generosity of employer-sponsored retiree coverage for future Medicare beneficiaries that has already been taking place. In addition to comments on how employers are likely to view each choice of coverage, we also seek comment on how the several options available to employers to continue or increase the generosity of their retiree coverage can be designed together to maximize the increase in availability of high-quality drug benefits for retirees. This includes a request for comments on modeling not just the choice by employers and unions of retiree drug subsidy, wrapping around Part D coverage, qualifying as an enhanced Part D plan directly, or using an enhanced PDP or MA plan, but also the impact of these choices on premium reductions and additional drug benefits for retirees and thus the impact on reducing retirees' net payments for drugs and other health services.

d. Historical Trends in the Availability and Generosity of Retiree Drug Coverage

As additional background, we provide a discussion of trends in the availability and generosity of employer-sponsored retiree drug coverage, based on data from several different sources. We note that there are a limited number of data sources relating to retiree coverage, and some of these data sources may not be directly comparable to one another due to differences in the scope of analysis (for example, overall retiree health benefits versus specific information on retiree drug coverage), unit of analysis (for example, retirees versus firms, or firms versus establishments), as well as differences in the age groups, types of retirees (current versus future), and employer sizes that are being analyzed. For these reasons, caution should be exercised in making comparisons across the various data sources that are cited in this section.

As noted previously, employer-sponsored insurance has been an important source of drug coverage for many Medicare beneficiaries. However, for well over a decade, the availability and generosity of employer-sponsored retiree health coverage has been eroding, particularly for future retirees. The level of employer-sponsored retiree health coverage has been relatively

stable for the nation's current retirees during recent years. However, the apparent stability of benefits has been changing for future retirees.

For example, the trend in retiree health coverage for older Medicare beneficiaries (ages 70 and older) was essentially flat between 1996 and 2000 ("Employer-Sponsored Health Insurance and Prescription Drug Coverage for New Retirees: Dramatic Declines in Five Years," Bruce Stuart et al, Health Affairs, July 23, 2003, available at *http://www.healthaffairs.org*).

From 1988 to 1991, the percentage of firms with 200 or more workers offering health benefits to active workers that also offered retiree health benefits declined substantially from 66 percent to 46 percent (KPMG Survey of Employer-Sponsored Health Benefits: 1988, 1991, cited in Kaiser/HRET 2003 Annual Survey of Employer-Sponsored Health Benefits, available at *http://www.kff.org*) due to the implementation of Financial Accounting Statement No. 106 (FAS 106) as well as increasing costs. FAS 106, which was published in December 1990, required companies to make significant changes in the way that they accounted for future retiree health benefits on their balance sheets for fiscal years ending after December 15, 1992 ("Retiree Health Benefits: Trends and Outlook," Paul Fronstin, Employee Benefit Research Institute (EBRI) Issue Brief No. 236, August 2001; "Statement of Financial Accounting Standards No. 106: Employers' Accounting for Postretirement Benefits Other Than Pensions," Financial Accounting Standards Board, December 1990, available at *http://www.fasb.org/pdf/fas106.pdf*). The percentage of large employers offering retiree health coverage has continued to decline during the past decade (General Accounting Office (GAO), "Retiree Health Benefits: Employer-Sponsored Benefits May Be Vulnerable To Further Erosion," May 2001, available at *http://www.gao.gov*). However, the recent declines have been more gradual than what occurred during the early 1990s, with slightly less than 40 percent of the nation's large firms with 200 or more workers that offer health benefits to active workers also offering retiree health benefits in 2003 (Kaiser/HRET 2003 Annual Survey of Employer-Sponsored Health Benefits, available at *http://www.kff.org*).

Many of the changes in availability of retiree health coverage in the past decade have primarily affected future retirees, rather than current retirees. (Fronstin, August 2001). For example, the percentage of large employers with 500 or more employees offering retiree health benefits to new Medicare-age (that is, ages 65 and older) retirees decreased from 40 percent in 1993 to 21 percent in 2003 (data from the National Survey of Employer-Sponsored Health Plans, 2003 cited in a press release entitled "Surprise slow-down in U.S. health benefit cost increase," Mercer Human Resource Consulting, December 8, 2003, available at *http://www.mercerhr.com*). As a result, new retirees are less likely to have employer-sponsored retiree drug coverage than current retirees.

Availability of retiree health coverage varies depending on the type of employer. Employers with union workers are more likely to offer retiree coverage than employers without union workers. Similarly, public sector employers are more likely to offer coverage to retirees than private sector employers. (Kaiser/HRET 2003 Annual Survey of Employer-Sponsored Health Benefits, available at *http://www.kff.org;* "How States Are Responding to the Challenge of Financing Health Care for Retirees," Jack Hoadley, Henry J. Kaiser Family Foundation, September 2003, available at *http://www.kff.org.*)

Availability of retiree health coverage also varies according to the size of the employer. Larger employers are more likely to offer retiree health coverage than smaller employers. For example, in 2003, 38 percent of the nation's private sector firms with 200 or more workers that offered health benefits to active workers also offered retiree health coverage to pre-age 65 and/or Medicare-age retirees (Kaiser/HRET, 2003). However, very few smaller employers offer retiree health insurance. Recent surveys have found that only 3 to 10 percent of the nation's smaller private sector firms (3 to 199 workers) that offer health benefits to active workers also offer retiree health coverage (Kaiser/HRET 2001, 2002 and 2003 Annual Surveys of Employer-Sponsored Health Benefits, available at *http://www.kff.org*).

Larger employers account for the majority of the beneficiaries with employer-sponsored retiree coverage. In 2001, data from the Medical Expenditures Panel Survey indicate that less than 1 percent of the nation's smallest private establishments (those with a "firm size," or total number of employees for the entire firm, of less than 50 employees) offered health insurance to Medicare-age retirees, compared with 37 percent of the nation's largest private sector establishments (those with a firm size of 1,000 or more employees). As a result, within the private sector, the largest firms (1,000 or more employees) covered approximately 90 percent of the Medicare-age retirees who had employer-sponsored retiree coverage, while smaller firms (fewer than 1,000 employees) covered only 10 percent of these retirees.

In an effort to control costs, many employers have been changing their benefit packages (for example, reducing the benefit that is offered and/or increasing the amount that the retiree has to pay), resulting in gradual erosion in the generosity of this coverage over time. For example, since the mid-1990s, some employers have made changes in eligibility for retiree health coverage (for example, age and service requirements), reduced their subsidization of retiree health costs (by increasing retirees' share of premiums and increasing retirees' co-payments and deductibles), placed caps on the employer contribution to retiree health costs (aggregate or per beneficiary), or moved to offering a defined contribution health benefit (Fronstin, August 2001; GAO, May 2001). Because many employers have identified prescription drug costs as a major contributor to rising retiree health benefit costs, they have adopted cost control measures in an effort to manage their retiree prescription drug costs (Kaiser/HRET, 2003).

The intent of Medicare Part D and the retiree drug subsidy is to provide employers and unions with a set of highly flexible options that are designed to make it more affordable for them to continue providing high-quality prescription drug assistance to their Medicare-eligible retirees. As discussed earlier, the MMA Conference Report indicates that by lowering the cost of providing retiree drug benefits and providing financial incentives for employers to maintain this coverage for their Medicare-eligible retirees through Medicare Part D and the retiree drug subsidy, it is hoped that the erosion in the availability of employer-sponsored retiree drug coverage will plateau or even improve.

Overall, we expect that the implementation of Medicare Part D, including the Medicare retiree drug subsidy and the other opportunities it affords employers for providing continued prescription drug assistance to their Medicare retirees, will result in combined aggregate payments by employers and Medicare for drug coverage on behalf of retirees generally being greater—and frequently significantly greater—than they otherwise would have been without the enactment of the MMA. Furthermore, the Medicare prescription drug benefit and alternative retiree drug subsidy represent a particularly important

strengthening of health care coverage for future Medicare-eligible retirees, given the erosion in the availability and generosity of employer-sponsored retiree coverage for future Medicare beneficiaries that has been taking place.

G. Anticipated Effect on the Federal Budget

The following section presents estimates of the effect of Medicare Part D on net Federal budgetary spending. As indicated previously there is a great deal of uncertainty related to making these estimates, including the implications of outstanding policy and administrative issues that are the subject of this rule making. These represent our current best mid-range estimates of the net Federal budgetary effects. We have explored various potential approaches. We believe that these estimates provide a reasonable representation of the likely effects of a variety of proposed policies and potential options.

We expect that the Medicare drug benefit will affect several components of the Federal budget. Specifically, we anticipate that it will increase Federal spending on Medicare benefits and decrease Federal spending on Medicaid benefits (as dual eligibles' drug coverage is shifted from Medicaid to Medicare). The net effect of these changes on Federal spending is estimated to be about $48 billion in CY 2006 and $67 billion in CY 2010, with the total effect estimated to be about $287 billion over the period from 2006–2010. Table V–2 provides year-by-year estimates of the net Federal budgetary effects [6] of Medicare and Medicaid benefit spending. We discuss these effects subsequently, as well as the expected impacts of the Medicare drug benefit on Federal administrative costs for Medicare, Medicaid, and the Social Security Administration.

1. Federal Medicare Spending

We estimate that the net Federal budgetary effect of Medicare benefit spending related to Medicare Part D, including the Medicare retiree drug subsidy program, will be nearly $59 billion in CY 2006 and $353 billion over the five-year period from CY 2006–2010. The estimated $353 billion in additional net Federal spending over the five-year period is made up of approximately $401 billion in net Federal spending on direct government subsidies, government reinsurance payments, low-income subsidies, and retiree drug subsidies, with an offset of nearly $49 billion in additional Medicare revenues received from States to partially compensate for Medicare coverage of dual eligibles' drug costs (overall, we estimate States will save due to reduced Medicaid spending, as is explained subsequently).[7]

In addition, CMS expects to incur administrative expenses related to the Medicare drug benefit. Implementing a new program of the size and scope of the Medicare drug benefit requires substantial implementation expenses, including extensive computer and other systems changes. We are in the process of developing estimates of these administrative costs as the policies and operational framework for the program are developed through the rulemaking process and other efforts.

2. Federal Medicaid Spending

As a result of Medicare Part D, there is expected to be a reduction in net Federal spending on Medicaid benefits for the period CY 2006–2010, with the reduction estimated to be about $10 billion in CY 2006 and about $66 billion over the five-year period from CY 2006–2010.

With the Medicare program providing drug coverage to dual eligibles who had previously received drug coverage through Medicaid, State Medicaid spending on prescription drugs will be reduced, and as a result Federal spending on Medicaid matching payments will also be reduced. We estimate reduced Federal Medicaid spending on prescription drugs for full-benefit dual eligibles of about $12 billion in CY 2006 and about $76 billion during the five-year period from CY 2006–2010.

The reduction in Federal spending for Medicaid prescription drug benefits will be partially offset by an increase in Federal Medicaid spending for newly enrolled dual eligibles. As discussed in more detail in the State impacts section, the additional benefits available to low-income beneficiaries through Medicare Part D and our outreach activities are likely to raise awareness of other benefits available to such individuals through Medicaid, including Medicare Savings (QMB/SLMB) programs, and lead to higher enrollment in these programs. We assume that 1.1 million more Medicare beneficiaries will enroll in Medicaid, including Medicare Savings (QMB/SLMB) programs, in CY 2006 as a result of the Medicare drug benefit. As discussed later in the State impacts section, we estimate that a larger share of these beneficiaries will receive benefits as QMB/SLMB individuals than will receive full Medicaid benefits. Among beneficiaries that are eligible for, but not enrolled in Medicaid, we assume a smaller Medicaid uptake rate among those beneficiaries that are eligible for full Medicaid benefits, because we believe that if these beneficiaries were likely to sign up for the richer full Medicaid benefit package, most would have done so already. We assume a somewhat higher uptake rate for those beneficiaries that are eligible for QMB/SLMB benefits. We estimate Federal matching payments for State Medicaid expenditures for these beneficiaries will be about $1.7 billion in CY 2006, and total about $10 billion during the five-year period from CY 2006–2010.

In addition, the Medicare drug benefit has implications for Federal spending on Medicaid administrative costs. The statute gives responsibility to State Medicaid programs as well as the Social Security Administration for conducting eligibility determinations for low-income benefits under Part D. In addition, States are required to provide CMS with data for the purposes of calculating the amounts States are required to pay Medicare to compensate for a portion of full-benefit dual eligibles' drug costs. These activities will generate State administrative costs. Just prior to enactment of the MMA, the State share of costs for these determinations was estimated at roughly $100 million per year beginning in FY 2005. The Federal share of costs would be expected to be roughly the same in any year, and we have projected about $106 million in Federal matching payments for these State administrative activities in the FY 2005 budget. We plan to develop an updated estimate of State administrative costs for eligibility determination activities once the operational processes for the eligibility determinations are more fully developed, including accounting for any efficiency gains resulting from SSA participation.

3. SSA Administrative Costs

As noted previously, the Social Security Administration (SSA) is one of the entities given responsibility by the MMA for making eligibility determinations for low-income benefits under Part D as well as conducting outreach activities. In addition, SSA will be involved in premium collection via withholds from Social Security checks. SSA's administrative costs associated with these functions will be

[6] We note that the estimated net Federal budgetary effect of Medicare subsidy payments excludes changes to governmental receipts (that is, tax collections) because we do not have sufficient data to estimate these effects at this time.

[7] For the purposes of this impact analysis, we do not assume any additional Medicare costs or savings related to risk corridors. We also do not assume any savings on Part A and Part B benefits.

paid out of the Medicare trust funds. Estimates of these administrative costs will be developed as the policies and operational framework for the program are formulated through the rulemaking process and other efforts.

TABLE V–2.—ESTIMATED NET FEDERAL BUDGETARY EFFECTS OF MEDICARE AND MEDICAID BENEFIT SPENDING, CY 2006–2010

[billions of dollars]

	2006	2007	2008	2009	2010	2006–2010
Net Effect of Medicare Benefit Spending Related to Medicare Part D						
Federal Spending Related to Medicare Part D, including the Retiree Drug Subsidy	67.2	73.1	79.7	86.8	94.7	401.4
State Payments to Partially Offset Medicare Drug Costs for Dual Eligibles	−8.5	−9.1	−9.7	−10.4	−11.1	−48.7
Subtotal	58.7	64.0	70.0	76.4	83.6	352.6
Net Effect of Medicaid Benefit Spending						
Additional Federal Matching Payments for Newly Enrolled Dual Eligibles	1.7	1.9	2.1	2.2	2.4	10.4
Reduction in Federal Matching Payments for Medicaid Drug Expenditures for Dual Eligibles	−12.0	−13.5	−15.1	−16.9	−18.9	−76.3
Subtotal	−10.2	−11.6	−13.0	−14.6	−16.4	−65.9
Net Federal Budgetary Effects of Medicare and Medicaid Benefit Spending	48.4	52.4	56.9	61.8	67.1	286.7

Note: Positive numbers denote increased spending; negative numbers denote reduced spending (that is, savings). Numbers may not sum to totals due to rounding and exclude effects on Federal revenues.

H. States

1. Overall State Budgetary Impacts

We estimate that, as a result of Medicare Part D, States will realize net savings of $8.2 billion over the CY 2006–2010 period. Estimated State savings range from approximately $500 million in CY 2006, increasing each year during the five-year period, to reach about $3 billion by CY 2010. The estimated $8.2 billion in net State savings over the five-year period are made up of $65.3 billion in State savings related to Medicare Part D that are partially offset by $57.1 billion in State costs related to Medicare Part D.

We estimate that States will save approximately $65 billion as the Medicare Part D drug benefit and Medicare retiree drug subsidy provide financial support for prescription drug costs of full-benefit dual eligibles, State retirees, and participants in State prescription drug assistance programs. The vast majority of these State savings are the result of Medicare Part D replacing drug coverage for full benefit dual eligibles that would otherwise be paid for by Medicaid. States will also achieve savings due to Medicare retiree drug subsidies that will be available to State governments that provide qualified prescription drug coverage for their retirees. States that operate prescription drug assistance programs, as well as states with Pharmacy Plus programs, will also realize additional savings as Medicare Part D displaces a portion of their spending on prescription drug coverage for enrollees. Savings for State prescription drug programs are discussed in more detail in a separate section later in this analysis.

The estimated $65 billion in State savings, discussed previously, will be partially offset by approximately $57 billion in State costs related to Medicare Part D over the period CY 2006–2010. Those costs include State payments to the Federal government to partially offset Medicare Part D costs for full-benefit dual eligibles, additional Medicaid benefit spending resulting from an anticipated increase in Medicaid enrollment, and reduced State premium tax revenues as some beneficiaries shift from drug coverage that is subject to State taxation to Medicare Part D which is exempt from taxation.

The largest component of these costs are State payments to the Federal government to defray a portion of the Medicare drug expenditures for full-benefit dual eligibles, estimated at about $48.7 billion from CY 2006–2010. As discussed in the preamble, the States and the District of Columbia are required to make these monthly payments beginning January 1, 2006. It is important to note that the data sources and methodology used to estimate these State payments for the purposes of this impact analysis differ somewhat from those that will be used, as stipulated by statute and described in more detail in Subpart S of the preamble, to calculate the actual State payment amounts for 2006. The expenditure data that will be used to calculate the actual State payment amounts are not yet available, and thus for the purposes of this impact analysis we relied on MCBS as the data source to produce an estimate of aggregate State payments.

Another component of these costs is increased State Medicaid spending due to increased Medicaid enrollment. We anticipate that in the process of outreach and applying for the Part D low-income subsidy, some beneficiaries will learn of their eligibility for other low-income assistance such as Medicaid or Medicare Savings (QMB/SLMB) programs and choose to enroll in these programs. We estimate that about 1.1 million additional beneficiaries will enroll in Medicaid or the Medicare Savings programs in CY 2006; with 23 percent of those beneficiaries estimated to receive full Medicaid, 19 percent to receive QMB benefits, and 58 percent to receive SLMB benefits. We estimate that State Medicaid spending on benefits for these individuals will be about $7.8 billion over the five-year period from CY 2006–2010.

Also included in our estimate of State costs is the effect of the MMA's prohibition on States imposing taxes on premiums related to Part D coverage. As a result of this prohibition, we estimate that States will realize reduced premium tax revenues of approximately $535 million over the period CY 2006–2010.

In addition, the statute gives responsibility to State Medicaid

programs as well as the Social Security Administration for conducting eligibility determinations for low-income benefits under Part D. We have not included these costs in our above estimates of net State savings. However, prior to enactment of the MMA, we roughly estimated the State share of costs for these determinations at approximately $100 million a year, beginning in FY 2005. We plan to develop an updated estimate of these costs once the operational processes for the eligibility determinations are more fully developed. Given that our net savings estimate averages $1.5 billion per calendar year and exceed $500 million in every year, we do not believe that these administrative costs significantly affect the level of savings States will realize from implementation of Medicare Part D.

We also note that States are generally responsible for issuing licenses to health insurers. While some new PDP plans will require new licenses, the States charge fees for licensing and the States already have the mechanisms in place to handle these new license applications. Furthermore, licensing would not affect current insurers that want to become PDPs if these insurers are already licensed as insurers in a given State; the PDP would simply be a new line of business for these insurers. Thus, we do not estimate any cost implications for the States associated with licensing insurers.

2. State Prescription Drug Assistance Programs

As mentioned previously, one of the components of our estimate of net State savings resulting from Medicare Part D is savings on State Pharmaceutical Assistance Programs (SPAPs). We estimate that SPAPs spend roughly $1.45 billion of State only resources on prescription drug assistance for 1.2 million individuals, based largely on FY 2002 data. Five States account for approximately 87 percent of the SPAP spending, and have approximately 77 percent of the enrollment. For Medicare beneficiaries who have income less than 135 percent of the Federal Poverty Level (FPL) and assets valued up to $6,000 per individual (or $9,000 per couple), Part D offers comprehensive drug coverage with a full Federal subsidy for the beneficiary premium and only nominal cost-sharing. Thus, SPAP expenditures on this group of Medicare beneficiaries will be mostly displaced by the Medicare prescription drug benefit. We estimate that the savings that will accrue to States as a result of Medicare Part D displacing SPAP expenditures for low-income beneficiaries will be approximately $600 million per year, or about $3 billion over the five-year period from CY 2006–2010.

States with SPAPs have shown a commitment to assisting their low-income residents with drug costs. As of Spring 2004, nineteen States were operating SPAPs that provide subsidized drug coverage to individuals who will be eligible for Medicare Part D. CMS anticipates that many of these States will choose to continue providing financial assistance with drug expenditures, because they can achieve the same or greater level of assistance for their beneficiaries at a lower cost to the States. Part D provides States with a number of options for continuing their provision of prescription drug assistance to Medicare beneficiaries, if they choose to do so. States, for example, have the flexibility to restructure their SPAP programs to wrap around the Part D benefit and pay deductibles and cost sharing for beneficiaries with the State's assistance counting toward the Medicare Part D annual out-of-pocket threshold triggering protection against catastrophic drug costs. States can also provide assistance by paying for Part D premiums for beneficiaries. As part of their SPAPs, States also have the flexibility to make arrangements with PDPs and MA–PDs to provide enhanced Part D benefits.

We believe that we are presenting a conservative estimate of the displacement of SPAP expenditures, because our assessment does not include any potential State savings for SPAP enrollees at income levels above 135 percent of FPL. States that choose to restructure their programs to complement Medicare Part D can still achieve savings because of the substantial Medicare displacement of SPAP spending for low-income beneficiaries as well as for individuals who enroll in Part D and do not qualify for the low-income subsidy.

We also note that, as discussed elsewhere in the preamble, Section 1860D–23(d) of the Act provides for the payment of transitional grants to States with Pharmaceutical Assistance Programs of up to $62.5 million in each of fiscal years 2005 and 2006. In addition, the statute provides the authority (Section 1860D–23(a) of the Act) for the Secretary to establish requirements for effective coordination between Part D plans and SPAPs. For further discussion related to coordination of benefits see the section on coordination of benefits under Administrative Costs.

To estimate potential SPAP savings resulting from Medicare Part D expenditures, we focus our analysis on SPAP expenditures that may be spent on individuals with income below 135 percent of FPL. We are primarily relying on State-published data that describe SPAPS and their eligibility standards (sources such as State government websites, program annual reports, and Governor's budget documents). Our ongoing work with States also provides us with certain information regarding enrollment and expenditures under SPAPs. Unless we have adequately detailed State-published data on SPAP expenditures for enrollees by income, we use the Census Bureau's Current Population Survey (CPS) data to help us estimate SPAP spending on beneficiaries with income under 135 percent of FPL.

We recognize that our methodology has significant limitations and that our estimates are imprecise. For example, our analysis does not take into account the effect of the Medicare Part D assets test and does not include an estimate of potential savings for SPAP enrollees with income greater than 135 percent of FPL. We believe that States, with their own internal data and resources, are in the best position to project individual State-level impacts. Therefore, we invite States to provide specific enrollment and expenditure data by FPL for their State and any State-specific savings estimates they may have developed, as well as comments on improvements in our methodology.

3. Pharmacy Plus Waiver Programs

Four States under Medicaid section 1115 waivers operate Pharmacy Plus demonstration programs that provide assistance to Medicare beneficiaries with the cost of prescription drugs. Expenditures for these services receive Federal matching payments in the same manner as do services for full benefit Medicaid beneficiaries. Similar to the impact on State only funded SPAPs, we expect that the new Medicare drug benefit will be assuming a large share of the costs for prescription drugs previously financed through Pharmacy Plus waiver programs and consequently we believe States will achieve savings as a result. To be conservative, State savings estimates for these four Pharmacy Plus programs have not been included in our estimates of overall State savings, and would be in addition to net State savings presented in this analysis.

As noted elsewhere in the preamble the statute affords State only funded SPAP expenditures special treatment relative to the application of the TrOOP, in that the SPAP expenditures can be counted toward the out-of-pocket

protection threshold. However, as previously discussed, Pharmacy Plus waiver programs are not considered to be SPAPs. Due to the special treatment SPAPs receive relative to the TrOOP, our analysis of the States with Pharmacy Plus waivers indicates that States that operate Pharmacy Plus programs and beneficiaries enrolled in those programs could benefit financially by States restructuring their Pharmacy Plus programs to use a State only SPAP design to wrap around Medicare Part D. Under such an approach, we believe that generally States could realize savings relative to their current Pharmacy Plus spending levels and that program participants would face lower out-of-pocket costs due to the generous Medicare Part D catastrophic coverage. We welcome comments on this, and as indicated previously we would welcome further data and analyses from States.

I. Administrative Costs

There are four major areas of administrative costs associated with Medicare Part D that will be incurred by the private and public sector that merit separate discussion. These areas include the costs for PDPs and MA–PDs for administering the Medicare prescription drug benefit, the cost of creditable coverage disclosure notices that the MMA requires be provided to Medicare beneficiaries, the administrative costs associated with certain coordination of benefits as required by the MMA, and the administrative costs associated with obtaining the Medicare retiree drug subsidy. The following provides a detailed discussion of each of these areas.

1. Prescription Drug Plans and MA–PD Plans

The administrative cost estimates are based on taking into account the normal fixed costs associated with administering a prescription drug benefit, for example, such functions as claims processing, responding to customer inquiries, information dissemination, appeals processes, pharmacy network negotiations and contracting, and drug manufacturer negotiations and contracting. In addition, we assume "risk-premium" costs associated with risk-based insurance products that require companies to maintain certain levels of financial reserves. The other factor taken into account when developing our estimate is that PDPs and MA–PDs will likely incur slightly higher administrative costs during the initial few years of the Part D benefit due to start-up costs related to implementation and initial operations for a new benefit, for example more marketing and enrollment activities. We also assume that entities that will participate as PDPs will have already made the necessary changes to be HIPAA compliant because of the other business arrangements they will have been functioning in prior to choosing to participate as a PDP under the Medicare drug benefit program.

As is typically done with insurance products, we express the average administrative costs as a percentage relative to net standard benefit expenses. This percentage is commonly referred to as the "administrative load." We estimate that the average administrative load will be 12.7 percent in CY 2006, with this declining slightly over time, and reaching 11.5 percent in CY 2010. The administrative load is expected to decline slightly over the period for two reasons: (1) Administrative costs are expected to grow at a somewhat slower rate than PDP and MA–PD plans' prescription drug costs and (2) initial administrative start-up costs associated with implementation are expected to phase out in the first few years of operations.

Our estimates for administrative costs are similar to those seen in the general insurance market. Our administrative load of 12.7 percent in 2006 translates into administrative costs being about 11.2 of total Part D plan expenditures (including both benefits and administrative costs). This is similar to the share of total health plan spending accounted for by administrative costs in the private sector. For example, as CMS reported in its "Health Care Industry Market Update on Managed Care" Blue Cross Blue Shield health plans had average sales, general and administrative (SG&A) expenses ranging from 12 percent in 1999, 11.7 percent in 2000, 11.3 percent in 2001, and 10.9 percent in the first half of 2002. Similarly, in examining our Medicare Advantage plans data we see variation in administrative costs, for example newer plans (less than 5 years) seem to have higher administrative costs (11 percent) than older plans (7 percent).

The MMA also requires PDPs and MA–PDs to pay a user fee to help offset ongoing beneficiary education and enrollment costs relating to the Medicare prescription drug benefit, which represents an expansion of the user fees that are currently required of MA plans. As discussed earlier in this preamble, the MMA authorizes up to $200 million for beneficiary education and enrollment activities in FY 2006 and thereafter, reduced by the fees that will be collected from MA organizations and PDP sponsors in that fiscal year. Our rough estimates of the user fees for beneficiary education and enrollment costs in CY 2006 are approximately $22 million for PDPs and $50 million for MA organizations, with the remainder (approximately $128 million) being the government's share. While the user fees will actually be collected on a fiscal year basis, we believe that these estimates, which are based on calendar year data, provide a reasonable estimate of what the magnitude of these user fees will be during a given fiscal year. We assume that the cost of these user fees will be built into the administrative cost structure of the PDPs and MA–PDs, and will therefore be reflected in bids. We note that these user fees represent a minuscule percentage of the estimated total payments to MA organizations and PDP sponsors under the Medicare program.

2. Disclosure Notice Requirements

A number of entities that provide prescription drug coverage to Medicare beneficiaries—Medigap plans, private and public sector employer or union sponsored plans that provide drug coverage to Medicare beneficiaries who are retired or who are active workers, State Medicaid programs including State Pharmacy Plus programs, and State Pharmacy Assistance programs (SPAPs)—are required to provide at certain times disclosure notices to beneficiaries on whether the coverage provided equals or exceeds the actuarial value of standard coverage. The largest cost for providing these notices is expected to occur in the months preceding the implementation of the drug benefit in January 2006. Thereafter, notices will generally only need to be provided by these entities if there is a change in creditable coverage status. Also, firms that provide drug coverage to active workers will have to provide disclosure notices in the future to those active workers who become new Medicare beneficiaries.

With the exception of Medigap insurers and group health plans that provide drug coverage only to Medicare beneficiaries who are active workers (and not retirees), implementation of the Medicare prescription drug benefit and the retiree drug subsidy is expected to produce net savings to public and private sector entities that provide drug coverage to Medicare beneficiaries. For State Medicaid programs, SPAPs, State Pharmacy Plus programs, and private and public sector employer sponsored plans that provide retiree drug coverage, we estimate that the cost of disclosure notices will be about $29 million in 2005, with anticipated savings from the

implementation of Medicare Part D expected to far exceed the disclosure notice costs for each of these entities.

For Medigap insurers and group health plans that offer coverage only to beneficiaries who are active workers, not retirees, the cost of providing disclosure notices is estimated to be approximately $69 million in 2005 (which translates into an average of roughly $154 per employer that offers drug coverage to Medicare beneficiaries who are active workers and about $11,050 per Medigap insurer).

We anticipate that disclosure notice costs in years after 2005 will generally be minimal. However, employer sponsored health plans that provide drug coverage to active workers are likely to expend some time in future years for disclosure notices for the more limited number of new beneficiaries who age into the Medicare program. These employer plans would also incur costs in the event that their plan has a substantial change in its benefit structure that makes a reconfirmation of their creditable coverage status appropriate. We estimate administrative costs of roughly $5 million to $6 million per year for these employers during the period 2006–2010.

In brief, we take the following approach to estimate the cost of disclosure notices. For the various entities that are required to provide disclosure notices, the circumstances of these different types of coverage and how they will relate to the new Medicare prescription drug benefit differ. Consequently the nature of the disclosure notice and any associated actuarial valuation will vary. Beyond the cost of the actuarial valuation are the costs of preparing and mailing the notices. We generally base our cost estimates on 2005 wage data for an actuary and administrative personnel loaded for compensation, overhead, general administration, and fee.

In terms of the basic costs of preparing and mailing the disclosure notice, we assume that each entity required to provide these notices expends 8 hours for developing the notice (with one exception), 1 hour per 60 notices for producing and disseminating the notices to beneficiaries, and 1 hour for providing a copy of the notice to CMS. The one exception to this is group health plans that provide drug coverage only to Medicare beneficiaries who are active workers, not retirees. We assume these entities expend less time developing the notice (2 hours) because we expect that this service is likely to be provided to them by insurers or health plan administrators who we anticipate will spread the cost of this service across many employers.

In terms of the time involved in performing the actuarial valuation that forms the basis of the disclosure notices, we anticipate that it will vary somewhat by the type of entity providing the notice. In the case of Medicaid, we assume that the actuarial valuation costs will be negligible as Medicare Part D will be assuming primary responsibility for drug coverage for full benefit dual eligibles and we assume that any supplemental coverage States may provide (for example, coverage for drugs not covered under Medicare Part D) would not be creditable. With respect to SPAPs and State Pharmacy Plus programs, we expect that the actuarial assessment is not likely to be complex, and that the disclosure notice will likely focus on how the State program will work with the new Medicare drug benefit. We assume that each SPAP and State Pharmacy Plus program would expend on average 2 hours for actuarial work.

The notice requirement related to Medigap drug policies we believe will be relatively straightforward. In accordance with section 104 of the MMA, CMS is developing a model disclosure notice for Medigap insurers in consultation with the NAIC. For standardized Medigap plans, we anticipate that the actuarial work involved in developing these notices will be negligible. As discussed elsewhere in the preamble, we believe that standard Medigap plans H and I are not creditable and that it is very unlikely that plan J would be creditable. In the case of the pre-standardized policies the nature of the actuarial valuation and the level of effort involved will likely vary with the nature of the benefit package. For the purposes of this analysis, we assume that on average an actuarial valuation for an insurer offering pre-standardized Medigap policies would involve 6 hours of an actuary's time. For the three Medigap waiver states, we assume that the actuarial valuation would be fairly straightforward since these States have generally prescribed a fixed benefits structure for Medigap drug coverage. Consequently, we have assumed an average of 3 hours of an actuary's time per insurer serving the waiver States.

Employer sponsored retiree health plans that apply for the Medicare retiree subsidy will have to perform an actuarial valuation for the purposes of their application. We assume that those plans will simply use the actuarial valuation developed for the subsidy application also for the disclosure notices. Thus, we assume negligible costs for the actuarial valuation related to the disclosure notices. Estimates of the administrative costs related to applying for the Medicare retiree subsidy, including the actuarial valuation, are discussed elsewhere in this document.

Disclosure notices are also required of group health plans that provide drug coverage to active workers who are Medicare beneficiaries (that is, beneficiaries where Medicare is the secondary payer). It is very difficult to know how many firms that provide health insurance to their active workers have a Medicare beneficiary in their workforce. We have estimated roughly as an upper bound that there may be as many as 440,000 firms that provide drug coverage to at least one Medicare beneficiary who is an active worker. We emphasize that this is a very rough estimate that extrapolates from data from a number of sources (including an IRS, SSA, CMS data match, Census data, BLS data, and a Kaiser survey).

We anticipate that many of these employers are purchasing standard health insurance products from insurers that sell these plans to numerous purchasers and that the cost of the actuarial valuation will be spread across a relatively large number of employers or third party purchasers. While self-insured employers may have more distinct health plan benefit structures, we believe that it is likely that their health plan administrators would be able to achieve economies of scale by building actuarial models that can serve a number of clients. In addition, the cost of the valuation for those employers that also offer retiree drug coverage could be incorporated into the costs required to do an actuarial valuation for both types of coverage and thus there may be some economies of scale. For these reasons, we assume that each of these employers will on average incur expenses for one-quarter of an hour of actuarial time. This relatively low number reflects our assumption that insurers will spread the cost of these valuations across a large number of purchasers.

In years after 2005, employers that provide drug coverage to Medicare beneficiaries who are active workers are likely to expend some additional time related to disclosure notices, but we anticipate this time will be substantially less than in 2005. In subsequent years, we anticipate that these employers will provide disclosure notices to their workers who age into the Medicare program and continue working. In addition, it is possible that a portion of employers may alter their drug benefit design to such an extent that a reconfirmation of their creditable

coverage status may be appropriate. We assume that those active workers who become new Medicare beneficiaries each year require notices, that about 25 percent of firms per year obtain a new actuarial valuation on their benefit design, and that about 1 percent of firms per year have a change in creditable coverage status that requires a notice.

As discussed previously, we anticipate that the disclosure notice cost per employer that offers drug coverage to Medicare beneficiaries who are active workers (and not retirees) will be relatively small—$154 per employer on average in 2005 and substantially less in future years. However, we are concerned about these expenditures in relation to their benefits to employers and Medicare beneficiaries who are active workers and the number of firms that could potentially be affected. We seek comment on ways to minimize burden on these employers and whether other approaches could lower these costs.

3. Coordination of Benefits Under Employer-Sponsored Plans and SPAPs

CMS is required under the statute to establish requirements for coordination of benefits between Medicare PDPs and MA–PDs and other insurers including SPAPs, Medicaid programs, group health plans, FEHBP, military coverage including TRICARE, and other coverage CMS may specify. Ensuring accurate and timely coordination of benefits is important for tracking the true out-of-pocket limit, a cornerstone of the benefit design. This will necessitate that an efficient and effective operational framework be established to track beneficiary out-of-pocket expenditures. As discussed elsewhere in the preamble, CMS is considering and seeking comment on a wide range of options related to coordination of benefits. For example, one of the fundamental issues is who should have responsibility for developing the systems infrastructure needed to track beneficiary out-of-pocket expenditures—PDPs and MA–PDs or the government. If the government were to develop a system to facilitate tracking beneficiary out-of-pocket expenditures, there is the additional question of how this system should be set up operationally and how data flow should be structured into and out of the system from pharmacies, supplemental insurers, and Part D plans. Given that such a wide range of approaches is under consideration for coordination of benefits, it is not possible to estimate the administrative costs associated with coordination of benefits at this time. We seek comment on the cost implications of various options discussed in the preamble and will be working to develop a cost estimate of coordination of benefits activities for the final rule.

4. Estimated Administrative Costs in Applying for Retiree Drug Subsidy

Qualified retiree prescription drug plans that choose to accept the Medicare retiree subsidy will incur some administrative costs associated with obtaining the subsidy. As discussed earlier in the preamble, sponsors will have to submit to CMS an application for the Medicare retiree drug subsidy, including an attestation that the actuarial value of the prescription drug coverage under their retiree plan or plans is at least equal to the actuarial value of standard prescription drug coverage under Medicare Part D, which must be signed by the plan sponsor (or a plan administrator designated by the sponsor). As part of this application, employers are also required to provide other information including data about the eligible covered Medicare retirees in their plan or plans. In addition, entities accepting the Medicare retiree drug subsidy payments will have to comply with certain reporting requirements and maintain records for purposes of audit and oversight by CMS. We also note that employer and union sponsored health plans that provide drug coverage to beneficiaries are required to provide, at certain times, creditable coverage disclosure notices to beneficiaries. These notices are required regardless of whether the plan sponsor applies for a subsidy, and consequently the costs of these notices are discussed in the section of this analysis on disclosure notices.

In developing the proposed rule, we have tried to minimize the administrative burden associated with the operation of the retiree subsidy program, and we seek comments regarding our proposed administrative approaches and reporting requirements. We want to establish an efficient administrative structure that provides maximum flexibility for qualified retiree prescription drug plans, while at the same time providing for an appropriate level of financial accountability that assures the accuracy of payments and safeguards the interests of beneficiaries, consistent with our fiduciary responsibility. Thus, we are seeking public comment on appropriate approaches for achieving this objective.

For purposes of the "Collection of Information Requirements" section and the accounting statement in this proposed rule, we have developed an estimate of the time and aggregate employer costs involved in the various administrative functions associated with employers obtaining the Medicare retiree subsidy including: subsidy application requirements, including performing the actuarial valuation; preparing the plan(s)' enrollment files to identify the eligible Medicare retiree population and other relevant information; assembling the application; and record retention. We base our cost estimates on 2005 wage data for an actuary and administrative personnel loaded for compensation, overhead, general administration, and fee.

a. Application for Retiree Drug Subsidy Including Actuarial Attestation

In applying for the subsidy, sponsors of qualified retiree prescription drug plans are required to provide to CMS an attestation that the actuarial value of the prescription drug coverage in each such plan is at least equal to the actuarial value of standard Medicare Part D prescription drug coverage. Sponsors of qualified retiree prescription drug plans will need to submit this attestation on an annual basis, and submit an updated attestation if there is a change during the year that materially affects actuarial value of their drug coverage. As discussed earlier in the preamble, a material change means any change that potentially causes a plan to no longer meet the actuarial equivalence test (these submissions would not be required when non-material changes are made to the coverage).

We are aware that many employers purchase retiree health coverage by paying premiums to insurance companies. Thus, one insurance company may be offering the same prescription drug benefit design to numerous employers, and consequently be able to spread the cost of the actuarial valuation across a number of purchasers. Similarly, many employers use pharmacy benefit managers (PBMs) to administer their prescription drug benefits, and again the same benefit design may be used by multiple employer plans, generating economies of scale.

We are also aware that any given sponsor may be offering more than one qualified retiree prescription drug plan in which Medicare beneficiaries are enrolled and for which Medicare retiree drug subsidy payments are sought. Another factor in the cost of actuarial attestations, however, is that employers can potentially use one actuarial model to analyze multiple plans' benefit designs that, for example, are similar in design but use different co-payments. Thus, there may also be economies of scale in conducting the analyses for employers that have multiple plans.

Because of these factors, the total time involved in preparing the actuarial valuation is likely to vary across qualified retiree plans. To develop assumptions, we had discussions with actuaries in CMS' Office of the Actuary and other industry experts. From these discussions, we developed a range of time estimates for preparing actuarial models, taking into consideration: The use of actual plan data if it is available and credible, the time to conduct the analyses, the issue of economies of scale in the use of one model to analyze multiple plans, and the time involved in preparing the written attestation report. Based on these discussions, our preliminary estimate is that total time involved in developing one actuarial model and preparing an analysis and report on one plan could range from 6 to 40 hours. For the purposes of this analysis, we assume that average time involved in the actuarial valuation per firm ranges from one-third of an hour for very small firms (where the actuarial valuation is performed by an insurance company and its cost is spread across a large number of purchasers) to 100 hours for very large firms that offer multiple plans. Based on these assumptions and taking into account the time involved for firms of different sizes, we estimate that the cost of the actuarial valuation would on average be in the range of about 1.8 percent of the value of the retiree subsidy.

In addition to the actuarial valuation, plans sponsors applying for the retiree subsidy will need to prepare the application and related enrollment data and information on retirees, and ultimately sign the agreement if approved to receive the subsidy. We anticipate that the time involved in preparing the application and required enrollment information will vary by firm size, with the average time ranging from 5 hours for the smallest firms with 6 retirees on average to 382 hours for the largest firms with more than 1,500 retirees on average. As discussed elsewhere, some of the information needed on eligible beneficiaries may not be routinely available to plan sponsors and consequently for initial start-up some level of effort may be needed to obtain this information. We have been conservative in our assumptions to reflect this possibility. It is important to note that a significant portion of the time involved would be a one-time expense. In addition, we estimate that each firm will expend one-half hour signing and submitting the final agreement. Based on these assumptions, we estimate that on average across large and small firms, the cost involved in preparing the application and related enrollment information (excluding the actuarial work) and ultimately signing the agreement would be in the range of about 3.2 percent of the value of the subsidy. It is important to note that after the first year, we believe these costs will decline as the initial work associated with identifying the eligible population will have been accomplished and as employers and their agents gain more experience with the program.

b. Reporting

In order to obtain the subsidy, sponsors of qualified retiree prescription drug plans will need to submit certain data to CMS and maintain certain records. This proposed rule outlines a number of different options we are considering in terms of data reporting. At this time, we have not determined which option is the most efficient and effective method of obtaining the data and information necessary for administering this program and we seek public comment on the various options.

As discussed in detail in the preamble and the alternatives considered section, the options that we are considering related to data reporting vary in terms of their scope, level of detail, and frequency of data reporting activities. Consequently, at this time it is not possible to estimate the administrative costs of reporting requirements under this proposed rule. However, we anticipate that the administrative costs associated with the data reporting will be small relative to the Medicare retiree drug subsidy payments received by employers. Because prescription drug data and records are highly automated, there are significant economies of scale related to reporting and audit requirements. In addition, one of our primary objectives in establishing the data reporting requirements will be to do so in as cost effective a manner as possible while upholding our fiduciary responsibilities. We seek public comment on the administrative costs associated with any of the data reporting options under consideration in this rule, as well as any other approaches for minimizing such costs.

In addition to data reporting, employers that receive the subsidy will also be required to retain data and records for six years. For the purposes of this analysis, we assume that the time involved in record retention would vary by firm size, with the average time ranging from 4 hours for the smallest firms to 20 hours for the largest firms. Based on these assumptions and taking into account the varied time involved across firms of different sizes, we estimate that on average the record retention would be in the range of about 0.5 percent of the value of the subsidy.

c. Conclusion

Based on our analyses, we estimate that the administrative costs associated with obtaining the retiree subsidy (excluding the data reporting requirements not yet determined) will represent on average in the range of about 5.5 percent of the value of the subsidy in 2006 and are expected to decline significantly in subsequent years. After the first year, we believe these costs will decline as the initial work associated with identifying the eligible population will have been accomplished and as employers and their agents gain more experience with the program.

J. Medigap Provisions

The MMA prohibits Medigap insurers from selling new Medigap policies that cover prescription drugs after December 31, 2005 and prohibits the renewal of existing Medigap policies with drug coverage for beneficiaries who enroll in Medicare Part D. Part D enrollees with current Medigap drug coverage have the choice of renewing their existing Medigap policy without drug coverage or buying certain other Medigap plans that do not have drug coverage if they enroll in a Part D plan in the initial enrollment period. We emphasize that the MMA itself directly restructures the role of Medigap insurance, and that it is not the result of this rulemaking.

We estimate that about 1.9 million beneficiaries would be enrolled in Medigap plans with drug coverage in 2006, absent the law change. As discussed elsewhere in this analysis, we assumed nearly all of these beneficiaries will enroll in Medicare Part D. As a result of the statutory prohibition on the sale of Medigap policies with drug coverage to Part D enrollees, we expect these beneficiaries will move from Medigap policies that contain prescription drug coverage to Medigap policies that do not contain such coverage. We expect that the policies without drug coverage will have lower premiums. If all beneficiaries with Medigap drug coverage enrolled in the Medicare drug benefit, we estimate that the reduction in Medigap insurers revenues associated with MMA prohibition on the sale or renewal of policies with drug coverage would be approximately $2.5 billion in 2006, $2.6 billion in 2007, $2.8 billion in 2008, $3.0 billion in 2009, and $3.2 billion in 2010. We note, however, that some Medigap insurers may choose to enter the PDP or MA–PD market and offer

those products. This market entry might mitigate the revenue impacts on these insurers, and could even possibly produce a revenue gain for these insurers, as the Medicare prescription drug benefit would be subsidized and likely attract more enrollees. In addition, we believe that the movement of beneficiaries from Medigap drug coverage to Medicare Part D will generate substantial savings for these beneficiaries on prescription drug costs. The standard Medicare Part D benefit provides a 75 percent subsidized benefit, catastrophic coverage, and cost savings from discounts and other cost management activities. It also is not likely to suffer from the substantial adverse selection, and resulting increased premiums, that are seen in Medigap plans with drug coverage.

Our estimates of Medigap enrollment in policies with drug coverage and the premiums associated with that drug coverage were developed using data from NAIC on standardized Medigap plans, and information gathered by a CMS contractor on pre-standardized Medigap plans and waiver State plans. While our estimates do not take into account standalone Medigap drug policies, these policies represent substantially less than 1 percent of the Medigap market and would not affect the estimates.

K. Small Business Analysis

The Regulatory Flexibility Act (RFA) requires agencies to determine whether a proposed rule will have a "significant economic impact on a substantial number of small entities."

If a rule is expected to have a significant economic impact on a substantial number of small entities the RFA requires that an Initial Regulatory Flexibility Analysis (IRFA) be performed. Under the RFA, a "small entity" is defined as a small business (as determined by the Small Business Administration (SBA)), a non-profit entity of any size that is not dominant in its field, or a small government jurisdiction. HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

With respect to the Medicare prescription drug benefit and retiree drug subsidy, there are three areas that we believe merit discussion related to small business impacts: (1) Pharmacies, (2) insurers and PBMs, and (3) employers. We anticipate that the pharmacy industry, which is comprised of both chains and a large number of independent pharmacies, will play a critical role in the Medicare drug benefit as it furnishes prescription medicines and pharmacy services to beneficiaries enrolled in Medicare Part D. While the Medicare prescription drug benefit is expected to have several effects on pharmacy revenues, both positive and negative, our estimate is that the impact on the overall pharmacy industry, including small pharmacies, will be positive.

Since PDPs and MA–PDs are the principal vehicles through which the Medicare prescription drug benefit is administered, we also examine whether there are any small business impacts on the types of businesses expected to apply to be prescription drug plans—that is, insurers and PBMs. Our analysis suggests that while the statutorily created Medicare Part D program would increase drug utilization and thus be favorable to insurers and PBMs, this proposed rule as such will have little overall effect on the insurance and PBM industry, and certainly not a significant adverse impact.

In the case of the small employers who continue to provide qualified prescription drug coverage for their retirees, we estimate that savings obtained from the Medicare retiree drug subsidy will greatly exceed the employer's administrative costs associated with obtaining the subsidy, and thus the result of the retiree drug subsidy provision is a net positive impact. We would like to make participation in the retiree drug subsidy program as simple as possible for small entities.

While we believe that we could certify that this proposed rule will not have a significant economic impact on a substantial number of small entities, we provide an Initial Regulatory Flexibility Analysis (IRFA) and request comment on this conclusion as well as any aspects of the rule that might adversely affect small businesses, or that could be modified to increase positive impacts.

In addition, in accordance with Section 1102(b) of the Social Security Act, we also address whether this rule will have an impact on the operations of small rural hospitals.

1. Pharmacies

The RFA requires us to determine whether this rule will have a significant economic impact on a substantial number of small pharmacies. SBA considers pharmacies with firm revenues of less than $6 million to be small businesses. The 1997 Economic Census (the latest available detailed data) indicates that there were about 21,000 firms operating about 41,000 retail pharmacies and drug store establishments (NAICS code 44661) continuously through 1997. Of these firms, about 20,000 had revenues under $5 million (which was the small business size standard in 1997) and operated a total of about 21,000 establishments. Since over 95 percent of pharmacy firms are small businesses (as defined by the SBA size standards), we do expect that the statutorily-created Medicare prescription drug benefit will have some effect on a substantial number of small pharmacies. However, we estimate that overall the revenue effect on the retail pharmacy industry, including small pharmacies, will be positive. Furthermore, we emphasize that this effect is really a result of the statutorily-created Medicare prescription drug benefit, and not this rulemaking.

We anticipate that, although the Medicare prescription drug benefit will lead to both revenue increases and decreases for pharmacies, the increase in revenues is estimated to more than offset the decrease in revenues. First, we expect that the vast majority of beneficiaries currently without prescription drug coverage will choose to enroll in Medicare Part D. The extension of drug coverage to these individuals, and the resulting lower out-of-pocket costs they face when purchasing prescription drugs, is expected to lead to higher drug utilization and total expenditures, and consequently higher revenues for pharmacies. At the same time, some of these beneficiaries without prior drug coverage, as well as some beneficiaries with Medigap drug coverage, would be expected to realize new pharmacy discounts under Medicare Part D that they otherwise would not obtain. We note that the Medicare prescription drug benefit would not lead to any additional pharmacy discounts for the majority of beneficiaries who currently have drug coverage as they already obtain pharmacy discounts through their current insurers (for example, employer-sponsored health plans, Medicare Advantage plans, and State plans). In addition, we have examined the potential for increased use of mail order pharmacies among some beneficiaries, and its potential impact on retail pharmacies. As described in more detail subsequently, we estimate that the countervailing effects of increased utilization and new pharmacy discounts and possibly new use of mail order pharmacies among some beneficiaries would result in a net increase in retail pharmacy revenues ranging from a lower bound of 1.7 percent to an upper bound of 3.0 percent.

Second, since State Medicaid programs typically pay higher reimbursement rates to pharmacies than private sector insurers. We expect that pharmacies would experience some reduction in revenues due to the movement of full-benefit dual eligibles from Medicaid drug coverage to Medicare drug coverage (through PDPs and MA–PDs). As discussed in more detail subsequently, our upper bound estimate of the average reduction in pharmacy revenues that could result from full-benefit dual eligibles receiving drug coverage from Medicare is 1.1 percent. We believe this is an overestimate of the revenue reduction because it does not take into account the effect of the Federal Upper Payment Limit on reducing Medicaid reimbursement rates for many multi-source drugs. Also, to the extent that a State Medicaid program has adopted managed care arrangements to lower the cost of drugs for dual eligibles, our estimate of the revenue impact of pharmacy reimbursement changes for full-benefit dual eligibles would be overstated.

Considering together the effect of increased utilization, new pharmacy discounts and possibly new use of mail order pharmacies among some beneficiaries, and reimbursement changes for full-benefit dual eligibles, we estimate that retail pharmacy revenues would experience a net increase ranging from 0.6 percent to 1.9 percent, as a result of the Medicare prescription drug benefit. Furthermore, while we are not able to provide a quantitative estimate at this time, we expect that pharmacies may realize additional revenues from the MMA requirement that PDPs and MA–PDs offer medication therapy management programs to targeted enrollees, which may be furnished by pharmacists. Our estimates also do not take into account that increased use of prescription drugs resulting from the Medicare drug benefit may lead to increased foot traffic in pharmacies and increased sales for pharmacies' other goods in addition to prescription medicines.

We note that our estimate of the overall impact on small pharmacies represents the average effect. We recognize that the effect on any specific pharmacy will likely vary to some extent around the average. While we have estimated that the average effect on small pharmacies would range from 0.6 percent to 1.9 percent, it is possible that some individual pharmacies could experience smaller positive effects and even in some cases negative revenue effects. While it is possible that a specific pharmacy because of unique circumstances could experience a negative revenue impact, we believe that this will be uncommon. For example, it is likely that pharmacies that serve a large population of full-benefit dual eligibles (for which pharmacies would experience a revenue decrease) would tend to be located in low-income areas that also serve a large population of beneficiaries without drug coverage (for which pharmacies would experience a revenue increase). This would suggest that pharmacies that experience larger than average revenue reductions for full-benefit dual eligibles would also tend to be those that experience larger than average revenue increases for beneficiaries without prior drug coverage. However, lack of data makes estimating the distributional effects among small pharmacies speculative. We seek comments and data that can help inform this issue.

a. Expansion of Drug Coverage and Increased Access to Pharmacy Discounts Among Beneficiaries Previously Lacking Such Coverage or Discounts

A substantial portion of beneficiaries (about 24 percent as of 2001) lack drug coverage. As discussed in Section E, we project that nearly all beneficiaries without drug coverage will enroll in the Medicare drug benefit. The expansion of drug coverage to these individuals is likely to have countervailing effects on pharmacy revenues. First, it is likely to lead to increased drug utilization and spending among beneficiaries without prior drug coverage, and thus increased pharmacy revenues. Second, it is likely to lead to increased access to pharmacy discounts for some beneficiaries who previously did not receive such discounts (specifically, many beneficiaries without drug coverage and beneficiaries with Medigap drug coverage), and thus decreased revenues for pharmacies. Because many beneficiaries that currently have prescription drug coverage (for example, those in employer sponsored retiree health plans or Medicare Advantage plans) already receive pharmacy discounts through those insurers, we do not expect the Medicare prescription drug benefit to generate any new pharmacy discounts for these beneficiaries. In addition, it is possible that the Medicare drug benefit may lead to new use of mail order pharmacies among beneficiaries without prior drug coverage and beneficiaries with Medigap drug coverage, potentially having some effect on retail pharmacy revenues. Overall, we estimate that increased utilization for beneficiaries without prior drug coverage and new pharmacy discounts and possibly new use of mail order pharmacies among some beneficiaries will result in a net positive revenue impact for retail pharmacies.

Medicare beneficiaries without prior drug coverage who enroll in the Medicare drug benefit will face a substantial reduction in out-of-pocket costs for prescription medicines, and consequently we expect that their drug utilization and expenditures will increase. Beneficiaries with drug coverage fill more prescriptions and have higher total drug spending than beneficiaries without drug coverage. Based on 2001 MCBS data, beneficiaries with drug coverage have average total drug spending that is 109 percent greater than beneficiaries without drug coverage. These spending differences hold true even among beneficiaries with similar numbers of chronic conditions. For example, average spending for beneficiaries with drug coverage was higher than for beneficiaries without drug coverage among beneficiaries with no chronic conditions (247 percent higher), 1–2 chronic conditions (107 percent higher), 3–4 chronic conditions (76 percent higher), and 5 or more chronic conditions (53 percent higher). Thus, we expect that the expansion of drug coverage to beneficiaries who previously did not have such coverage will lead to increased drug utilization and spending, and thus higher pharmacy revenues. For the purposes of this analysis, we assume that beneficiaries without prior drug coverage who enroll in the Medicare drug benefit will experience a 76 percent increase in total drug spending. We base this assumption on the fact that most beneficiaries without drug coverage fall into the category of having 1–2 chronic conditions or 3–4 chronic conditions, and we have chosen the more modest use difference seen in the 3–4 chronic condition group. Furthermore, we believe that this is a conservative assumption because the average difference across the population in drug spending for beneficiaries with and without coverage is 109 percent. Since beneficiaries without drug coverage account for about 13 percent of all drug spending by Medicare beneficiaries (based on 2001 MCBS data), if we assume that all of these previously uninsured beneficiaries enroll in the Medicare drug benefit and experience a 76 percent increase in drug expenditures due to a use effect, this would represent about a 9.9 percent increase in total drug spending by Medicare beneficiaries.

At the same time, to the extent that beneficiaries without drug coverage did not receive pharmacy discounts prior to

Medicare Part D, we would expect that pharmacy discounts negotiated by PDPs and MA–PDs could result in some reduction in pharmacy revenues. While the vast majority of beneficiaries who currently have drug coverage are likely to already be receiving pharmacy discounts, and thus the Medicare drug benefit would not result in any change in pharmacy discounts for these beneficiaries, this may not be the case for beneficiaries without drug coverage. As mentioned previously, the April 2000 HHS Report "Prescription Drug Coverage, Spending, Utilization, and Prices" found that on average individuals with drug coverage paid a 15 percent lower price for prescription drugs at the point of sale than individuals without drug coverage. The discount insured individuals receive at the point of sale reflects a combination of pharmacy and manufacturer discounts. However, to take a conservative approach, we assume that Medicare Part D enrollees without prior drug coverage realize 15 percent price discounts at the point of sale, all of which reflect pharmacy discounts. This assumption is conservative not only because it assumes that the entire 15 percent discount comes from pharmacies, but also because some of these beneficiaries are likely to have received pharmacy discounts previously through the Medicare drug discount card, which began offering discounts in June 2004 and which includes substantial discounts from drug manufacturers, and through senior pharmacy discounts previously offered by many pharmacies. Thus, our assumption that all Part D enrollees without prior drug coverage would receive new pharmacy discounts of 15 percent under Medicare Part D overstates the negative revenue impact on pharmacies. With these beneficiaries accounting for about 13 percent of all drug spending by Medicare beneficiaries, we estimate that extending a 15 percent discount to these beneficiaries would result in about a 2 percent decrease in total drug spending by Medicare beneficiaries.

Another group of beneficiaries who we believe may obtain new pharmacy discounts under Medicare Part D are beneficiaries with Medigap drug coverage. Some Medigap plans do not actively negotiate prescription drug discounts for enrollees. As a result, these beneficiaries who enroll in Medicare Part D may also realize new pharmacy discounts. As discussed elsewhere in this impact analysis, we estimate that 1.9 million beneficiaries would have Medigap drug coverage in 2006, absent the law change. To be conservative, we assume that all of these beneficiaries with Medigap drug coverage obtain new pharmacy discounts under the Medicare drug benefit. With these beneficiaries accounting for about 4 percent of prescription drug spending by all beneficiaries, we estimate that extending pharmacy discounts to these beneficiaries could result in about a 0.6 percent decline in total Medicare drug spending by beneficiaries.

It is also possible that the Medicare prescription drug benefit may result in new use of mail order pharmacies by some beneficiaries. We believe that the new Medicare benefit is unlikely to affect the use of mail order pharmacies among beneficiaries currently with employer sponsored or Medicare Advantage drug coverage as mail order is an option currently available to these beneficiaries and the implementation of Medicare Part D makes no changes in this regard. We also believe that there is likely to be no effect on mail order use by beneficiaries who qualify for the low-income subsidy because nominal cost sharing exists regardless of where the beneficiary purchases the prescriptions (and as noted above, for those without prior drug coverage or less generous prior drug coverage, we expect that these beneficiaries will fill significantly more prescriptions). The two groups where it is possible that mail order usage may increase are beneficiaries without prior drug coverage and beneficiaries with Medigap drug coverage. The effect of Medicare Part D on mail order use by these beneficiaries, however, is uncertain. For example, Medicare Part D includes a provision that allows retail pharmacies (subject to state pharmacy laws) to provide a 90-day supply, putting them on equal footing with mail order pharmacies in this regard.

To estimate the potential effect of new mail order use among beneficiaries without prior drug coverage and beneficiaries with prior Medigap drug coverage, we take the approach of making estimates based on two alternate assumptions. As a lower bound, we assume that there is no additional mail order use. As an upper bound, we assume that the percent of beneficiaries using mail order pharmacies among these two groups of beneficiaries increases to be similar to the rate of use among beneficiaries with private employer-based drug coverage. There is limited publicly available data related to mail order utilization. To supplement publicly available data we tried to obtain information from proprietary sources to help inform our upper bound estimates. For our upper bound assumptions, we use data from the Medical Expenditure Panel Survey (MEPS) to assign higher rates of mail order use (that is, the percentage of population that fills at least one prescription through mail order) to the population that gains drug coverage and to beneficiaries with prior Medigap drug coverage. We also tried to obtain data on the share of drug spending through mail order pharmacies that occurs among individuals who use these pharmacies. However, we were unable to obtain this type of information. We were able to obtain some proprietary information regarding the share of total plan spending occurring through mail order and retail pharmacies for a commercially insured over 65 population. Using this information in combination with the recognition that a number of prescriptions are unlikely to be filled through mail order (for example such as antibiotics and pain medication used to treat acute conditions, or newly prescribed medications), we developed an upper bound assumption that as much as 50 percent of drug spending among new users of mail order might occur through mail order pharmacies. We do not expect mail order use to approach this level; we use it simply for purposes of estimating the maximum potential impact. Under this upper bound assumption, we estimate that as a result of mail order effects, aggregate Medicare drug spending in retail pharmacies could decrease by as much as 1.9 percent. Thus, based on our lower bound and upper bound assumptions, we estimate that possible new use of mail order pharmacies among some beneficiaries could result in a decrease in retail pharmacy revenues of somewhere between 0 to 1.9 percent. If a shift in mail order use were to occur, our prior estimates of utilization and discount effects would be altered slightly since they are based on the assumption of no change in mail order use. We estimate that under our upper bound assumptions related to mail order, our previous estimates of the combined effect of utilization increases and new pharmacy discounts for some beneficiaries would need to be adjusted downward by as much as 1.2 percentage points. We note that even with these adjustments based on a very high upper bound assumption, the net effect for retail pharmacies remains positive. We welcome additional data that could help inform our assumptions and analysis related to new mail order use by beneficiaries who previously did not have drug coverage.

Taken together, we estimate that the effect of expanding access to prescription drug coverage among beneficiaries without prior drug coverage and the effect of new pharmacy discounts and possibly new use of mail order pharmacies by some beneficiaries will result in a net increase in total prescription drug spending by Medicare beneficiaries at retail pharmacies of between 4.1 percent and 7.3 percent. We estimate that this would represent an average increase in retail pharmacy revenues of between 1.7 percent and 3.0 percent, as Medicare beneficiaries account for about 40.5 percent of outpatient prescription drug spending for the non-institutionalized population according to 1999 MEPS data (Stagnitti MN et al., AHRQ, "Outpatient Prescription Drug Expenses, 1999", 2003). Furthermore, while not quantifiable at this time, we expect that pharmacies may realize additional revenues from the MMA requirement that PDPs and MA–PDs offer medication therapy management programs to targeted enrollees, which may be furnished by pharmacists. In addition, it is likely that increased use of prescription drugs by Medicare beneficiaries will lead to increased foot traffic in pharmacies and increased pharmacy revenues from non-pharmaceutical products as well.

b. Medicare's Assumption of Drug Coverage for Full-Benefit Dual Eligibles

Because State Medicaid programs typically pay higher reimbursement rates to pharmacies than private sector insurers, the movement of full-benefit dual eligibles from Medicaid drug coverage to Medicare drug coverage (through PDPs and MA–PDs) has potential implications for pharmacy revenues. Our upper bound estimate of the average reduction in pharmacy revenues that could result from full-benefit dual eligibles receiving drug coverage from Medicare is 1.1 percent. We believe that this is an overestimate because it does not take into account the effect the Federal Upper Payment Limit has in reducing Medicaid reimbursement rates for multi-source drugs with at least three generic equivalents. Also, to the extent that a State Medicaid program has adopted managed care arrangements to lower the cost of drugs for dual eligibles, our estimate of the revenue impact of pharmacy reimbursement changes for full-benefit dual eligibles would be overstated.

We conducted the following analysis to estimate how the transfer of dual-eligibles' drug coverage from Medicaid to Medicare would affect pharmacy revenues. First, we developed an estimate of the average Medicaid drug reimbursement rate across States. To begin, we considered how Medicaid reimburses pharmacies for drugs. Medicaid reimburses pharmacies for drugs based on the estimated acquisition costs (EAC) plus a dispensing fee. There is variation across States in how they define and the level at which they set EAC and the dispensing fee. The vast majority of States define EAC as the average wholesale price (AWP) less a certain percentage discount, while a small number define it as wholesale acquisition cost (WAC) plus a certain percentage or the lower of an AWP-based or WAC-based payment amount. Dispensing fees also vary by State and typically range from $3 to $5. Some States use the same reimbursement formula for brand and generic drugs, while others institute a greater discount off of AWP for generic drugs or a higher dispensing fee for generic drugs, and in some cases both. In addition, Medicaid reimbursement rates for multi-source drugs with 3 or more generic equivalents are generally capped by the Federal Upper Payment Limit.

Based on information on the Medicaid EAC and dispensing fee for each State for brand and generic drugs as of January 2004, we estimated the overall drug reimbursement rate (EAC plus dispensing fee) as a percent of AWP separately for brand and generic drugs. We did this by estimating the dispensing fee as a percent of the average AWP, using unpublished Express Scripts data on the average AWP for brand drugs ($77.42) and generic drugs ($32.57) in 2002.[8] (It should be noted that under this methodology the total reimbursement rate for generic drugs (including the ingredient cost and the dispensing fee) as a percent of AWP is much greater than the reimbursement rate as a percent of AWP for the ingredient cost alone, because the dispensing fee represents a fairly high percentage of AWP for low cost generic drugs.) For States that set EAC based on WAC rather than AWP, we express their reimbursement formula in AWP terms by assuming that WAC is equivalent to roughly 20 percent of AWP, based on information about the typical relationship between WAC and AWP in the 2000 HHS Prescription Drug study. After estimating an overall Medicaid reimbursement amount for brand and generic drugs for each State, we estimate the weighted average reimbursement rate across States, using the number of full-benefit dual eligibles with drug coverage in each State for weights. Based on this method, we estimate that average Medicaid reimbursement to pharmacies (for ingredient cost and dispensing fee combined) is roughly equivalent to AWP minus 7 percent for brand drugs and AWP for generic drugs. It should be noted that this likely overstates the Medicaid reimbursement rate for generic drugs because it does not take into account that Medicaid reimbursement for multi-source drugs with 3 or more generic equivalents is generally capped by the Federal upper payment limit.

We then estimated an average Medicaid reimbursement rate across all drugs (brand and generic) by weighting the average reimbursement estimates for brand and generic drugs by the percent of Medicaid expenditures we assume they comprise. According to a survey of State Medicaid programs by the Kaiser Family Foundation, States estimate that 80 percent of State Medicaid drug expenditures are on brand drugs and 20 percent on generics. Using these figures for weights, we estimate an overall average Medicaid drug reimbursement rate (including dispensing fee) of roughly 5 percent off of AWP.

Second, for the purposes of this analysis, we make assumptions about the average pharmacy reimbursement rate for brand and generic drugs under PDPs and MA–PDs. We base these assumptions on available literature about typical pharmacy reimbursement rates under private sector insured products. It must be noted that these assumptions are not meant to convey our expectation of the actual pharmacy reimbursement rates negotiated by PDPs and MA–PDs with pharmacies under the Medicare drug. Instead, they are assumptions made solely for this regulatory flexibility analysis. According to a survey sponsored by Takeda Lilly of employer sponsored insurance plans covering more than 17 million lives, the average reimbursement for ingredient cost for a brand drug in 2002 was about 14 percent off of AWP (Takeda, "The Prescription Drug Benefit Cost and Plan Design Survey Report," 2003). In addition, according to a report by Express Scripts, there tends to be about a three times greater discount off of AWP for generic drug ingredient cost than for brand drug ingredient cost (Express Scripts, "Drug Trends 2002

[8] These unpublished Express Scripts estimates of average AWP for brand and generic drugs in 2002 reflect the average AWP for a 30-day equivalent weighted by the number of scripts, based on utilization data from a commercially insured population age 65 and older, with employer sponsored insurance and with an integrated benefit (network and mail prescription coverage).

Report," June 2003). Based on these studies, we assume reimbursement for ingredient costs of 14 percent off of AWP for brand drugs and 42 percent off of AWP for generic drugs. In terms of dispensing fees, the Novartis Pharmacy Benefit Reports, which is a survey of HMO plans, finds an average dispensing fee of $1.79 for brand drugs and $2.08 for generic drugs as of 2002 (Novartis, "Pharmacy Benefit Report: Facts and Figures," 2003). The Takeda Lilly survey of employer-sponsored plans indicates an average dispensing fee of $2.13 for brand and $2.22 for generic drugs. For the purposes of this analysis, we average the findings from the two studies and assume a dispensing fee of $1.96 for brand drugs and $2.11 for generic. Similar to the Medicaid reimbursement analysis, we estimate these dispensing fees as a percent of average AWP for brand and generic drugs and then add them to our ingredient cost reimbursement assumptions to arrive at average reimbursement estimates—11 percent off of AWP for brand drugs and 35 percent off of AWP for generic drugs. We then weight the average reimbursement estimates for brand and generic drugs by the percent of expenditures they are assumed to comprise to arrive at an overall average reimbursement estimate (including dispensing fee) of 16 percent off AWP for all drugs.

Third, we estimated the share of national retail prescription drug spending accounted for by Medicaid drug expenditures on dual eligibles. According to a special analysis by the Kaiser Commission on Medicaid and the Uninsured, Medicaid prescription drug spending on dual eligibles was $9.5 billion in 2000, including fee-for-service and managed care and netting out manufacturer rebates (Kaiser Commission on Medicaid and the Uninsured, "The Proposed Medicare Prescription Drug Benefit: A Detailed Review of Implications for Dual Eligibles and Other Low-Income Medicare Beneficiaries," September 2003). In addition, national retail prescription drug spending, net of manufacturer rebates, was $121.5 billion in 2000 according to National Health Expenditures projections by our Office of the Actuary. *(http://www.cms.hhs.gov/statistics/nhe/projections-2003/t11.asp).* Based on the above figures, we estimate Medicaid drug spending on dual eligibles comprised about 7.8 percent of total national retail prescription drug spending net of rebates in 2000. While this estimate is based on drug spending adjusted for rebates, drug spending without adjustments for rebates would be a better measure of the actual amount of revenues flowing through pharmacies. Manufacturer rebates typically occur on the back end between manufacturers and third party insurers and do not impact pharmacy revenues. Therefore, we adjust our estimate to pre-rebate levels of drug spending using the following method. We take national retail prescription drug spending net of rebates and inflate it based on our Office of the Actuary's estimate that national retail prescription drug spending in 2000 would be 6 percent higher without the adjustments for rebates. We also take our estimate of Medicaid prescription drug spending for dual eligibles and inflate it based on information from the Kaiser Study, which indicates that rebates reduced Medicaid fee-for-service drug spending in 2000 by an average of about 19 percent. Absent information on the percent of Medicaid drug spending for dual eligibles that is under fee-for-service versus managed care, we take an extremely conservative approach and inflate Medicaid drug spending to pre-rebate as though all spending had been fee-for-service. It should be noted that we strongly believe this overstates the amount of Medicaid drug spending on dual eligibles, and thus overstates any negative revenue impact on pharmacies. Based on the above, we estimate that Medicaid drug spending on dual eligibles is about 9.1 percent of total national retail prescription drug spending. Finally, we estimate the potential impact on pharmacy revenues of transferring responsibility for drug coverage of full benefit dual eligibles from Medicaid to Medicare.

Based on our previous estimates of average pharmacy drug reimbursement rates under Medicaid and private insurers, we estimate that prescription drug spending on dual eligibles would account for about 8.1 percent of national retail prescription drug spending if drugs were reimbursed at rates typical of private sector insurer rates rather than Medicaid.[9] Thus, our upper bound estimate of the average reduction in pharmacy revenues that could result from full-benefit dual eligibles receiving drug coverage from Medicare is about 1.1 percent.[10] As mentioned previously, we believe that this is an overestimate of the impact on pharmacies because it does not take into account existing policies that reduce Medicaid reimbursement rates such as the Federal Upper Payment limit for multi-source drugs with at least three generic equivalents.

c. Conclusion

Considering together the effect of increased utilization, new pharmacy discounts and possibly new use of mail order pharmacies among some beneficiaries, and reimbursement changes for full-benefit dual eligibles, we estimate that retail pharmacy revenues would increase on average by between 0.6 percent and 1.9 percent as a result of the Medicare prescription drug benefit. This is the result of an increase in prescription drug revenues ranging from 1.7 percent to 3.0 percent due to the net effect of increased utilization, new pharmacy discounts, and possibly new use of mail order pharmacies among some beneficiaries, and a 1.1 percent decrease in pharmacy revenues (upper bound estimate) due to drug coverage for full-benefit dual eligibles shifting from Medicaid to Medicare.

In addition, we believe that these estimates understate the degree to which pharmacy revenues increase as a result of the Medicare prescription drug benefit for several reasons. Our estimate of the revenue reduction resulting from the transfer of drug coverage for full benefit dual eligibles from Medicaid to Medicare is likely to be overstated because it does not take into account the effect of the Medicaid upper payment limit on reducing Medicaid reimbursement rates for some multi-source drugs. In addition to revenue effects we have estimated, the Medicare prescription drug benefit is likely to provide other sources of revenue increases for pharmacies; for example, through targeted medication therapy management programs under Medicare Part D which may be furnished by pharmacists, or through increased foot traffic in pharmacies leading to increased pharmacy sales of other goods in addition to prescription medicines. For these reasons, we estimate that the Medicare prescription drug benefit will have a positive revenue impact on the pharmacy industry overall.

We believe that the program's effect on small pharmacies specifically will also be positive. We expect that small pharmacies will participate in the networks of Medicare Part D plans and consequently will share in the positive revenue impacts. We believe that given the current industry practice of broad

[9] The 8.1 percent figure is computed by multiplying our estimate of drug spending for dual eligibles as a percent of NHE (9.1 percent) by our estimate of pharmacy reimbursement rates typical of private sector insurers (AWP—16 percent, or 84 percent of AWP) and dividing by our estimate of average Medicaid pharmacy reimbursement (AWP–5 percent, or 95 percent of AWP).

[10] The 1.1 percent decrease does not equal 9.1 percent –8.1 percent due to rounding.

pharmacy networks, together with the special any willing provider provision for pharmacies under Medicare Part D, all pharmacies that wish to participate in the program will be able to do so. As shown previously, over 95 percent of pharmacy firms are small businesses, and these firms operate about half of all retail pharmacies. The general practice of PBM companies is to build large networks that encompass both chains and independents in an area. According to a study by PricewaterhouseCoopers, the average PBM has 42,000 pharmacies in its network and the two largest PBM networks contain approximately 57,000 pharmacies, 98 percent of all pharmacies in the United States (PricewaterhouseCoopers report "Study of Pharmaceutical Benefit Management" at *http://www.cms.hhs.gov/researchers/reports/2001/cms.pdf*). Furthermore, a survey by the Pharmaceutical Care Management Association of five Medicare drug discount card programs found that on average the card program networks contained about 80 percent of pharmacies, with one of the five programs surveyed including nearly 95 percent of pharmacies. While broad pharmacy networks are typical of current industry practice, the MMA includes a special "any willing provider" provision that further promotes inclusiveness in pharmacy networks under the Medicare drug benefit. The MMA requires that a PDP or MA–PD must accept a pharmacy into its network if the pharmacy is willing to agree to contractual terms offered by the sponsor. This type of arrangement is not typical of standard industry practice, and was not required in the Medicare Drug Discount Card program. We believe that it helps ensure that all pharmacies that wish to do so have the ability to participate in the Medicare prescription drug benefit. Finally, according to the PricewaterhouseCoopers study, independent pharmacies also have the ability to participate in pharmacy networks through a Pharmacy Services Administrative Organization, which gives them group purchasing leverage and the ability to secure PBM reimbursement rates that are comparable to those attained by chains. For these reasons, we would expect the great majority of small business pharmacies to share in the increased business created by the Part D drug benefit.

Although we believe that the revenue effects on small pharmacies will be positive, we seek comments on this conclusion and on any aspect of this proposed rule that may adversely affect pharmacies of any size.

2. Insurers and Pharmacy Benefit Managers (PBMs)

This proposed rule sets forth the terms and conditions that must be met by firms to be approved to offer the Medicare prescription drug benefit. Organizations sponsoring the Medicare prescription drug benefit can be either stand alone Prescription Drug Plans (PDPs) or Medicare Advantage Prescription Drug Plans (MA–PDs). The requirements for Medicare Advantage are discussed in our separate proposed rule. That proposed rule includes an IRFA specific to the Medicare Advantage program. Consequently the discussion here will focus on PDP sponsors. As discussed previously in the preamble, in order to be approved to offer the Medicare prescription drug benefit as a PDP an entity must be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan, or have secured a time-limited Federal waiver. The SBA size standard for "small entity" health insurance firms is annual revenue of $6 million or less.

Our IRFA for the Medicare Advantage proposed rule includes an extensive discussion related to insurance firms that might potentially be eligible to be MA plans. That analysis is also applicable to insurance firms that might be interested in being a PDP. As noted for the MA market and equally applicable to the PDP market, essentially all of the insurance firms affected by the statute and our proposed rule exceed size standards for "small entities" within the meaning of the RFA and implementing SBA guidelines, which state that an insurance firm is "small" only if its revenues are below $6 million annually. Standalone drug insurance policies are not a typical product in the insurance market today. Thus, the range of insurance companies that may choose to enter this market is uncertain. However, we anticipate that a portion of the insurance firms that might be interested in being a PDP and thus affected by these proposed rules are "small entities" by virtue of their non-profit status.

PDP eligibility provisions in the MMA rely on the Medicare Advantage enrollment provision (continued unchanged from prior law) that no health insurance plan is normally eligible to participate unless it already serves at least 5,000 enrollees. Section 1860D–12(b)(3) of the Act provides that this minimum shall be waived during the first contract year in a region, since PDPs in the context of Part D are new entities. While there is also a 1,500 minimum standard enrollment for plans that predominantly serve rural populations, in the context of PDP services areas designed on a regional basis, we do not believe a predominantly rural situation would occur. Consequently, we have not considered this level of enrollment in our analysis. We welcome comment on this issue. At the 5,000-enrollee level, no insurance plan would fall below the SBA revenue cutoff assuming estimated average per enrollee revenue of approximately $1,675 in 2006, a revenue level similar to that of prescription drug plans under the standard Medicare Part D benefit. Therefore, the statutory limits generally prevent any insurance firm defined as "small" pursuant to the RFA's size standards from participating in the program. It is also important to note that PDPs will only operate on a regional basis. The MMA specifically states that there will be no fewer than 10 regions and no more than 50 regions, not including the territories. Thus, the statute itself envisions risk-bearing entities that are operating on a fairly large-scale basis.

In our IRFA for the Medicare Advantage program, we include a detailed analysis on regional Medicare Advantage market and small entities. That discussion is applicable to the PDP market, and therefore we are not repeating that same discussion here. That analysis also reviews the local Medicare Advantage market. As is noted in that analysis the option to be a local MA–PD plan provides opportunity for health insurance entities of all types and sizes (but probably not below the "small" insurance entity cutoff level defined by the SBA, which is lower than appears viable for a Part D risk-bearing insurance plan) to participate in offering the Medicare prescription drug benefit, albeit as part of a comprehensive benefit offered on a local basis. We point out that many HMOs are non-profit entities, as are several dozen Blue Cross and Blue Shield plans, and conclude that on balance Medicare Advantage provide favorable opportunities for them, although regional boundaries may pose problems for some. We note that a number of HMOs and other insurers including a number of Blue Cross plans are sponsoring Medicare-endorsed drug discount cards under that new program, which suggests their future ability to participate as PDP or MA–PD participants, regardless of profit status. While this proposed rule extends

certain requirements related to the provision of Part D benefits to Medicare Advantage plans (for example, network adequacy standards and any willing pharmacy provisions), we believe that these requirements will not result in consequential additional costs for MA–PD plans. We believe that any well-designed plan would already meet or readily be able to accommodate these standards. For example, we believe that competition among plans for enrollees will necessitate that they have a pharmacy network that is at least as broad as those stipulated by our network adequacy standards.

The other organizations that we think potentially may be interested in being PDP sponsors, or most certainly working closely with PDP and MA–PD sponsors to administer all or part of their drug programs, are pharmacy benefit managers (PBMs). PBMs are a relatively new player in the health care market. A major limitation on PBMs being PDP sponsors, however, is the statutory requirement for State licensure as a risk bearing entity, a status PBMs have not historically achieved. As discussed in section C (Federalism) of this Regulatory Impact Analysis, the MMA provides for a time-limited waiver to obtain State licensure, during which an organization can be approved by CMS to be a PDP sponsor. Since the Part D benefit is new, we do not currently have information on whether PBMs are considering becoming PDP sponsors, and would welcome comment regarding this issue.

There are basically two types of PBMs in the market today. Some are subsidiaries of health plans (that is, managed care organizations or insurance companies), and others are independent PBMs. PBMs have evolved over time in the nature of services they provide. In the late 1970s and early 1980s they offered claims processing services. In the late 1980s and early 1990s their services evolved to include pharmacy network design and management, formulary design and manufacturer rebate negotiations, mail order pharmacy services, drug utilization review, and enrollee services (for example, call centers). During the 1990s, PBMs generally expanded to become managers of a wide array of pharmacy services as plan sponsors sought to control drug costs. For example, some PBMs now also provide clinical services such as disease management, and physician and patient education.

Under the "carve-out" trend by which pharmacy benefits are administered separately from medical benefits in employer-sponsored insurance, PBMs are now believed to administer roughly half of all pharmacy benefits for employer health plans, and this share is rising rapidly. The primary reasons are analyzed in a 2003 General Accounting Office report ("Federal Employees Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies" available at *http://www.gao.gov*; see also the CMS study on PBMs cited above). These reports and others conclude that PBMs help insurance plans achieve significant savings in their drug coverage, for example, through use of discounts and rebates to lower prices, through drug utilization review, and through shifting sales from name brands to generics. Obviously, insurance plans can do these things for themselves, but most find that PBMs substantially improve their ability to achieve savings.

Because PBMs rely heavily on computerized systems to manage pharmacy records, they also provide safeguards against many kinds of medication errors through drug utilization review. Which services a PBM provides to a particular plan sponsor is negotiated between the PBM and the sponsor. Selection of a PBM (usually one, but sometimes two, one for mail order and one for retail) by plan sponsors is strongly influenced by the expected cost of drug benefits, with PBMs gaining a competitive advantage in contractual negotiations by offering lower average costs per prescription.

There are believed to be about one hundred PBM firms. Some are standalone companies, but most are subsidiaries of health insurance firms (for example, Wellpoint and Anthem) or owned by drug store chains (for example, Walgreens). Although a handful of particularly large firms account for most of the "covered lives" and industry revenue, the industry is regarded by analysts as highly competitive. We have no information on the size of the smaller firms in the industry, but it is likely that none of them, or at most a very small number, would fall below the $6 million annual revenue threshold used by the SBA for defining "small entities" in the insurance industry. (The smallest companies are in any event most likely to be subsidiaries or components of health insurance companies and other large firms). This is an industry in which there appear to be marked advantages to larger size, through both economies of scale and bargaining power. Nor do we believe that a substantial number, if any, are non-profit entities. We do, however, request additional information on the characteristics of this industry and its firms.

The MMA will expand PBM business in two ways. First, assuming that all or most PDPs and many MA–PDs will use PBMs, and that nearly all beneficiaries without drug coverage will enroll in a plan providing drug coverage, we anticipate that millions of beneficiaries will start purchasing their drugs using PBM-managed benefits. Second, all or most of those currently enrolled in plans that cover drug purchases on an indemnity basis (rather than through PBMs), and who sign up for PDP or MA–PD plans, will start using PBM services. This latter group includes most of the 1.9 million persons we estimate are currently enrolled in Medigap plans that offer drug coverage. Thus, drug insurance plans using PBMs are likely to enroll millions of new covered lives. Because these enrollees are on average much higher utilizers of drugs than most covered lives in the private sector, this will create positive and significant economic impact on the future volume of business for these firms.

Obviously, the scope, timing, and nature of additional PBM business will depend on the future decisions of PDP and MA–PD sponsors, and the PBMs themselves, and ultimately on the decisions of Medicare beneficiaries as they make choices among their various insurance options. Nothing in this rule directly regulates PBMs, positively or negatively, or directly encourages or discourages their use over alternative methods of managing drug benefits. Furthermore, there are many other influences on the role of PBMs and on the amount of drug spending that they manage. Chief among these is the continuing growth in spending on prescription drugs and the incentives this creates to control costs.

It is possible that decisions on regional boundaries (not part of this proposed rule) may affect the ability of some PBM firms to compete for PDP and MA–PD contracts, but we believe that most if not all PBMs that are not plan-specific will compete in broad regions or the entire nation. We welcome information on any possible problems that regional boundary decisions could create.

For all the reasons given above, we conclude that while the statutorily-created Part D and Medicare Advantage programs will be largely favorable to PBMs, this proposed rule as such will have little or no direct effect on the PBM industry, and certainly not a significantly adverse effect on a substantial number of small entity PBMs. However, we request comments on this conclusion and on any provisions that might adversely affect such firms.

3. Small Employers

In the case of the small employers, public and private, who provide qualified prescription drug coverage for their retirees, we estimate that savings obtained from the Medicare retiree drug subsidy will exceed by several-fold the employer's administrative costs associated with obtaining the subsidy, and thus the result of the retiree drug subsidy provision is a net positive impact. We would like to make participation in the retiree drug subsidy program as simple as possible for small entities. Accordingly, we request comments on any provisions of this proposed rule that may be particularly difficult for small entities, and on any alternatives that might lessen such burdens.

As noted earlier, we estimate that the administrative costs associated with obtaining the Medicare retiree drug subsidy (excluding data reporting costs, which are not yet quantifiable) will represent on average about 5.5 percent of the Medicare retiree drug subsidy payments in 2006 (declining in subsequent years after initial start-up costs), and that the bulk of these costs will be associated with preparing the actuarial valuation, retiree drug subsidy application, and related enrollment information. It is important to note that this estimate reflects an average across all employers. While administrative costs for small employers as a percent of retiree subsidy dollars are likely to be somewhat higher than the average, we believe that subsidy payments to small employers are still likely to exceed the administrative costs of obtaining the subsidy by more than several-fold. Although smaller employers will spread their administrative costs across fewer qualifying retirees for whom they will be receiving Medicare retiree drug subsidy payments than larger employers, they are expected to have lower costs associated with identifying their Medicare retirees and related enrollment information than large employers. Additionally, we expect that small employers that purchase retiree coverage from insurance companies are likely to have lower direct costs associated with the actuarial valuation due to the spreading of these costs across many employers that are purchasing the same insurance product. Alternatively, as discussed elsewhere in this document, employers (both small and large) may decide to restructure their prescription drug coverage to provide continued coverage by providing enhanced benefits or providing supplemental wraparound coverage, and thus will be positively impacted as a result of beneficiaries now receiving contributions to their drug coverage from Medicare.

We believe that affected small businesses are unlikely to experience increased revenues of the magnitude that would approach 3 to 5 percent of revenues due to the Medicare retiree drug subsidy payments. We arrive at this conclusion as follows. First, we estimate the number of covered lives per firm offering retiree coverage. To make this estimate, we use 2001 data from the Medical Expenditure Panel Survey (MEPS) on the number of establishments (by firm size), with retiree coverage for the over 65 population, and the number of retirees covered by these establishments. As a conservative approach, we assume two covered lives per retiree to estimate the number of covered lives in these establishments. This assumption overstates the number of covered lives as not all Medicare beneficiaries will be married, or are married to an individual who is also a Medicare beneficiary. Second, we convert the number of establishments offering age 65 and over retiree coverage to a firm based count using the ratio of the number of establishments to the number of firms, based on the U.S. Census Bureau's Statistics on U.S. Businesses for 2001 (*see http://www.census.gov/epcd/www/smallbus.htm#EmpSize*). Using this firm based count we then estimate the average number of age 65 and over covered lives per firm. For firms with fewer than 100 employees our estimated average number of 65 and older covered lives was 6.15; the corresponding figure for firms with a firm size of 100 to 999 employees was 44.7. Data for 2001 on the overall number of establishments, the overall estimated number of firms, the number of estimated firms with retiree coverage for retirees aged 65 and over, the number of covered retirees, and the estimated number of retirees and covered lives per firm, are shown in Table V–3.

As an extreme example, we assume the absolute maximum subsidy per person that an employer can receive in 2006 is $1,330 (that is, 28 percent of the difference between $250 and $5,000, and assuming no further adjustment related to netting out discounts, chargebacks or rebates). As discussed earlier, we estimated an average per capita Medicare retiree drug subsidy amount at $611 in 2006 (which, for example, would be equivalent to about $815 of taxable income for employers with a marginal tax rate of 25 percent and about $940 of taxable income for employers with a marginal tax rate of 35 percent). Using the $1,330 value, the retiree drug subsidy payments would be about $8,178 per firm with less than 100 employees and $59,456 for firms with 100 to 999 employees. These amounts almost certainly are overstated because they assume that every qualifying covered retiree would have annual allowable prescription drug costs of at least $5,000 in 2006, and that each firm would thus receive the maximum retiree drug subsidy payment for every covered individual, which is unlikely.

We compare these estimates with revenues for firms of these respective sizes. We trend forward 1997 revenue data by firm size, from the U.S. Census, to 2001 based on the annual change in the average Consumer Price Index (CPI). While revenues would likely grow at a faster rate than the CPI due to increases in the quantity of items and/or services sold, we take a conservative approach by only accounting for increases in prices from 1997 to 2001 via the annual changes in the average CPI. The most recent year that data on revenues are available is for 1997. We used U.S. Census Bureau data for 2001 for estimating the number of firms. The estimated per firm average revenues for 2001 are about $1.2 million for firms with a firm size of less than 100 employees and $28 million for firms with a firm size of 100 to 499 employees.

The Medicare retiree drug subsidy payments, therefore, represent only 0.7 percent of total revenues for firms with a firm size of less than 100 employees, and 0.2 percent for firms with a firm size of 100 to 999 employees. Because revenue data are not available for firms with 100 to 999 employees, we conservatively use the per-firm revenues for firms with a firm size of 100 to 499 employees to represent the per firm revenues for firms with a firm size of 100 to 999 employees. For further illustrative purposes, Table V–4 shows by different firm sizes the revenue impacts using the maximum assumption on retiree drug subsidy payments. Even for the smallest firms, the revenue impacts of the subsidy would be less than 2 percent. The table shows that, as the firm size increases, the percentage of the revenues accounted for by the subsidy decreases. We therefore conclude that this proposed rule will not have a significant economic impact on a substantial number of small employers. This conclusion applies equally to non-profit employers and small local government employers, though we do not have detailed data on these groups (had we the data, the comparison would have been on a cost rather than revenue basis, but the relationships of retirees to active

employees would have been similar.) Because of the likely interest in the Medicare retiree drug subsidy program, however, we present some additional background information related to the number of small entities that might potentially be eligible to receive the Medicare retiree drug subsidy payments.

To estimate the number of potentially eligible small businesses for RFA purposes, we need to determine the appropriate standards for identifying a small business. In general, the Small Business Administration (SBA) has size standards that define small businesses within a given industry based on either the average annual receipts (millions of dollars) or average employment (number of employees) of a firm ("Table of Size Standards Matched To North American Industry Classification System Codes, January 28, 2004," U.S. Small Business Administration, available at *http://www.sba.gov*). However, we did not have data available on retiree coverage among either establishments or firms by annual revenues, but these data are available by employee size. We used an alternative size standard for RFA purposes based on our consultation with the Office of Advocacy at the Small Business Administration (SBA). The alternative size standards are based on the number of the firm's employees, rather than the firm's annual revenues.

Because our data from the Medical Expenditure Panel Survey (MEPS) on the number of establishments providing retiree drug coverage are at the 2-digit North American Industry Classification System (NAICS) code level and the MEPS industry group level (which is based on rolling-up 2-digit NAICS codes), while the SBA size standards are at the 6-digit NAICS code level, we developed an approach for rolling up the size standards to the 2-digit NAICS code level. For the purpose of our analysis, we classified a business within a 2-digit NAICS code as small business based on the largest SBA employment size standard among all the six-digit NAICS codes that comprised that two-digit NAICS code. It is likely that this methodology overstates the number of small businesses because some large businesses are likely counted as small businesses. Our employee firm size standards ranged from 150 to 1,500 employees.[11]

We estimate the number of small businesses who offer retiree drug coverage based on an analysis of 2001 MEPS data. We mapped the 19 two-digit NAICS codes to nine MEPS industry groups. Where the MEPS industry group consisted of two or more two-digit NAICS codes, we defined a small business using the largest employee size standard among the two-digit NAICS codes that crosswalked to the MEPS industry code. However, for each of nine MEPS industry groups, the MEPS data do have the number of establishments offering retiree health insurance coverage by the number of employees in the firm. We estimate that in 2001, there were 399,751 establishments offering retiree coverage to their retirees age 65 and older. Of this total, 65,208 (not shown in Table V–3) were small businesses, based on the small business size standards (that is, 150 to 1,500 as noted earlier). These businesses represented 1.3 percent of all small establishments. These businesses also accounted for 16 percent of all establishments offering retiree coverage to their retirees that were age 65 and over.

While in the case of small businesses the number of establishments is very similar to our estimate of number of firms, this relationship is not the case for the largest firms; that is, those firms with more than 1,000 employees. As a result, from a firm perspective, we estimate that firms with less than 1,000 employees account for 93 percent of all firms offering coverage to retirees age 65 and over, but account for only 10 percent of all retirees with employer-sponsored coverage.

While we have data on the number of small employers who offer retiree coverage, by industry sector, we do not have data on the number of retirees covered by small employers by industry sector. The only analysis we are able to do is the distribution of age 65 and over retirees between large firms with 1,000 or more employees and firms with less than 1,000 employees that offer retiree health coverage to this population. Most covered retirees receive their drug coverage from large employers, both because these large employers are more likely to provide coverage, and large employers have a large number of retirees. According to data from MEPS, in 2001 the largest private sector firms (1,000 or more employees) covered 90 percent of all the retirees who had employer-sponsored retiree coverage, with only 10 percent of retirees being covered in firms of less than 1,000 employees.

As discussed previously, we expect that Medicare Part D will also positively impact those small employers that had provided retiree drug coverage prior to implementation of the Medicare prescription drug benefit but choose not to obtain the Medicare retiree drug subsidy payments. For example, some of these employers may choose to provide alternate forms of prescription drug coverage by either offering enhanced Medicare Part D benefits for their retirees or providing wraparound coverage. These employers would see reductions in their spending on retiree drug coverage, as the Medicare prescription drug benefit would partially offset their spending on drug coverage.

TABLE V–3.—ESTIMATED NUMBER OF COVERED RETIREES IN PRIVATE SECTOR ESTABLISHMENTS AND FIRMS, 2001

Firm size	Number of private sector establishments, 2001 *	Number of private sector firms, 2001 *	Ratio of number of establishments to number of firms	Number of private sector establishments that offer coverage to retirees aged 65 and over, 2001 **	Estimated number of private sector firms that offer coverage to retirees 65 and Over, 2001	Number of covered retirees aged 65 and over **, 2001	Estimated average number of retirees per private sector firm	Estimated number of covered lives, per private sector firm (assuming 2 covered lives per retiree)
Less 100 than employees	5,058,525	4,851,266	1.04	39,308	37,697	115,899	3.1	6.15
100 to 999 employees	418,085	93,876	4.45	29,438	6,610	147,745	22.4	44.70
1,000 or more employees	913,080	8,795	103.82	331,006	3,188	2,432,542	763.0	1,525.91

[11] We used the following alternative size standards for the purpose of this RFA: less than 150 employees (NAICS codes 42 and 44), less than 500 employees (NAICS codes 11, 23, 56, 71, 72, and 81), and less than 1,500 employees (NAICS codes 21, 22, 31, 48, 51, 52, 53, 54, 55, 61, and 62).

TABLE V–3.—ESTIMATED NUMBER OF COVERED RETIREES IN PRIVATE SECTOR ESTABLISHMENTS AND FIRMS, 2001—Continued

Firm size	Number of private sector establishments, 2001 *	Number of private sector firms, 2001 *	Ratio of number of establishments to number of firms	Number of private sector establishments that offer coverage to retirees aged 65 and over, 2001 **	Estimated number of private sector firms that offer coverage to retirees 65 and Over, 2001	Number of covered retirees aged 65 and over **, 2001	Estimated average number of retirees per private sector firm	Estimated number of covered lives, per private sector firm (assuming 2 covered lives per retiree)
Total	6,389,690	4,953,937	n/a	399,751	47,496	2,696,186	56.8	113.53

Sources: *U.S. Census Bureau, Statistics of U.S. Businesses, 2001, *http://www.census.gov/epcd/www/smallbus.htm#EmpSize.*
**Medical Expenditure Panel Survey (MEPS), 2001.

TABLE V–4.—ANALYSIS OF MEDICARE RETIREE DRUG SUBSIDY IMPACTS FOR DIFFERENT PRIVATE SECTOR FIRM SIZES

Firm size	Number of private sector firms, 2001	Total revenues, 2001 (in 000s)	Estimated per firm revenues, 2001	Estimated number of covered lives per firm	Maximum per person subsidy	Total estimated retiree drug subsidy amount	Estimated subsidy as percent of revenues (percent)
1 to 9 employees	3,716,934	$1,815,857,996	$488,535	6.15	$1,330	$8,178	1.7
10 to 19 employees	616,064	1,049,691,336	1,703,867	6.15	1,330	8,178	0.5
20 to 99 emmployees	518,258	2,781,101,533	5,366,249	6.15	1,330	8,178	0.2
100 to 499 employees	85,304	2,385,814,720	27,968,380	44.70	1,330	59,456	0.1

Sources: Number of Firms, Revenues: U.S. Census Bureau, Statistics of U.S. Businesses, *http://www.census.gov/epcd/www/smallbus.htm#EmpSize.*

4. Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory flexibility impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This rule will not affect small rural hospitals since the program will be directed at outpatient prescription drugs, not drugs provided during a hospital stay. Prescription drugs provided during hospital stays are covered under Medicare as part of Medicare payments to hospitals. Therefore, we are not providing an analysis.

5. Other Requirements in the Regulatory Flexibility Act

The RFA lists five general requirements for an IRFA and four categories of burden reducing alternatives to be considered. We know of no relevant Federal rules that duplicate, overlap, or conflict with the proposed rule (which in any event establishes a new program). The analysis above, taken together with the rest of this preamble, addresses all these general requirements.

We have not, however, addressed the various categories of burden reducing alternatives listed in the RFA as appropriate in IRFAs. These alternatives, such as an exemption from coverage of the rule for small entities, establishment of less onerous requirements for small entities, or use of performance rather than design standards, simply do not apply to a situation in which a program beneficial to entities both large and small is being created, and in which the regulations do not create economically "significant" burdens. Furthermore, the consumer choice-driven Medicare prescription drug benefit is overwhelmingly a "performance" system rewarding plans that operate at lower costs, provide better services as evaluated by enrollees and potential enrollees. For Part D benefits, CMS operates in a stewardship role, not as the promulgator of detailed design standards (except in a few areas, such as protections for enrollees). As to the retiree drug subsidy program, we likewise propose no detailed design standards, restricting our regulations to the minimum necessary to meet statutory requirements and to assure that benefits are actuarially qualified and payments to employers soundly administered. However, throughout the preamble we identify issues and options for attention by affected entities. We welcome comments on these and suggestions for additional steps we can take, consistent with the underlying statute, to minimize any unnecessary burdens on plans, pharmacies, employers, or other affected entities.

L. Accounting Statement

In accordance with the OMB A–4 circular on regulatory impact analyses, we have included an accounting statement in Table V–5. The Medicare prescription drug benefit and retiree drug subsidy represents a transfer of revenues from taxpayers to Medicare beneficiaries, States, and retiree plans sponsored by employers and unions. The table provides an estimate of the annualized amount of transfers from taxpayers to these entities over the five-year period from 2006–2010. For the purposes of the accounting statement, these estimates are shown separately with a 3 percent and 7 percent discount rate in 2001 dollars.

The table also indicates that there will be some "off-budget" administrative costs associated with the Medicare prescription drug benefit, specifically the costs associated with disclosure notices, coordination of benefits, and the Medicare retiree drug subsidy. Costs associated with these activities are discussed in the respective sections of this impact analysis.

The accounting statement also provides a summary of the effects of the proposed rule on State and local governments and small businesses, as

discussed in the relevant sections of the analysis.

TABLE V–5.—ACCOUNTING STATEMENT ANNUALIZED ESTIMATES FOR MEDICARE PRESCRIPTION DRUG BENEFIT AND RETIREE DRUG SUBSIDY, 2006–2010

(2001 dollars in billions)

	3 percent discount rate	7 percent discount rate
Transfers		
Monetized Transfers: "on budget":		
From Taxpayers to Beneficiaries, States, and Employers.	$45.9	$40.9
Administrative Costs: "off budget":		
Notice Requirement	$0.02	$0.02
Coordination of Benefits	Not quantifiable at this time	Not quantifiable at this time
Administrative Costs Incurred by Employers to Obtain the Medicare Retiree Drug Subsidy (Excluding Data Reporting Costs).	5.5 percent of subsidy in 2006 and declining in subsequent years.	5.5 percent of subsidy in 2006 and declining in subsequent years
Category	Effects	
Effect on State and Local Governments	Net positive effect on State and Local Governments: $1.9 billion (3 percent discount rate) and $1.7 billion (7 percent discount rate).	
Effect on small business	Small Pharmacies: Positive impact. Estimated economic impact is not expected to reach the threshold for significant (3 to 5 percent of revenues). Small PBMs: Impact favorable for PBM industry, and no significant adverse impact on a substantial number of small entities. Small Insurers: Impact favorable on insurance industry, and no significant adverse impact on a substantial number of small entities as defined by SBA. Small Employers: Positive impact. Estimated economic impact is not expected to reach the threshold for significant (3 to 5 percent of revenues).	

M. Alternatives Considered

1. Designation of Regions

The MMA requires that we establish between 10 to 50 PDP regions within the 50 States and District of Columbia and at least one PDP Region covering the territories. These regions will define PDP service areas. PDPs that provide service in a particular region must cover that region entirely. PDPs can submit bids to provide services in anywhere from one to all regions.

The MMA stipulates that, to the extent practicable, PDP regions must be consistent with MA regions. However, if we determine that access to Part D benefits would be improved by establishing PDP regions that are different than MA regions, we may do so. As discussed in the preamble, we anticipate designating PDP and MA regions before January 1, 2005. The designation of regions will be made after the market study required by the MMA and the opportunity for public discussion and comment on this study..

In designating PDP regions, our primary objective will be to ensure that all beneficiaries have reliable access to PDP plans at the lowest possible cost. The law requires that beneficiaries have a choice of enrolling in at least 2 qualifying plans, at least one of which is a PDP. If it is not possible to achieve that with PDP plans undertaking the standard level of risk, the law makes provision for limited risk PDPs, and in cases where that does not occur a fallback plan that is paid based on cost.

For several reasons, we believe it is beneficial to have several PDP plans operating in a region. Most importantly, more plans means greater beneficiary ability to obtain coverage that meets their needs and greater competitive pressure to provide high quality and low costs. We also believe that PDPs that assume some financial risk, as opposed to a fallback plan that is paid based on cost, are likely to negotiate larger price concessions for beneficiaries. In addition, more competition for enrollees between PDPs, as well as MA–PDs, is likely to generate higher quality service for beneficiaries.

Given the goal of providing beneficiary access to risk-bearing PDP plans in as many areas as possible, an important question is what type of regional configuration, or method of configuring regions, has the greatest likelihood of achieving this. One of the principal questions is whether regions should be comprised of the largest possible number (the 50 States, or a close approximation), or a smaller number of regions covering much larger geographic areas. Designating a smaller number of regions that cover large geographic areas might be desirable in the sense that areas that might be less likely to attract market interest could be grouped with other more sought after areas. Large regions might also offer PDPs a larger potential enrollee market that would provide more leverage in negotiating rebates and discounts with manufacturers. On the other hand, regions of too large a size could deter participation if there are concerns by PDPs about providing uniform benefits and bearing financial risk across large and possibly diverse health care markets. In addition, large regions may make it more difficult for small organizations to participate as PDPs, although there is nothing to preclude small organizations from forming joint ventures to participate.

We recognize that there are a number of other factors that would affect any decision on the designation of regions, including State licensure issues for insurers and size and capital requirements for plans, as well as other potential barriers to initial or subsequent market entry; the number of competitors that are likely to operate in an area; and the goal of initiating and sustaining competition. We seek public comment on the various factors that may influence potential PDP plans' participation decisions and on how we can design regions in such a way to best ensure access to PDP plans.

The experience of the Medicare drug discount card program may provide some preliminary information that has

relevance to the designation of regions and ensuring access to PDPs under the Medicare drug benefit. The MMA required that beneficiaries have a choice of at least 2 Medicare endorsed drug discount cards. Card sponsors were allowed to designate their own service area, which could be as small as one State. If any portion of a State was included in a card sponsor's service area, the entire State must be included.

In total, 73 drug discount card programs were originally approved by Medicare. Forty of these programs were national in scope, available in every State and the District of Columbia (with three of these cards also available in the territories), exceeding the MMA requirement of choice of at least two discount cards per State. While there were numerous national cards, we believe it is uncertain whether this level of market entry would occur in the context of the Medicare drug benefit since PDPs are required to assume some financial risk unlike Medicare-approved drug card programs. Furthermore, it is possible that some discount card sponsors that entered the Medicare market at the national level did so with the intention of gathering information and experience about Medicare beneficiaries' prescription drug expenditures to guide their decision making about what regions to focus on under the Medicare drug benefit.

The remaining Medicare-approved drug cards were regional or State cards being offered in 42 States, including the District of Columbia. There was one additional card serving exclusively the territories. There were 25 regional cards that entered an individual State, the smallest possible market area. The 7 remaining regional cards entered at least two States. Nine States had no regional discount cards: Massachusetts, Rhode Island and Vermont (contiguous States); Washington and Oregon (contiguous States); Arkansas and Mississippi (contiguous States) and Alaska and Hawaii. In addition, three of these States—Alaska, Mississippi, and Vermont—did not have Medicare Advantage drug card sponsors in operation. This might suggest that in the context of the Medicare drug benefit if regions were defined at the individual State level there could be a lack of PDP participation in some regions. However, we note that it is difficult to generalize from the experience of market entry in the Medicare drug discount card program to the Medicare drug benefit, and we note that PDP sponsors with national market interests can participate in multiple regions. The large number of national Medicare-approved discount cards may also have influenced market entry by potential regional card sponsors. If there are fewer national plans under the Medicare drug benefit, it is possible that more regional market entry might occur. However, the requirement that PDPs bear some financial risk, which is not the case with the Medicare-approved drug card program, may result in different market entry behavior at both the national and regional level.

Also noteworthy in considering the regional boundaries for the prescription drug benefit would be the number of risk bearing companies that entered the Medicare drug discount card market. There were 23 drug cards that were sponsored by insurance companies (21 of which are distinct companies). We counted Anthem and BlueCross BlueShield companies separately, due to the distinct drug card markets they serve, as well as their legal status as separate companies; but other insurance companies that were offering more than one national card were counted only once. There were 33 cards sponsored by PBMs (17 of which are distinct companies). While PBMs administer drug benefits, they historically have not been licensed as risk bearing entities although they are not precluded from doing so in the future. Thus, only 21 of the drug card sponsors were risk-bearing companies. Three of the 21 risk bearing insurance companies developed national drug cards, two others entered markets of either three or five States, and the remaining companies were sponsoring drug cards in single States.

Another issue to be considered in designating PDP regions is whether they should be the same as Medicare Advantage (MA) regions. The statute stipulates that to the extent practicable, PDP and MA regions should be the same. However, because of the nature of health plan markets for physician and provider services, as opposed to the kind of product that PDPs will be offering and the uncertainty related to configuring insurance pools for risk-based drug only products, we believe potentially it may not be feasible to have the same regional configurations for each of these programs. For example, as shown in the regional market entry for the Medicare drug discount card, there are States in which there are no entrants by regional based drug card programs, yet these are markets in which there are MA plans. Also, there were States in which there was market entry by regional card programs but in which no MA plans participate. This might suggest that different regions may be appropriate for PDPs and MA plans. However, as noted previously, it is uncertain the extent to which experience with market entry by Medicare-approved discount card sponsors foreshadows what might occur under the Medicare drug benefit. We welcome comments on issues that should be considered in determining whether or not PDP and MA regions should be the same.

As discussed in the Medicare Advantage proposed rule, we have conducted a preliminary market survey (through Research Triangle Institute) to inform the designation of PDP and MA regions. We are providing opportunity for public input during the course of that work.

2. Bid Level Negotiations

As mentioned previously, the FEHBP standard in 5 U.S.C. 8902(i) requires us to ascertain that a PDP's or MA-PD's bid "reasonably and equitably reflects the costs of benefits provided." In addition, we note that section 1860D–11(e)(2)(c) of the Act requires that the portion of the bid attributable to basic prescription drug coverage must "reasonably and equitably" reflect revenue requirements * * * for benefits provided under that plan, less the sum * * * of the actuarial value of reinsurance payments." Analogous to the manner in which FEHBP views its management responsibilities, we see this requirement as imposing the fiduciary responsibility to evaluate the appropriateness of the overall bid amount.

In general, we expect to evaluate the reasonableness of bids submitted by at-risk plans by means of the actuarial valuation analysis. This would require evaluating the plan's assumptions regarding the expected distribution of costs, including average utilization and cost by drug coverage tier, for example, in the case of standard coverage—(1) those with no claims; (2) those with claims up to deductible; (3) those with claims between the deductible and the initial coverage limit; (4) those with claims between the initial coverage limit and the catastrophic limit; and (5) those with claims in excess of the catastrophic limit. We could test these assumptions for reasonableness through actuarial analysis and comparison to industry standards and other comparable bids. Bid negotiation could take the form of negotiating changes upward or downward in the utilization and cost per script assumptions underlying the bid's actuarial basis.

As discussed in greater detail in the preamble, we considered the circumstances and manner under which we would need to use our authority to carry out bid level negotiations. We anticipate that market forces will generally lead to efficient and

appropriate bid prices. In areas where there is competition for enrollees among a number of PDPs and MA-PDs that are at-risk for the provision of Part D drug coverage to beneficiaries, our strong expectation is that we will be able to rely on the incentives provided by competitive bidding, and we would use our authority for bid level negotiations only on the rare occasion we find that a plan's data differs significantly from its peers without any indication as to the factors accounting for this result. If there are any Regions with minimal competition (for example, just two Part D plans) or less financial risk (for example, just limited risk PDPs), we anticipate that it is possible that bid-level negotiations might be slightly more common.

A second issue we considered is to what extent we could negotiate aggregate bid prices with fallback plans. As mentioned elsewhere in the preamble, similar to at-risk and limited-risk plans, we will evaluate whether a fallback plan bid is reasonably justified, and if the price reference points appear too high or low, we may request an explanation of the bidder's pricing structure and the nature of their arrangements with manufacturers. We would also ensure that there is no conflict of interest leading to higher bids.

In addition, since fallback plans are paid on a cost basis, there is significantly less incentive for them to negotiate lower drug prices and take other steps to reduce drug expenditures. Consequently, we also considered options through the contracting process to provide fallback plans with some incentives to control cost. We are proposing to tie fallback plan performance payments to the plan's ability to keep drug costs below a certain level. We believe that this carries out Congress' requirement under 1860D–11(g)(5)(B)(i) of the Act that payments to fallback plans take into account the plan's ability to contain costs through mechanisms such as generic substitution or price discounts. Under this approach, we might include performance incentives similar to those used in many pharmacy benefit management contracts today, such as the plan achieving certain targets such as an average discount (including manufacturer discounts) off of AWP (or other pricing reference points chosen by CMS), average cost per script, average generic substitution rate, average dispensing fee per script, or average administrative fee per script. However, because these incentives would apply only to fallback plan performance fees, they would not provide as strong incentives for drug cost control as the incentives faced by risk-bearing plans to keep overall costs down.

3. Coordination of Benefits

The MMA requires that beneficiaries' incurred costs be tracked to determine when a Medicare beneficiary enrolled in Part D is eligible for catastrophic coverage. The MMA provides that with respect to out-of-pocket expenditures: "such costs shall be treated as incurred only if they are paid by the part D eligible individual (or by another person, such as a family member, on behalf of the individual), under section 1860D–14, or under a State Pharmaceutical Assistance Program and the part D eligible individual (or other person) is not reimbursed through insurance or otherwise, a group health plan or other third party arrangement (other than under such section or such a Program) for such costs." This means that beneficiary prescription drug expenditures covered by supplemental insurers (other than SPAPs) are not considered incurred costs that count toward the true out-of-pocket cost limit (TrOOP) that triggers catastrophic coverage. Consequently, the MMA requires coordination between Part D plans and other insurers with respect to payment of claims for any prescription drug coverage that is supplemental to Medicare Part D coverage. This will necessitate that an efficient and effective operational framework be established to track beneficiary out-of-pocket expenditures. Elsewhere, the preamble of this rule discusses and seeks comment on a number of options that could be considered for developing such a framework.

There are a number of issues to be considered. One of the principal issues is what entity or entities should be responsible for creating any infrastructure needed to track TrOOP incurred costs. Should it be the responsibility of PDPs and MA–PDs or should the government be responsible for developing a system that can collect and distribute information on costs reimbursed by all payors in order to facilitate accurate calculation of TrOOP? If the government took responsibility for developing such a system, there is the additional question of whether that system should operate in such a way that pharmacies query the system or that the system provides information to Part D plans which in turn provide information to pharmacies. Another issue is whether reporting of information by supplemental insurers to a coordination of benefits system should be mandatory or voluntary. We are also considering whether or not we should mandate that Part D plans collect information related to coordination of benefits under the Part D program, and whether or not we should mandate that beneficiaries enrolling in Part D provide third party payment information as part of their enrollment application (which might be validated through a HIPAA compliant beneficiary release of information).

In considering these various options, we believe there are a number of issues to be considered. One is the extent to which the various alternatives would advance the goal of accurately tracking beneficiary out-of-pocket expenditures. Another is the cost-effectiveness and efficiency of various options under consideration. We also think it is important to consider the cost that any coordination of benefits approach may place on various entities and the degree to which the burden is shared. We seek public comment on all of the coordination of benefits options and issues under consideration.

4. Charitable Assistance and TrOOP

We also consider the issue of whether beneficiary cost-sharing for Medicare Part D enrollees paid for by charities should be considered incurred costs that count toward the true out-of-pocket threshold (TrOOP) that triggers Medicare Part D comprehensive coverage. The MMA States with regard to out-of-pocket expenditures: "such costs shall be treated as incurred only if they are paid by the part D eligible individual (or by another person, such as a family member, on behalf of the individual), under section 1860D–14, or under a State Pharmaceutical Assistance Program and the part D eligible individual (or other person) is not reimbursed through insurance or otherwise, a group health plan or other third party arrangement (other than under such section or such a Program) for such costs." This raises the question of how cost-sharing paid for by private charities relates to the true-out-of-pocket threshold.

We believe that the statute provides discretion in terms of whether a charity's payment of a Part D enrollee's cost-sharing should be considered incurred costs that count toward the TrOOP. Many laws define "person" to include corporate entities or organizations. Since private charities tend to be corporate entities or organizations that likely do not fall into the categories of "insurance or otherwise, group health plan, or other third party arrangement," we believe there is statutory discretion to count a charity as "another person" for purposes of the TrOOP calculation.

We have proposed in this rule that payment of Part D cost-sharing by a charity should be considered incurred costs that count toward the TrOOP, provided that charitable organization does not meet the definition of "insurance or otherwise, group health plan, or other third party arrangement," as outlined in the preamble. By allowing charitable payment of Part D cost-sharing to count toward the TrOOP, we believe this will help beneficiaries who are most in need of financial assistance in affording prescription drugs. While this decision to allow charitable dollars to count toward TrOOP would increase Medicare program expenditures slightly by allowing more beneficiaries to qualify for catastrophic coverage, we would expect the additional Medicare costs to be quite small. The number of people helped by charity organizations will likely be rather modest and the impact on Medicare costs would be only for the subset of these people with catastrophic expenses. Given the very small effect on Medicare program spending and that many beneficiaries will have incomes or assets that exceed the criteria for the low-income subsidy, we feel that promoting the maintenance of charitable assistance to beneficiaries by counting charitable payments of beneficiary cost-sharing toward the TrOOP is important.

5. Actuarial Equivalence of Retiree Drug Subsidy and Interactions With Other Means of Enhancing Retiree Drug Coverage

As mentioned previously, the MMA provides the Secretary with the authority to determine the standards and methods for actuarial equivalence. In considering the issues related to actuarial equivalence we have been very cognizant that the Congress has clearly and repeatedly articulated four key policy objectives for the Medicare retiree drug subsidy program and for securing and enhancing retiree drug coverage more generally. The first goal involves maximizing the number of retirees retaining employer-based drug coverage, primarily through the retiree drug subsidy program created by Section 1860D–22 of the Act but also through the other means of assuring high-quality retiree drug coverage that are provided by the Act (including, as described above, employer wraparound coverage and employer support for enhanced Part D plans). The second goal entails not creating windfalls, where retirees might receive a smaller subsidy from sponsors of their retiree drug plans than Medicare would pay on their behalf. The third goal is to minimize the administrative burdens on beneficiaries, employers, and unions. The final goal is to minimize costs to the government of providing retiree drug subsidies (and not exceed the budget estimates). While the first, third and fourth goals received extensive discussion during the creation of the MMA, the second goal has also emerged in response to the possibility that the MMA might create the potential for an unintended windfall.

As discussed previously in the preamble, our consideration of various alternatives reflects the four objectives of maximizing the number of beneficiaries who receive high-quality retiree drug coverage, avoiding windfalls, minimizing administrative burden, and not exceeding budget estimates. The MMA provisions creating Part D provide multiple options for plan sponsors, ranging from participating in the retiree drug subsidy to various mechanisms for enrolling retirees in Part D prescription drug plans while offering enhanced benefits. Our goal is not only to protect but also to enhance coverage offered retirees. As discussed elsewhere in this document, prior to enactment of the MMA, employers have been systematically restricting drug coverage for future retirees. Taken together, these legal and behavioral factors introduce substantial uncertainty about how plan sponsors will assess their options and react to the new Part D benefit.

We believe the Secretary has authority to achieve these goals. One key element of this authority is the requirements that plans qualifying for the retiree drug subsidy must offer at least actuarially equivalent benefits to those offered by standard Part D prescription drug plans (PDPs). We seek comments on how best to use the Secretary's statutory authority in setting the specific actuarial equivalence requirements to qualify for the retiree drug subsidy, recognizing any tradeoffs and interactions among our key goals and that our implementation of this definition must be consistent with the statutory authority provided the Secretary. As discussed previously in the preamble, there is a range of aspects of the actuarial equivalence definition, each of which may have an impact on achieving the key objectives.

a. Alternative 1: Gross Value Test

One possible definition would stipulate that plans must meet the same test as for "creditable coverage." The test for creditable coverage requires that the total or "gross" value of the benefit package offered by the employer at least equal that of the standard Part D benefit offered by PDPs, without regard to the financing of this benefit package. More specifically, under this approach the sponsor of a retiree prescription drug plan would be eligible for a subsidy if the expected amount of paid claims under the retiree prescription drug plan is at least equal to the expected amount of paid claims under standard Medicare Part D prescription drug coverage.

However, this "single prong" approach to defining actuarial equivalence could not by itself preclude the existence of windfalls. This is because, without considering financing, an employer theoretically could impose as much as the full cost of the benefit package on the employee through employee premiums, and still be eligible for a subsidy payment if the package the employee was buying met the actuarial equivalence test. That is, the employer could contribute a smaller amount toward the financing of the package than it would receive in a subsidy payment. We seek comments on whether additional steps associated with this approach could preclude windfalls. In particular, some observers have argued that the forces in a competitive labor market, collectively bargained contracts, and constraints on changing state, local and other public sector retiree health plans obviate the likelihood of windfalls. We have serious reservations about the adequacy of such forces in precluding the existence of any windfalls without significant additional administrative monitoring by Medicare or others to assure that benefit subsidy payments are passed on to augment benefits received by retirees. Such approaches may create excessive administrative burdens on retirees, employers, and unions, and thus alternative approaches to precluding windfalls are likely to be preferable.

b. Alternative 2: Gross Value Test With Subsidy Not To Exceed Plan Sponsor Contribution

Another possible policy option would combine the gross value test with a requirement that the amount of the retiree drug subsidy could not exceed the amount paid by plan sponsors on behalf their retirees. This approach would assure the elimination of windfalls: The subsidy provided by the employer or union to the retiree's drug coverage would have to exceed the Medicare subsidy payment to the employer or union. While this approach is simple both to describe and operationalize, we have questions about the adequacy of the legal basis underpinning such a policy.

c. Alternative 3: Two-Prong Actuarial Equivalence

A third approach, which could be implemented in a variety of ways, would establish a "two-prong" test of actuarial equivalence: The "gross" test assures the total value of benefits, and the "net" test reflects only the value of benefits not financed by beneficiaries. This third approach is also structured to preclude windfalls.

Under this approach, in order to qualify for the subsidy a sponsor's plan would have to meet both prongs of the actuarial equivalence standard. The first prong would again be a test based strictly on plan design, as described in more detail previously. The second prong would be a "net value" test in which the gross value of the plan design would be reduced to account for the level of benefits financed solely by the beneficiary. For instance, the net value of the coverage could be calculated by subtracting the retiree premium from the expected amount of paid claims under the retiree drug program.

The "net" prong of the two-prong test of actuarial equivalence has several variants. While each variant of the two-prong test precludes windfalls, each presents a different balance among potentially competing objectives. At a minimum, we believe as a policy matter that the net value of the creditable coverage should at least equal the per capita amount that Medicare would expect to pay as the retiree drug subsidy. As noted above, using MCBS data, we roughly estimate this value at $611 in 2006, though we acknowledge that other data sources may produce other estimates. While there may be policy advantages to this approach, we have questions about the adequacy of the legal basis underpinning such a policy. We specifically invite comment on the question of whether the language could reasonably be interpreted to support this approach.

Alternatively, a higher threshold might be required, though as the threshold is raised, it would be more difficult for retiree plans to qualify that do not provide windfalls and that offer coverage that is at least as generous in overall actuarial value as the Medicare subsidy. Two other benchmarks are conceptually possible as alternative values for the net test. These two conceptually possible values would be tied either to a specified fraction of the expected value of the Medicare payment to standard Part D PDPs for retirees with enhanced coverage or to the value of the $611 retiree drug subsidy after taking taxes into account.[12] Determining the appropriate amount for the threshold value poses a significant data problem because of the heterogeneity of the plan sponsors. For example, we estimate that at least 60 percent of retirees that are age 65 and older receive retiree health benefits from entities that are exempt from taxation (including both public and nonprofit entities, based on data from the 2001 Medical Expenditure Panel Survey); for those plan sponsors subject to taxation, their rates of taxation vary markedly. In addition, as mentioned above, we have questions about the adequacy of the legal basis underpinning this approach.

Similarly, the value of benefits offered by plans providing creditable coverage varies widely, ranging from being only marginally more generous than standard Part D benefits to being extremely generous. (Some retiree plans provide less generous coverage, but as noted previously, they would not be creditable for purposes of the subsidy.) As a result, it could be challenging to calculate appropriate reinsurance payments and equitably operationalize the subsidies for these plans.

As noted above, adopting a two-prong test with the higher value for the net test could arguably provide greater protection to beneficiaries but might drive more sponsors out of participating in the retiree drug subsidy and toward using the Part D-based options for supporting and enhancing drug coverage Conversely, adopting a lower value for the net test might qualify more plan sponsors to participate in the retiree drug subsidy, but it might also discourage some employers and unions from increasing their contributions to reach the higher threshold level, and thereby increasing generosity of coverage.

Finally, the employer's decision about using the retiree subsidy versus continuing to provide enhanced retiree coverage through other means (offering supplemental drug coverage that wraps around Part D, qualifying directly for the Part D subsidy as a Part D enhanced plan, and/or paying the additional costs on top of the Medicare Part D subsidy for enhanced benefits in PDPs or in MA plans) depends on the attractiveness of each of these options. We note that none of these alternatives permit employer windfalls. We intend for these additional approaches to providing generous retiree coverage to be attractive to employers who may not make sufficient contributions or provide sufficiently generous coverage on their own to qualify for the retiree drug subsidy. This combination of approaches will maximize the number of beneficiaries who receive additional drug coverage as a result of adding together Medicare contributions and contributions from employers and unions.

Public comment would help limit uncertainty by clarifying the likely responses of plan sponsors to these different approaches. In addition, we solicit comments not just on desirability of the different options, but as noted above on the legal bases for possible options, and on the impact of the combination of approaches on increasing the overall generosity of drug coverage available to retirees.

6. Payment Methodology—Method and Frequency of Medicare Retiree Drug Subsidy Payments

We believe that the MMA gives us broad discretion to determine the methodology for distributing the Medicare retiree drug subsidy payments. We wish to develop a payment methodology that is least burdensome to employers, technologically feasible, and cost-efficient. Additionally, our payment methodology must accommodate the exclusion of rebates from retiree drug subsidy payments.

As discussed earlier in the preamble, we are considering four potential approaches for making Medicare retiree drug subsidy payments. The first alternative that we are considering is our proposed approach, which combines monthly payments based on actual experience with monthly adjustments for price concessions as they are received. We are also considering three potential alternatives to our proposed approach: annual retroactive retiree drug subsidy payments, interim payments throughout the year with a settlement after the end of the plan or calendar year, and lagged payments based on actual experience on a periodic basis throughout the year with a settlement after the end of the year. We discuss the pros and cons of these four alternatives further below.

a. Alternative 1: Monthly Retiree Drug Subsidy Payments Based on Actual Experience With Monthly Adjustments for Price Concessions

Under the first alternative, CMS would make monthly Medicare retiree drug subsidy payments to employers based on actual claims experience throughout the year, with monthly adjustments for price concessions as

[12] There is special tax treatment available for the retiree drug subsidy. Plan sponsors get to deduct all the associated expenses but the value of the subsidy payments is not recognized as income.

they are received, along with any adjustments to actual expenditures for prior months, and a final reconciliation no later than 45 days after the end of the calendar year (excluding outstanding rebates and discounts).

Specifically, by the 15th day of each month, each qualified plan sponsor would submit information to CMS certifying the total amount by which actual retiree-beneficiary gross drug spending (based on actual claims experience) exceeded the cost threshold yet remained below the cost limit for the preceding month, and Medicare would pay 28 percent of the certified amount to the sponsor by the 30th of that month. As part of their monthly data submission to CMS, plan sponsors would also apply the appropriate share of any discounts, rebates, or other price concessions, along with any adjustments to the actual expenditures for prior months. Any amounts owed to the government would offset the retiree drug subsidy payment for that month, and to the extent that the amount owed to the government exceeds any applicable monthly payment, the plan sponsor would pay that amount to CMS. No later than 45 days after the end of the calendar year, the plan sponsor would submit a final reconciliation to CMS for payment by or, if applicable, to CMS (excluding any outstanding rebates and discounts, which may not be received until after the close of the their plan year). Plan sponsors or plan administrators would be required to maintain detailed records of claims payment and other matters.

While this alternative is arguably the most data intensive of the four alternatives that we are considering here, we believe that it is the most straightforward option, minimizing reliance on projections and actuarial representations. This option would also facilitate ensuring that sponsors receive expeditious payment of the full retiree drug subsidy amounts to which they are entitled. As discussed previously, we are considering and seek comment on whether to require a surety bond type of instrument or preferred creditor status in order to address situations related to businesses that may terminate or experience bankruptcy prior to completion of a final reconciliation.

b. Alternative 2: Annual Retroactive Retiree Drug Subsidy Payments

Under the second alternative, CMS would make an annual retroactive Medicare retiree drug subsidy payment to each employer after the end of the year. By the beginning of the fourth month after the end of the year, each employer would submit information to CMS on the number of months of coverage for each qualifying covered retiree and their gross and allowable costs. These costs would be based on data derived directly from claims payments and retiree cost-sharing for prescriptions dispensed during the year and discounts, chargebacks and rebates for that year. CMS would review this submission and make a payment for the year by the end of the following month. This alternative would be the simplest to administer of the four alternatives considered here and would obviate the need for interaction between CMS and employers other than during the review process. From the perspective of employers, however, this alternative may be problematic since payment would not be received until after the end of the year.

c. Alternative 3: Interim Retiree Drug Subsidy Payments With Year End Settlement

Under the third alternative, CMS would make interim payments throughout the year with a settlement after the end of the year. Employers that sponsor qualified retiree plans would estimate the per capita Medicare retiree drug subsidy payments they would expect to receive, based on historical data on prescription drug claims for their qualifying covered retirees, along with rebates or discounts that the employer has received from drug manufacturers. Employers would submit their estimated per capita retiree drug subsidy payment and any supporting documentation to CMS at the same time that they submit their attestation of their qualified retiree prescription drug plan's actuarial equivalence to standard Medicare Part D coverage. CMS would review each employer's estimate and related documentation, and would determine an interim monthly per capita amount.

In order to minimize the possibility of having to recoup large amounts of money at the time of settlement, CMS would pay each plan sponsor a percentage of this interim monthly per capita amount on a periodic basis for each of their qualifying covered retirees. We are proposing under this alternative to pay 70 percent of the interim monthly per capita amount in 2006 and 2007, given the significant uncertainty that will exist in estimating Medicare retiree drug subsidy payments. This alternative is more administratively complex than the second alternative because it entails calculating an interim payment amount for each employer; making periodic payments during the year; and conducting a settlement with each employer after the end of the year with actual claims data. It would, however, provide Medicare retiree drug subsidy payments to employers during the year, which could be beneficial to employers from a cash flow perspective.

d. Alternative 4: Lagged Interim Retiree Drug Subsidy Payments

Under the fourth alternative, CMS would make lagged Medicare retiree drug subsidy payments to employers based on actual claims experience, on a periodic basis throughout the year, with a settlement after the end of the year that would be limited to reconciling estimated versus actual discounts, chargebacks, and rebates. By the 15th day of the month after the end of the payment period, each qualified employer would submit information to CMS on gross and allowable costs for the previous payment period for each of their qualifying covered retirees whose gross costs to date exceeded the cost threshold, but did not exceed the cost limit. Employers would base the cost data that they submit to CMS on their actual claims experience, adjusted on a percentage basis for estimated discounts, chargebacks and rebates (each employer would also submit a justification for the percentage used).

By the 15th of the following month, CMS would review the submission and make a Medicare retiree drug subsidy payment to the employer. By the beginning of the fourth month after the close of the year, the employer would submit documentation on actual discounts, chargebacks and rebates that were received for the plan, with a comparison to the estimated discounts, chargebacks and rebates that were used in calculating the payments. We would correct any underpayment or overpayment by adjusting the employer's subsequent periodic payments.

Similar to the first, this fourth alternative is more administratively complex than the second and third alternatives considered here, but as with the first alternative it would provide employers with a payment stream that comes closer to subsidizing their actual plan expenditures as they occur. However in contrast to the first alternative, it relies on projected amounts related to retrospective discounts, chargebacks, and rebates, with a reconciliation process, and thus does not come as close as the first alternative to ensuring that sponsors receive expeditious payment of the full retiree drug subsidy amounts to which they are entitled. Compared with the first and third alternatives, this fourth alternative would reduce somewhat the risk to the government and employers

that substantial overpayments or underpayments would need to be redeemed.

e. Frequency of Retiree Drug Subsidy Payments

If an interim payment process is chosen, then there would be the additional question of the frequency of the Medicare retiree drug subsidy payments. One could envision a system of bi-annual, quarterly or monthly payments under either of these alternatives. The advantage of making more frequent retiree drug subsidy payments is that it would provide a more even cash flow for employers. On the other hand, a disadvantage of more frequent payments may be increased administrative costs for both CMS and employers. This may particularly be the case for the first and fourth alternatives, which would require employers to submit actual cost data to CMS following the end of each payment period in order to receive the retiree drug subsidy payments.

We are also considering a variable payment alternative in which the frequency of payment would vary in accordance with the size of the employer's plan. Under this scenario, employers with 10,000 or more qualifying covered retirees would receive monthly Medicare retiree drug subsidy payments while employers with fewer than 10,000 qualifying covered retirees would receive quarterly payments, and very small employers could choose to minimize their reporting burden by receiving payments on an annual basis. This alternative would enable employers that have very large numbers of qualifying covered retirees, for whom the Medicare retiree drug subsidy payments would potentially represent a large amount of money, to receive their periodic subsidy payments on a more frequent basis. Making more frequent Medicare retiree drug subsidy payments to employers that provide drug coverage to large numbers of qualifying covered retirees would balance the administrative workload considerations that are associated with more frequent payments with the desire to assist these employers by matching the distribution of their Medicare retiree drug subsidy payments more closely with the timeframe during which the related expenses were incurred. However, we are concerned that this alternative may be too administratively complex for CMS to implement. We are also seeking comment on whether to use more than one of the payment alternatives described above, while determining which payment method would apply based on the size of the sponsor's plan (for example, in order to minimize administrative burden on small businesses, sponsors with fewer than 100 qualifying covered retirees could receive an annual retroactive payment, while sponsors with larger plans could have access to one of the other payment alternatives).

7. Data Collection—Aggregate vs. Individual Level

Qualified retiree prescription drug plan sponsors (or the plan administrators that have been designated by the sponsors) will need to submit cost data relating to their qualifying covered retirees so that CMS will be able to accurately calculate each sponsor's Medicare retiree drug subsidy payment. As discussed earlier, in addition to certain beneficiary identifying and eligibility information, each plan sponsor (or plan administrator that has been designated by the sponsor) will be required to submit cost data for each of their qualifying covered retirees (including information about the period of time when these costs was incurred). We are considering three alternatives relating to the level of detail of this cost data: (1) Submission of aggregate allowable costs data, (2) submission of beneficiary-level total allowable costs data, and (3) submission of actual claims data. We discuss these three alternatives further below.

a. Alternative 1: Submission of Aggregate Level Cost Data

Under this alternative, CMS would require the plan sponsor (or the plan administrator designated by the sponsor) to submit the aggregate total of all allowable drug costs for all of the qualifying covered retirees that were enrolled in the plan during the time period in question. These costs would represent the allowable costs incurred between the cost threshold and cost limit for each qualifying covered retiree, with a reduction for the anticipated rebates and discounts (which would be calculated based upon historical data).

Under this alternative, the plan sponsors would not submit separate cost data for each qualifying covered retiree. However, each plan sponsor (or their administrator) would have to maintain the individual-level claims data that support its submission for audit purposes. While this alternative would probably be easier for the sponsors and would be the most protective of the individual's privacy, it may be the most problematic in terms of accurately calculating the Medicare retiree drug subsidy payments.

b. Alternative 2: Submission of Beneficiary Level Cost Data

Under this alternative, the plan sponsor (or its plan administrator) would submit the total allowable costs for each individual qualifying covered retiree during the time period in question. This alternative would be more complex for the sponsor and would raise some privacy questions, but it would be more reliable in terms of calculating the Medicare retiree drug subsidy payments.

c. Alternative 3: Submission of Actual Claims Data

Under this third alternative, each plan sponsor (or its plan administrator) would submit the actual claims data for each qualifying covered retiree during the time period in question. However, this alternative would be the most complex in terms of calculating the Medicare retiree drug subsidy payments and would be the most problematic in terms of privacy concerns. Accordingly, we have ruled out this alternative.

N. Conclusion

We estimate that about 41 million Medicare beneficiaries will receive drug coverage either through a Medicare Part D plan (that is, by enrolling in a PDP or a MA-PD) or through an employer or union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy in calendar year (CY) 2006. By CY 2010, due to growth in the overall Medicare population, we estimate that nearly 45 million Medicare beneficiaries will be receiving such coverage. The net Federal budgetary effect of the Medicare prescription drug benefit and retiree drug subsidy is estimated to be about $287 billion during CY 2006–2010. Medicare Part D is estimated to generate about $8.2 billion in net savings for States over the five-year period from 2006–2010.

All Medicare beneficiaries will have access to a benefit that protects against catastrophic drug costs. On average, for non-low-income beneficiaries the benefit will cover approximately half their costs, and for beneficiaries with very high drug costs it covers substantially more. For low-income beneficiaries coverage is comprehensive covering on average about 95 percent of their prescription drug costs.

Medicare beneficiaries who have no drug coverage today will now be able to obtain an affordable benefit that provides substantial assistance with prescription drug costs. Those beneficiaries with existing private coverage through retirement benefits and Medicare Advantage plans will

receive the benefits of new Medicare subsidies to maintain and enhance their coverage. Beneficiaries with public coverage through Medicaid and State programs will have more secure (and potentially more generous) benefits because of the comprehensive low-income Medicare benefit. Beneficiaries who pay the full costs for limited Medigap drug coverage will now be able to obtain highly-subsidized, more generous coverage.

Overall, we anticipate that by giving beneficiaries access to affordable insurance coverage that helps them to pay for their outpatient prescription drugs—which have become a critical component in the delivery of comprehensive, quality health care services—the Medicare prescription drug benefit will help beneficiaries to lead healthier, more productive lives.

List of Subjects

42 CFR Part 403

Grant programs—health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements

42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professions, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements

For reasons set forth in the preamble in this proposed regulation, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as follows:

PART 403—SPECIAL PROGRAMS AND PROJECTS

1. The authority citation for part 403 continues to read as follows:

Authority: 42.U.S.C. 1359b-3 and secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Medicare Supplemental Policies

2. Section 403.205 is revised to read as follows:

§ 403.205 Medicare supplemental policy.

(a) Except as specified in paragraph (e) of this section, Medicare supplemental (or Medigap) policy means a health insurance policy or other health benefit plan that—

(1) A private entity offers to a Medicare beneficiary; and

(2) Is primarily designed, or is advertised, marketed, or otherwise purported to provide payment for expenses incurred for services and items that are not reimbursed under the Medicare program because of deductibles, coinsurance, or other limitations under Medicare.

(b) The term policy includes both policy form and policy as specified in paragraphs (b)(1) and (b)(2) of this section.

(1) *Policy form.* Policy form is the form of health insurance contract that is approved by and on file with the State agency for the regulation of insurance.

(2) *Policy.* Policy is the contract'

(i) Issued under the policy form; and

(ii) Held by the policy holder.

(c) Medicare supplemental policy includes—

(1) An individual policy;

(2) A group policy;

(3) A rider attached to an individual or group policy; or

(4) As of January 1, 2006, a stand-alone limited health benefit plan or policy that supplements Medicare benefits and is sold primarily to Medicare beneficiaries or that otherwise meets the definition of a Medicare supplemental policy as defined in this section.

(d) Any rider attached to a Medicare supplemental policy becomes an integral part of the basic policy.

(e) Medicare supplemental policy does not include a Medicare Advantage plan, a Prescription Drug plan under Part D, or any of the other types of health insurance policies or health benefit plans that are excluded from the definition of a Medicare supplemental policy in section 1882(g)(1) of the Act.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

3. The authority citation for part 411 is revised to read as follows:

Authority: Secs.1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

Subpart J—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services

4. In § 411.351, the definition of "Outpatient prescription drugs" is revised to read as follows:

* * * * *

§ 411.351 Definitions

* * * * *

Outpatient prescription drugs means all drugs covered by Medicare Part B and Part D.

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

5. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

6. In § 417.440, add paragraph (b)(1)(iii) to read as follows:

§ 417.440 Entitlement to health care services from an HMO or CMP.

* * * * *

(b) * * *

(1) * * *

(iii) Medicare Part D services, to the extent the HMO or CMP offers qualified prescription drug coverage under Part D, and the enrollee is entitled to benefits under Part D.

* * * * *

7. In § 417.534, add paragraph (c) to read as follows:

§ 417.534 Allowable costs.

* * * * *

(c) *Medicare Part D program costs.* To the extent that an HMO or CMP provides qualified prescription drug coverage to enrollees under Part D, no costs related to the offering or provision of Part D benefits will be reimbursed under this part. These costs will be reimbursed solely under the applicable provisions of part 423 of this chapter.

8. Part 423 is added as set forth below:

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

Subpart A—General Provisions

Sec.

423.1 Basis and Scope.

423.4 Definitions.

423.6 Cost-Sharing in beneficiary education and enrollment.

Subpart B—Eligibility and Enrollment

423.30 Eligibility to enroll.

423.34 Enrollment process.

Authority: Secs 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

Subpart A—General Provisions

§ 423.1 Basis and scope.

(a) *Basis.* (1) This part is based on the indicated provisions of the following sections of the Social Security Act:

1860D–1. Eligibility, enrollment, and information.
1860D–2. Prescription drug benefits.
1860D–3. Access to a choice of qualified prescription drug coverage.
1860D–4. Beneficiary protections for qualified prescription drug coverage.
1860D–11. PDP regions; submission of bids; plan approval.
1860D–12. Requirements for and contracts with prescription drug plan (PDP) sponsors.
1860D–13. Premiums; late enrollment penalty.
1860D–14. Premium and cost-sharing subsidies for low-income individuals.
1860D–15. Subsidies for Part D eligible individuals for qualified prescription drug coverage.
1860D–16. Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.
1860D–21. Application to Medicare Advantage program and related managed care programs.
1860D–23. State pharmaceutical assistance programs.
1860D–24. Coordination requirements for plans providing prescription drug coverage.
1860D–31. Medicare prescription drug discount card and transitional assistance program.
1860D–41. Definitions; treatment of references to provisions in Part C.
1860D–42. Miscellaneous provisions.

(2) The following specific sections of the Medicare Modernization Act also address the prescription drug benefit program:

Sec. 102 Medicare Advantage conforming amendments.
Sec. 103 Medicaid amendments.
Sec. 104 Medigap.
Sec. 109 Expanding the work of Medicare Quality Improvement Organizations to include Parts C and D.

(b) *Scope.* This part establishes standards for beneficiary eligibility, access, benefits, protections, and low-income subsidies in Part D, as well as establishes standards and sets forth requirements, limitations, procedures and payments for organizations participating in the Voluntary Medicare Prescription Drug Program.

§ 423.4 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Actuarial equivalence means a state of equivalent value demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D–11(c) of the Act and with CMS guidelines described at § 423.265(c)(3).

Brand name drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), including an application referred to in section 505(b)(2) of the Act (21 U.S.C. 355(b)(2))

Fallback prescription drug plan means a prescription drug plan offered by a fallback entity that—

(1) Offers only standard prescription drug coverage;

(2) Provides access to negotiated prices; and

(3) Meets other requirements as specified by CMS in subpart Q of this part.

Formulary means the entire list of Part D drugs covered by a PDP sponsor's or Medicare Advantage organization's drug plan.

Full-benefit dual eligible beneficiary means an individual who meets the criteria established in § 423.772, regarding coverage under both Part D and Medicaid.

Generic drug means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is approved.

Insurance risk means, for a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs or productivity).

MA stands for Medicare Advantage, which refers to the program authorized under Part C of the Act.

MA plan means health benefits coverage offered under a policy or contract with Medicare by an MA organization as defined in § 422.2.

MA–PD plan means an MA plan that provides qualified prescription drug coverage.

Medicare prescription drug account means the account created within the Federal Supplementary Medical Insurance Trust Fund for purposes of Medicare Part D.

Part D eligible individual means an individual who is entitled to or enrolled in Medicare benefits under Part A and/or Part B.

PDP region means a prescription drug plan region as determined by CMS under § 423.112.

PDP sponsor means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part that apply to entities that offer prescription drug plans.

Prescription drug plan or PDP means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in § 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K of this part.

Service area means, for purposes of eligibility to enroll to receive Part D benefits, (1) for a prescription drug plan, an area established in § 423.112(a)

within which access standards under § 423.120 are met; and (2) for an MA–PD plan, an area that meets the definition of MA service area as described in § 422.2, and within which access standards under § 423.120 are met.

State Pharmaceutical Assistance Program (SPAP) means a program (other than the Medicaid program) operated by a State (or under contract with a State) that—

(1) Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals;

(2) Provides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls;

(3) Meets the benefit coordination requirements specified in subpart J of this part; and

(4) Does not change or affect the primary payor status of a Part D plan.

Subsidy-eligible individual means a Part D eligible individual who is enrolled in a PDP or MA–PD plan and who has an income below 150 percent of the poverty level as applicable to a family of the size involved and who meets the resource requirements specified in subpart P of this part.

Tiered cost-sharing means a process of grouping Part D drugs into different cost sharing levels within a PDP sponsor's formulary.

§ 423.6 Cost-sharing in beneficiary education and enrollment-related costs.

The requirements of section 1857(e)(2) of the Act and § 422.6 with regard to the payment of fees established by CMS for cost sharing of enrollment related costs apply to PDP sponsors under Part D.

Subpart B—Eligibility and Enrollment

§ 423.30 Eligibility to enroll.

(a) *Enrollment in a PDP.* Except as otherwise provided in paragraph (b) of this section, a Part D eligible individual is eligible to enroll in a PDP or fallback plan if he or she lives in the plan's service area.

(b) MA enrollees are not eligible to enroll in a PDP except as follows:

(1) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MA private fee-for-service plan (as defined in section 1859(b)(2) of the Act) that does not provide qualified prescription drug coverage; and

(2) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MSA plan (as defined in section 1859(b)(3) of the Act).

(c) *Enrollment in a MA–PD Plan.* A Part D eligible individual enrolled in a MA–PD plan must obtain qualified prescription drug coverage through that plan.

§ 423.34 Enrollment process.

(a) *General Rule.* A PDP sponsor must enroll in its PDP all Part D eligible individuals who are eligible to enroll in its plan under § 423.30(a) and who elect to enroll in the plan during the individual's initial enrollment period, the annual coordinated election period, or a special enrollment period as specified in § 423.36.

(b) *Enrollment.* (1) A Part D eligible individual seeking to enroll in a PDP must complete the PDP's enrollment form or other enrollment process permitted by CMS.

(2) The PDP sponsor must process an individual's enrollment request in accordance with CMS enrollment guidelines.

(c) *Notice requirement.* The PDP sponsor must provide the individual with prompt notice of acceptance or denial of the individual's enrollment request, in a format and manner specified by CMS.

(d) *Enrollment requirement for full benefit dual eligibles.* (1) *General rule.* Full benefit dual eligible individuals who fail to enroll in a PDP or a MA–PD plan during their initial enrollment period or special enrollment period under § 423.36(c)(4) will be automatically enrolled into—

(i) A PDP offering basic prescription drug coverage in the PDP region where the individual resides that has a monthly beneficiary premium that does not exceed the premium subsidy amount, or,

(ii) In the case of an individual enrolled in an MA plan without qualified prescription drug coverage, a MA–PD plan offered by the same MA organization that has a monthly beneficiary premium that does not exceed the premium subsidy amount, in accordance with procedures established by CMS.

(2) *When there is more than one PDP in a PDP region.* In the event that there is more than one PDP in a PDP region with a monthly beneficiary premium at or below the premium subsidy amount, full benefit dual eligible individuals subject to automatic enrollment under this paragraph will be enrolled in such PDPs on a random basis.

(3) *Declining enrollment & disenrollment.* Nothing in this paragraph shall be deemed to prevent these full benefit dual eligible individuals from—

(i) Affirmatively declining enrollment in a PDP or MA–PDP, or

(ii) Disenrolling from the PDP or MA–PDP in which they have been automatically enrolled and electing a new PDP or MA–PD plan, pursuant to the special election period, as provided for under § 423.42.

§ 423.36 Enrollment periods.

(a) *Initial enrollment period for Part D—Basic rule.* The initial enrollment period is the period during which an individual is first eligible to enroll in a Part D plan.

(1) *In 2005.* An individual who is first eligible to enroll in a Part D plan on or prior to January 31, 2006, has an initial enrollment period from November 15, 2005 through May 15, 2006.

(2) *February 2006.* An individual who is first eligible to enroll in a Part D plan in February 2006 has an initial enrollment period from November 15, 2005 through May 31, 2006.

(3) *March 2006 and subsequent months.* (i) Except as provided in (3)(ii) below, the initial enrollment period for an individual who is first eligible to enroll in a Part D plan on or after March 2006 is the same as the initial enrollment period for Medicare Part B under § 407.14.

(ii) *Exception.* For those individuals who are not eligible to enroll in a Part D plan at any time during their initial enrollment period for Medicare Part B, their initial enrollment period under this Part will be the 3 months before becoming eligible for Part D, the month of eligibility, and the three months following eligibility to Part D.

(b) *Annual coordinated election period.* (1) *For 2006.* This period begins on November 15, 2005 and ends on May 15, 2006.

(2) *For 2007 and subsequent years.* For coverage beginning 2007 or any subsequent year, the annual coordinate election period is November 15th through December 31st for coverage beginning the following calendar year.

(c) *Special enrollment periods.* An individual eligible to enroll in a Part D plan enroll in a PDP or disenroll from a PDP and enroll in another PDP, as applicable, at any time under any of the following circumstances—

(1) The individual involuntarily loses creditable prescription drug coverage or such coverage is involuntarily reduced so that it is no longer creditable coverage under § 423.56(a). Loss of credible prescription drug coverage due to failure to pay any required premium shall not be considered involuntary loss of such coverage.

(2) The individual was not adequately informed, as required by standards established by CMS under § 423.56, that he or she has lost his or her creditable prescription drug coverage, never had credible prescription drug coverage, or the coverage is involuntarily reduced so that it is no longer creditable prescription drug coverage.

(3) The individual's enrollment or nonenrollment in Part D is unintentional, inadvertent, or erroneous because of the error, misrepresentation, or inaction of a Federal employee, or any person authorized by the Federal government to act on its behalf.

(4) The individual is a full-benefit dual eligible individual as defined under section 1935(c)(6) of the Act.

(5) The individual elects to disenroll from a MA–PD plan and elects coverage under Medicare Part A and Part B in accordance with § 422.62(c).

(6) The PDP sponsor's contract is terminated by the PDP sponsor or by CMS, as provided under § 422.507 through § 422.510.

(7) The individual is no longer eligible for the PDP because of a change in his or her place of residence to a location outside of the PDP region(s) in which the PDP is offered.

(8) The individual demonstrates to CMS, in accordance with guidelines issued by CMS, that—

(i) The PDP sponsor offering the PDP substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to the following—

(A) Failure to provide the individual on a timely basis benefits available under the plan;

(B) Failure to provide benefits in accordance with applicable quality standards; or

(C) The PDP (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in marketing the plan to the individual.

(ii) The individual meets other exceptional circumstances as CMS may provide.

§ 423.38 Effective dates.

(a) *Initial enrollment period.* An enrollment made prior to the month of entitlement to or enrollment in Medicare benefits under Part A and/or enrollment in Part B is effective the first day of the month the individual is entitled to or enrolled in Part A or enrolled in Part B. An enrollment made during or after the month of entitlement to or enrollment in Part A and/or enrollment in Part B is effective the first day of the calendar month following the month in which the enrollment in Part D is made. If the individual is not eligible to enroll in Part D on the first day of the calendar month following the month in which the election to enroll in Part D is made, the enrollment in Part D will be effective the first day of the month the individual is eligible for Part D. In no case will an enrollment in Part D be effective before January 1, 2006 or before entitlement to or enrollment in Part A and/or Part B.

(b) *Annual coordinated election periods.* (1) *General Rule.* Except as provided under paragraph (b)(2) of this section, for an enrollment or change of enrollment in Part D made during an annual coordinated election period as described in § 423.36(a)(2), the coverage or change in coverage is effective as of first day of the following calendar year.

(2) *Exception for January 1, 2006–May 15, 2006.* Enrollment elections made during the annual election period between January 1, 2006 and May 15, 2006 will be effective the first day of the calendar month following the month in which the enrollment in Part D is made.

(c) *Special enrollment periods.* For an enrollment or change of enrollment in Part D made during a special enrollment period specified in § 423.36(a)(3), the effective date shall be determined by CMS, which, to the extent practicable, will be determined in a manner consistent with protecting the continuity of health benefits coverage.

§ 423.42 Coordination of enrollment and disenrollment through PDPs.

(a) *Enrollment.* An individual who wishes to enroll in a PDP may enroll during the enrollment periods specified in § 423.36, by filing the appropriate enrollment form with the PDP or through other mechanisms CMS determines are appropriate.

(b) *Disenrollment.* An individual who wishes to disenroll from a PDP may disenroll during the periods specified in § 423.36 in either of the following manners:

(1) Enroll in a different PDP plan;

(2) Submit a disenrollment request to the PDP in the form and manner prescribed by CMS; or

(3) File the appropriate disenrollment request through other mechanisms as determined by CMS.

(c) Responsibilities of the PDP sponsor. The PDP sponsor must—

(1) Submit a disenrollment notice to CMS within timeframes CMS specifies;

(2) Provide the enrollee with a notice of disenrollment as CMS determines and approves; and

(3) File and retain disenrollment requests for the period specified in CMS instructions.

(d) *Retroactive disenrollment.* CMS may grant retroactive disenrollment in the following cases:

(1) There never was a legally valid enrollment;

or, (2) A valid request for disenrollment was properly made but not processed or acted upon.

(e) *Maintenance of Enrollment.* An individual who is enrolled in a PDP will remain enrolled in that PDP until one of the following occurs:

(i) The individual successfully enrolls in another PDP;

(ii) The individual voluntarily disenrolls from the PDP;

(iii) The individual is involuntarily disenrolled from the PDP or;

(iv) The PDP is discontinued and no longer serves the area in which the individual resides.

§ 423.44 Disenrollment by the PDP.

(a) *General Rule.* Except as provided in paragraphs (b) through (d) of this section, a PDP sponsor may not—

(1) Involuntarily disenroll an individual from any PDP it offers; or

(2) Orally or in writing, or by any action or inaction, request or encourage an individual to disenroll.

(b) *Basis for disenrollment.* (1) *Optional involuntary disenrollment.* A PDP sponsor may disenroll an individual from a PDP it offers in any of the following circumstances:

(i) Any monthly premium is not paid on a timely basis, as specified under paragraph (d)(1) of this section; or

(ii) The individual has engaged in disruptive behavior, as specified under paragraph (d)(2) of this section.

(2) *Required involuntary disenrollment.* A PDP sponsor must disenroll an individual from a PDP it offers in any of the following circumstances:

(i) The individual no longer resides in the PDP's service area.

(ii) The individual loses entitlement or enrollment to Medicare benefits under Part A and/or Part B.

(iii) Death of the individual.

(iv) The PDP sponsor's contract is terminated by CMS or that terminates a PDP. The PDP sponsor must disenroll affected enrollees in accordance with the procedures for disenrollment set forth at § 423.507 through § 423.510.

(v) The individual materially misrepresents information, as determined by CMS, to the PDP sponsor that the individual has or expects to receive reimbursement for third-party coverage.

(c) *Notice Requirement.* (1) If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i), or (b)(iv) of this section (that is, other

than death or loss of entitlement or enrollment to benefits under Part A and/or enrollment in Part B), the PDP sponsor must give the individual timely notice of the disenrollment with an explanation of why the PDP is planning to disenroll the individual.

(2) Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) and (b)(2)(iv) of this section must—

(i) Be provided to the individual before submission of the disenrollment notice to CMS; and

(ii) Include an explanation of the individual's right to a hearing under the PDP's grievance procedures.

(d) *Process for Disenrollment.* (1) *Monthly PDP premiums that are not paid timely.* A PDP sponsor may disenroll an individual from the PDP for failure to pay any monthly premium under the following circumstances:

(i) The PDP sponsor can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount.

(ii) The PDP sponsor gives the enrollee notice of disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) *Reenrollment in the PDP.* If an individual is disenrolled from the PDP for failure to pay monthly PDP premiums, the PDP sponsor has the option to decline future enrollment by such individual in any of its PDPs until the individual has paid any past premiums due to the PDP sponsor.

(2) *Disruptive or threatening behavior.* (i) *Basis for disenrollment.* A PDP sponsor may disenroll an individual from its PDP if the individual's behavior is disruptive, unruly, abusive, uncooperative or threatening. Disruptive behavior may not be based upon noncompliance with medical advice. An individual may be deemed to engage in disruptive or threatening behavior if the individual exhibits any of the following:

(A) Behavior that jeopardizes his or her health or safety, or the health and safety of others; or

(B) Behavior that impairs the PDP sponsor (or a network pharmacy's) ability to furnish services to either the individual or other individuals enrolled in the plan; or

(C) An individual with decision-making capacity who refuses to comply with the material terms of the enrollment agreement.

(ii) *Effort to resolve the problem.* The PDP sponsor must make a good faith effort to resolve the problems the individual presents, including the use (or attempted use) of the PDP's grievance procedures. The beneficiary has a right to submit any information or explanation that he or she may wish to submit to the PDP.

(iii) *Documentation.* The PDP sponsor must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraphs (d)(2)(i) through (d)(2)(iii) of this section and any extenuating circumstances. The PDP sponsor must also submit to CMS such documentation, as well as any documentation received by the beneficiary.

(iv) *CMS review of the proposed disenrollment.* CMS decides after reviewing the documentation submitted by the PDP sponsor whether the sponsor has met the criteria for disenrollment for disruptive or threatening behavior.

(v) *Effective date of disenrollment.* If CMS permits a PDP to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the PDP gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(vi) *Reenrollment in the PDP.* Once an individual is disenrolled from the PDP for disruptive behavior, the PDP sponsor has the option to decline future enrollment by the individual in any of its PDPs for a period of time CMS specifies.

(vii) *Expedited process.* In the event that an individual's disruptive or threatening behavior is so extreme as to have caused harm to others or prevented the PDP from providing services, CMS may consider allowing an expedited disenrollment process in accordance with procedures established by CMS.

(3) *Loss of entitlement or enrollment in Part A and Part B benefits.* If an individual is no longer entitled or enrolled to Medicare benefits under Part A and enrolled in Part B, CMS will notify the PDP that the disenrollment is effective the first day of the calendar month following the last month of entitlement or enrollment to benefits under Part A or Part B.

(4) *Death of the individual.* If the individual dies, disenrollment is effective the first day of the calendar month following the month of death.

(5) *Plan termination.*

(i) When a PDP contract terminates as provided in § 423.507 through 423.510 as the PDP sponsor must give each affected PDP enrollee notice of the effective date of the plan termination and a description of alternatives for obtaining benefits under Part D, as specified by CMS.

(ii) The notice must be sent before the effective date of the plan termination or area reduction, and in the timeframes specified by CMS.

(6) *Misrepresentation of third-party reimbursement.* (i) If CMS determines an individual has materially misrepresented information to the PDP regarding whether the individual has or expects to receive reimbursement from group health plans, insurers or otherwise, or similar third party arrangements for incurred costs for covered Part D drugs under § 423.44(b)(2)(v), the termination is effective the first day of the calendar month after the month in which the PDP gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(ii) *Reenrollment in the PDP.* Once an individual is disenrolled from the PDP for misrepresentation of third party reimbursement, the PDP sponsor has the option to decline future enrollment by the individual in any of its PDPs for a period of time CMS specifies.

(iii) *Ineligibility for SEP.* An individual who is disenrolled for misrepresentation of third party reimbursement is not eligible for an SEP. The individual may enroll in a PDP during the next annual coordinated election period as provided in § 423.36(b)

§ 423.46 Late enrollment penalty.

(a) *General.* A Part D eligible individual must pay the late penalty described under § 423.286(d)(3) if there is a continuous period of 63 days or longer at any time after termination of the individual's initial enrollment period during all of which the individual meets the following conditions:

(1) The individual was eligible to enroll in a PDP or MA–PD plan;

(2) The individual was not covered under any creditable prescription drug coverage; and

(3) The individual was not enrolled in a PDP or MA–PD plan.

(b) [Reserved]

§ 423.48 Information about Part D.

Each PDP and MA–PD plan must provide, on an annual basis, and in a format and using standard terminology that CMS may specify in guidance, the information necessary to enable CMS to provide to current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage.

§ 423.50 Approval of marketing materials and enrollment forms.

(a) *CMS review of marketing materials.* (1) Except as provided in paragraph (a)(2) of this section, a PDP may not distribute any marketing materials (as defined in paragraph (b) of

this section), or enrollment forms, or make such materials or forms available to Part D eligible individuals, unless—

(i) At least 45 days (or 10 days if using marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution, the PDP sponsor submits the material or form to CMS for review under the guidelines in paragraph (c) of this section; and

(ii) CMS does not disapprove the distribution of the material or form.

(2) If the PDP sponsor is deemed by CMS to meet certain performance requirements established by CMS, the PDP sponsor may distribute designated marketing materials 5 days following their submission to CMS.

(b) *Definition of marketing materials.* Marketing materials include any informational materials targeted to Medicare beneficiaries which—

(1) Promote the PDP;

(2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in a PDP;

(3) Explain the benefits of enrollment in a PDP, or rules that apply to enrollees;

(4) Explain how Medicare services are covered under a PDP, including conditions that apply to such coverage;

(5) Examples of marketing materials include, but are not limited to—

(i) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet.

(ii) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(iii) Presentation materials such as slides and charts.

(iv) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers).

(v) Membership communication materials such as membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees.

(vi) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.

(vii) Membership or claims processing activities.

(c) *Guidelines for CMS review.* In reviewing marketing material or enrollment forms under paragraph (a) of this section, CMS determines (unless otherwise specified in additional guidance) that the marketing materials—

(1) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling—

(i) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(ii) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each.

(iii) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(2) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area.

(3) Include in the written materials notice that the PDP is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the PDP.

(4) Are not materially inaccurate or misleading or otherwise make material misrepresentations.

(5) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

(d) *Deemed approval.* If CMS has not disapproved the distribution of a marketing materials or form submitted by a PDP sponsor with respect to a PDP plan in a region, CMS is deemed not to have disapproved the distribution of the marketing material or form in all other regions covered by the PDP, with the exception of any portion of the material or form that is specific to the particular region.

(e) *Standards for PDP marketing.* (1) In conducting marketing activities, a PDP may not—

(i) Provide for cash or other remuneration as an inducement for enrollment or otherwise. This does not prohibit explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the PDP.

(ii) Engage in any discriminatory activity such as, including targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(iii) Solicit Medicare beneficiaries door-to-door.

(iv) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the PDP sponsor or its PDP. The PDP organization may not claim that it is recommended or endorsed by CMS or Medicare or the Department of Health and Human Services or that CMS or Medicare or the Department of Health and Human Services recommends that the beneficiary enroll in the PDP. It may, however, explain that the organization is approved for participation in Medicare.

(v) Use providers or provider groups to distribute printed information comparing the benefits of different PDPs unless the materials have the concurrence of all PDP sponsors involved and have received prior approval by CMS.

(vi) Accept PDP enrollment forms in provider offices or other places where health care is delivered.

(vii) Employ PDP plan names that suggest that a plan is not available to all Medicare beneficiaries

(viii) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(2) In its marketing, the PDP organization must—

(i) Demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(ii) Establish and maintain a system for confirming that enrolled beneficiaries have in fact enrolled in the PDP and understand the rules applicable under the plan.

§ 423.56 Procedures to determine and document creditable status of prescription drug coverage.

(a) *Definition. Creditable prescription drug coverage* means any of the following types of coverage, but only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage as demonstrated through the use of generally accepted actuarial principles and in accordance with the requirements of § 423.265(c)(3):

(1) Prescription drug coverage under a PDP or MA–PD plan.

(2) Medicaid coverage under title XIX of the Act or under a waiver under section 1115 of the Act.

(3) Coverage under a group health plan, including the Federal employees health benefits program, and qualified retiree prescription drug plans as defined in section 1860D–22(a)(2) of the Act.

(4) Coverage under programs that provide financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals.

(5) Coverage of prescription drugs for veterans, survivors and dependents under chapter 17 of title 38, U.S.C.

(6) Coverage under a Medicare supplemental policy (Medigap policy) under section 1882 of the Act, and as specified in 42 CFR 403.205, that provides prescription drug benefits, whether or not the coverage was issued pursuant to standardization requirements under section 1882(p)(1) of the Act.

(7) Military coverage under chapter 55 of title 10, U.S.C., including TRICARE.

(8) Individual health insurance coverage (as defined in section 2791(b)(5) of the Public Health Service Act) that includes coverage for outpatient prescription drugs and that does not meet the definition of an excepted benefit (as defined in section 2791(c) of the Public Health Service Act).

(9) Coverage provided by the medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U).

(b) *General.* With the exception of PDPs and MA–PD plans under 423.56(a)(1), each entity that offers prescription drug coverage under any of the types described in § 423.56(a), must disclose to all Part D eligible individuals enrolled in or seeking to enroll in such coverage whether such coverage meets the requirements of actuarial equivalence of § 423.265.

(c) *Disclosure of non-creditable coverage.* In the case that the coverage does not meet the actuarial equivalence requirements at § 423.265 the disclosure described in paragraph (b) of this section to Part D eligible individuals must include:

(1) The fact that the coverage does not meet the actuarial equivalence requirement under 423.265;

(2) That there are limitations on the periods in a year in which the individual may enroll under a PDP or MA–PD plan; and

(3) That the individual may be subject to a late enrollment penalty, under § 423.46.

(d) *Disclosure to CMS.* Each entity must disclose the creditable coverage status to CMS in a form and manner described by CMS.

(e) *Notification.* Notification to Part-D eligible individuals must be provided in a form and manner prescribed by CMS.

(f) *When an individual is not adequately informed of coverage.* If an individual establishes to CMS that he or she was not adequately informed that his or her prescription drug coverage was not creditable, the individual may apply to CMS to have such coverage treated as creditable coverage for purposes of applying § 423.46.

Subpart C—Benefits and Beneficiary Protections

§ 423.100 Definitions.

As used in this subpart, unless otherwise specified—

Alternative prescription drug coverage means coverage of covered Part D drugs other than standard prescription drug coverage that meets the requirements of § 423.104(f). The term "alternative prescription drug coverage" must be either—

(1) *Basic alternative coverage* (alternative coverage that is actuarially equivalent to defined standard coverage), as determined through processes and methods established under § 423.265; or

(2) *Enhanced alternative coverage* (alternative coverage that meets the requirements of § 423.104(g)(1)).

Basic prescription drug coverage means coverage of covered Part D drugs that is either standard prescription drug coverage or basic alternative coverage.

Bioequivalent has the meaning given such term in section 505(j)(8) of the Food, Drug, and Cosmetic Act.

Covered Part D drug means—

(1) Unless excluded under number (2) of this definition, any of the following if used for a medically accepted indication (as defined in section 1927(k)(6) of the Act)—

(i) A drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act;

(ii) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act;

(iii) Insulin described in section 1927(k)(2)(C) of the Act;

(iv) The following medical supplies associated with the injection of insulin: syringes, needles, alcohol swabs, and gauze; or

(v) A vaccine licensed under section 351 of the Public Health Service Act.

(2) Does not include—

(i) Drugs for which payment as so prescribed and dispensed or administered to an individual is available with respect to that individual under Parts A or B (even though a deductible may apply, or even though the individual is eligible for coverage under Parts A or B but has declined to enroll in Parts A or B); and

(ii) Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid pursuant to sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.

Group health plan has the meaning given such term in § 411.101 of this chapter.

Incurred costs means costs incurred by a Part D enrollee for covered part D drugs covered under (or treated as covered under) a prescription drug plan or MA–PD plan—

(1) That are not paid for under the prescription drug plan or MA–PD as a result of application of any annual deductible or other cost-sharing rules for covered part D drugs prior to the Part D enrollee satisfying the out-of-pocket threshold under § 423.104(e)(5)(iii), including any price differential for which the Part D enrollee is responsible under § 423.120(a)(6) and § 423.124(b)(2); and

(2) That are paid for—

(i) By the Part D enrollee or on behalf of the Part D enrollee by another person, and the Part D enrollee (or person paying on behalf of the Part D enrollee) is not reimbursed through insurance or otherwise, a group health plan, or other third party payment arrangement, or the person paying on behalf of the Part D enrollee is not paying under insurance or otherwise, a group health plan, or third party payment arrangement;

(ii) Under a State Pharmaceutical Assistance Program as described in § 423.454); or

(iii) Under § 423.782.

Insurance or otherwise means a plan (other than a group health plan) or program that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the Public Health Service Act, 42 U.S.C. 300gg-91(a)(2)), including any of the following:

(1) Health insurance coverage as defined in 42 U.S.C. 300gg-91(b)(1);

(2) An MA plan as described in § 422.2 of this chapter.

(3) A program of all-inclusive care for the elderly (PACE) under titles XVIII and XIX of the Act;

(4) An approved State child health plan under title XXI of the Act providing benefits for child health assistance that meet the requirements of section 2103 of the Act;

(5) The Medicaid program under title XIX of the Act or a waiver pursuant to section 1115 of the Act;

(6) The veterans health care program under chapter 17 of title 38 of the U.S.C.

(7) Any other government-funded program whose principal activity is the direct provision of health care to individuals.

I/T/U pharmacy means a pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603.

Long-term care facility means a skilled nursing facility, as defined in

section 1819(a) of the Act, or nursing facility, as defined in section 1919(a) of the Act.

Long-term care pharmacy means a pharmacy owned by or under contract with a long-term care facility to provide prescription drugs to the facility's residents.

Long-term care network pharmacy means a long-term care pharmacy that is a network pharmacy.

Negotiated prices means prices for covered Part D drugs that—

(1) Are available to beneficiaries at the point of sale at network pharmacies; and

(2) Take into account discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations and include any dispensing fees.

Network pharmacy means a licensed pharmacy that is not a mail order pharmacy and that is under contract with a PDP sponsor or MA organization offering an MA–PD plan to provide negotiated prices to its prescription drug plan or MA–PD plan enrollees.

Non-preferred pharmacy means a network pharmacy that offers Part D enrollees higher cost-sharing for covered Part D drugs than a preferred pharmacy.

Out-of-network pharmacy means a licensed pharmacy that is not under contract with a PDP sponsor or MA organization offering an MA–PD plan to provide negotiated prices to its prescription drug plan or MA–PD plan enrollees.

Person means a natural person, corporation, mutual company, unincorporated association, partnership, joint venture, limited liability company, trust, estate, foundation, not-for-profit corporation, unincorporated organization, government or governmental subdivision or agency.

Plan allowance means the amount prescription drug plans and MA–PD plans use to determine their payment and Part D enrollees' cost-sharing for covered Part D drugs purchased at out-of-network pharmacies in accordance with the requirements of § 423.124(b).

Preferred drug means a covered part D drug on a prescription drug plan or MA–PD plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug in the plan's formulary.

Preferred pharmacy means a network pharmacy that offers Part D enrollees lower cost-sharing for covered Part D drugs than a non-preferred pharmacy.

Qualified prescription drug coverage means any standard prescription drug coverage or alternative prescription drug coverage that meets the requirements of § 423.104(d).

Required prescription drug coverage means coverage of covered Part D drugs under an MA–PD plan that consists of either—

(1) Basic prescription drug coverage; or

(2) Enhanced alternative coverage, provided there is no MA monthly supplemental beneficiary premium applied under the plan due to the application of a credit against the premium of a rebate under § 422.266(b) of this chapter.

Rural means a five-digit ZIP code in which the population density is less than 1,000 individuals per square mile.

Standard prescription drug coverage means coverage of covered Part D drugs that meets the requirements of § 423.104(e). The term "standard prescription drug coverage" must be either—

(1) *Defined standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in §§ 423.104(e)(2)(i)(A) and (e)(5)(i)); or

(2) *Actuarially equivalent standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(e)(2)(i)(B) or cost-sharing as described in § 423.104(e)(5)(ii), or both).

Suburban means a five-digit ZIP code in which the population density is between 1,000 and 3,000 individuals per square mile.

Supplemental benefits means benefits that meet the requirements of § 423.104(g)(1)(ii).

Therapeutically equivalent refers to drugs that are rated as therapeutic equivalents under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations."

Third party payment arrangement means any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs.

Urban means a five-digit ZIP code in which the population density is greater than 3,000 individuals per square mile.

Usual and customary (U&C) price means the price that a pharmacy charges a customer who does not have any form of prescription drug coverage.

§ 423.104 Requirements related to qualified prescription drug coverage.

(a) *General.* Subject to the conditions and limitations set forth in this subpart, a PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan must provide enrollees with coverage of the benefits described in paragraph (c) of this section. The benefits may be provided directly by the PDP sponsor or MA organization or through arrangements with other entities. CMS reviews and approves these benefits consistent with § 423.272, and using written policy guidelines and requirements in this part and other CMS instructions.

(b) *Availability of plans.* Except as provided in § 422.60(b) of this chapter, a PDP sponsor offering a prescription drug plan must offer that plan to all Part D eligible beneficiaries residing in the plan's service area.

(c) *Types of benefits.* A prescription drug plan or MA–PD plan must include qualified prescription drug coverage.

(d) *Qualified prescription drug coverage.* Qualified prescription drug coverage includes—

(1) Standard prescription drug coverage consistent with paragraph (e) of this section; or

(2) Alternative prescription drug coverage consistent with paragraph (f) of this section.

(e) *Standard prescription drug coverage.* Standard prescription drug coverage includes access to negotiated prices as described under paragraph (h)(1) of this section, provides coverage of covered Part D drugs, and must meet the following requirements—

(1) *Deductible.* An annual deductible equal to—

(i) *For 2006.* $250; or

(ii) *For years subsequent to 2006.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (e)(5)(iv) of this section, and rounded to the nearest multiple of $5.

(2) *Cost-sharing under the initial coverage limit.*

(i) *25 Percent coinsurance.* Coinsurance for costs for covered Part D drugs covered under the plan above the annual deductible specified in paragraph (e)(1) of this section, and up to the initial coverage limit under paragraph (e)(3) of this section, that is—

(A) Equal to 25 percent for defined standard coverage; or

(B) Actuarially equivalent to an average expected coinsurance of no more than 25 percent, as determined through processes and methods established under § 423.265, for actuarially equivalent standard coverage.

(ii) *Tiered copayments.* A prescription drug plan or MA–PD plan may apply tiered copayments without limit, provided that any tiered copayments are consistent with paragraph (e)(2)(i)(B) of this section and are reviewed as described in § 423.272(b)(2).

(3) *Initial coverage limit.* The initial coverage limit is equal to—

(i) *For 2006.* $2,250.

(ii) *For years subsequent to 2006.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (e)(5)(iv) of this section, and rounded to the nearest multiple of $10.

(4) *Cost-sharing between the initial coverage limit and the annual out-of-pocket threshold.* Coinsurance for costs for covered Part D drugs covered under the plan above the initial coverage limit described in paragraph (e)(3) of this section and annual out-of-pocket threshold described in paragraph (e)(5)(iii) of this section that is equal to 100 percent.

(5) *Protection against high out-of-pocket expenditures.* (i) After an enrollee's incurred costs exceed the annual out-of-pocket threshold described in paragraph (e)(5)(iii) of this section, cost-sharing equal to the greater of—

(A) *Copayments.* (*1*) In 2006, $2 for a generic drug or preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug; and

(*2*) For subsequent years, the copayment amounts specified in this paragraph for the previous year increased by the annual percentage increase described in paragraph (e)(5)(iv) of this section and rounded to the nearest multiple of 5 cents; or

(B) *Coinsurance.* Five percent coinsurance.

(ii) As determined through processes and methods established under § 423.265, a prescription drug plan or MA–PD plan may substitute for cost-sharing under paragraph (e)(5)(i) of this section an amount that is actuarially equivalent to expected cost-sharing under paragraph (e)(5)(i) of this section.

(iii) *Annual out-of-pocket threshold.* For purposes of this part, the annual out-of-pocket threshold equals—

(A) *For 2006.* $3,600.

(B) *For years subsequent to 2006.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (e)(5)(iv) of this section, and rounded to the nearest multiple of $50.

(iv) *Annual percentage increase.* The annual percentage increase for each year is equal to the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals and is based on data for the 12-month period ending in July of the previous year.

(f) *Alternative prescription drug coverage.* Alternative prescription drug coverage includes access to negotiated prices as described under paragraph (h)(1) of this section, provides coverage of covered Part D drugs, and must meet the following requirements—

(1) Has an annual deductible that does not exceed the annual deductible specified in paragraph (e)(1) of this section;

(2) Imposes cost-sharing no greater than that specified in paragraph (e)(5)(i) or (ii) of this section once the annual out-of-pocket threshold described in paragraph (e)(5)(iii) is met;

(3) Has an unsubsidized value that is at least equal to the unsubsidized value of standard prescription drug coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under § 423.782 with respect to such coverage; and

(4) Provides coverage that is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, with respect to costs incurred that are equal to the initial coverage limit under paragraph (e)(3) of this section, of an amount equal to at least the product of—

(i) The amount by which the initial coverage limit described in paragraph (e)(3) of this section for the year exceeds the deductible described in paragraph (e)(1) of this section; and

(ii) 100 percent minus the coinsurance percentage specified in paragraph (e)(2)(i) of this section.

(g) *Enhanced alternative coverage.* (1) Enhanced alternative coverage must meet the requirements under paragraph (f) of this section and includes—

(i) Basic prescription drug coverage, as defined in § 423.100; and

(ii) Supplemental benefits, which include—

(A) Coverage of drugs other than covered Part D drugs; and/or

(B) Any of the following changes or combination of changes that increase the actuarial value of benefits above the actuarial value of defined standard prescription drug coverage, as determined through processes and methods established under § 423.265—

(*1*) A reduction in the annual deductible described in paragraph (e)(1) of this section;

(*2*) A reduction in the cost-sharing described in paragraphs (e)(2) or (e)(5) of this section, or

(*3*) An increase in the initial coverage limit described in paragraph (e)(3) of this section.

(2) *Restrictions on the offering of enhanced alternative coverage by PDP sponsors.* A PDP sponsor may not offer enhanced alternative coverage in a service area unless the PDP sponsor also offers a prescription drug plan in that service area that provides basic prescription drug coverage.

(3) *Restrictions on the offering of enhanced alternative coverage by MA organizations.* Effective January 1, 2006, an MA organization—

(i) May not offer an MA coordinated care plan, as defined in § 422.4 of this chapter, in an area unless either that plan (or another MA plan offered by the MA organization in that same service area) includes required prescription drug coverage; and

(ii) May not offer prescription drug coverage (other than that required under Parts A and B of Title XVIII of the Act) to an enrollee—

(A) Under an MSA plan, as defined in § 422.2 of this chapter; or

(B) Under another MA plan (including a private fee-for-service plan, as defined in § 422.4 of this chapter) unless the drug coverage under such other plan provides qualified prescription drug coverage and unless the requirements of paragraph (g)(3)(i) of this section are met.

(h) *Negotiated prices.* (1) *Access to negotiated prices.* Under qualified prescription drug coverage offered by a PDP sponsor or an MA organization, the PDP sponsor or MA organization is required to provide its enrollees with access to negotiated prices for covered Part D drugs included in its plan's formulary. Negotiated prices must be provided even if no benefits are payable to the beneficiary for covered Part D drugs because of the application of any deductible or 100 percent coinsurance requirement following satisfaction of any initial coverage limit.

(2) *Interaction with Medicaid best price.* Prices negotiated with a pharmaceutical manufacturer, including discounts, subsidies, rebates, and other price concessions, for covered Part D drugs by the following entities will not be taken into account in establishing Medicaid's best price under section 1927(c)(1)(C) of the Act—

(i) A prescription drug plan;

(ii) An MA–PD plan; or

(iii) A qualified retiree prescription drug plan (as defined in § 423.882) for Part D eligible individuals.

(3) *Disclosure.* (i) A PDP sponsor or an MA organization offering qualified prescription drug coverage is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers and passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies paid by CMS on behalf of low-income individuals described in § 423.782, or in the form of lower monthly beneficiary premiums

and/or lower covered Part D drug prices at the point of sale, as specified in § 423.336(c)(1) and § 423.343(c)(1).

(ii) Information on negotiated prices disclosed to CMS under paragraph (h)(3) of this section is protected under the confidentiality provisions applicable under section 1927(b)(3)(D) of the Act.

(4) *Audits.* CMS may conduct periodic audits of the financial statements and all records of PDP sponsors and MA organizations pertaining to any qualified prescription drug coverage they may offer under either a prescription drug plan or an MA–PD plan.

§ 423.112 Establishment of prescription drug plan service areas.

(a) *Service area for prescription drug plans.* The service area for a prescription drug plan consists of one or more PDP regions as established under paragraphs (b) and (c) of this section.

(b) *Establishment of PDP regions.* (1) *General.* CMS establishes PDP regions in a manner consistent with the requirements for the establishment of MA regions as described at § 422.455 of this chapter.

(2) *Relation to MA regions.* To the extent practicable, PDP regions are the same as MA regions. CMS may establish PDP regions that are not the same as MA regions if CMS determines that the establishment of these regions improves access to prescription drug plan benefits for Part D eligible individuals.

(c) *Authority for territories.* CMS establishes a PDP region or regions for States that are not within the 50 States and the District of Columbia.

(d) *Revision of PDP regions.* CMS may revise the PDP regions established under paragraphs (b) and (c) of this section.

(e) *Regional or national plan.* Nothing in this section prevents a prescription drug plan from being offered in two or more PDP regions in their entirety or in all PDP regions in their entirety.

§ 423.120 Access to covered Part D drugs.

(a) *Assuring pharmacy access.* (1) *Convenient access to network pharmacies.* Except as provided in paragraph (a)(3) of this section, a prescription drug plan or MA–PD plan must have a contracted pharmacy network, consisting of pharmacies other than mail-order pharmacies, sufficient to ensure that for beneficiaries residing in the prescription drug plan's service area, as described in § 423.112, or the MA–PD plan's service area, as described in § 422.2 of this chapter, the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the prescription drug plan or MA–PD plan live within 2 miles of a network pharmacy;

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the prescription drug plan or MA–PD plan live within 5 miles of a network pharmacy; and

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the prescription drug plan or MA–PD plan live within 15 miles of a network pharmacy.

(2) *Access to mail-order pharmacies.* A prescription drug plan's or MA–PD plan's contracted pharmacy network may be supplemented by pharmacies offering home delivery via mail-order, provided the requirements of paragraph (a)(1) of this section are met.

(3) *Waiver of pharmacy access requirements.* CMS waives the requirements under paragraph (a)(1) of this section in the case of—

(i) An MA–PD plan that provides its enrollees with access to covered Part D drugs through pharmacies owned and operated by the MA organization, provided the organization's pharmacy network is sufficient to provide access to its enrollees that is comparable to the standard set forth under paragraph (a)(1) of this section.

(ii) An MA private fee-for-service plan described in § 422.4 of this chapter that—

(A) Offers qualified prescription drug coverage;

(B) Provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies and without charging cost-sharing in excess of that described in §§ 423.104(e)(2) and (5).

(4) *Pharmacy network contracting requirements.* In establishing its contracted pharmacy network, a PDP sponsor or MA organization offering qualified prescription drug coverage—

(i) Must contract with any pharmacy that meets the prescription drug plan's or MA–PD plan's terms and conditions; and

(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the PDP plan's or MA–PD plan's network.

(5) *Discounts for preferred pharmacies.* A PDP sponsor or MA organization offering a prescription drug plan or an MA–PD plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs (relative to the copayments or coinsurance applicable when those covered Part D drugs are obtained through a non-preferred pharmacy) when a Part D eligible individual enrolled in its prescription drug plan or MA–PD plan obtains the covered Part D drug through a preferred pharmacy. If the prescription drug plan or MA–PD plan provides actuarially equivalent standard coverage, the plan must still meet the requirements under §§ 423.104(e)(2) and (5). Any cost-sharing reduction must not increase CMS payments under § 423.329.

(6) *Level playing field between mail-order and network pharmacies.* A PDP sponsor or MA organization must permit its prescription drug plan or MA–PD plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at a network retail pharmacy instead of a network mail-order pharmacy, provided an enrollee obtaining a covered Part D drug a network retail pharmacy pays for any differential in the negotiated price for the covered Part D drug at the network retail pharmacy and network mail-order pharmacy.

(b) *Formulary requirements.* A PDP sponsor or MA organization that uses a formulary under its qualified prescription drug coverage must meet the following requirements—

(1) *Development and revision by a pharmacy and therapeutic committee.* A PDP sponsor or MA organization's formulary must be reviewed by a pharmacy and therapeutic committee that—

(i) Includes a majority of members who are practicing physicians and/or practicing pharmacists.

(ii) Includes at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict with respect to the PDP sponsor and prescription drug plan, or MA organization and MA–PD plan, and who are experts regarding care of elderly or disabled individuals.

(iii) Bases clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate.

(iv) Considers whether the inclusion of a particular covered Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy.

(v) Documents in writing its decisions regarding formulary development and revision.

(2) *Inclusion of drugs in all therapeutic categories and classes.* A prescription drug plan's or MA–PD plan's formulary must include at least two covered Part D drugs within each therapeutic category and class of

covered Part D drugs, with different strengths and doses available for those drugs. Only one covered Part D drug must be included in a particular category or class of covered Part D drugs if the category or class includes only one covered Part D drug.

(3) *Limitation on changes in therapeutic classification.* Except as CMS may permit to account for new therapeutic uses and newly approved covered Part D drugs, a PDP sponsor or MA organization offering an MA–PD plan may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year.

(4) *Periodic evaluation of protocols.* A PDP sponsor or MA organization offering an MA–PD plan must periodically evaluate and analyze treatment protocols and procedures related to its plan's formulary.

(5) *Provision of notice regarding formulary changes.* A PDP sponsor or MA organization offering an MA–PD plan must provide at least 30 days notice to CMS, affected enrollees, authorized prescribers, pharmacies, and pharmacists prior to removing a covered Part D drug from its plan's formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug.

(6) *Limitation on formulary changes prior to the beginning of a contract year.* A PDP sponsor or MA organization offering an MA–PD plan may not remove a covered Part D drug from its plan's formulary, or make any change in the preferred or tiered cost-sharing status of a covered Part D drug, between the beginning of the annual coordinated election period described in § 423.36(b) and 30 days after the beginning of the contract year associated with that annual coordinated election period.

(7) *Provider and patient education.* A PDP sponsor or MA organization offering an MA–PD plan must establish policies and procedures to educate and inform health care providers and enrollees concerning its formulary.

(c) *Use of standardized technology.* A PDP sponsor or MA organization offering an MA–PD plan must issue and reissue, as necessary, a card or other type of technology that its enrollees may use to access negotiated prices for covered Part D drugs as provided under § 423.104(h). The card or other technology must comply with standards CMS establishes.

§ 423.124 Special rules for access to covered Part D drugs at out-of-network pharmacies

(a) *Out-of-network access to covered part D drugs.* A PDP sponsor or MA organization offering an MA–PD plan must assure that Part D enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when such enrollees cannot reasonably be expected to obtain such drugs at a network pharmacy.

(b) *Financial responsibility for out-of-network access to covered Part D drugs.* A Part D enrollee is financially responsible for the sum of the following costs of a covered Part D drug obtained as provided in paragraph (a) of this section—

(1) Any deductible or cost-sharing (relative to the plan allowance, as described in § 423.100, for that covered Part D drug); and

(2) Any differential between the out-of-network pharmacy's usual and customary price and the PDP sponsor or MA organization's plan allowance (including any applicable beneficiary cost-sharing) for that covered Part D drug.

§ 423.128 Dissemination of plan information.

(a) *Detailed description.* A PDP sponsor or MA organization offering an MA–PD plan must disclose the information specified in paragraph (b) of this section—

(1) To each enrollee of a prescription drug plan offered by the PDP sponsor or the MA–PD plan offered by the MA organization under this part;

(2) In a clear, accurate, and standardized form; and

(3) At the time of enrollment and at least annually thereafter.

(b) *Content of plan description.* The plan description must include the following information about the qualified prescription drug coverage offered under a prescription drug plan or an MA–PD plan—

(1) *Service area.* The plan's service area.

(2) *Benefits.* The benefits offered under the plan, including—

(i) Applicable conditions and limitations.

(ii) Premiums.

(iii) Cost-sharing (such as copayments, deductibles, and coinsurance), and cost-sharing for subsidy eligible individuals.

(iv) Any other conditions associated with receipt or use of benefits.

(3) *Cost-sharing.* A description of how a Part D eligible individual may obtain more information on cost-sharing requirements, including tiered or other copayment levels applicable to each drug (or class of drugs), in accordance with paragraph (d) of this section.

(4) *Formulary.* The manner in which any formulary (including any tiered formulary structure) functions, including—

(i) The process for obtaining an exception to a prescription drug plan's or MA–PD plan's tiered cost-sharing structure;

(ii) A description of how a Part D eligible individual may obtain additional information on the formulary, including the formulary itself, in accordance with paragraph (d) of this section.

(5) *Access.* The number, mix, and distribution (addresses) of network pharmacies from which enrollees may reasonably be expected to obtain covered Part D drugs and how the prescription drug plan sponsor or MA organization meets the requirements of § 423.120(a)(1) for access to covered Part D drugs;

(6) *Out-of-network coverage.* Provisions for access to covered Part D drugs at out-of-network pharmacies, consistent with § 423.124(a).

(7) *Grievance, coverage determinations, reconsideration, exceptions, and appeals procedures.* All grievance, coverage determination, reconsideration, exceptions, and appeal rights and procedures required under § 423.564 et. seq.

(8) *Quality assurance program.* A description of the quality assurance program required under § 423.153(c), including the medication therapy management program required under § 423.153(d).

(9) *Disenrollment rights and responsibilities.*

(c) *Disclosure upon request of general coverage information, utilization, and grievance information.* Upon request of a Part D eligible individual, a PDP sponsor or MA organization offering an MA–PD plan must provide the following information—

(1) *General coverage information.* General coverage information, including—

(i) *Enrollment procedures.* Information and instructions on how to exercise election options under this part;

(ii) *Rights.* A general description of procedural rights (including grievance, coverage determination, reconsideration, exceptions, and appeals procedures) under this part;

(iii) *Potential for contract termination.* The fact that a PDP sponsor or MA organization may terminate or refuse to renew its contract, or, in the case of an MA organization, reduce the service area included in its contract, and the effect that any of those actions may have on individuals enrolled in a prescription drug plan or MA–PD plan;

(iv) *Benefits.* (A) Covered services under the prescription drug plan;

(B) Any beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts, including cost-sharing for subsidy eligible individuals;

(C) Any maximum limitations on out-of-pocket expenses;

(D) The extent to which an enrollee may obtain benefits from out-of-network providers;

(E) The types of pharmacies that participate in the prescription drug plan's or MA–PD plan's network and the extent to which an enrollee may select among those pharmacies; and

(F) Out-of-network pharmacy access.

(v) Premiums;

(vi) The prescription drug plan's or MA–PD plan's formulary;

(vii) The prescription drug plan's or MA–PD plan's service area; and

(viii) Quality and performance indicators for benefits under a plan as determined by CMS.

(2) The procedures the PDP sponsor or MA organization offering an MA–PD plan uses to control utilization of services and expenditures.

(3) The number of disputes, and the disposition in the aggregate, in a manner and form described by CMS. These disputes are categorized as—

(i) Grievances according to § 422.564 of this chapter;

(ii) Rights to a reconsideration according to § 422.578 *et seq* of this chapter.

(4) Financial condition of the PDP sponsor or MA organization, including the most recently audited information regarding, at a minimum, a description of the financial condition of the PDP sponsor or MA organization offering the prescription drug plan or MA–PD plan.

(d) *Provision of specific information.* Each PDP sponsor or MA organization offering qualified prescription drug coverage must have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms must include—

(1) A toll-free customer call center that—

(i) Is open during usual business hours.

(ii) Provides customer telephone service, including to pharmacists, in accordance with standard business practices.

(2) An Internet Web site that—

(i) Includes, at a minimum, the information required in paragraph (b) of this section.

(ii) Includes a current formulary for its PDP plan or MA–PD plan, updated at least weekly.

(iii) Provides current and prospective Part D enrollees with at least 30 days notice regarding the removal or change in the preferred or tiered cost-sharing status of a covered Part D drug on its prescription drug plan's or MA–PD plan's formulary.

(3) The provision of information in writing, upon request.

(e) *Claims information.* A PDP sponsor or MA organization offering qualified prescription drug coverage must furnish to enrollees, in a form easily understandable to such enrollees, an explanation of benefits when prescription drug benefits are provided under qualified prescription drug coverage. The explanation of benefits must—

(1) List the item or service for which payment was made and the amount of the payment for each item or service.

(2) Include a notice of the individual's right to request an itemized statement.

(3) Include the cumulative, year-to-date total amount of benefits provided, in relation to—

(i) The deductible for the current year.

(ii) The initial coverage limit for the current year.

(iii) The annual out-of-pocket threshold for the current year.

(4) Include the cumulative, year-to-date total of incurred costs to the extent practicable.

(5) Include any applicable formulary changes as described in § 423.120(b)(5).

(6) Be provided during any month when prescription drug benefits are provided under this part.

§ 423.132 Public disclosure of pharmaceutical prices for equivalent drugs.

(a) *General requirements.* Except as provided under paragraph (c) of this section, a PDP sponsor or an MA organization offering an MA–PD plan must require a pharmacy that dispenses a covered Part D drug to inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that drug available at that pharmacy, unless the particular covered Part D drug being purchased is the lowest-priced generic version of that drug available at that pharmacy.

(b) *Timing of notice.* Subject to paragraph (d) of this section, the information under paragraph (a) of this section must be provided at the point of sale or, in the case of dispensing by mail order, at the time of delivery of the drug.

(c) *Waiver of public disclosure requirement.* CMS waives the requirement under paragraph (a) of this section in the case of—

(1) An MA private fee-for-service plan described in § 422.4 of this chapter that—

(i) Offers qualified prescription drug coverage and provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies; and

(ii) Does not charge additional cost-sharing for access to covered Part D drugs dispensed at out-of-network pharmacies.

(2) An out-of-network pharmacy;

(3) An I/T/U network pharmacy; and

(4) A network pharmacy that is located in any of the U.S. territories; and

(5) Such other circumstances where CMS deems compliance with the requirements of paragraph (a) of this section to be impossible or impracticable.

(d) *Modification of timing requirement.* CMS modifies the requirement under paragraph (b) of this section as follows—

(1) For long-term care network pharmacies, which must meet the requirement in paragraph (a) of this section within a time period specified by CMS; and

(2) Under such other circumstances where CMS deems compliance with the requirement under paragraph (b) of this section to be impossible or impracticable.

§ 423.136 Privacy, confidentiality, and accuracy of enrollee records.

The provisions of § 422.118 of this chapter apply to a PDP sponsor and prescription drug plan in the same manner as they apply to an MA organization and an MA plan.

Subpart D—Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

§ 423.150 Scope.

The regulations in this subpart specify requirements relating to the following:

(a) Cost and utilization management programs, quality assurance programs, medication therapy management programs (MTMP), and programs to control fraud, abuse, and waste for PDP sponsors and MA organizations offering MA–PD plans.

(b) CMS consumer satisfaction surveys of prescription drug plan and MA–PD.

(c) Electronic prescription program.

(d) Compliance deemed on the basis of accreditation.

(e) Accreditation organizations.

(f) Procedures for the approval of accreditation organizations as a basis for deeming compliance.

§ 423.153 Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste.

(a) *General rule.* Each PDP sponsor or MA organization offering an MA–PD plan must have established, for covered Part D drugs, furnished through a prescription drug plan or MA–PD plan, a cost-effective drug utilization management program, a quality assurance program, an MTMP, and a program to control fraud, abuse, and waste as described in § 423.153(b), § 423.153(c), § 423.153(d), and § 423.153(e) of this section.

(b) *Cost-effective drug utilization management.* A cost-effective drug utilization management program must—

(1) Include incentives to reduce costs when medically appropriate; and

(2) Maintain policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications.

(c) *Quality assurance program.* A quality assurance program must include measures and systems to reduce medication errors and adverse drug interactions and improve medication use. The program must establish processes for—

(1) Drug utilization review;

(2) Patient counseling; and

(3) Patient information record-keeping

(d) *Medication therapy management program.* (1) *General rule.* A medication therapy management program—

(i) Must assure that drugs prescribed to targeted beneficiaries described in paragraph (d)(2) of this section are appropriately used to optimize therapeutic outcomes through improved medication use;

(ii) Must, for the targeted beneficiaries described in paragraph (d)(2) of this section, reduce the risk of adverse events, including adverse drug interactions;

(iii) May be furnished by a pharmacist; and

(iv) May distinguish between services in ambulatory and institutional settings.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the medication therapy management program described in paragraph (d)(1) of this section are enrolled Part D eligible individuals who—

(i) Have multiple chronic diseases;

(ii) Are taking multiple covered Part D drugs; and

(iii) Are likely to incur annual costs for covered Part D drugs that exceed a predetermined level that CMS determines.

(3) *Use of experts.* The MTMP must be developed in cooperation with licensed and practicing pharmacists and physicians.

(4) *Coordination with care management plans.* The MTMP must be coordinated with any care management plan established for a targeted individual under a chronic care improvement program under section 1807 of MMA.

(5) *Considerations in pharmacy fees.* An applicant to become a PDP sponsor or an MA organization wishing to offer an MA–PD plan must—

(i) Describe in its application how it will take into account the resources used and time required to implement the MTMP it chooses to adopt in establishing fees for pharmacists or others providing medication therapy management services for covered Part D drugs under a prescription drug plan.

(ii) Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for medication therapy management services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

(e) *Program to control fraud, abuse, and waste.* PDP sponsors and MA organizations offering MA–PD plans must develop performance standards to evaluate, prevent, and investigate fraud, abuse, and waste. These standards will apply to the PDP sponsor's or MA organization's evaluation of PDPs, MA–PDs, pharmacy benefit managers, or other subcontractors managing or coordinating the benefit for the organization or sponsor, pharmacies, physicians, and any other providers with whom the PDP sponsor or MA organizations does business.

(f) *Exception for private fee-for-service MA plans offering qualified prescription drug coverage.* In the case of an MA plan described in § 422.4(a)(3) of this chapter, the requirements under paragraphs (b) and (d) of this section do not apply.

§ 423.156 Consumer satisfaction surveys.

CMS conducts consumer satisfaction surveys of PDP and MA–PD enrollees similar to the surveys it conducts of MA enrollees under § 422.152 (b) of this chapter.

§ 423.159 Electronic prescription program.

(a) *Electronic prescription standards.* PDP sponsors and MA organizations offering qualified prescription drug coverage must have the capacity to support and must comply with electronic prescription standards relating to covered Part D drugs, for Part D eligible individuals, developed by CMS, once final standards are effective.

(b) *Promotion of electronic prescribing by MA–PD plans.* An MA organization offering an MA-PD plan may provide for a separate or differential payment to a participating physician that prescribes covered Part D drugs in accordance with electronic prescription standards, including voluntary standards promulgated by CMS as well as final standards established by CMS once final standards are effective.

§ 423.162 Quality Improvement Organization activities.

(a) *General rule.* Quality Improvement Organizations (QIOs) are required to offer providers, practitioners, MA organizations, and PDP sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy. QIOs offer assistance according to contracts established with the Secretary.

(b) *Collection of information.* Information collected, acquired, or generated by a QIO in the performance of its responsibilities under this section is subject to the confidentiality provisions of 42 CFR Part 480. PDP sponsors and MA organizations offering MA–PD plans are required to provide specified information to CMS for distribution to the QIOs as well as directly to QIOs.

(c) *MA organizations and PDP sponsors.* For purposes of 42 CFR Parts 476 and 480, MA organizations and PDP sponsors are included in the definition of "health care facility."

§ 423.165 Compliance deemed on the basis of accreditation.

(a) *General rule.* A PDP sponsor or MA organization offering an MA–PD plan is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The PDP sponsor or MA organization is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by CMS; and

(2) The accreditation organization uses the standards approved by CMS for the purposes of assessing the PDP sponsor or MA organization's compliance with Medicare requirements.

(b) *Deemable requirements.* The requirements relating to the following areas are deemable:

(1) Access to covered drugs, as provided under § 423.120 and § 423.124.

(2) Cost and utilization management, quality assurance, medication therapy management programs, and programs to

control fraud, abuse, and waste, as provided under § 423.153.

(3) Privacy, confidentiality, and accuracy of enrollee records, as provided under § 423.136.

(c) *Effective date of deemed status.* The date the PDP sponsor or MA organization offering an MA–PD plan is deemed to meet the applicable requirements is the later of the following:

(1) The date the accreditation organization is approved by CMS.

(2) The date the PDP sponsor or MA organization is accredited by the accreditation organization.

(d) *Obligations of deemed PDP sponsors and MA organizations offering MA–PD plans.* A PDP sponsor or MA organization offering an MA–PD plan deemed to meet Medicare requirements must—

(1) Submit to surveys by CMS to validate its accreditation organization's accreditation process; and

(2) Authorize its accreditation organization to release to CMS a copy of its most recent accreditation survey, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(e) *Removal of deemed status.* CMS removes part or all of a PDP sponsor or MA organization's deemed status for any of the following reasons—

(1) CMS determines, on the basis of its own investigation, that the PDP sponsor or MA organization does not meet the Medicare requirements for which deemed status was granted.

(2) CMS withdraws its approval of the accreditation organization that accredited the PDP sponsor or MA organization.

(3) The PDP sponsor or MA organization fails to meet the requirements of paragraph (d) of this section.

(f) *Enforcement authority.* CMS retains the authority to initiate enforcement action against any PDP sponsor or MA organization offering an MA–PD plan that it determines, on the basis of its own survey or the results of an accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.

§ 423.168 Accreditation organizations.

(a) *Conditions for approval.* CMS may approve an accreditation organization for a given standard under this part if it meets the following conditions:

(1) In accrediting PDP sponsors and MA organizations offering MA–PD plans, it applies and enforces standards that are at least as stringent as Medicare requirements for the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in § 423.171.

(3) It ensures that—

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity;

(ii) The majority of the membership of its governing body is not comprised of managed care organizations, PDP sponsors or their representatives; and

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

(b) *Notice and comment.* (1) *Proposed notice.* CMS publishes a notice in the **Federal Register** whenever it is considering granting an accreditation organization's application for approval. The notice—

(i) Announces CMS's receipt of the accreditation organization's application for approval;

(ii) Describes the criteria CMS uses in evaluating the application; and

(iii) Provides at least a 30-day comment period.

(2) *Final notice.* (i) After reviewing public comments, CMS publishes a final notice in the **Federal Register** indicating whether it has granted the accreditation organization's request for approval.

(ii) If CMS grants the request, the final notice specifies the effective date and the term of the approval that may not exceed 6 years.

(c) *Ongoing responsibilities of an approved accreditation organization.* An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in written form and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to deemed PDP sponsors or MA organizations.

(iv) Information about any PDP sponsor or MA organization against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the PDP sponsor's or MA organization's accreditation. (The accreditation organization must provide this information within 30 days of taking the remedial or adverse action.)

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in CMS requirements, submit the following to CMS—

(i) An acknowledgment of CMS's notification of the change.

(ii) A revised crosswalk reflecting the new requirements.

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the timeframes specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 3 days of identifying, in an accredited PDP sponsor or MA organization, a deficiency that poses immediate jeopardy to the organization's enrollees or to the general public, give CMS written notice of the deficiency.

(5) Within 10 days of CMS's notice of withdrawal of approval, give written notice of the withdrawal to all accredited PDP sponsors and MA organizations.

(6) On an annual basis, provide summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations.* Specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization include the following:

(1) *Equivalency review.* CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation review.* CMS or its agent may conduct a survey of an accredited organization, examine the results of the accreditation organization's own survey, or attend the accreditation organization's survey to validate the organization's accreditation process. At the conclusion of the review, CMS identifies any

accreditation programs for which validation survey results indicate—

(i) A 20 percent rate of disparity between certification by the accreditation organization and certification by CMS or its agent on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Any disparity between certification by the accreditation organization and certification by CMS or its agent on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) That, regardless of the rate of disparity, there are widespread or systematic problems in an organization's accreditation process that accreditation no longer provides assurance that the Medicare requirements are met or exceeded.

(3) *Onsite observation.* CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to the following:

(i) Reviewing documents.

(ii) Auditing meetings concerning the accreditation process.

(iii) Evaluating survey results or the accreditation status decision-making process.

(iv) Interviewing the organization's staff.

(4) *Notice of intent to withdraw approval.* If an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this subpart, CMS will give the organization written notice of its intent to withdraw approval.

(5) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Deeming, based on accreditation, no longer guarantees that the PDP sponsor or MA organization meets the requirements for offering qualified prescription drug coverage, and failure to meet those requirements may jeopardize the health or safety of Medicare enrollees and constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations under this section or under § 423.158 or § 423.162.

(6) *Reconsideration of withdrawal of approval.* An accreditation organization dissatisfied with a determination to withdraw CMS approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter.

§ 423.171 Procedures for approval of accreditation as a basis for deeming compliance.

(a) *Required information and materials.* A private, national accreditation organization applying for approval must furnish to CMS all of the following information and materials (when reapplying for approval, the organization need furnish only the particular information and materials requested by CMS):

(1) The types of prescription drug plans and MA–PD plans that it reviews as part of its accreditation process.

(2) A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk).

(3) Detailed information about the organization's survey process, including the following:

(i) Frequency of surveys and whether surveys are announced or unannounced.

(ii) Copies of survey forms, and guidelines and instructions to surveyors.

(iii) Descriptions of—

(A) The survey review process and the accreditation status decision making process;

(B) The procedures used to notify accredited PDP sponsors and MA organizations of deficiencies and to monitor the correction of those deficiencies; and

(C) The procedures used to enforce compliance with accreditation requirements.

(4) Detailed information about the individuals who perform surveys for the accreditation organization, including the—

(i) Size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process;

(ii) Education and experience requirements surveyors must meet;

(iii) Content and frequency of the in-service training provided to survey personnel;

(iv) Evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) Organization's policies and practice for the participation, in surveys or in the accreditation decision process by an individual who is professionally or financially affiliated with the entity being surveyed.

(5) A description of the organization's data management and analysis system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(6) 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.

(7) A description of the organization's policies and procedures for 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.

(8) A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or 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 serve as a basis for accreditation if CMS approves the accreditation organization.

(9) A list of all currently accredited PDP sponsors and MA organizations and the type, category, and expiration date of the accreditation held by each of them.

(10) A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by CMS.

(11) The name and address of each person with an ownership or control interest in the accreditation organization.

(b) *Required supporting documentation.* A private, national accreditation organization applying or reapplying for approval also must submit the following supporting documentation—

(1) A written presentation that demonstrates its ability to furnish CMS with electronic data in CMS compatible format.

(2) A resource analysis that demonstrates that it's staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(3) A statement acknowledging that, as a condition for approval, it agrees to comply with the ongoing responsibility requirements of § 423.168(c).

(c) *Additional information.* If CMS determines that it needs additional information for a determination to grant or deny the accreditation organization's request for approval, it notifies the organization and allows time for the

organization to provide the additional information.

(d) *Onsite visit.* CMS may visit the accreditation organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents and interviews with the organization's staff.

(e) *Notice of determination.* CMS gives the accreditation organization, within 210 days of receipt of its completed application, a formal notice that—

(1) States whether the request for approval has been granted or denied;

(2) Gives the rationale for any denial; and

(3) Describes the reconsideration and reapplication procedures.

(f) *Withdrawal.* An accreditation organization may withdraw its application for approval at any time before it receives the formal notice specified in paragraph (e) of this section.

(g) *Reconsideration of adverse determination.* An accreditation organization that has received a notice of denial of its request for approval may request a reconsideration in accordance with subpart D of part 488 of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an accreditation organization that has received notice of denial of its request for approval may submit a new request if it—

(i) Has revised its accreditation program to correct the deficiencies on which the denial was based.

(ii) Can demonstrate that the PDP sponsors and MA organizations that it has accredited meet or exceed applicable Medicare requirements; and

(iii) Resubmits the application in its entirety.

(2) An accreditation organization that has requested reconsideration of CMS' denial of its request for approval may not submit a new request until the reconsideration is administratively final.

Subpart F—Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

§ 423.251 Scope.

This section sets forth the requirements and limitations on submission, review, negotiation and approval of competitive bids for prescription drug plans and MA–PD plans; the calculation of the national average bid amount; and the determination of enrollee premiums.

§ 423.258 Definitions.

For the purposes of this part, the following definitions apply:

Full risk plan means a prescription drug plan that is not a limited risk plan or a fallback prescription drug plan.

Limited risk plan means a prescription drug plan that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level described in § 423.265(d) in its bid submitted for the plan. This term does not include a fallback prescription drug plan.

Standardized bid amount means, for a prescription drug plan that provides basic prescription drug coverage, the PDP approved bid; for a prescription drug plan that provides supplemental prescription drug coverage, the portion of the PDP approved bid that is attributable to basic prescription drug coverage; for a MA–PD plan, the portion of the accepted bid amount that is attributable to basic prescription drug coverage.

§ 423.265 Submission of bids and related information.

(a) *Eligibility for bidding.* (1) *Eligible entities.* With the exception set forth in paragraph (a)(2) of this section, an applicant may submit a bid to become a PDP sponsor or to become an MA organization offering an MA–PD plan

(2) *Limitation on entities offering fallback prescription drug plans.* CMS will not accept a bid from a potential PDP sponsor for the offering of a full risk or limited risk prescription drug plan in a PDP region for a year if the applicant—

(i) Submitted a bid under § 423.863 for the year (as the first year of a contract period under § 423.863) to offer a fallback prescription drug plan in any PDP region;

(ii) Offers a fallback prescription drug plan in any PDP region during the year; or

(iii) Offered a fallback prescription drug plan in that PDP region during the previous year.

(3) *Construction.* For purposes of this paragraph, an entity is treated as submitting a bid for a prescription drug plan or offering a fallback prescription drug plan if the entity is acting as a subcontractor of a PDP sponsor that is offering a plan. The previous sentence does not apply to entities that are subcontractors of an MA organization except insofar as the MA organization is applying to act as a PDP sponsor of a prescription drug plan.

(b) *Bid Submission.* Not later than the first Monday in June, each potential PDP sponsor or MA organization planning to offer an MA–PD plan must submit bids and supplemental information described in this section for each prescription drug or MA–PD plan it intends to offer in the subsequent calendar year.

(c) *Basic rule for bid.* Each potential PDP sponsor or MA organization must submit a bid in a format to be specified by CMS for each prescription drug plan or MA–PD plan it offers. Each bid must reflect a uniform benefit package, including premium (except as provided for the late enrollment penalty described in § 423.286(d)(3)) and all applicable cost sharing, for all individuals enrolled in the plan. Each bid must reflect the applicant's estimate of its average monthly revenue requirements to provide qualified prescription drug coverage (including any supplemental coverage) for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1).

(1) *Included costs.* The bid includes costs (including administrative costs and return on investment/profit) for which the plan is responsible in providing basic and supplemental benefits.

(2) *Excluded costs.* The bid does not include costs associated with payments by the enrollee for deductible, copayments, coinsurance, payments projected to be made by CMS for reinsurance, or any other costs for which the sponsor is not responsible.

(3) *Actuarial valuation.* The bid must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles. A qualified actuary must certify the plan's actuarial valuation (which may be prepared by others under his/her direction or review), and must be a member of the American Academy of Actuaries to be deemed qualified. Applicants may use qualified outside actuaries to prepare their bids.

(d) *Specific requirements for bids.* The bid submission must include the following information:

(1) *Coverage.* A description of the coverage to be provided under the plan, including any supplemental coverage and the deductible and other cost sharing.

(2) *Actuarial value of bid components.* The applicant must provide the following information on bid components, as well as actuarial certification that the values are calculated according to CMS guidelines on actuarial valuation, including adjustment for the effect that providing alternative prescription drug coverage (rather than defined standard prescription drug coverage) has on drug utilization, if applicable.

(i) The actuarial value of the qualified prescription drug coverage to be offered under each plan for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1) and the basis for the estimate.

(ii) The portion of the bid attributable to basic prescription drug coverage and the portion (if any) attributable to supplemental benefits.

(iii) The assumptions regarding reinsurance amounts payable under § 423.329(c) used in calculating the bid.

(iv) The assumptions regarding low-income cost-sharing payable under § 423.329(d) used in calculating the bid.

(v) The amount of administrative costs and return on investment or profit included in the bid.

(3) *Service area.* A description of the service area of the plan.

(4) *Level of risk assumed.* For a potential PDP sponsor, the level of risk assumed in the bid specified in paragraph (e) of this section.

(5) *Plan Average Risk Score.* An estimate of the plan's average prescription drug risk score (as established under § 423.329(b)) for all projected enrollees for purposes of risk adjusting any supplemental premium.

(6) *Additional information.* Additional information CMS requests to support bid amounts and facilitate negotiation.

(e) *Special rule for PDP sponsors.* Bids for all plans offered by a potential PDP sponsor in a region, but not those of potential MA organizations offering MA–PD plans, may include a uniform modification of the amount of risk assumed (based on a process to be specified) as described in one or more of the following paragraphs. Any such modification will apply to all plans offered by the PDP sponsor in a PDP region.

(1) *Increase in Federal percentage assumed in initial risk corridor.* An equal percentage point increase in the percents applied for costs between the first and second threshold limits under § 423.336(b)(2)(i) and (b)(2)(ii)(A) and § 423.336 (b)(3)(i) and (b)(3)(ii)(A). This provision does not affect the application of a higher percentage for plans in 2006 or 2007 under § 423.336(b)(2)(iii).

(2) *Increase in Federal percentage assumed in second risk corridor.* An equal percentage point increase in the percents applied for costs above the second threshold upper limit or below the second threshold upper limit under paragraphs § 423.336(b)(2)(ii)(B) and (b)(3)(ii)(B).

(3) *Decrease in size of risk corridors.* A decrease in the size of the risk corridors by means of reductions in the threshold risk percentages specified in § 423.336(a)(2)(ii)(A) and/or (a)(2)(ii)(B).

(f) *Special rule for fallback plans.* Fallback plan bids are not subject to the rules in this section. They must follow requirements specified in § 423.863.

§ 423.272 Review and negotiation of bid and approval of plans submitted by potential PDP sponsors or MA organizations planning to offer MA–PD plans.

(a) *Review and negotiation regarding information, terms and conditions.* CMS reviews the information filed under § 423.265(c) in order to conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan using authority similar to that of the Director of the Office of Personnel Management for health benefit plans under Chapter 89 of title 5, U.S.C.

(b) *Approval of proposed plans.* CMS will approve the prescription drug plan or MA–PD plan only if the plan and the PDP sponsor or MA organization offering the plan comply with all applicable CMS Part D requirements, including those related to the provision of qualified prescription drug coverage and actuarial determinations.

(1) *Application of revenue requirements standard.* CMS only approves a bid if it determines that the portions of the bid attributable to basic and supplemental prescription drug coverage are supported by the actuarial bases provided and reasonably and equitably reflect the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for benefits provided under that plan, less the sum (determined on a monthly per capita basis) of the actuarial value of the reinsurance payments under section § 423.329(c).

(2) *Plan design.* CMS does not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan. If the design of the categories and classes within a formulary is consistent with the model guidelines (if any) established by the United States Pharmacopeia, that formulary may not be found to discourage enrollment on the basis of its categories and classes alone.

(c) *Limited risk plans.* (1) *Application of limited risk plans.* There is no limit on the number of full risk plans that CMS approves under paragraph (b) of this section. CMS only approves a limited risk plan in accordance with paragraphs (c)(2) and (c)(3) of this section if the access requirements under § 423.859 are not otherwise met for a PDP region.

(2) *Maximizing assumption of risk.* CMS gives priority in approval for those limited risk plans bearing the highest level of risk, but may take into account the level of the bids submitted by the plans and is not required to accept the plan with the highest assumption of risk. In no case does CMS approve a limited risk plan under which the modification of risk level provides for no (or a minimal) level of financial risk.

(3) *Limited exercise of authority.* CMS only approves the minimum number of limited risk plans needed to meet the access requirements.

(d) *Special rules for private fee-for-service (PFFS) plans that offer prescription drug coverage.* PFFS plans choosing to offer prescription drug coverage are subject to all MA–PD bid submission and approval requirements with the following exceptions:

(1) *Exemption from negotiations.* These plans are exempt from the review and negotiation process in paragraph (a) of this section, and are not held to the revenue requirements standard in paragraph (b)(1) of this section.

(2) *Requirements regarding negotiated prices.* These plans are not required to provide access to negotiated prices. However, if they do, they must meet the applicable requirements of § 423.104(h).

(3) *Modification of pharmacy access standard and disclosure requirement.* If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost sharing and without regard to whether they are participating providers, §§ 423.120(a) and 423.132 requiring certain network access standards and the disclosure of the availability of lower cost bioequivalent generic drugs does not apply to the plan.

§ 423.279 National average monthly bid amount.

(a) *Bids included.* For each year (beginning with 2006) CMS computes a national average monthly bid amount from approved bids in order to calculate the base beneficiary premium, as provided in § 423.286(c). The national average monthly bid amount is equal to a weighted average of the standardized bid amounts for each prescription drug plan and for each MA–PD plan described in section 1851(a)(2)(A)(i) of the Act. The calculation does not include bids submitted for MSA plans, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894, and under reasonable cost reimbursement contracts under section 1876(h) of the Act.

(b) *Calculation of weighted average.* The national average monthly bid amount is a weighted average, with the weight for each plan equal to a percentage with the numerator equal to the number of Part D eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1)) and the denominator equal to the total number of Part D eligible individuals enrolled in all the Part D plans included in the calculation of the national average bid amount in the reference month. For purposes of calculating the monthly national average monthly bid amount for 2006, CMS determines the weighted average for 2005.

(c) *Geographic adjustment.* (1) CMS establishes an appropriate methodology for adjusting the national average monthly bid amount to take into account differences in prices for covered Part D drugs among PDP regions.

(2) CMS does not apply any geographic adjustments if CMS determines that price variations among PDP regions are negligible.

(3) CMS applies any geographic adjustment in a budget neutral manner so as to not result in a change in the aggregate payments that may have been made if CMS had not applied an adjustment.

§ 423.286 Rules regarding premiums.

(a) *General rule.* Except as provided in paragraphs (d)(3) and (e) of this section, and in § 423.463(b) with regard to employer group waivers, the monthly beneficiary premium for a prescription drug plan or MA–PD plan in a PDP region is the same for all part D eligible individuals enrolled in the plan. The monthly beneficiary premium for a prescription drug plan or MA–PD plan is the base beneficiary premium, as determined in paragraph (c) of this section, adjusted as described in paragraph (d) of this section for the difference between the bid and the national average monthly bid amount, any supplemental benefits and for any late enrollment penalties.

(b) *Beneficiary premium percentage.* The beneficiary premium percentage for any year is a fraction, the—

(1) Numerator of which is 25.5 percent; and

(2) Denominator of which is as follows:

(i) 100 percent minus the percentage established in paragraph (b)(2)(ii) of this section.

(ii) The percentage established in this paragraph equals:

(A) The total reinsurance payments that CMS estimates will be paid under § 423.329(c) for the coverage year; divided by—

(B) The amount estimated under paragraph (b)(2)(ii)(A) of this section for the year plus total payments that CMS estimates will be paid to prescription drug plans and MA–PD plans that are attributable to the standardized bid amount during the year, taking into account amounts paid by both CMS and enrollees.

(c) *Base beneficiary premium.* The base beneficiary premium for a prescription drug plan for a month is equal to the product of the—

(1) Beneficiary premium percentage as specified in paragraph (b) of this section; and

(2) National average monthly bid amount (computed under § 423.279) for the month.

(d) *Adjustments to base beneficiary premium.* The base beneficiary premium may be adjusted to reflect any of the following scenarios, if applicable.

(1) *Adjustment to reflect difference between bid and national average bid.* If the amount of the standardized bid amount exceeds the amount of the adjusted national average monthly bid amount, the monthly base beneficiary premium is increased by the amount of the excess. If the amount of the adjusted national average monthly bid amount exceeds the standardized bid amount, the monthly base beneficiary premium is decreased by the amount of the excess.

(2) *Increase for supplemental prescription drug benefits.* The portion of the PDP or MA–PD plan approved bid that is attributable to supplemental prescription drug benefits increases the beneficiary premium. This supplemental portion of the bid may be adjusted to reflect the average risk score of the plan by multiplying by the plan average risk score provided in § 423.265(d)(5).

(3) *Increase for late enrollment penalty.* The base beneficiary premium is increased on a monthly basis by the amount of any late enrollment penalty.

(i) *Late Enrollment Penalty Amount.* The penalty amount for a Part D eligible individual for a continuous period of eligibility (as provided in § 423.46(a)) is the greater of—

(A) An amount that CMS determines is actuarially sound for each uncovered month in the same continuous period of eligibility; or

(B) 1 percent of the base beneficiary premium (computed under paragraph (c) of this section) for each uncovered month in the period.

(ii) *Special rule for 2006 and 2007.* In 2006 and 2007 the penalty amount discussed in paragraph (d)(3) will equal the amount referenced in paragraph (d)(3)(i)(B) of this section unless another amount is specified in a separate issuance based on available analysis or other information as determined by the Secretary.

(e) *Decrease in monthly beneficiary premium for low-income assistance.* The monthly beneficiary premium may be eliminated or decreased in the case of a subsidy-eligible individual under § 423.780.

(f) *Special rules for fallback plans.* The monthly beneficiary premium charged under a fallback plan is calculated under § 423.867(a).

§ 423.293 Collection of monthly beneficiary premium.

(a) *General rule.* Subject to paragraphs (c) and (d) of this section, the provisions of section 1854(d) of the Act (as specified in § 422.262(b) on the consolidated monthly premium and paragraph (f) of this section on beneficiary payment options), apply to PDP sponsors and premiums (and any late enrollment penalty) under this part in the same manner as they apply to MA organizations and beneficiary premiums under Part C except that any reference to a Trust Fund is deemed for this purpose a reference to the Medicare Prescription Drug Account.

(b) *Crediting of late enrollment penalty.* CMS estimates and specifies the portion of the late enrollment penalty imposed under § 423.286(d)(3) attributable to increased actuarial costs assumed by the PDP sponsor or MA organization (and not taken into account through risk adjustment provided under § 423.329(b)(1) or through reinsurance payments under § 423.329(c)) as a result of the late enrollment.

(c) *Collection of late enrollment penalty.*

(1) *Collection through withholding.* In the case of a late enrollment penalty that is collected from a Part D eligible individual in the manner described in § 422.262(f)(1), CMS pays only the portion of the late enrollment penalty described in paragraph (b) of this section to the PDP sponsor or MA organization offering the Part D plan in which the individual is enrolled

(2) *Collection by plan.* In the case of a late enrollment penalty collected from a Part D eligible individual in a manner other than the manner described in § 422.262(f)(1), CMS reduces payments otherwise made to the PDP sponsor or MA organization by an amount equal to this portion of the late enrollment penalty.

(d) *Special rule for fallback plans.* The collection requirements of this section do not apply to fallback

prescription drug plans. The fallback plans follow the requirements set forth in § 423.867(b).

Subpart G—Payments to PDP Sponsors and MA Organizations Offering MA–PD Plans For All Medicare Beneficiaries For Qualified Prescription Drug Coverage

§ 423.301 Scope.

This section sets forth rules for the calculation and payment of CMS direct and reinsurance subsidies for prescription drug plans and MA–PD plans; the application of risk corridors and risk-sharing adjustments to payments; and retroactive adjustments and reconciliations to actual enrollment and interim payments.

§ 423.308 Definitions and terminology.

For the purposes of this part, the following definitions apply—

Actually paid means that the costs must be actually incurred by the sponsor and must be net of any direct or indirect remuneration (including discounts, chargebacks or average percentage rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred by the sponsor for the drug.

Allowable reinsurance costs means the subset of gross covered prescription drug costs that are attributable to basic or standard benefits only and that are actually paid by the sponsor or organization or by (or on behalf of) an enrollee under the plan. The costs for any plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic coverage, but also to exclude any basic coverage costs determined to be attributable to increased utilization over the standard benefit as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

Allowable risk corridor costs means the subset of prescription drug costs (not including administrative costs, but including costs directly related to the dispensing of covered Part D drugs during the year) that are attributable to basic or standard benefits only and that are incurred and actually paid by the sponsor or organization under the plan. Costs may be based upon imposition of the maximum amount of copayments permitted under § 423.782. The costs for any plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic coverage, but also to exclude any basic coverage costs determined to be attributable to increased utilization over the standard benefit as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

Coverage year means a calendar year in which covered Part D drugs are dispensed if the claim for those drugs (and payment on the claim) is made not later than 3 months after the end of the year.

Gross covered prescription drug costs means those costs incurred under a Part D plan, excluding administrative costs, but including costs related to the dispensing of covered Part D drugs during the year and costs relating to the deductible. They equal—

(1) All reimbursement paid by a PDP sponsor or an MA organization offering an MA–PD plan to a pharmacy (or other intermediary) or to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining drugs under the plan; plus

(2) All amounts paid under the plan by or on behalf of an enrollee (such as the deductible, coinsurance, cost-sharing, or amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain drugs covered under the plan. These costs are determined regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

Target amount for any prescription drug plan or MA–PD plan equals the total amount of payments (from CMS and enrollees) to that plan for the year for all standardized bid amounts as risk adjusted under § 423.329(b)(1), less the administrative expenses (including return on investment) assumed in the standardized bids.

§ 423.315 General payment provisions.

(a) *Source of payments.* CMS payments under this section are made from the Medicare Prescription Drug Account.

(b) *Monthly payments.* CMS provides a direct subsidy in the form of advance monthly payments equal to the plan's standardized bid, risk adjusted for health status as provided in § 423.329(b), minus the beneficiary monthly premium as determined in § 423.286.

(c) *Reinsurance subsidies.* CMS provides reinsurance subsidy payments described in § 423.329(c) through payments of amounts on an as-incurred basis as provided under § 423.329(c)(2)(i) and final reconciliation to actual allowable reinsurance costs as provided in § 423.343(c).

(d) *Low-income subsidies.* CMS makes payments for premium and cost sharing subsidies, including additional coverage above the initial coverage limit, on behalf of certain subsidy-eligible enrollees as provided in § 423.780 and § 423.782. CMS provides low-income cost-sharing subsidy payments described in § 423.782 through interim payments of amounts as provided under § 423.329(d)(2)(i) and reconciliation to actual allowable reinsurance costs as provided in § 423.343(d).

(e) *Risk-sharing arrangements.* CMS may issue lump-sum payments or adjust monthly payments in the following payment year based on the relationship of the plan's adjusted allowable risk corridor costs to predetermined risk corridor thresholds in the coverage year as provided in § 423.336.

(f) *Retroactive adjustments and reconciliations.* CMS reconciles payment year disbursements with updated enrollment and health status data, actual low-income cost-sharing costs and actual allowable reinsurance costs as provided in § 423.343.

(g) *Special rules for private fee-for-service plans.*

(1) *Application of reinsurance.* For private fee-for-service plans, CMS determines the amount of reinsurance payments as provided under § 423.329(c)(3).

(2) *Exemption from risk corridor provisions.* The provisions of § 423.336 regarding risk sharing do not apply.

(h) *Special rules for fallback plans.* In lieu of the amounts otherwise payable under § 423.329, the amount payable to a PDP sponsor offering a fallback prescription drug plan is the amount determined under the contract for the plan in accordance with § 423.871(e).

§ 423.322 Requirement for disclosure of information.

(a) *Payment conditional upon provision of information.* Payments to a PDP sponsor or MA organization are conditioned upon provision of information to CMS that is necessary to carry out this subpart, or as required by law.

(b) *Restriction on use of information.* Officers, employees and contractors of the Department of Health and Human Services may use the information disclosed or obtained in accordance with the provisions of this subpart only for the purposes of, and to the extent necessary in, carrying out this subpart

including, but not limited to, determination of payments and payment-related oversight and program integrity activities. This restriction does not limit OIG authority to conduct audits and evaluations necessary for carrying out these regulations.

§ 423.329 Determination of payment.

(a) *Subsidy payments.* (1) *Direct subsidy.* CMS makes a direct subsidy payment for each eligible beneficiary enrolled in a prescription drug plan or MA–PD plan for a month equal to the amount of the plan's approved standardized bid, adjusted for health status (as determined under § 423.329(b)(1)), and reduced by the base beneficiary premium for the plan (as determined under § 423.286(c) and adjusted in § 423.286(d)(1)).

(2) *Subsidy through reinsurance.* CMS makes reinsurance subsidy payments as provided under paragraph (c) of this section.

(3) *Low-income cost-sharing subsidy.* CMS makes low-income cost-sharing subsidy payments as provided under paragraph (d) of this section.

(b) *Health status risk adjustment.* (1) *Establishment of risk factors.* CMS establishes an appropriate methodology for adjusting the standardized bid amount under paragraph (a)(1) of this section, to take into account variation in costs for basic prescription drug coverage among prescription drug plans and MA–PD plans based on the differences in actuarial risk of different enrollees being served. Any risk adjustment is designed in a manner so as to be budget neutral in the aggregate to the risk of the Part D eligible individuals who enroll in Part D plans.

(2) *Considerations.* In establishing the methodology under paragraph (b)(1) of this section, CMS takes into account the similar methodologies used under § 422.308(c)(1) to adjust payments to MA organizations for benefits under the original Medicare fee-for-service program option.

(3) *Data collection.* In order to carry out this paragraph, CMS requires—

(i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to Part A and Part B data in a form and manner similar to the process provided under § 422.310 and other information as CMS determines necessary; and

(ii) MA organizations that offer MA–PD plans to submit data regarding drug claims that can be linked at the individual level to other data that the organizations are required to submit to CMS in a form and manner similar to the process provided under § 422.310 and other information as CMS determines necessary.

(4) *Publication.* At the time of publication of risk adjustment factors under § 422.312(a)(1)(ii), CMS publishes the risk adjusters established under this paragraph of this section for the upcoming calendar year.

(c) *Reinsurance payment amount.* (1) *General rule.* The reinsurance payment amount for a Part D eligible individual enrolled in a prescription drug plan or MA–PD plan for a coverage year is an amount equal to 80 percent of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred in the coverage year after the individual has truly incurred out-of-pocket costs that exceed the annual out-of-pocket threshold specified in § 423.108(b)(4)(iii).

(2) *Payment method.* Payments under this section are based on a method as CMS determines.

(i) *Payments during the coverage year.* CMS establishes a payment method by which monthly payments of amounts under this section are made during a year based on allowable reinsurance costs incurred in each month of the coverage year.

(ii) *Final payments.* CMS reconciles the payments made during the coverage year to final actual allowable reinsurance costs as provided in § 423.343(c).

(3) *Special rules for private fee-for-service Plans offering prescription drug coverage.* CMS determines the amount of reinsurance payments for private fee-for-service plans offering prescription drug coverage using a methodology that—

(i) Bases the amount on CMS' estimate of the amount of the payments that are payable if the plan were an MA–PD plan described in section 1851(a)(2)(A)(i); and

(ii) Takes into account the average reinsurance payments made under § 423.329(c) for populations of similar risk under MA–PD plans described in the section.

(d) *Low-income cost sharing subsidy payment amount.*

(1) *General rule.* The low-income cost-sharing subsidy payment amount on behalf of a low-income subsidy eligible individual enrolled in a prescription drug plan or MA–PD plan for a coverage year is the amount described in § 423.782.

(2) *Payment method.* Payments under this section are based on a method that CMS determines.

(i) *Interim payments.* CMS establishes a payment method by which interim payments of amounts under this section are made during a year based on the low-income cost-sharing assumptions submitted with plan bids under § 423.265(d)(2)(iv) and negotiated and approved under § 423.272.

(ii) *Final payments.* CMS reconciles the interim payments to actual incurred low-income cost-sharing costs as provided in § 423.343(d).

§ 423.336 Risk-sharing arrangements.

(a) *Portion of total payments to a sponsor or organization subject to risk.* (1) *Adjusted allowable risk corridor costs.* For purposes of this paragraph, the term adjusted allowable risk corridor costs means—

(i) The allowable risk corridor costs for the plan for the coverage year, reduced by—

(ii) The sum of—

(A) The total reinsurance payments made under § 423.329(c) to the sponsor of the plan for the year; and

(B) The total non-premium subsidy payments made under § 423.782 to the sponsor of the plan for the coverage year.

(2) *Establishment of risk corridors.* (i) *Risk corridors.* For each year, CMS establishes a risk corridor for each prescription drug plan and each MA–PD plan. The risk corridor for a plan for a year is equal to a range as follows:

(A) *First threshold lower limit.* The first threshold lower limit of the corridor is equal to—

(1) The target amount for the plan; minus

(2) An amount equal to the first threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(A) of this section) of the target amount.

(B) *Second threshold lower limit.* The second threshold lower limit of the corridor is equal to—

(1) The target amount for the plan; minus

(2) An amount equal to the second threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(B) of this section) of the target amount.

(C) *First threshold upper limit.* The first threshold upper limit of the corridor is equal to the sum of—

(1) The target amount; and

(2) An amount equal to the first threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(A) of this section) of the target amount.

(D) *Second threshold upper limit.* The second threshold upper limit of the corridor is equal to the sum of—

(1) The target amount; and

(2) An amount equal to the second threshold risk percentage for the plan,

(as determined under paragraph (a)(2)(ii)(B) of this section) of the target amount.

(ii) *First and second threshold risk percentage defined.* (A) *First threshold risk percentage.* Subject to paragraph (a)(2)(iii) of this section, the first threshold risk percentage is for—

(1) 2006 and 2007, and 2.5 percent;

(2) 2008 through 2011, 5 percent; and

(3) 2012 and subsequent years, a percentage CMS establishes, but in no case less than 5 percent.

(B) *Second threshold risk percentage.* Subject to paragraph (a)(2)(iii) of this section, the second threshold risk percentage is for—

(1) 2006 and 2007, 5.0 percent;

(2) 2008 through 2011, 10 percent

(3) 2012 and subsequent years, a percentage CMS establishes that is greater than the percent established for the year under paragraph (a)(2)(ii)(A)*(3)* of this section, but in no case less than 10 percent.

(iii) *Reduction of risk percentage to ensure two Plans in an area.* In accordance with § 423.265(e), a PDP sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (b) of this section.

(3) *Plans at risk for entire amount of supplemental prescription drug coverage.* A PDP sponsor and MA organization that offer a plan that provides supplemental prescription drug benefits are at full financial risk for the provision of the supplemental benefits.

(b) *Payment adjustments.* (1) *No adjustment if adjusted allowable risk corridor costs within risk corridor.* If the adjusted allowable risk corridor costs for the plan for the year are at least equal to the first threshold lower limit of the risk corridor (specified in paragraph (a)(2)(i)(A) of this section) but not greater than the first threshold upper limit of the risk corridor (specified in paragraph (a)(2)(i)(C) of this section) for the plan for the year, CMS makes no payment adjustment.

(2) *Increase in payment if adjusted allowable risk corridor costs above upper limit of risk corridor.*

(i) *Costs between first and second threshold upper limits.* If the adjusted allowable risk corridor costs for the plan for the year are greater than the first threshold upper limit, but not greater than the second threshold upper limit, of the risk corridor for the plan for the year, CMS increases the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in paragraph (b)(2)(iii) of this section are met for the year) of the difference between the adjusted allowable risk corridor costs and the first threshold upper limit of the risk corridor.

(ii) *Costs above second threshold upper limits.* If the adjusted allowable risk corridor costs for the plan for the year are greater than the second threshold upper limit of the risk corridor for the plan for the year, CMS increases the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to the sum of—

(A) 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions specified in paragraph (b)(2)(iii) of this section are met for the year) of the difference between the second threshold upper limit and the first threshold upper limit; and

(B) 80 percent of the difference between the adjusted allowable risk corridor costs and the second threshold upper limit of the risk corridor.

(iii) *Conditions for application of higher percentage for 2006 and 2007.* The conditions specified in this paragraph are met for 2006 or 2007 if CMS determines for the year that—

(A) At least 60 percent of prescription drug plans and MA–PD plans to which this paragraph applies have adjusted allowable risk corridor costs for the plan for the year that are more than the first threshold upper limit of the risk corridor for the plan for the year; and

(B) The plans represent at least 60 percent of Part D eligible individuals enrolled in any prescription drug plan or MA–PD plan.

(3) *Reduction in payment if adjusted allowable risk corridor costs below lower limit of risk corridor.*

(i) *Costs between first and second threshold lower limits.* If the adjusted allowable risk corridor costs for the plan for the year are less than the first threshold lower limit, but not less than the second threshold lower limit, of the risk corridor for the plan for the year, CMS reduces the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recovers from the sponsor or organization an amount) equal to 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit of the risk corridor and the adjusted allowable risk corridor costs.

(ii) *Costs below second threshold lower limit.* If the adjusted allowable risk corridor costs for the plan for the year are less the second threshold lower limit of the risk corridor for the plan for the year, CMS reduces the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recovers from the sponsor or organization an amount) equal to the sum of—

(A) 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit and the second threshold lower limit; and

(B) 80 percent of the difference between the second threshold upper limit of the risk corridor and the adjusted allowable risk corridor costs.

(c) *Payment methods.* CMS makes payments after a coverage year after obtaining all of the cost data information in paragraph (c)(1) of this section necessary to determine the amount of payment. CMS will not make payments under this section if the PDP sponsor or MA organization fails to provide the cost data information in paragraph (c)(1) of this section.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the PDP sponsor or MA organization offering a MA–PD plan sponsor must provide to CMS the following information:

(i) The gross covered prescription drug costs segregated by enrollee and date of service.

(ii) The allowable risk corridor costs (defined in § 423.308) for the coverage year.

(iii) The adjusted allowable risk corridor costs for the coverage year.

(iv) Costs incurred for supplemental benefits distinguished from those for basic coverage.

(v) Other information stipulated by CMS.

(2) *Lump sum and adjusted monthly payments.* CMS at its discretion makes either lump-sum payments or adjusts monthly payments in the following payment year based on the relationship of the plan's adjusted allowable risk corridor costs to the predetermined risk corridor thresholds in the coverage year, as determined under paragraph (a) of this section.

(d) *No effect on monthly premium.* No adjustment in payments made by reason of this section may affect the monthly beneficiary premium or the MA monthly prescription drug beneficiary premium.

§ 423.343 Retroactive adjustments and reconciliations.

(a) *Application of enrollee adjustment.* The provisions of § 422.308 apply to payments to PDP sponsors under this section in the same manner as they apply to payments to MA

organizations under section 1853(a) of the Act.

(b) *Health status.* CMS makes adjustments to payments made under § 423.329(a)(1) to account for updated health status risk adjustment data as provided under § 422.310(g)(2). CMS may recover payments associated with health status adjustments if the MA organization or PDP sponsor fails to provide the information described in § 423.329(b)(3).

(c) *Reinsurance.* CMS makes final payment for reinsurance after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months after the end of a coverage year, the PDP sponsor or MA organization offering a MA–PD plan must provide CMS the following information:

(i) The gross covered prescription drug costs segregated by enrollee and date of service.

(ii) The allowable reinsurance costs segregated by enrollee and date of service.

(iii) The costs incurred by the plan delineated separately from those incurred by or on behalf of the enrollee for purposes of determining out-of-pocket expenditures.

(iv) Costs incurred for supplemental benefits distinguished from those for basic coverage.

(v) Other information stipulated by CMS.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between monthly reinsurance payments made during the coverage year and the amount payable in § 423.329(c) for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if the monthly reinsurance payments made during the coverage year exceed the amount payable under § 423.329(c) or if the PDP sponsor or MA organization does not provide the data in paragraph (c)(1) of this section.

(d) *Low-income cost-sharing subsidy.* CMS makes final payment for low-income cost-sharing subsidies after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months after the end of a coverage year, the PDP sponsor or MA organization offering a MA–PD plan must provide CMS the following information:

(i) The gross covered prescription drug costs segregated by enrollee and date of service.

(ii) The costs incurred by the plan delineated separately than those incurred by or on behalf of the enrollee for purposes of determining out-of-pocket expenditures.

(iii) Other information stipulated by CMS.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between interim low-income cost-sharing subsidy payments and total low-income cost-sharing subsidy costs eligible for subsidy under § 423.782 submitted by the plan for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if interim low-income cost-sharing subsidy payments exceed the amount payable under § 423.782 or if the PDP sponsor or MA organization does not provide the data in paragraph (d)(1) of this section.

§ 423.346 Reopening

(a) CMS may reopen and revise a final payment determination (including a determination on the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low income subsidy described in § 423.329(d), or final risk corridor payments as described in § 423.336)—

(1) For any reason, within 12 months from the date of the notice of the final determination to the PDP sponsor or MA organization;

(2) After that 12-month period, but within 4 years after the date of the notice of the initial determination to the individual, upon establishment of good cause for reopening; or

(3) At any time when the determination or decision was procured by fraud or similar fault of the PDP sponsor, MA organization, or any subcontractor of such sponsor or organization.

(b) For purposes of this section, CMS will find good cause if—

(1) New and material evidence that was not readily available at the time the final determination was made is furnished;

(2) A clerical error in the computation of payments was made; or

(3) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(c) For purposes of this section, CMS will not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the final determination was made.

Subpart I—Organization Compliance With State Law and Preemption by Federal Law

§ 423.401 General requirements for PDP sponsors.

(a) *General requirements.* Each PDP sponsor of a prescription drug plan must meet the following requirements:

(1) *Licensure.* Except in cases where there is a waiver as specified at § 423.410, the sponsor is organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan. If not commercially licensed, the sponsor obtains certification from the State that the organization meets a level of financial solvency and other standards as the State may require for it to operate as a PDP sponsor.

(2) *Assumption of financial risk for unsubsidized coverage.* The entity assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under 1860D–15(b) of the Act.

(b) *Reinsurance permitted.* The plan sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing the coverage.

(c) *Solvency for unlicensed sponsors.* In the case of a PDP sponsor that is not described in § 423.401(a)(1) and for which a waiver is approved under § 423.410, the sponsor must meet § 423.420.

§ 423.410 Waiver of certain requirements to expand choice.

(a) *Authorizing waiver.* In the case of an entity that seeks to offer a prescription drug plan in a State, CMS waives the licensure requirement at § 423.401(a)(1), which requires that the entity be licensed in that State if CMS determines, based on the application and other evidence presented, that any of the grounds for approval of the application described in paragraphs (c), (d), or (e) of this section are met.

(b) *Application of regional plan waiver rule.* In addition to the waiver available under paragraphs (c), (d) and (e) of this section, the following waiver may be requested—

(1) *In general.* Subject to paragraphs (b)(2) and (b)(3) of this section, if an

applicant seeking to become a PDP sponsor operates in more than one State in a region, and is licensed as a risk bearing entity in at least one State in such region, then the applicant may receive a regional plan waiver for the States in which it is not licensed.

(2) *Filing of application.* The applicant must demonstrate to the satisfaction of CMS that it filed the necessary licensure applications with each State in the region for which it does not already have State licensure, except that no such application is necessary if CMS determines that the State does not have a licensing process for potential PDP sponsors.

(3) *Time limit.* The waiver will expire at the end of the time period that the Secretary determines is appropriate for timely processing of the application, but in no case will a waiver extend beyond the end of the calendar year.

(c) *Grounds for approval of waivers.* Subject to the waiver requirements specified in § 423.410(f), waivers may be granted under any of the following conditions:

(1) *Failure to act on licensure application on a timely basis.* The State failed to complete action on the licensing application within 90 days of the date that the State received a substantially complete application.

(2) *Denial of application based on discriminatory treatment.* The State has—

(i) Denied the license application on the basis of material requirements, procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or

(ii) Required, as a condition of licensure that the organization offer any product or plan other than a prescription drug plan.

(3) *Denial of application based on application of solvency requirements.*

(i) The State has denied the licensure application, in whole or in part, on the basis of the PDP sponsor's failure to meet solvency requirements that are different from the solvency standards CMS established under 423.420; or

(ii) CMS determines that the State has imposed, as a condition of licensing, any documentation or information requirements relating to solvency that are different from the standards CMS establishes pursuant to § 423.420.

(4) *Grounds other than those required by federal law.* The application by a State of any grounds other than those required under Federal law.

(d) *Waiver when licensing process not in effect.* The grounds for approval specified in paragraph(c)(1) of this section are deemed met if the State does not have a licensing process in effect with respect to PDP sponsors.

(e) *Special waiver for plan years beginning before January 1, 2008.* For plan years beginning before January 1, 2008, if the State has a prescription drug plan or PDP sponsor licensing process in effect, CMS grants a waiver upon a demonstration that a PDP sponsor has submitted a substantially complete licensure application to the State.

(f) *Waiver requirements.* Except for the waivers described in paragraph (b) of this section, the following rules apply to waiver applications or waivers granted under this section.

(1) *Treatment of waiver.* The waiver applies only to that State, is effective only for 36 months and cannot be renewed.

(2) *Prompt action on application.* CMS grants or denies a waiver application under this section within 60 days after CMS determines that a substantially complete waiver application is received by CMS.

(3) In the case of a State that does not have a PDP sponsor licensing process, the 36 month deadline on the waiver discussed in paragraph (f)(1) of this section does not apply, and the waiver may continue in effect for a given State as long as the State does not have a PDP sponsor licensing process in effect.

§ 423.420 Solvency standards for non-licensed entities.

(a) *Establishment and publication.* CMS establishes and publishes reasonable financial solvency and capital adequacy standards for entities specified in paragraph (b) of this section.

(b) *Compliance with standards.* A PDP sponsor that is not licensed by a State and for which a waiver application is approved by CMS under § 423.410 (b), (c), (d), or (e) must maintain reasonable financial solvency and capital adequacy in accordance with the standards established by CMS under paragraph(a) of this section.

§ 423.425 Licensure does not substitute for or constitute certification.

The fact that a PDP sponsor is State licensed or has a waiver application approved under § 423.410 does not deem the sponsor to meet other requirements imposed under this part for a PDP sponsor.

§ 423.440 Prohibition of State imposition of premium taxes; relation to State laws.

(a) *Federal preemption of State law.* The standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to prescription drug plans offered by PDP sponsors and MA–PD plans offered by MA organizations.

(b) *State premium taxes prohibited.*

(1) *Basic rule.* No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, the Mariana Islands or any of their political subdivisions or other governmental authorities with respect to any payment CMS makes on behalf of MA–PD plan or prescription drug plan enrollees under subpart G of this part; or with respect to any payment made to prescription drug plans or MA–PD plans by a beneficiary or by a third party on behalf of a beneficiary.

(2) *Construction.* Nothing in this section shall be construed to exempt any PDP sponsor from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization from business conducted under this part, if that tax, fee, or payment is applicable to a broad range of business activity.

Subpart J—Coordination Under Part D With Other Prescription Drug Coverage

§ 423.452 Scope.

This section sets forth the application of Part D rules to Part C plans, establishes waivers for employer-sponsored group prescription drug plans, and establishes requirements for coordination of benefits with State Pharmaceutical Assistance Programs and other providers of prescription drug coverage.

§ 423.454 Definitions and Terminology.

For purposes of this subpart, the following definitions apply—

Part D plan or *Medicare Part D plan* is a prescription drug plan or an MA–PD plan.

Employer-sponsored group prescription drug plan means a prescription drug plan under a contract between a PDP sponsor or an MA organization offering an MA–PD plan and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations to furnish prescription drug benefits under employment-based retiree health coverage (as defined in § 423.822). (Published elsewhere in this **Federal Register**.)

State Pharmaceutical Assistance Program (SPAP) means a State program (operated by or under contract with a State) that meets the requirements described under § 423.464(c).

§ 423.458 Application of Part D rules to MA–PD plans on and after January 1, 2006.

(a) *Relationship to Part C.* Except as otherwise provided in this Part, the requirements of this Part apply to prescription drug coverage provided by Medicare Advantage prescription drug plans offered by Medicare Advantage organizations.

(b) *MA Waiver.* CMS waives any provision of this Part as applied to MA–PD plans to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the MA organization or MA–PD plan under Part C of Medicare or as may be necessary in order to improve coordination of this part with the benefits under Part C.

(1) *Application of Waiver.* Any waiver or modification granted by CMS under this section will apply to any other similarly situated organization offering or seeking to offer a MA–PD plan that meets the conditions of the waiver.

(2) *Request for waivers.* Organizations offering or seeking to offer a Medicare Advantage-Prescription Drug plan may request from CMS in writing—

(i) A waiver of those requirements under Part D of Medicare that are duplicative of, or that are in conflict with provisions otherwise applicable to the MA–PD plan, or proposed MA–PD plan, under Part C of Medicare.

(ii) A waiver of a requirement under Medicare Part D, if such waiver would improve coordination of benefits provided under Part C of Medicare with the benefits under Part D.

(c) *Employer Group Waiver.* (1) *General rule.* Prescription drug plans may request, in writing, a waiver or modification of those requirements under Part D of Medicare that hinder the design of, the offering of, or the enrollment in, an employer-sponsored group prescription drug plan. This provision applies to prescription drug plans in the same manner that the provisions of section 1857(i) of the Act apply to an MA plan or MA–PD plan in relation to employer-sponsored group MA plans or MA–PD plans, including authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group prescription drug plan and limitations on enrollment in such plan to Part D eligible individuals participating in the employment-based retiree health coverage sponsored by the employer, labor organization, or the trustees of a fund established by one or more employers or labor organizations.

(2) *Use of waiver.* Waivers or modifications approved by CMS under this section apply to any similarly situated prescription drug plan meeting the conditions of the waiver or modification.

(d) *Other Waivers.* CMS waives any provision of this Part as applied to a section 1876 cost HMO/CMP (as defined in § 417.401) or PACE organization (as defined in § 460.6) that offers qualified prescription drug coverage under Part D to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the 1876 cost HMO/CMP under section 1876 of the Act or provisions applicable to PACE organizations under sections 1894 and 1934 of the Act or as may be necessary in order to improve coordination of this Part with the benefits offered by 1876 cost HMOs/CMPs or PACE organizations.

(1) *Application of Waiver.* Any waiver or modification granted by CMS under this section will apply to any other similarly situated organization offering or seeking to offer qualified prescription drug coverage as an 1876 cost HMO/CMP or as a PACE organization that meets the conditions of the waiver.

(2) *Request for waivers.* Section 1876 cost HMOs/CMPs or PACE organizations seeking to offer qualified prescription drug coverage may request from CMS in writing—

(i) A waiver of those requirements under Part D of Medicare that are duplicative of, or that are in conflict with provisions otherwise applicable to 1876 cost HMOs/CMPs or PACE organizations.

(ii) A waiver of a requirement under Medicare Part D, if such waiver would improve coordination of benefits provided by the section 1876 cost HMO/CMP or PACE organization with the benefits under Part D.

§ 423.462 Medicare secondary payer procedures.

The provisions of § 422.108 of this chapter regarding Medicare secondary payer procedures apply to PDP sponsors in the same way as they apply to MA organizations under Part C of Title XVIII of the Act, except all references to MA organizations are considered references to PDP sponsors.

§ 423.464 Coordination of Benefits With Other Providers of Prescription Drug Coverage.

(a) *General rule.* A PDP sponsor and Medicare Advantage organization offering a MA–PD plan must permit State Pharmaceutical Assistance Programs described in paragraph (e) of this section and the plans described in paragraph (f) of this section to coordinate benefits with the prescription drug plan or MA–PD plan and must comply with all administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between a Part D plan and a State pharmaceutical assistance program and other plans providing prescription drug coverage for—

(1) Payment of premiums and coverage; and

(2) Payment for supplemental prescription drug benefits as described in § 423.104(g)(1)(ii) (including payment to a Medicare Part D plan on a lump sum per capita basis) for Part D eligible individuals enrolled in the Part D plan and the SPAP or other plan.

(b) *Medicare as primary payer.* The requirements of this subpart do not change or affect the primary or secondary payor status of a Medicare Part D plan and a SPAP or other plan. A Medicare Part D plan is always the primary payor relative to a State Pharmaceutical Assistance Program.

(c) *User fees.* CMS may impose user fees for the transmittal of information necessary for benefit coordination in accordance with administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between a Part D plan and a State Pharmaceutical Assistance Program and other plans providing prescription drug coverage in a manner similar to the manner in which user fees are imposed under section 1842(h)(3)(B), except that CMS may retain a portion of user fees to defray costs in carrying out such procedures. CMS will not impose user fees under this subpart for a State pharmaceutical assistance program.

(d) *Cost management tools.* The requirements of this subpart do not prevent an organization sponsoring a Medicare Part D plan from using cost management tools (including differential payments) under all methods of operation.

(e) *Coordination with State Pharmaceutical Assistance Programs.*

(1) *Requirements to be a State Pharmaceutical Assistance Program (SPAP).* A program operated by or under contract with a State will be considered to be a State Pharmaceutical Assistance Program for purposes of this part if it—

(i) Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals;

(ii) Provides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls;

(iii) Meets the benefit coordination requirements specified in this part; and

(iv) Does not follow or adopt rules that change or affect the primary payor status of a Part D plan. The definition of SPAP excludes State Medicaid programs, section 1115 demonstration programs, and any other program where the majority of the funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding.

(2) *Special treatment under out-of-pocket rule.* A PDP sponsor and Medicare Advantage organization offering a MA–PD plan shall collect information on and apply expenditures made by SPAPs for costs of covered Part D drugs meeting the definition of incurred costs (as described in § 423.100) for purposes of reaching the out-of-pocket threshold provided under § 423.104(e)(5)(iii).

(3) *Use of a single card.* A card that is issued under § 423.120(c) for use under a Medicare Part D plan may also be used in connection with coverage of benefits provided under a State pharmaceutical assistance program and, in such a case, may contain an emblem or symbol indicating such connection.

(4) *Construction.* Nothing in this subpart requires a State Pharmaceutical Assistance Program to coordinate with, or provide financial assistance to enrollees in, any Medicare Part D plan.

(f) *Coordination with other plans.* (1) *Definition of other plans.* Other plans that provide prescription drug coverage include any of the following:

(i) *Medicaid programs.* A State plan under title XIX of the Act, including such a plan operating under a waiver under section 1115 of the Act, if it meets the requirements of paragraph (e)(1)(ii) of this section.

(ii) *Group health plans.* An employer group health plan as defined in § 411.101.

(iii) *FEHBP.* The Federal employees' health benefits plan under chapter 89 of title 5, United States Code.

(iv) *Military coverage (including TRICARE).* Coverage under chapter 55 of title 10, United States Code.

(v) *Other health benefit plans or programs.* Other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of Medicare Part D eligible individuals as CMS may specify.

(2) *Treatment under out-of-pocket rule.* A PDP sponsor and Medicare Advantage organization offering a MA–PD plan shall exclude expenditures made by other plans for costs of covered Part D drugs for purposes of reaching the out-of-pocket threshold provided under § 423.104(e)(5)(iii).

(3) *Imposition of fees.* A prescription drug plan sponsor or an organization offering an MA–PD plan may not impose fees on other plans that are unrelated to the cost of the coordination of benefits.

Subpart K—Application Procedures and Contracts With PDP Sponsors

§ 423.501 Definitions.

For purposes of this subpart, the following definitions apply:

Business transaction means any of the following kinds of transactions:

(1) Sale, exchange, or lease of property.

(2) Loan of money or extension of credit.

(3) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(i) Salaries paid to employees for services performed in the normal course of their employment; or

(ii) Health services furnished to the PDP sponsor's enrollees by pharmacies and other providers, by PDP sponsor staff, medical groups, or independent practice associations, or by any combination of those entities.

Significant business transaction means any business transaction or series of transactions of the kind specified in the above definition of business transaction that, during any fiscal year of the PDP sponsor, have a total value that exceeds $25,000 or 5 percent of the PDP sponsor's total operating expenses, whichever is less.

Downstream entity means any party that enters into an acceptable written arrangement below the level of the arrangement between a PDP sponsor (or contract applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

First tier entity means any party that enters into an acceptable written arrangement with a PDP sponsor or contract applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

Party in interest means the following:

(1) Any director, officer, partner, or employee responsible for management or administration of a PDP sponsor.

(2) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(3) In the case of a PDP sponsor organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law.

(4) Any entity in which a person specified in paragraphs (1), (2), or (3) of this definition—

(i) Is an officer, director, or partner; or

(ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

(5) Any person that directly or indirectly controls, is controlled by, or is under common control with the PDP sponsor.

(6) Any spouse, child, or parent of an individual specified in paragraphs (1), (2), or (3) of this definition.

Related entity means any entity that is related to the PDP sponsor by common ownership or control and—

(1) Performs some of the PDP sponsor's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the PDP sponsor at a cost of more than $2,500 during a contract period.

§ 423.502 Application requirements.

(a) *Scope.* This section sets forth application requirements for an entity that seeks a contract with CMS as a PDP sponsor.

(b) *Completion of an application.* (1) In order to obtain a determination on whether it meets the requirements to become a PDP sponsor, an entity, or an individual authorized to act for the entity (the applicant), must complete a certified application in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards as specified in subpart I of this part; or

(ii) A Federal waiver as specified in subpart I of this part.

(2) The authorized individual must describe thoroughly how the entity meets, or plans to meet, the requirements described in this part.

(c) *Responsibility for making determinations.* CMS is responsible for determining whether an entity qualifies as a PDP sponsor and meets the requirements of this part.

(d) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of

exceptions provided in 45 CFR part 5 (the Department's regulations providing exceptions to disclosure), must label the material "privileged" and include an explanation of the applicability of an exception specified in 45 CFR part 5.

§ 423.503 Evaluation and determination procedures for applications to be a sponsor.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an entity's application for a contract as a PDP sponsor on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits, publicly available information, and any other appropriate procedures.

(2) If the application is incomplete, CMS notifies the contract applicant and allows 10 days from the date of the notice for the contract applicant to furnish the missing information.

(3) After evaluating all relevant information, CMS determines whether the contract applicant's application meets the applicable requirements specified in § 423.504.

(b) *Use of information from a prior contracting period.* If a PDP sponsor, Medicare Advantage Organization, or Medicare cost plan fails to comply with the terms of a previous year's contract with CMS under title XVIII of the Act, or fails to complete a corrective action plan during the term of the contract, CMS may deny an application from a contract applicant based on the contract applicant's failure to comply with that prior contract with CMS even if the contract applicant meets all of the current requirements.

(c) *Notice of determination.* CMS notifies each applicant that applies for a contract as a PDP sponsor, under this part, of its determination on the application and the basis for the determination. The determination may be one of the following:

(1) *Approval of application.* If CMS approves the application, it gives written notice to the contract applicant, indicating that it meets the requirements for a contract as a PDP sponsor.

(2) *Intent to deny.* (i) If CMS finds that the contract applicant does not appear to meet the requirements for a PDP sponsor contract, it gives the contract applicant notice of intent to deny the application for a PDP contract and a summary of the basis for this preliminary finding.

(ii) Within 10 days from the date of the notice, the contract applicant may respond in writing to the issues or other matters that were the basis for CMS's preliminary finding and may revise its application to remedy any defects CMS identified.

(d) *Denial of application.* If CMS denies the application, it gives written notice to the contract applicant indicating—

(1) That the contract applicant does not meet the contract requirements under Part D of title XVIII of the Act;

(2) The reasons why the contract applicant does not meet the contract requirements; and

(3) The contract applicant's right to request reconsideration in accordance with the procedures specified in § 423.644.

(e) *Oversight of continuing compliance.* (1) CMS oversees a PDP sponsor's continued compliance with the requirements for a PDP sponsor.

(2) If a PDP sponsor no longer meets those requirements, CMS terminates the contract in accordance with § 423.509.

§ 423.504 General provisions.

(a) *General rule.* Subject to the provisions at § 423.265(a)(1) concerning submission of bids, to enroll beneficiaries in any prescription drug plan it offers and be paid on behalf of Medicare beneficiaries enrolled in those plans, a PDP sponsor must enter into a contract with CMS. The contract may cover more than one prescription drug plan.

(b) *Conditions necessary to contract as a PDP sponsor.* Any entity seeking to contract as a PDP sponsor must—

(1) Complete an application as described in § 423.502.

(2) Be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan, or have secured a Federal waiver, as described in subpart I of this part.

(3) Meet the minimum enrollment requirements of § 423.512(a) unless waived under § 423.512(b) or (c).

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following:

(i) A policy making body that exercises oversight and control over the PDP sponsor's policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees.

(ii) Personnel and systems sufficient for the PDP sponsor to organize, implement, control, and evaluate financial and marketing activities, the furnishing of prescription drug services, the quality assurance, medical therapy management, and drug and or utilization management programs, and the administrative and management aspects of the organization.

(iii) At a minimum, an executive manager whose appointment and removal are under the control of the policy making body.

(iv) A fidelity bond or bonds, procured and maintained by the PDP sponsor, in an amount fixed by its policymaking body but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the PDP sponsor.

(v) Insurance policies or other arrangements, secured and maintained by the PDP sponsor and approved by CMS to insure the PDP sponsor against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(vi) A compliance plan that consists of the following—

(A) Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State standards.

(B) The designation of a compliance officer and compliance committee accountable to senior management.

(C) Effective training and education between the compliance officer and organization employees.

(D) Effective lines of communication between the compliance officer and the organization's employees.

(E) Enforcement of standards through well-publicized disciplinary guidelines.

(F) Procedures for internal monitoring and auditing.

(G) Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as a PDP sponsor.

(*1*) If the PDP sponsor discovers from any source evidence of misconduct related to payment or delivery of prescription drug items or services under the contract, it must conduct a timely, reasonable inquiry into that misconduct;

(*2*) If, after reasonable inquiry, the PDP sponsor has determined that the misconduct may violate criminal, civil or administrative law, the sponsor must report the existence of the misconduct to the appropriate Government authority within a reasonable period, but not more than 60 days after the determination that a violation may have occurred. If the potential violation relates to Federal criminal law, the civil False Claims Act, Federal Anti-Kickback provisions, the civil monetary penalties authorities (primarily under section 1128A and 1857 of the Act), or related statutes enforced by the HHS Office of

Inspector General, the report must be made to that Office.

(3) The PDP sponsor must conduct appropriate corrective actions (for example, repayment of overpayments and disciplinary actions against responsible employees) in response to the potential violation referenced above.

(4) The PDP sponsor's contract must not have been non-renewed under § 422.507 within the past 2 years unless—

(i) During the 6-month period, beginning on the date the organization notified CMS of the intention to non-renew the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing PDP sponsor payments in the payment area or areas at issue; or

(ii) CMS has otherwise determined that circumstances warrant special consideration.

(c) *Contracting authority.* Under section 1860D–12 (b)(3)(B) of the Act, CMS may enter into contracts under this part, or in order to carry out this part, without regard to Federal and Departmental acquisition regulations set forth in Title 48 of the CFR and provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if CMS determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program. Some of the FAR provisions may apply to fallback plans. See subparts F and Q of this part for any contracting provisions unique to fallback plans.

(d) *Protection against fraud and beneficiary protections.* (1) CMS annually audits the financial records (including, but not limited to, data relating to Medicare utilization and costs, including allowable reinsurance and risk corridor costs as well as low income subsidies and other costs) under this part of at least one-third of the PDP sponsors (including fallback plans) offering prescription drug plans.

(2) Each contract under this section must provide that CMS, or any person or organization designated by CMS, has the right to—

(i) Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the PDP sponsor's contract;

(ii) Inspect or otherwise evaluate the facilities of the organization when there is reasonable evidence of some need for the inspection; and

(iii) Audit and inspect any books, contracts, and records of the PDP sponsor that pertain to—

(A) The ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or

(B) Services performed or determinations of amounts payable under the contract.

(e) *Severability of contracts.* The contract must provide that, upon CMS' request—

(1) The contract could be amended to exclude any State-licensed entity, or a PDP plan specified by CMS; and

(2) A separate contract for any excluded plan or entity must be deemed to be in place when a request is made.

§ 423.505 Contract provisions.

(a) *General rule.* The contract between the PDP sponsor and CMS must contain the provisions specified in paragraph (b) of this section.

(b) *Specific provisions.* The PDP sponsor agrees to comply with the following:

(1) All the applicable requirements and conditions set forth in this part and in general instructions.

(2) To accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in subpart B of this part.

(3) To comply with the prohibition in § 423.34(a) on discrimination in beneficiary enrollment.

(4) To provide the basic benefits as required under § 423.108 and, to the extent applicable, supplemental benefits under § 423.112.

(5) To disclose information to beneficiaries in the manner and the form specified by CMS under § 423.128.

(6) To operate quality assurance, cost and utilization management, medication therapy management, and fraud, abuse and waste programs as required under subpart D of this part.

(7) To comply with all requirements in subpart M of this part governing coverage determinations, grievances, and appeals.

(8) To comply with the reporting requirements in § 423.514 and the requirements in § 423.329(b)(3) for submitting drug claims and related information to CMS for its use in risk adjustment calculations.

(9) Each contract under this part provides that—(i) The PDP sponsor offering a prescription drug plan must provide CMS with the information CMS determines is necessary to carry out payment provisions in subpart G of this part.

(ii) CMS has the right, as applied under section 1860D–12(b)(3)(C) of the Act and in accordance with section 1857(d)(2)(B) of the Act, to inspect and audit any books and records of a PDP sponsor that pertain to the information regarding costs provided to CMS under paragraph(9)(i) of this section.

(10) To be paid under the contract in accordance with the payment rules in subpart G of this part.

(11) To submit its bid, including all required information on premiums, benefits, and cost-sharing, by the due date, as provided in subpart F of this part.

(12) That its contract may not be renewed or may be terminated in accordance with this subpart and subpart N of this part.

(13) To comply with the confidentiality and enrollee record accuracy specified in § 423.136.

(14) To comply with State law and preemption by Federal law requirements described in subpart I of this part.

(15) To comply with the coordination requirements with plans and programs that provide prescription drug coverage as described in subpart J of this part.

(16) To provide benefits by means of point of service systems to adjudicate drug claims, except when necessary to provide access in underserved areas, I/T/U pharmacies (as defined in § 423.100), and long-term care pharmacies.

(c) *Communication with CMS.* The PDP sponsor must have the capacity to communicate with CMS electronically in accordance with CMS requirements.

(d) *Maintenance of records.* The PDP sponsor agrees to maintain, for 6 years, books, records, documents, and other evidence of accounting procedures and practices that—

(1) Are sufficient to do the following:

(i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the bid of PDP sponsors).

(ii) Enable CMS to inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the contract and the facilities of the organization.

(iii) Enable CMS to audit and inspect any books and records of the PDP sponsor that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.

(iv) Properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the PDP sponsor's bid and necessary for the calculation of gross covered prescription drug costs, allowable reinsurance costs, and allowable risk corridor costs (as defined in § 423.308).

(v) Establish the basis for the components, assumptions, and analysis used by the PDP in determining the actuarial valuation of standard, basic alternative, or enhanced alternative coverage offered in accordance with the CMS guidelines specified in § 423.265(b)(3).

(2) Include records of the following:

(i) Ownership and operation of the PDP sponsor's financial, medical, and other record keeping systems.

(ii) Financial statements for the current contract period and 6 prior periods.

(iii) Federal income tax or informational returns for the current contract period and 6 prior periods.

(iv) Asset acquisition, lease, sale, or other action.

(v) Agreements, contracts, and subcontracts.

(vi) Franchise, marketing, and management agreements.

(vii) Matters pertaining to costs of operations.

(viii) Amounts of income received by source and payment.

(ix) Cash flow statements.

(x) Any financial reports filed with other Federal programs or State authorities.

(xi) All prescription drug claims for the current contract period and 6 prior periods.

(xii) All price concessions (including concessions offered by manufacturers) for the current contract period and 6 prior periods accounted for separately from other administrative fees.

(e) *Access to facilities and records.* The PDP sponsor agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through inspection or other means—

(i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;

(ii) The facilities of the PDP sponsor; and

(iii) The enrollment and disenrollment records for the current contract period and 6 prior periods.

(2) HHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of the PDP sponsor, related entity(s), contractor(s), subcontractor(s), or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

(3) The PDP sponsor agrees to make available, for the purposes specified in paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require.

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 6 years from the end of the final contract period or completion of audit, whichever is later unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the PDP sponsor at least 30 days before the normal disposition date;

(ii) There is a termination, dispute, or allegation of fraud or similar fault by the PDP sponsor, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or

(iii) CMS determines that there is a reasonable possibility of fraud or similar fault, in which case CMS may inspect, evaluate, and audit the PDP sponsor at any time.

(f) *Disclosure of information.* The PDP sponsor agrees to submit to CMS—

(1) Certified financial information that must include the following:

(i) Information as CMS may require demonstrating that the organization has a fiscally sound operation.

(ii) Information as CMS may require pertaining to the disclosure of ownership and control of the PDP sponsor.

(2) All information to CMS that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining prescription drug coverage. This information includes, but is not limited to:

(i) The benefits covered under a prescription drug plan.

(ii) The PDP monthly basic beneficiary premium and PDP monthly supplemental beneficiary premium, if any, for the plan.

(iii) The service area of each plan.

(iv) Plan quality and performance indicators for the benefits under the plan including—

(A) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;

(B) Information on Medicare enrollee satisfaction;

(C) The recent records regarding compliance of the plan with requirements of this part, as determined by CMS; and

(D) Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice regarding PDP plans.

(v) Information about beneficiary appeals and their disposition.

(vi) Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization.

(vii) Any other information deemed necessary to CMS for the administration or evaluation of the Medicare program.

(3) To its enrollees, all informational requirements under § 423.128(b) and, upon an enrollee's request, the financial disclosure information required under § 423.128(c)(4).

(g) *Beneficiary financial protections.* The PDP sponsor agrees to comply with the following requirements:

(1) Each PDP sponsor must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the PDP sponsor. To meet this requirement, the PDP sponsor must—

(i) Ensure that all contractual or other written arrangements prohibit the organization's contracting agents from holding any beneficiary enrollee liable for payment of any such fees; and

(ii) Indemnify the beneficiary enrollee for payment of any fees that are the legal obligation of the PDP sponsor for covered prescription drugs furnished by non-contracting pharmacists, or that have not otherwise entered into an agreement with the PDP sponsor, to provide services to the organization's beneficiary enrollees.

(2) In meeting the requirements of this paragraph, other than the provider contract requirements specified in paragraph (g)(1)(i) of this section, the PDP sponsor may use—

(i) Contractual arrangements;

(ii) Insurance acceptable to CMS;

(iii) Financial reserves acceptable to CMS; or

(iv) Any other arrangement acceptable to CMS.

(h) *Requirements of other laws and regulations.* The PDP sponsor agrees to comply with—

(1) Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 84.

(2) The Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91.

(3) The Rehabilitation Act of 1973.

(4) The Americans with Disabilities Act.

(5) HIPAA Administrative Simplification rules at 45 CFR Parts 160, 162, and 164.

(6) Other laws applicable to recipients of Federal funds.

(7) All other applicable laws and rules.

(8) PDP sponsors receiving Federal payments under PDP sponsor contracts, and related entities, contractors, and subcontractors paid by a PDP sponsor to fulfill its obligations under its contract with CMS, are subject to certain laws that are applicable to individuals and entities receiving Federal funds. PDP sponsors must inform all related entities, contractors and subcontractors that payments they receive are, in whole or in part, from Federal funds.

(i) *PDP sponsor relationship with related entities, contractors, and subcontractors.* (1) Notwithstanding any relationship(s) that the PDP sponsor may have with related entities, contractors, or subcontractors, the PDP sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.

(2) The PDP sponsor agrees to require all related entities, contractors, or subcontractors to agree that—

(i) HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records of the related entity(s), contractor(s), or subcontractor(s) involving transactions related to CMS' contract with the PDP sponsor; and

(ii) HHS', the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period exists through 6 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(3) All contracts or written arrangements between PDP sponsors and providers, related entities, contractors, subcontractors, first tier and downstream entities must contain the following:

(i) Enrollee protection provisions that provide, consistent with paragraph (g)(1) of this section, arrangements that prohibit pharmacies from holding an enrollee liable for payment of any fees that are the obligation of the PDP sponsor.

(ii) Accountability provisions that indicate that the PDP sponsor may only delegate activities or functions to a pharmacy, related entity, contractor, or subcontractor in a manner consistent with requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a related entity, contractor, subcontractor, or first-tier or downstream entity in accordance with a contract or written agreement are consistent and comply with the PDP sponsor's contractual obligations.

(4) If any of the PDP sponsors' activities or responsibilities under its contract with CMS is delegated to other parties, the following requirements apply to any related entity, contractor, subcontractor, or pharmacy:

(i) Written arrangements must specify delegated activities and reporting responsibilities.

(ii) Written arrangements must either provide for revocation of the delegation activities and reporting requirements or specify other remedies in instances when CMS or the PDP sponsor determine that the parties have not performed satisfactorily.

(iii) Written arrangements must specify that the PDP sponsor on an ongoing basis monitors the performance of the parties.

(iv) All contracts or written arrangements must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions.

(5) If the PDP sponsor delegates selection of its prescription drug providers to another organization, the PDP sponsor's written arrangements with that organization must state that the CMS-contracting PDP sponsor retains the right to approve, suspend, or terminate any such arrangement.

(j) *Additional contract terms.* The PDP sponsor agrees to include in the contract other terms and conditions as CMS may find necessary and appropriate in order to implement requirements in this part.

(k) *Severability of contracts.* The contract must provide that, upon CMS's request—

(1) The contract is amended to exclude any State-licensed entity, or PDP sponsor specified by CMS; and

(2) A separate contract for any excluded plan or entity is deemed to be in place when the request is made.

(l) *Certification of data that determine payment.* (1) *General rule.* As a condition for receiving a monthly payment under subpart G of this part, the PDP sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.

(2) *Certification of enrollment and payment information.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

(3) *Certification of claims data.* The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. If the claims data are generated by a related entity, contractor, or subcontractor of a PDP sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.

(4) *Certification of bid submission information.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information in its bid submission and assumptions related to projected reinsurance and low income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the requirements in § 423.265.

(5) *Certification of allowable costs for risk corridor and reinsurance information.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs, as defined in § 423.308, is accurate, complete, and truthful and fully conforms to the requirements in § 423.336(c) and § 423.343(c) and acknowledge that this information will be used for the

purposes of obtaining Federal reimbursement.

(6) *Certification of Accuracy of Data for Price Comparison.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of price comparison is accurate, complete, and truthful.

§ 423.506 Effective date and term of contract.

(a) *Effective date.* The contract is effective on the date specified in the contract between the PDP sponsor and CMS.

(b) *Term of contract.* Each contract is for a period of 12 months. The contract period for a fallback plan is specified in § 423.871(b).

(c) *Renewal of contract.* In accordance with § 423.507 of this subpart, contracts are renewed annually only if—

(1) CMS informs the PDP sponsor that it authorizes a renewal; and

(2) The PDP sponsor has not provided CMS with a notice of intention not to renew.

§ 423.507 Nonrenewal of Contract.

(a) *Nonrenewal by a PDP sponsor.* (1) A PDP sponsor may elect not to renew its contract with CMS as of the end of the term of the contract for any reason provided it meets the timeframes for doing so set forth in paragraphs (a)(2) and (a)(3) of this section.

(2) If a PDP sponsor does not intend to renew its contract, it must notify—

(i) CMS in writing by the first Monday of June in the year in which the contract ends;

(ii) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice must include a written description of alternatives available for obtaining Medicare prescription drug services within the PDP region, including MA–PDs, and other PDPs, and must receive CMS approval prior to issuance; and

(iii) The general public, at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area.

(3) If a PDP sponsor does not renew a contract under paragraph (a) of this section, CMS cannot enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.

(b) *CMS decision not to renew.* (1) CMS may elect not to authorize renewal of a contract for any of the following reasons:

(i) For any of the reasons listed in § 423.509(a) that also permits CMS to terminate the contract.

(ii) The PDP sponsor has committed any of the acts in § 423.752 that supports the imposition of intermediate sanctions or civil money penalties under § 423.750.

(2) *Notice of decision.* CMS provides notice of its decision whether to authorize renewal of the contract as follows:

(i) To the PDP sponsor by May 1 of the contract year.

(ii) If CMS decides not to authorize a renewal of the contract, to the PDP sponsor's Medicare enrollees by mail at least 90 days before the end of the current calendar year.

(iii) If CMS decides not to authorize a renewal of the contract, to the general public at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area.

(3) *Notice of appeal rights.* CMS gives the PDP sponsor written notice of its right to appeal the decision not to renew in accordance with § 423.642(b).

§ 423.508 Modification or termination of contract by mutual consent.

(a) *General rule.* A contract may be modified or terminated at any time by written mutual consent.

(b) *Notification of termination.* If the contract is terminated by mutual consent, the PDP sponsor must provide notice to its Medicare enrollees and the general public as provided in paragraph (c) of this section.

(c) *Notification of modification.* If the contract is modified by mutual consent, the PDP sponsor must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

§ 423.509 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may terminate a contract for any of the following reasons if the PDP sponsor—

(1) Failed substantially to carry out the terms of its contract with CMS;

(2) Is carrying out its contract with CMS in a manner that is inconsistent with the effective and efficient implementation of this part;

(3) No longer meets the requirements of this part for being a contracting organization;

(4) There is credible evidence that the PDP sponsor committed or participated in false, fraudulent, or abusive activities affecting the Medicare program, including submission of false or fraudulent data;

(5) Experiences financial difficulties so severe that its ability to provide necessary prescription drug coverage is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that a risk to health exists;

(6) Substantially fails to comply with the requirements in subpart M of this part relating to grievances and appeals;

(7) Fails to provide CMS with valid risk adjustment, reinsurance and risk corridor related data as required under § 423.329;

(8) Substantially fails to comply with the service access requirements in § 423.120;

(9) Substantially fails to comply with the marketing requirements in § 423.128;

(10) Substantially fails to comply with the coordination with plans and programs that provide prescription drug coverage as described in subpart J of this part; or

(11) Substantially fails to comply with the cost and utilization management, quality improvement, medication therapy management and fraud, abuse and waste program requirements as specified in subpart D of this part.

(b) *Notice of termination.* If CMS decides to terminate a contract for reasons other than the grounds specified in § 423.509(a)(4) or (a)(5) of this section, it gives notice of the termination as follows:

(1) *Termination of contract by CMS.* (i) CMS notifies the PDP sponsor in writing 90 days before the intended date of the termination.

(ii) The PDP sponsor notifies its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

(iii) The PDP sponsor notifies the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area.

(2) *Immediate termination of contract by CMS.* (i) For terminations based on violations specified in § 423.509(a)(4) or § 423.509(a)(5) of this section, CMS notifies the PDP sponsor in writing that its contract is terminated effective the date of the termination decision by CMS. If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the prospective monthly payments made to the PDP sponsor covering the period of

the month following the contract termination.

(ii) CMS notifies the PDP sponsor's Medicare enrollees in writing of CMS's decision to terminate the PDP sponsor's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the PDP sponsor's contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining prescription drug coverage, including alternative PDP sponsors and MA–PDs in a similar geographic area.

(iii) CMS notifies the general public of the termination no later than 30 days after notifying the plan of CMS's decision to terminate the PDP sponsor's contract. This notice is published in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area.

(c) *Corrective action plan.* (1) *General rule.* Before terminating a contract for reasons other than the grounds specified in paragraph (a)(4) or (a)(5) of this section, CMS provides the PDP sponsor with reasonable opportunity to develop and receive CMS approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

(2) *Exception.* If a contract is terminated under § 423.509(a)(4) or § 423.509(a)(5) of this section, the PDP sponsor does not have the opportunity to submit a corrective action plan.

(d) *Appeal rights.* If CMS decides to terminate a contract, it sends written notice to the PDP sponsor informing it of its termination appeal rights in accordance with § 423.642.

§ 423.510 Termination of contract by the PDP sponsor.

(a) *Cause for termination.* The PDP sponsor may terminate its contract if CMS fails to substantially carry out the terms of the contract.

(b) *Notice of termination.* The PDP sponsor must give advance notice as follows:

(1) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the PDP sponsor is requesting contract termination.

(2) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining Medicare drug services within the services area, including alternative PDPs, MA–PDPs, and original Medicare and must receive CMS approval.

(3) To the general public, at least 60 days before the termination effective date by publishing a CMS-approved notice in one or more newspapers of general circulation in each community or county located in the PDP sponsor's geographic area.

(c) *Effective date of termination.* The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the PDP sponsor's notice of intent to terminate.

(d) *CMS's liability.* CMS's liability for payment to the PDP sponsor ends as of the first day of the month after the last month for which the contract is in effect.

(e) *Effect of termination by the organization.* CMS will not enter into an agreement with an organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

§ 423.512 Minimum enrollment requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, CMS will not enter into a contract under this subpart unless the organization meets the following minimum enrollment requirement:

(1) At least 5,000 individuals are enrolled for the purpose of receiving prescription drug benefits from the organization; or

(2) At least 1,500 individuals are enrolled for purposes of receiving prescription drug benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in § 412.62(f) of this chapter;

(3) Except as provided for in paragraph (b) of this section, a PDP sponsor must maintain a minimum enrollment as defined in paragraphs (a)(1) and (a)(2) of this section for the duration of its contract.

(b) *Minimum enrollment waiver.* CMS waives the requirement of paragraphs (a)(1) and (a)(2) of this section during the first contract year for an organization in a region.

§ 423.514 Reporting requirements.

(a) *Required information.* Each PDP sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires statistics indicating the following—

(1) The cost of its operations.

(2) The patterns of utilization of its services.

(3) The availability, accessibility, and acceptability of its services.

(4) Information demonstrating that the PDP sponsor has a fiscally sound operation.

(5) Other matters that CMS may require.

(b) *Significant business transactions.* Each PDP sponsor must report to CMS annually, within 120 days of the end of its fiscal year (unless, for good cause shown, CMS authorizes an extension of time), the following:

(1) A description of significant business transactions, as defined in § 423.501, between the PDP sponsor and a party in interest, includes the following:

(i) Indication that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that are incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(2) A combined financial statement for the PDP sponsor and a party in interest if either of the following conditions is met:

(i) Thirty five percent or more of the costs of operation of the PDP sponsor go to a party in interest.

(ii) Thirty five percent or more of the revenue of a party in interest is from the PDP sponsor.

(c) *Requirements for combined financial statements.*

(1) The combined financial statements required by paragraph (b)(2) of this section must display in separate columns the financial information for the PDP sponsor and each of the parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) The statements must be examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from a PDP sponsor showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) of this section for a particular entity.

(d) *Reporting and disclosure under Employee Retirement Income Security Act of 1974 (ERISA).* (1) For any employees' health benefits plan that includes a PDP sponsor in its offerings, the PDP sponsor must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (for the particular PDP sponsor) under the Employee

Retirement Income Security Act of 1974 (ERISA).

(2) The PDP sponsor must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term "administrator" is defined in ERISA.

(e) *Loan information.* Each organization must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

(f) *Enrollee access to information.* Each PDP sponsor must make the information reported to CMS under this section available to its enrollees upon reasonable request.

§ 423.516 Prohibition of midyear implementation of significant new regulatory requirements.

CMS may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

§ 423.551 General provisions.

(a) *Change of ownership.* The following constitute a change of ownership:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) *Asset sale.* Transfer of substantially all the assets of the sponsor to another party constitutes a change of ownership.

(3) *Corporation.* The merger of the PDP sponsor's corporation into another corporation or the consolidation of the PDP sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception.* Transfer of corporate stock or the merger of another corporation into the PDP sponsor's corporation, with the PDP sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement.* (1) A PDP sponsor that has a Medicare contract in effect under § 423.502 and is considering or is negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The PDP sponsor must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) If the PDP sponsor fails to give CMS the required notice in a timely manner, it continues to be liable for payments that CMS makes to it on behalf of Medicare enrollees after the date of change of ownership.

(d) *Novation agreement defined.* A novation agreement is an agreement among the current owner of the PDP sponsor, the prospective new owner, and CMS—

(1) That is embodied in a document executed and signed by all 3 parties;

(2) That meets the requirements of § 423.552; and

(3) Under which CMS recognizes the new owner as the successor in interest to the current owner's Medicare contract.

(e) *Effect of change of ownership without novation agreement.* Except to the extent provided in paragraph (c)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The existing contract becomes invalid; and

(2) If the new owner wishes to participate in the Medicare program, it must apply for, and enter into, a contract in accordance with subpart K of this part.

(f) *Effect of change of ownership with novation agreement.* If the PDP sponsor submits a novation agreement that meets the requirements of § 423.552 and CMS signs it, the new owner becomes the successor in interest to the current owner's Medicare contract under § 423.502.

§ 423.552 Novation agreement requirements.

(a) *Conditions for CMS approval of a novation agreement.* CMS approves a novation agreement if the following conditions are met:

(1) *Advance notification.* The PDP sponsor notifies CMS at least 60 days before the date of the proposed change of ownership. The PDP sponsor also provides CMS with updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) *Advance submittal of agreement.* The PDP sponsor submits to CMS, at least 30 days before the proposed change of ownership date, three signed copies of the novation agreement containing the provisions specified in paragraph (b) of this section, and one copy of other relevant documents required by CMS.

(3) *CMS's determination.* When reviewing a novation agreement, CMS makes a determination concerning the following—

(i) The proposed new owner is in fact a successor in interest to the contract.

(ii) Recognition of the new owner as a successor in interest to the contract is in the best interest of the Medicare program.

(iii) The successor organization meets the requirements to qualify as a PDP sponsor under subpart K of this part.

(b) *Provisions of a novation agreement.* A valid novation agreement requires the following:

(1) *Assumption of contract obligations.* The new owner must assume all obligations under the contract.

(2) *Waiver of right to reimbursement.* The previous owner must waive its rights to reimbursement for covered services furnished during the rest of the current contract period.

(3) *Guarantee of performance.* The previous owner must—

(i) Guarantee performance of the contract by the new owner during the contract period; or

(ii) Post a performance bond that is satisfactory to CMS.

(4) *Records access.* The previous owner must agree to make its books and records and other necessary information available to the new owner and to CMS to permit an accurate determination of costs for the final settlement of the contract period.

§ 423.553 Effect of leasing of a PDP sponsor's facilities.

(a) *General effect of leasing.* If a PDP sponsor leases all or part of its facilities to another entity, the other entity does not acquire PDP sponsor status under section 1860D–12(b) of the Act.

(b) *Effect of lease of all facilities.* (1) If a PDP sponsor leases all of its facilities to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as a PDP sponsor, it must apply for and enter into a contract in accordance with § 423.502.

(c) *Effect of partial lease of facilities.* If the PDP sponsor leases part of its facilities to another entity, its contract with CMS remains in effect while CMS surveys the PDP sponsor to determine whether it continues to be in compliance with the applicable requirements and qualifying conditions specified in subpart K of this part.

Subpart M—Grievances, Coverage Determinations, and Appeals

§ 423.560 Definitions.

As used in this subpart, unless the context indicates otherwise—

Appeal means any of the procedures that deal with the review of adverse

coverage determinations made by the PDP sponsor on the benefits under a prescription drug plan the enrollee believes he or she is entitled to receive, including delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in § 423.566(b). These procedures include redeterminations by the PDP sponsor, and if necessary, appeals to an independent review entity, hearings before ALJs, review by the Medicare Appeals Council (MAC), and judicial review. An appeal does not include a grievance or a request for an exception to a tiered cost-sharing structure or formulary.

Authorized representative means an individual authorized by an enrollee, or under State law, to act on his or her behalf in obtaining a coverage determination or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M of this chapter, to the extent they are appropriate, unless otherwise stated in this subpart.

Drug Use means an enrollee is receiving the drug in the course of treatment, including time off if it is part of the treatment.

Enrollee means a Part D eligible individual, or his or her authorized representative, who has elected a prescription drug plan offered by a PDP sponsor.

Grievance means any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of a PDP sponsor's operations, activities, or behavior, regardless of whether remedial action is requested.

Physician has the meaning given the term in section 1861(r) of the Act.

Reconsideration means a review of an adverse coverage determination by an independent review entity (IRE), the evidence and findings upon which it was based, and any other evidence the enrollee submits or the IRE obtains.

Redetermination means a review of an adverse coverage determination by a PDP sponsor, the evidence and findings upon which it is based, and any other evidence the enrollee submits or the PDP sponsor obtains.

§ 423.562 General provisions.

(a) *Responsibilities of the PDP sponsor.* A PDP sponsor must meet all of the following requirements.

(1) A PDP sponsor, for each prescription drug plan that it offers, must establish and maintain—

(i) A grievance procedure as described in § 423.564 for addressing issues that do not involve coverage determinations;

(ii) A procedure for making timely coverage determinations;

(iii) A procedure for handling exceptions to a tiered cost-sharing structure;

(iv) A procedure for handling exceptions to a formulary; and

(v) Redetermination and appeal procedures that meet the requirements of this subpart for issues that involve coverage determinations.

(2) A PDP sponsor must ensure that all enrollees receive written information about the—

(i) Grievance and appeal procedures that are available to them through the PDP sponsor; and

(ii) Complaint process available to the enrollee under the QIO process as set forth under section 1154(a)(14) of the Act.

(3) In accordance with subpart K of this part, if the PDP sponsor delegates any of its responsibilities under this subpart to another entity or individual through which the sponsor provides covered benefits, the PDP sponsor is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.

(b) *Rights of PDP enrollees.* In accordance with the provisions of this subpart, enrollees have all of the following rights in relation to PDP sponsors:

(1) The right to have grievances between the enrollee and the PDP sponsor heard and resolved by the sponsor, as described in § 423.564.

(2) The right to a timely coverage determination by the sponsor, as specified in § 423.566.

(3) The right to request from the sponsor an expedited coverage determination, as specified in § 423.570.

(4) The right to request from the sponsor an exception to a PDP's tiered cost-sharing structure or formulary, as specified in § 423.578.

(5) If dissatisfied with any part of a coverage determination, all of the following appeal rights:

(i) The right to a redetermination of the adverse coverage determination by the PDP sponsor, as specified in § 423.580.

(ii) The right to request an expedited redetermination, as provided under § 423.584.

(iii) If, as a result of a redetermination, a PDP sponsor affirms, in whole or in part, its adverse coverage determination, the right to a reconsideration by an independent review entity (IRE) contracted by CMS, as specified in § 423.600.

(iv) The right to an ALJ hearing if the amount in controversy meets the requirements in § 423.610 and part 422, subpart M of this chapter.

(v) The right to request MAC review of the ALJ hearing decision, as specified in § 423.620.

(vi) The right to judicial review of the hearing decision if the amount in controversy meets the requirements in § 423.630 and part 422, subpart M of this chapter.

(c) *Limits on when this subpart applies.* (1) If an enrollee has no further liability to pay for prescription drugs furnished through a PDP, a determination regarding these items or services is not subject to appeal.

(2) If an enrollee seeks coverage of prescription drugs received from a non-network provider (that is, a non-network pharmacy), except in those situations in which, under subpart C of this part, the PDP is obligated to cover such drugs, a determination regarding the prescription drugs is not subject to appeal.

(d) *When other regulations apply.* Unless this subpart provides otherwise, the regulations in part 422, subpart M of this chapter (concerning the administrative review and hearing processes under titles II and XVIII, and representation of parties under title XVIII of the Act) and any interpretive rules or CMS rulings issued under these regulations, apply under this subpart to the extent they are appropriate.

§ 423.564 Grievance procedures.

(a) *General rule.* Each PDP sponsor must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the sponsor or any other entity or individual through whom the sponsor provides covered benefits under any PDP it offers.

(b) *Distinguished from appeals.* Grievance procedures are separate and distinct from appeal procedures, which address coverage determinations as defined in § 423.566(b). Upon receiving a complaint, a PDP sponsor must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures.

(c) *Distinguished from the quality improvement organization complaint process.* Under section 1154(a)(14) of the Act, the quality improvement organization (QIO) must review enrollees' written complaints about the quality of services they have received under the Medicare program. This process is separate and distinct from the grievance procedures of the PDP sponsor. For quality of care issues, an enrollee may file a grievance with the

PDP sponsor, file a written complaint with the QIO, or both. For any complaint submitted to a QIO, the PDP sponsor must cooperate with the QIO in resolving the complaint.

(d) *Expedited grievances.* A PDP sponsor must respond to an enrollee's grievance within 24 hours if—

(1) The complaint involves a PDP sponsor's decision to invoke an extension relating to a coverage determination or redetermination.

(2) The complaint involves a PDP sponsor's refusal to grant an enrollee's request for an expedited coverage determination under § 423.570 or expedited redetermination under § 423.584, and the enrollee has not yet purchased or received the drug that is in dispute.

(e) *Record keeping.* The PDP sponsor must have an established process to track and maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the PDP sponsor notified the enrollee of the disposition.

§ 423.566 Coverage determinations.

(a) *Responsibilities of the PDP sponsor.* Each PDP sponsor must have a procedure for making timely coverage determinations in accordance with the requirements of this subpart regarding the prescription drug benefits an enrollee is entitled to receive under a PDP, including basic coverage as specified in § 423.108 and supplemental coverage as specified in § 423.112, and the amount, if any, that the enrollee is required to pay for a drug. The PDP sponsor must have a standard procedure for making determinations, in accordance with § 423.568, and an expedited procedure for situations in which applying the standard procedure may seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with § 423.570.

(b) *Actions that are coverage determinations.* The following actions by a PDP sponsor are coverage determinations:

(1) Failure to provide or pay for a covered Part D drug (including failure to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the sponsor determines that the drug is otherwise excluded under section 1862(a) of the Act) that the enrollee believes may be furnished by the PDP.

(2) Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee.

(3) A decision on the amount of cost sharing for a drug.

(4) A decision on whether a drug is a preferred drug for an enrollee.

(c) *Who can request a coverage determination.* Individuals who can request a standard or expedited coverage determination are—

(1) The enrollee, including his or her authorized representative; or

(2) The prescribing physician, on behalf of the enrollee.

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

(a) *Timeframe for requests for drug benefits.*

(1) When a party makes a request for a drug benefit, the PDP sponsor must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after receipt of the request.

(2) The PDP sponsor may extend the timeframe by up to 14 calendar days under the following circumstances:

(i) If the enrollee requests the extension.

(ii) If the sponsor justifies a need for additional information and explains how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence may change a sponsor's decision to deny).

(3) If the PDP sponsor extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the sponsor's decision to invoke an extension.

(4) For extensions, the PDP sponsor must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(b) *Timeframe for requests for payment.* When a party makes a request for payment, the PDP sponsor must notify the enrollee of its determination no later than 30 calendar days after receipt of the request.

(c) *Written notice for PDP sponsor denials.* If a PDP sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination.

(d) *Form and content of the denial notice.* The notice of any denial under paragraph (c) of this section must—

(1) Use approved notice language in a readable and understandable form;

(2) State the specific reasons for the denial;

(3) Inform the enrollee of his or her right to a redetermination;

(i) For drug coverage denials, describe both the standard and expedited redetermination processes, including the enrollee's right to, and conditions for, obtaining an expedited redetermination and the rest of the appeal process;

(ii) For payment denials, describe the standard redetermination process and the rest of the appeal process; and

(4) Comply with any other notice requirements specified by CMS.

(e) *Effect of failure to provide timely notice.* If the PDP sponsor fails to provide the enrollee with timely notice of a coverage determination as specified in subparagraph (a) of this section, this failure itself constitutes an adverse determination and may be appealed.

§ 423.570 Expediting certain coverage determinations.

(a) *Request for expedited determination.* An enrollee or an enrollee's prescribing physician may request that a PDP sponsor expedite a coverage determination involving issues described in § 423.566(b). This does not include requests for payment of prescription drugs already furnished.

(b) *How to make a request.* (1) To ask for an expedited determination, an enrollee or an enrollee's prescribing physician on behalf of the enrollee must submit an oral or written request directly to the PDP sponsor, or if applicable, to the entity responsible for making the determination, as directed by the PDP sponsor.

(2) A prescribing physician may provide oral or written support for an enrollee's request for an expedited determination.

(c) *How the PDP sponsor must process requests.* The PDP sponsor must establish and maintain the following procedures for processing requests for expedited determinations:

(1) An efficient and convenient means for individuals to submit oral or written requests.

(2) Documentation of all oral requests in writing and maintain the documentation in the case file.

(3) Prompt decisions on expediting a determination, based on the following requirements:

(i) For a request made by an enrollee, provide an expedited determination if it determines that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by an enrollee's prescribing physician, provide an expedited determination if

the physician indicates that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If a PDP sponsor denies a request for expedited determination, it must take the following actions:

(1) Automatically transfer the request to the standard timeframe and make the determination within the 14-calendar day timeframe established in § 423.568(a) for a standard determination. The 14-calendar day period begins with the day the PDP sponsor receives the request for expedited determination.

(2) Give the enrollee prompt oral notice of the denial and subsequently deliver, within 3 calendar days, a written letter that—

(i) Explains that the PDP sponsor must process the request using the 14-calendar day timeframe for standard determinations;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the PDP sponsor's decision not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

(e) *Actions on accepted requests for expedited determination.* If a PDP sponsor grants a request for expedited determination, it must make the determination and give notice in accordance with § 423.572.

§ 423.572 Timeframes and notice requirements for expedited coverage determinations.

(a) *Timeframe for determinations and notification.* Except as provided in paragraph (b) of this section, a PDP sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

(b) *Extensions of timeframe.* (1) *General rule.* The PDP sponsor may extend the 72-hour timeframe by up to 14 calendar days if the enrollee requests the extension or if the sponsor justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence may change a PDP sponsor's decision to deny).

(2) *Notification of extension.* When the PDP sponsor extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the sponsor's decision to invoke an extension.

(3) *Timeframe for notification of extension.* The PDP sponsor must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(c) *Confirmation of oral notice.* If the PDP sponsor first notifies an enrollee of an adverse expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(d) *Content of the notice of expedited determination.*

(1) The notice of any expedited determination must state the specific reasons for the determination in understandable language.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Inform the enrollee of his or her right to a redetermination;

(ii) Describe both the standard and expedited redetermination processes, including the enrollee's right to request, and conditions for obtaining, an expedited redetermination, and the rest of the appeal process; and

(iii) Comply with any other requirements specified by CMS.

(e) *Effect of failure to provide a timely notice.* If the PDP sponsor fails to provide the enrollee with timely notice of an expedited coverage determination as specified in this section, this failure constitutes an adverse coverage determination and may be appealed.

§ 423.576 Effect of a coverage determination.

The coverage determination is binding on the PDP sponsor and the enrollee unless it is reconsidered under § 423.580 through § 423.630 or is reopened and revised under § 423.634.

§ 423.578 Exceptions process.

(a) *Requests for exceptions to a PDP's tiered cost-sharing structure.* Each PDP sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a tiered formulary must establish and maintain an exceptions process.

(1) The sponsor's exceptions process must address each of the following circumstances:

(i) The enrollee is using a drug and the applicable tiered cost-sharing structure changes mid-year;

(ii) The enrollee is using a drug and the applicable tiered cost-sharing structure changes at the beginning of a new plan year; or

(iii) There is no pre-existing use of the drug by the enrollee.

(2) A PDP sponsor's exception criteria must include, but are not limited to—

(i) A description of the criteria a PDP sponsor uses to evaluate a determination made by the enrollee's prescribing physician under paragraph (a)(3) of this section.

(ii) Consideration of the cost difference between the *preferred drug* and the requested prescription drug that is the subject of the exceptions request.

(iii) Consideration of whether the requested prescription drug that is the subject of the exceptions request is the therapeutic equivalent of any other drug on the sponsor's formulary. For purposes of this subpart, drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the requested drug.

(iv) Consideration of the number of drugs on the sponsor's formulary that are in the same class and category as the requested prescription drug that is the subject of the exceptions request.

(3) An enrollee, the enrollee's authorized representative, or the enrollee's prescribing physician may file a request for an exception.

(4) A PDP sponsor may require a written certification from the enrollee's prescribing physician that the preferred drug on the sponsor's formulary is not as effective for the enrollee as the requested drug that is the subject of the requested exception, or that the preferred drug on the sponsor's formulary may have adverse effects for the enrollee, or both.

(5) The PDP sponsor may require the written certification to include only the following information:

(i) The enrollee's name, group or contract number, subscriber number or other information necessary to identify the enrollee.

(ii) The enrollee's patient history.

(iii) The primary diagnosis related to the requested prescription drug that is the subject of the exceptions request.

(iv) Why the "preferred drug" is not acceptable for the enrollee.

(v) Why the prescription drug that is the subject of the exceptions request is needed for the enrollee.

(vi) Any other information reasonably necessary to evaluate the medical necessity of the exceptions request.

(b) *Request for exceptions involving a nonformulary drug.* Each PDP sponsor

that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a formulary must establish and maintain an exceptions process. Formulary use includes the application of a dose restriction that causes a particular drug not to be covered for the number of doses prescribed or a step therapy requirement that causes a particular drug not to be covered until the requirements of the sponsor's coverage policy are met.

(1) The sponsor's exceptions process must address each of the following circumstances:

(i) Coverage of a prescription drug that is not covered based on the PDP sponsor's formulary.

(ii) Continued coverage of a particular prescription drug that the sponsor is discontinuing coverage on the formulary for reasons other than safety or because the prescription drug cannot be supplied by or was withdrawn from the market by the drug's manufacturer.

(iii) An exception to a sponsor's coverage policy that causes a prescription drug not to be covered until the step therapy requirement is satisfied or not to be covered at the prescribed number of doses.

(2) A PDP sponsor's exception procedures must include, but are not limited to—

(i) A description of the criteria a PDP sponsor uses to evaluate a prescribing physician's determination made under paragraph (b)(3) of this section;

(ii) A process for comparing applicable medical and scientific evidence on the safety and effectiveness of the requested nonformulary drug with the formulary drug for the enrollee; and

(iii) A description of the cost-sharing scheme that will be applied when coverage is provided for a non-formulary drug.

(iv) If the sponsor covers a non-formulary drug, the cost(s) incurred by the enrollee for that drug are treated as being included for purposes of calculating and meeting the annual out-of-pocket threshold.

(3) An enrollee, the enrollee's authorized representative, or the prescribing physician (on behalf of the enrollee) may file a request for an exception request.

(4) A PDP sponsor may require a written certification from the enrollee's prescribing physician that the requested prescription drug is medically necessary to treat the enrollee's disease or medical condition because—

(i) There is not a prescription drug listed on the formulary to treat the enrollee's disease or medical condition that is an acceptable clinical alternative;

(ii) The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements—

(A) Has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(B) Has caused or based on sound clinical evidence and medical and scientific evidence is likely to cause an adverse reaction or other harm to the enrollee; or

(iii) The number of doses that is available under a dose restriction for the prescription drug has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

(5) The PDP sponsor may require the written certification to include only the following information:

(i) The enrollee's name, group or contract number, subscriber number or other information necessary to identify the enrollee.

(ii) Patient history.

(iii) The primary diagnosis related to the requested prescription drug that is the subject of the exceptions request.

(iv) Based on paragraph (b)(4) of this section, the reason—

(A) Why the formulary drug is not acceptable for the enrollee;

(B) If the medical exceptions request involves a step therapy requirement, why the prescription drug required to be used is not acceptable for the enrollee; or

(C) If the medical exceptions request involves a dose restriction, why the available number of doses for the prescription drug is not acceptable for the enrollee;

(D) The reason why the prescription drug that is the subject of the exceptions request is needed for the enrollee; and

(E) Any other information reasonably necessary to evaluate the medical necessity of the medical exceptions request.

(c) *PDP sponsor requirements for exceptions determinations.* (1) *General rule.* A PDP sponsor's decision concerning an exceptions request under this section constitutes a PDP coverage determination as specified at § 423.566.

(2) *When a sponsor does not make a timely decision.* If the PDP sponsor fails to make a decision on an exceptions request for continued coverage of a drug the sponsor is removing from its formulary (for reasons other than safety or because the drug cannot be supplied or is withdrawn from the market by the manufacturer) and to provide notice of the decision within the timeframe required under § 423.568(a)—

(i) The enrollee is entitled to have coverage for up to 1 month's supply of the prescription drug that is the subject of the request; and

(ii) The PDP sponsor must make a decision on the exceptions request before the enrollee's completion of the supply in paragraph (c)(2)(i) of this section.

(iii) If the PDP sponsor fails to make a decision on the exceptions request and provide notice of the decision before to the enrollee's completion of the supply provided in paragraph (c)(2)(i) of this section, the sponsor must maintain coverage, as specified in paragraph (c)(2)(i) of this section, unless—

(A) There is a material change in the enrollee's terms of coverage or the applicable benefit limits have been exhausted;

(B) The drug is no longer prescribed for the enrollee or is not considered safe for the treatment of the enrollee's disease or medical condition; or

(C) A decision is made on the exceptions request and notice of that decision is provided.

(3) *When an exceptions request is approved.* Whenever an exceptions request made under § 423.578 is approved, the PDP sponsor must provide coverage for the approved prescription drug and must not—

(i) Require the enrollee to request approval for a refill or a new prescription to continue using the prescription drug after the refills for the initial prescription are exhausted, as long as—

(A) The enrollee's prescribing physician continues to prescribe the drug; and

(B) The drug continues to be considered safe for treating the enrollee's disease or medical condition.

(ii) Establish a special formulary tier or copayment or other cost-sharing requirement that is applicable only to prescription drugs approved for coverage under this section.

(d) Nothing in this section will be construed to allow an enrollee to use the exceptions processes set out in this

section to request coverage for a prescription drug that is not a covered Part D drug.

§ 423.580 Right to a redetermination.

An enrollee who has received a coverage determination (including one that is reopened and revised as described in § 423.634) may request that it be redetermined under the procedures described in § 423.582, which address requests for a standard redetermination. An enrollee or an enrollee's prescribing physician (acting on behalf of an enrollee) may request an expedited redetermination specified in § 423.584.

§ 423.582 Request for a standard redetermination.

(a) *Method and place for filing a request.* An enrollee must ask for a redetermination by making an oral or written request with the PDP sponsor that made the coverage determination.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, an enrollee must file a request for a redetermination within 60 calendar days from the date of the notice of the coverage determination.

(c) *Extending the time for filing a request.* (1) *General rule.* If an enrollee shows good cause, the PDP sponsor may extend the timeframe for filing a request for redetermination.

(2) *How to request an extension of timeframe.* If the 60-day period in which to file a request for a redetermination has expired, an enrollee may file a request for redetermination and extension of time frame with the PDP sponsor. The request for redetermination and to extend the timeframe must—

(i) Be in writing; and

(ii) State why the request for redetermination was not filed on time.

(d) *Withdrawing a request.* The person who files a request for redetermination may withdraw it by filing a written request for withdrawal at one of the places listed in paragraph (a) of this section.

§ 423.584 Expediting certain redeterminations.

(a) *Who may request an expedited redetermination.* An enrollee or an enrollee's prescribing physician may request that a PDP sponsor expedite a redetermination that involves the issues specified in § 423.566(b)(1) and (b)(2). (This does not include requests for payment of drugs already furnished.)

(b) *How to make a request.*

(1) To ask for an expedited redetermination, an enrollee or a prescribing physician acting on behalf of an enrollee must submit an oral or written request directly to the PDP sponsor or, if applicable, to the entity responsible for making the redetermination, as directed by the PDP sponsor.

(2) A prescribing physician may provide oral or written support for an enrollee's request for an expedited redetermination.

(c) *How the PDP sponsor must process requests.* The PDP sponsor must establish and maintain the following procedures for processing requests for expedited redetermination:

(1) *Handling of requests.* The PDP sponsor must establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the documentation in the case file.

(2) *Prompt decision.* The PDP sponsor must promptly decide on whether to expedite the redetermination or follow the timeframe for standard redetermination based on the following requirements:

(i) For a request made by an enrollee, the PDP sponsor must provide an expedited redetermination if it determines that applying the standard timeframe for making a redetermination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a prescribing physician, the PDP sponsor must provide an expedited redetermination if the physician indicates that applying the standard timeframe for conducting a redetermination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial of a request.* If a PDP sponsor denies a request for expedited redetermination, it must take the following actions:

(1) Automatically transfer a request to the standard timeframe and make the determination within the 30-day timeframe established in § 423.590(a). The 30-day period begins the day the PDP sponsor receives the request for expedited redetermination.

(2) Give the enrollee prompt oral notice, and subsequently deliver, within 3 calendar days, a written letter that—

(i) Explains that the PDP sponsor processes the enrollee's request using the 30-day timeframe for standard redetermination;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the sponsor's decision not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited redetermination with the prescribing physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

(e) *Action following acceptance of a request.* If a PDP sponsor grants a request for expedited redetermination, it must conduct the redetermination and give notice in accordance with § 423.590(d).

§ 423.586 Opportunity to submit evidence.

The PDP sponsor must provide the enrollee or the prescribing physician, as appropriate, with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In the case of an expedited redetermination, the opportunity to present evidence is limited by the short timeframe for making a decision. Therefore, the PDP sponsor must inform the enrollee or the prescribing physician of the conditions for submitting the evidence.

§ 423.590 Timeframes and responsibility for making redeterminations.

a. *Standard redetermination—request for covered drug benefits.* (1) If the PDP sponsor makes a redetermination that is completely favorable to the enrollee, the PDP sponsor must issue the redetermination (and effectuate it in accordance with § 423.636(a)(1)) as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard redetermination.

(2) If the PDP sponsor makes a redetermination that affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard redetermination.

(3) The PDP sponsor may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the sponsor justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence may change a PDP sponsor's decision to deny).

(4) When the PDP sponsor extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the PDP sponsor's decision to invoke an extension.

(5) For extensions, the PDP sponsor must issue its determination as

expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(b) *Standard redetermination—request for payment.* (1) If the PDP sponsor makes a redetermination that is completely favorable to the enrollee, the PDP sponsor must issue its redetermination to the enrollee (and effectuate it in accordance with § 423.636(a)(2)) no later than 60 calendar days from the date it receives the request for redetermination.

(2) If the PDP sponsor affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination no later than 60 calendar days from the date it receives the request for redetermination.

(c) *Effect of failure to meet timeframe for standard redetermination.* If the PDP sponsor fails to provide the enrollee with a redetermination within the timeframes specified in paragraphs (a) or (b) of this section, this failure constitutes an affirmation of its adverse coverage determination and is subject to appeal to the IRE.

(d) *Expedited redetermination.* (1) *Timeframe.* Except as provided in paragraph (d)(2) of this section, a PDP sponsor that approves a request for expedited redetermination must complete its redetermination and give the enrollee (and the prescribing physician involved, as appropriate) notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

(2) *Extensions.* The PDP sponsor may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the sponsor justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence may change a PDP sponsor's decision to deny).

(3) *Notification of extension.* (i) *Timeframe.* The PDP sponsor must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

(ii) *Content of notification.* When the PDP sponsor extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the PDP sponsor's decision to invoke an extension.

(4) *How the PDP sponsor must request additional information.* If the PDP sponsor must receive medical information, the PDP sponsor must request the necessary information within 24 hours of the initial request for an expedited redetermination. Regardless of whether the PDP sponsor must request additional information, the PDP sponsor is responsible for meeting the timeframe and notice requirements.

(5) *Affirmation of an adverse expedited coverage determination.* If, as a result of its redetermination, the PDP sponsor affirms, in whole or in part, its adverse expedited coverage determination, the PDP sponsor must give the enrollee (and the prescribing physician involved, as appropriate) notice of its decision as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request (or no later than the expiration of an extension specified in paragraph (d)(2) of this section).

(e) *Failure to meet timeframe for expedited redetermination.* If the PDP sponsor fails to provide the enrollee or the prescribing physician, as appropriate, with the results of its expedited redetermination within the timeframe described in paragraph (d) of this section, this failure constitutes an affirmation of its adverse expedited coverage determination and is subject to appeal to the IRE.

(f) *Who must reconsider an adverse coverage determination.* (1) A person or persons who were not involved in making the coverage determination must conduct the redetermination.

(2) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the redetermination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the redetermination need not, in all cases, be of the same specialty or subspecialty as the prescribing physician.

§ 423.600 Reconsideration by an independent review entity (IRE).

(a) An enrollee who is dissatisfied with the redetermination of a PDP sponsor has a right to a reconsideration by an independent review entity that contracts with CMS. An enrollee must file a written request for reconsideration at one of the places listed in § 423.582(a) or with the IRE within 60 days of the date of the sponsor's redetermination.

(b) When an enrollee files an appeal, the IRE is required to solicit the views of the prescribing physician.

(c) In order for an enrollee to request an IRE reconsideration of a PDP sponsor's determination not to provide for a covered Part D drug that is not on the PDP formulary, the prescribing physician must determine that all covered Part D drugs on any tier of the formulary for treatment of the same condition is not as effective for the individual as the nonformulary drug, has adverse effects for the individual, or both.

(d) The independent review entity must conduct the reconsideration as expeditiously as the enrollee's health condition requires but must not exceed the deadlines specified in its contract.

§ 423.602 Notice of reconsideration determination by the independent review entity.

(a) *Responsibility for the notice.* When the IRE makes its reconsideration determination, it is responsible for mailing a notice of its determination to the enrollee and PDP sponsor, and for sending a copy to CMS.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the IRE's decision in understandable language;

(2) If the reconsideration determination is adverse (that is, does not completely reverse the PDP sponsor's adverse coverage determination), inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under § 423.610;

(3) Describe the procedures that must be followed to obtain an ALJ hearing; and

(4) Comply with any other requirements specified by CMS.

§ 423.604 Effect of a reconsideration determination.

A reconsideration determination is final and binding on the enrollee and the PDP sponsor, unless the enrollee files a request for a hearing under the provisions of § 423.612.

§ 423.610 Right to an ALJ hearing.

(a) If the amount remaining in controversy after the IRE reconsideration meets the threshold requirement established annually by the Secretary, an enrollee who is dissatisfied with the IRE reconsideration determination has a right to a hearing before an ALJ.

(b) If the basis for the appeal is the PDP sponsor's refusal to provide drug benefits, CMS uses the projected value of those benefits to compute the amount remaining in controversy.

(c) *Aggregating appeals to meet the amount in controversy.* (1) *Enrollee.* Two or more appeals may be aggregated by an enrollee to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The request for ALJ hearing lists all of the appeals to be aggregated and is filed within 60 days after all of the IRE reconsideration determinations being appealed have been received; and

(iii) The ALJ determines that the appeals the enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee.

(2) *Multiple enrollees.* Two or more appeals may be aggregated by multiple enrollees to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The request for ALJ hearing lists all of the appeals to be aggregated and is filed within 60 days after all of the IRE reconsideration determinations being appealed have been received; and

(iii) The ALJ determines that the appeals the enrollees seek to aggregate involve the same prescription drug.

§ 423.612 Request for an ALJ hearing.

(a) *How and where to file a request.* The enrollee must file a written request for a hearing at one of the places specified in § 423.582(a) or with the IRE. The organizations specified in § 423.582(a) forward the request to the independent review entity, which is responsible for transferring the case to the appropriate ALJ office.

(b) *When to file a request.* Except when an ALJ extends the timeframe as provided in part 422, subpart M of this chapter, the enrollee must file a request for a hearing within 60 days of the date of the notice of an IRE reconsideration determination.

(c) *Insufficient amount in controversy.* (1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 423.610, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under § 423.610, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.

§ 423.620 Medicare Appeals Council (MAC) review.

An enrollee who is dissatisfied with an ALJ hearing decision may request that the MAC review the ALJ's decision or dismissal. The regulations under part 422, subpart M of this chapter regarding MAC review apply to matters addressed by this subpart.

§ 423.630 Judicial review.

(a) *Review of ALJ's Decision.* The enrollee may request judicial review of an ALJ's decision if—

(1) The MAC denied the enrollee's request for review; and

(2) The amount in controversy meets the threshold requirement established annually by the Secretary.

(b) *Review of MAC decision.* The enrollee may request judicial review of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) *How to request judicial review.* In order to request judicial review, an enrollee must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. (See part 422, subpart M of this chapter, for a description of the procedures to follow in requesting judicial review.)

§ 423.634 Reopening and revising determinations and decisions.

(a) A coverage determination or reconsideration made by a PDP sponsor, a reconsideration made by the independent review entity specified in § 423.600, or the decision of an ALJ or the MAC that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in part 422, subpart M of this chapter.

(b) The filing of a request for reopening does not relieve the PDP sponsor of its obligation to make payment or provide benefits as specified in § 423.636 or § 423.638.

(c) Once an entity issues a revised determination or decision, the revisions made by the decision may be appealed.

(d) A decision of a PDP sponsor or any other entity not to reopen is not subject to review.

§ 423.636 How a PDP sponsor must effectuate standard predeterminations, reconsideration determinations, or decisions.

(a) *Reversals by the PDP sponsor.* (1) *Requests for benefits.* If, on redetermination of a request for benefit, the PDP sponsor completely reverses its coverage determination, the sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the date the PDP sponsor receives the request for redetermination (or no later than upon expiration of an extension described in § 423.590(a)(3)).

(2) *Requests for payment.* If, on redetermination of a request for payment, the PDP sponsor completely reverses its coverage determination, the sponsor must pay for the benefit no later than 60 calendar days after the date the PDP sponsor receives the request for redetermination.

(b) *Reversals by the independent review entity.* (1) *Requests for benefits.* If, on reconsideration of a request for benefit, the PDP sponsor's determination is reversed in whole or in part by the independent review entity, the PDP sponsor must authorize the benefit under dispute within 72 hours from the date it receives notice reversing the determination, or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days from that date. The PDP sponsor must inform the independent review entity that the sponsor has effectuated the decision.

(2) *Requests for payment.* If, on reconsideration of a request for payment, the PDP sponsor's determination is reversed in whole or in part by the independent review entity, the PDP sponsor must pay for the benefit no later than 30 calendar days from the date it receives notice reversing the coverage determination. The PDP sponsor must inform the independent review entity that the sponsor has effectuated the decision.

(c) *Reversals other than by the PDP sponsor or the independent review entity.* If the IRE's determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the PDP sponsor must pay for, authorize, or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date it receives notice reversing the determination. The PDP sponsor must inform the independent review entity that the sponsor has effectuated the decision.

§ 423.638 How a PDP sponsor must effectuate expedited redeterminations or reconsidered determinations.

(a) *Reversals by the PDP sponsor.* If, on redetermination of an expedited request for benefits, the PDP sponsor completely reverses its coverage determination, the PDP sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the PDP sponsor receives the request for redetermination (or no later than upon expiration of an extension specified in § 423.590(d)(2)).

(b) *Reversals by the independent review entity.* If the PDP sponsor's determination is reversed in whole or in part by the independent review entity, the PDP sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health

condition requires but no later than 72 hours from the date it receives notice reversing the determination. The PDP sponsor must inform the independent review entity that the sponsor has effectuated the decision.

(c) *Reversals other than by the PDP sponsor or the independent review entity.* If the IRE's expedited determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the PDP sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 days from the date it receives notice reversing the determination. The PDP sponsor must inform the independent review entity that the sponsor has effectuated the decision.

Subpart N—Medicare Contract Determinations and Appeals

§ 423.641 Contract determinations.

This subpart establishes the procedures for making and reviewing the following contract determinations:

(a) A determination that an entity is not qualified to enter into a contract with CMS under Part D of Title XVIII of the Act.

(b) A determination to terminate a contract with a PDP sponsor in accordance with § 423.509.

(c) A determination not to authorize a renewal of a contract with a PDP sponsor in accordance with § 423.507(b).

§ 423.642 Notice of contract determination.

(a) When CMS makes a contract determination, it gives the PDP sponsor written notice.

(b) The notice specifies the—

(1) Reasons for the determination; and

(2) PDP sponsor's right to request reconsideration.

(c) For CMS-initiated terminations, CMS mails notice 90 days before the anticipated effective date of the termination. For terminations based on initial determinations described at § 423.509(a)(4) or (a)(5), CMS immediately notifies the PDP sponsor of its decision to terminate the organization's PDP contract.

(d) When CMS determines that it is not going to authorize a contract renewal, CMS mails the notice to the PDP sponsor by May 1 of the current contract year.

§ 423.643 Effect of contract determination.

The contract determination is final and binding unless—

(a) The determination is reconsidered in accordance with § 423.644 through § 423.649;

(b) A timely request for a hearing is filed under § 423.651; or

(c) The reconsideration decision is revised as a result of a reopening under § 423.668.

§ 423.644 Reconsideration: Applicability.

(a) Reconsideration is the first step for appealing a contract determination specified in § 423.641.

(b) CMS reconsiders the specified determinations if the contract applicant or the PDP sponsor files a written request in accordance with § 423.645.

§ 423.645 Request for reconsideration.

(a) *Method and place for filing a request.* A request for reconsideration must be made in writing and filed with any CMS office.

(b) *Time for filing a request.* The request for reconsideration must be filed within 15 days from the date of the notice of the initial determination.

(c) *Proper party to file a request.* Only an authorized official of the contract applicant or PDP sponsor that was the subject of a contract determination may file the request for reconsideration.

(d) *Withdrawal of a request.* The PDP sponsor or contract applicant who filed the request for a reconsideration may withdraw it at any time before the notice of the reconsidered determination is mailed. The request for withdrawal must be in writing and filed with CMS.

§ 423.646 Opportunity to submit evidence.

CMS provides the PDP sponsor or contract applicant and the CMS official or officials who made the contract determination reasonable opportunity, not to exceed the timeframe in which a PDP sponsor chooses to request a hearing as described at § 423.651, to present as evidence any documents or written statements that are relevant and material to the matters at issue.

§ 423.647 Reconsidered determination.

A reconsidered determination is a new determination that—

(a) Is based on a review of the contract determination, the evidence and findings upon which that was based, and any other written evidence submitted before notice of the reconsidered determination is mailed, including facts relating to the status of the PDP sponsor subsequent to the contract determination; and

(b) Affirms, reverses, or modifies the initial determination.

§ 423.648 Notice of reconsidered determination.

(a) CMS gives the PDP sponsor or contract applicant written notice of the reconsidered determination.

(b) The notice—

(1) Contains findings for the contract applicant's qualifications to enter into, or the PDP sponsor's qualifications to remain under, a contract with CMS under Part D of the Act;

(2) States the specific reasons for the reconsidered determination; and

(3) Informs the PDP sponsor or contract applicant of its right to a hearing if it is dissatisfied with the determination.

§ 423.649 Effect of reconsidered determination.

A reconsidered determination is final and binding unless a request for a hearing is filed in accordance with § 423.651 or it is revised in accordance with § 423.668.

§ 423.650 Right to a hearing.

The following parties are entitled to a hearing:

(a) A contract applicant that is determined in a reconsidered determination to be unqualified to enter into a contract with CMS under Part D of title XVIII of the Act.

(b) A PDP sponsor whose contract with CMS is terminated or is not renewed as a result of a contract determination as provided in § 423.641.

§ 423.651 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or PDP sponsor that was the party to the determination under appeal. The request for a hearing must be filed with any CMS office.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 days after the date of the reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 423.650;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

§ 423.652 Postponement of effective date of a contract determination when a request for a hearing for a contract determination is filed timely.

(a) CMS postpones the proposed effective date of the contract determination to terminate a contract with a PDP sponsor until a hearing decision is reached and affirmed by the Administrator following review under § 423.666 in instances where a PDP sponsor requests review by the Administrator; and

(b) CMS extends the current contract at the end of the contract period (in the case of a determination not to renew) only—

(1) If CMS finds that an extension of the contract is consistent with the purpose of this part; and

(2) For the period as CMS and the PDP sponsor agree.

(c) *Exception:* A contract terminated in accordance with § 423.509(a)(4) or (a)(5) is immediately terminated and is not postponed if a hearing is requested.

§ 423.653 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 423.654 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

§ 423.655 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing, which is not to exceed 30 days from the receipt of the request for the hearing, and sends written notice to the parties. The notice also informs the parties of the general and specific issues to be resolved and information about the hearing procedure.

(b) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing. The hearing officer may adjourn or postpone the hearing.

(c) The hearing officer gives the parties reasonable notice of any change in time or place of hearing, or of adjournment or postponement.

§ 423.656 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before the Secretary or otherwise prohibited by law.

§ 423.657 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 423.656, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it is sent to the party.

§ 423.658 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

§ 423.659 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that is inadmissible under rules applicable to court procedures.

§ 423.660 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

§ 423.661 Discovery.

(a) Prehearing discovery is permitted upon timely request of a party.

(b) A request is timely if it is made before the beginning of the hearing.

(c) A reasonable time for inspection and reproduction of documents is provided by order of the hearing officer.

(d) The hearing officer's order on all discovery matters is final.

§ 423.662 Prehearing.

The hearing officer may schedule a prehearing conference if he or she believes that a conference may more clearly define the issues.

§ 423.663 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision is issued.

§ 423.664 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.

§ 423.665 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under § 423.666, or reopened and revised in accordance with § 423.668.

§ 423.666 Review by the Administrator.

(a) *Request for review by Administrator.* A PDP sponsor that receives a hearing decision upholding a contract termination determination may request review by the Administrator within 15 days of receiving the hearing decision as provided under § 423.665(b).

(b) *Review by the Administrator.* The Administrator must review the hearing officer's decision, and determine, based upon this decision, the hearing record, and any written arguments submitted by the PDP sponsor, whether the termination decision must be upheld, reversed, or modified.

(c) *Decision by the Administrator.* The Administrator issues a written decision, and furnishes the decision to the PDP sponsor requesting review.

§ 423.667 Effect of Administrator's decision.

A decision by the Administrator under section § 423.666(c) is final and binding unless it is reopened and revised in accordance with § 423.668.

§ 423.668 Reopening of contract or reconsidered determination or decision of a hearing officer or the Administrator.

(a) *Initial or reconsidered determination.* CMS may reopen and revise an initial or reconsidered determination upon its own motion within 1 year of the date of the notice of determination.

(b) *Decision of hearing officer.* A decision of a hearing officer that is

unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within 1 year of the notice of the hearing decision. Another hearing officer designated by CMS may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator.* A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within 1 year of the notice of the Administrator's decision.

(d) *Notices.* (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

§ 423.669 Effect of revised determination.

The revision of a contract or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 423.651.

§ 423.650 Right to a hearing.

The following parties are entitled to a hearing:

(a) A contract applicant that is determined in a reconsidered determination to be unqualified to enter into a contract with CMS under Part D of title XVIII of the Act.

(b) A PDP sponsor whose contract with CMS is terminated or is not renewed as a result of a contract determination as provided in § 423.641.

§ 423.651 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or PDP sponsor that was the party to the determination under appeal. The request for a hearing must be filed with any CMS office.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 days after the date of the reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 423.650;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

§ 423.652 Postponement of effective date of a contract determination when a request for a hearing for a contract determination is filed timely.

(a) CMS postpones the proposed effective date of the contract determination to terminate a contract with a PDP sponsor until a hearing decision is reached and affirmed by the Administrator following review under § 423.666 in instances where a PDP sponsor requests review by the Administrator; and

(b) CMS extends the current contract at the end of the contract period (in the case of a determination not to renew) only—

(1) If CMS finds that an extension of the contract is consistent with the purpose of this part; and

(2) For the period as CMS and the PDP sponsor agree.

(c) *Exception:* A contract terminated in accordance with § 423.509 (a)(4) or (a)(5) is immediately terminated and is not be postponed if a hearing is requested.

§ 423.653 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 423.654 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

§ 423.655 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing, which is not to exceed 30 days from the receipt of the request for the hearing, and sends written notice to the parties. The notice also informs the parties of the general and specific issues to be resolved and information about the hearing procedure.

(b) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing. The hearing officer may adjourn or postpone the hearing.

(c) The hearing officer gives the parties reasonable notice of any change in time or place of hearing, or of adjournment or postponement.

§ 423.656 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before the Secretary or otherwise prohibited by law.

§ 423.657 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 423.656, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it is sent to the party.

§ 423.658 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

§ 423.659 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that is inadmissible under rules applicable to court procedures.

§ 423.660 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

§ 423.661 Discovery.

(a) Prehearing discovery is permitted upon timely request of a party.

(b) A request is timely if it is made before the beginning of the hearing.

(c) A reasonable time for inspection and reproduction of documents is provided by order of the hearing officer.

(d) The hearing officer's order on all discovery matters is final.

§ 423.662 Prehearing.

The hearing officer may schedule a prehearing conference if he or she believes that a conference may more clearly define the issues.

§ 423.663 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision is issued.

§ 423.664 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.

§ 423.665 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under § 423.666, or reopened and revised in accordance with § 423.668.

§ 423.666 Review by the Administrator.

(a) *Request for review by Administrator.* A PDP sponsor that receives a hearing decision upholding a contract termination determination may request review by the Administrator within 15 days of receiving the hearing decision as provided under § 423.665(b).

(b) *Review by the Administrator.* The Administrator must review the hearing officer's decision, and determine, based upon this decision, the hearing record, and any written arguments submitted by the PDP sponsor, whether the termination decision must be upheld, reversed, or modified.

(c) *Decision by the Administrator.* The Administrator issues a written decision, and furnishes the decision to the PDP sponsor requesting review.

§ 423.667 Effect of Administrator's decision.

A decision by the Administrator under section § 423.666(c) is final and binding unless it is reopened and revised in accordance with § 423.668.

§ 423.668 Reopening of contract or reconsidered determination or decision of a hearing officer or the Administrator.

(a) *Initial or reconsidered determination.* CMS may reopen and revise an initial or reconsidered determination upon its own motion within 1 year of the date of the notice of determination.

(b) *Decision of hearing officer.* A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within 1 year of the notice of the hearing decision. Another hearing officer designated by CMS may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator.* A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within 1 year of the notice of the Administrator's decision.

(d) *Notices.* (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

§ 423.669 Effect of revised determination.

The revision of a contract or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 423.651.

§ 423.650 Right to a hearing.

The following parties are entitled to a hearing:

(a) A contract applicant that is determined in a reconsidered determination to be unqualified to enter into a contract with CMS under Part D of title XVIII of the Act.

(b) A PDP sponsor whose contract with CMS is terminated or is not renewed as a result of a contract determination as provided in § 423.641.

§ 423.651 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or PDP sponsor that was the party to the determination under appeal. The request for a hearing must be filed with any CMS office.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 days after the date of the reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 423.650;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

§ 423.652 Postponement of effective date of a contract determination when a request for a hearing for a contract determination is filed timely.

(a) CMS postpones the proposed effective date of the contract determination to terminate a contract with a PDP sponsor until a hearing decision is reached and affirmed by the Administrator following review under § 423.666 in instances where a PDP sponsor requests review by the Administrator; and

(b) CMS extends the current contract at the end of the contract period (in the case of a determination not to renew) only—

(1) If CMS finds that an extension of the contract is consistent with the purpose of this part; and

(2) For the period as CMS and the PDP sponsor agree.

(c) *Exception:* A contract terminated in accordance with § 423.509(a)(4) or (a)(5) is immediately terminated and is not postponed if a hearing is requested.

§ 423.653 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 423.654 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before

another hearing officer. The objections must be submitted in writing to CMS.

§ 423.655 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing, which is not to exceed 30 days from the receipt of the request for the hearing, and sends written notice to the parties. The notice also informs the parties of the general and specific issues to be resolved and information about the hearing procedure.

(b) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing. The hearing officer may adjourn or postpone the hearing.

(c) The hearing officer gives the parties reasonable notice of any change in time or place of hearing, or of adjournment or postponement.

§ 423.656 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before the Secretary or otherwise prohibited by law.

§ 423.657 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 423.656, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it is sent to the party.

§ 423.658 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

§ 423.659 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that is inadmissible under rules applicable to court procedures.

§ 423.660 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

§ 423.661 Discovery.

(a) Prehearing discovery is permitted upon timely request of a party.

(b) A request is timely if it is made before the beginning of the hearing.

(c) A reasonable time for inspection and reproduction of documents is provided by order of the hearing officer.

(d) The hearing officer's order on all discovery matters is final.

§ 423.662 Prehearing.

The hearing officer may schedule a prehearing conference if he or she believes that a conference may more clearly define the issues.

§ 423.663 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision is issued.

§ 423.664 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.

§ 423.665 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under § 423.666, or reopened and revised in accordance with § 423.668.

§ 423.666 Review by the Administrator.

(a) *Request for review by Administrator.* A PDP sponsor that receives a hearing decision upholding a contract termination determination may request review by the Administrator within 15 days of receiving the hearing decision as provided under § 423.665(b).

(b) *Review by the Administrator.* The Administrator must review the hearing officer's decision, and determine, based upon this decision, the hearing record, and any written arguments submitted by the PDP sponsor, whether the termination decision must be upheld, reversed, or modified.

(c) *Decision by the Administrator.* The Administrator issues a written decision, and furnishes the decision to the PDP sponsor requesting review.

§ 423.667 Effect of Administrator's decision.

A decision by the Administrator under section § 423.666(c) is final and binding unless it is reopened and revised in accordance with § 423.668.

§ 423.668 Reopening of contract or reconsidered determination or decision of a hearing officer or the Administrator.

(a) *Initial or reconsidered determination.* CMS may reopen and revise an initial or reconsidered determination upon its own motion within 1 year of the date of the notice of determination.

(b) *Decision of hearing officer.* A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within 1 year of the notice of the hearing decision. Another hearing officer designated by CMS may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator.* A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within 1 year of the notice of the Administrator's decision.

(d) *Notices.* (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

§ 423.669 Effect of revised determination.

The revision of a contract or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 423.651.

Subpart O—Intermediate Sanctions

§ 423.750 Kinds of sanctions.

(a) The following intermediate sanctions and civil money penalties may be imposed:

(1) Civil money penalties ranging from $10,000 to $100,000 depending upon the violation.

(2) Suspension of enrollment of Medicare beneficiaries.

(3) Suspension of payment to the PDP sponsor for Medicare beneficiaries who enroll.

(4) Suspension of all PDP marketing activities to Medicare beneficiaries for the MA plan subject to the intermediate sanctions.

(b) The enrollment, payment, and marketing sanctions continue in effect until CMS is satisfied that the deficiency on which the determination was based is corrected and is not likely to recur.

§ 423.752 Basis for imposing sanctions.

(a) *All intermediate sanctions.* For the violations listed below, CMS may impose any of the sanctions specified in § 423.750 on any PDP sponsor that has a contract in effect. The PDP sponsor may also be subject to other applicable remedies available under law.

(1) Fails substantially to provide, to a PDP enrollee, medically necessary services that the organization is required to provide (under law or under the contract) to a PDP enrollee, and that failure adversely affects (or is substantially likely to adversely affect) the enrollee.

(2) Imposes on PDP enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under section 1860D of the Act and subpart F of this part.

(3) Acts to expel or refuses to reenroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that may reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services.

(5) Misrepresents or falsifies information that it furnishes—

(i) To CMS; or

(ii) To an individual or to any other entity under the Part D drug benefit program.

(6) Employs or contracts with an individual or entity who is excluded from participation in Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with an individual or entity) for the provision of any of the following:

(i) Health care.

(ii) Utilization review.

(iii) Medical social work.

(iv) Administrative services.

(b) *Suspension of enrollment and marketing.* If CMS makes a determination that could lead to a contract termination under § 423.509(a), CMS may instead impose the intermediate sanctions in § 423.756(c)(1) and (c)(3).

§ 423.756 Procedures for imposing sanctions.

(a) *Notice of sanction and opportunity to respond.*

(1) *Notice of sanction.* Before imposing the intermediate sanctions specified in paragraph (c) of this section CMS—

(i) Sends a written notice to the PDP sponsor stating the nature and basis of the proposed sanction; and

(ii) Sends the Office of the Inspector General a copy of the notice.

(2) *Opportunity to respond.* CMS allows the PDP sponsor 15 days from receipt of the notice to provide evidence that it has not committed an act or failed to comply with the requirements described in § 423.752, as applicable. CMS may allow a 15-day addition to the original 15 days upon receipt of a written request from the PDP sponsor. To be approved, the request must provide a credible explanation of why additional time is necessary and be received by CMS before the end of the 15-day period following the date of receipt of the sanction notice. CMS does not grant an extension if it determines that the PDP sponsor's conduct poses a threat to an enrollee's health and safety.

(b) *Informal reconsideration.* If, consistent with paragraph (a)(2) of this section, the PDP sponsor submits a timely response to CMS' notice of sanction, CMS conducts an informal reconsideration that—

(1) Consists of a review of the evidence by an CMS official who did not participate in the initial decision to impose a sanction; and

(2) Gives the PDP sponsor a concise written decision setting forth the factual and legal basis for the decision that affirms or rescinds the original determination.

(c) *Specific sanctions.* If CMS determines that a PDP sponsor has acted or failed to act as specified in § 423.752 and affirms this determination in accordance with paragraph (b) of this section, CMS may—

(1) Require the PDP sponsor to suspend acceptance of applications made by Medicare beneficiaries for enrollment in the sanctioned plan during the sanction period;

(2) In the case of a violation under § 423.752(a), suspend payments to the PDP sponsor for Medicare beneficiaries enrolled in the sanctioned plan during the sanction period; and

(3) Require the PDP sponsor to suspend all marketing activities for the sanctioned plan to Medicare enrollees.

(d) *Effective date and duration of sanctions.* (1) *Effective date.* Except as provided in paragraph (d)(2) of this section, a sanction is effective 15 days after the date that the organization is notified of the decision to impose the sanction or, if the PDP sponsor seeks reconsideration in a timely manner under paragraph (b) of this section, on the date specified in the notice of CMS' reconsidered determination.

(2) *Exception.* If CMS determines that the PDP sponsor's conduct poses a serious threat to an enrollee's health and safety, CMS may make the sanction effective on a date before issuance of CMS' reconsidered determination.

(3) *Duration of sanction.* The sanction remains in effect until CMS notifies the PDP sponsor that CMS is satisfied that the basis for imposing the sanction is corrected and is not likely to recur.

(e) *Termination by CMS.* In addition to or as an alternative to the sanctions described in paragraph (c) of this section, CMS may decline to authorize the renewal of an organization's contract in accordance with § 423.507(b)(2) and (b)(3), or terminate the contract in accordance with § 423.509.

(f) *Civil money penalties.* (1) If CMS determines that a PDP sponsor has committed an act or failed to comply with a requirement described in § 423.752, CMS notifies the OIG of this determination, and also notifies OIG when CMS reverses or terminates a sanction imposed under this part.

(2) In the case of a violation described in § 423.752(a), or a determination under § 423.752(b) based upon a violation under § 423.509(a)(4) (involving fraudulent or abusive activities), in accordance with the provisions of part 1005 of this chapter, the OIG may impose civil money penalties on the PDP sponsor in accordance with part 1005 of this chapter in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

(3) In the case of a determination under § 423.752(b) other than a determination based upon a violation under § 423.509(a)(4), in accordance with the provisions of part 1005 of this chapter, CMS may impose civil money penalties on the PDP sponsor in the amounts specified in § 423.758 in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

§ 423.758 Maximum amount of civil money penalties imposed by CMS.

If CMS makes a determination under § 423.752(b), based on any determination under § 423.509(a) except a determination under § 423.509(a)(4), CMS may impose civil money penalties in the following amounts:

(a) If the deficiency on which the determination is based has directly

adversely affected (or has the substantial likelihood of adversely affecting) one or more PDP enrollees—up to $25,000 for each determination.

(b) For each week that a deficiency remains uncorrected after the week in which the PDP sponsor receives CMS' notice of the determination—up to $10,000 per week.

(c) If CMS makes a determination under § 423.752(b) and § 423.756(f)(3), based on a determination under § 423.509(a)(1) that a PDP sponsor has terminated its contract with CMS in a manner other than described under § 423.510—$250 per Medicare enrollee from the terminated PDP plan or plans at the time the PDP sponsor terminated its contract, or $100,000, whichever is greater.

§ 423.760 Other applicable provisions.

The provisions of section 1128A of the Act (except paragraphs (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A of the Act.

Subpart P—Premiums and Cost-Sharing Subsidies for Low-Income Individuals

Note: Regulations concerning the low-income premium and cost-sharing subsidy under Medicaid can be found at Subpart S, Special Rules for States—Eligibility Determinations for Subsidies and General Payment Provisions.

§ 423.771 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D–14 of the Act.

(b) *Scope.* This subpart sets forth the requirements and limitations for payments by and on behalf of low-income Medicare beneficiaries who enroll in a prescription drug plan or MA–PD plan.

§ 423.772 Definitions.

For purposes of this subpart, the following definitions apply:

Family size means the applicant, the spouse who is living in the same household, if any, and the number of individuals who are related to the applicant or applicants, who are living in the same household and who are dependent on the applicant or the applicant's spouse for at least one-half of their financial support.

Federal poverty line (FPL) has the meaning given that term in section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)), including any revision required by that section.

Full benefit dual eligible individual means an individual who, for any month—

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA–PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus program demonstrations.) It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) for any month if the individual was eligible for medical assistance in any part of the month.

Full subsidy eligible individuals means individuals meeting the eligibility requirements under § 423.773(b).

Income means income as described under section 1905(p)(1) of the Act without use of any more liberal disregards under section 1902(r)(2) of the Act (that is, as defined by section 1612 of the Act). This definition includes the income of the applicant and spouse who is living in the same household, if any, regardless of whether the spouse is also an applicant.

Institutionalized individual means a full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month, as defined under section 1902(q)(1)(B) of the Act.

Other subsidy eligible individuals means those individuals meeting the eligibility requirements under § 423.773(d).

Personal representatives means—

(1) Individuals who are authorized to act on behalf of the applicant;

(2) If the applicant is incapacitated; or incompetent, someone acting responsibly on their behalf, or

(3) An individual of the applicant's choice who is requested by the applicant to act as his or her representative in the application process.

Resources means liquid resources of the individual (and his or her spouse if the individual is married, who is living in the same household), such as checking and savings accounts, stocks, bonds, and other resources that can be readily converted to cash within 20 days, that are not excluded from resources in section 1613 of the Act, and real estate that is not the applicant's primary residence or the land on which the primary residence is located.

State means for purposes of this subpart each of the 50 States and the District of Columbia.

Subsidy eligible individuals means those individuals meeting the eligibility requirements under § 423.773.

§ 423.773 Requirements for eligibility

(a) *Subsidy eligible individual.* A subsidy eligible individual is a Part D eligible individual residing in a State who is enrolled in a prescription drug plan or MA–PD plan and meets the following requirements:

(1) Has income below 150 percent of the FPL applicable to the individual's family size.

(2) Has resources at or below the resource thresholds set forth in § 423.773(b)(2) or (d)(2).

(b) *Full subsidy eligible individual.* A full subsidy eligible individual is a subsidy eligible individual who—

(1) Has income below 135 percent of the FPL applicable to the individual's family size; and

(2) Has resources that do not exceed—

(i) For 2006, 3 times the amount of resources an individual may have and still be eligible for benefits under the SSI program (including the assets or resources of the individual's spouse).

(ii) For subsequent years, the amount of resources allowable for the previous year under this paragraph (b)(2) increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of that previous year, rounded to the nearest multiple of $10.

(c) *Individuals treated as full subsidy eligible.* An individual must be treated as meeting the eligibility requirements for full subsidy eligible individuals under paragraph (b) of this section if the individual is a—

(1) Full benefit dual eligible individual;

(2) Recipient of SSI benefits under title XVI of the Act; or

(3) Eligible for Medicaid as a Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or a Qualifying Individual (QI) under a State's plan. The State agency must notify an individual treated as a full benefit dual eligible that the individual is eligible for a full subsidy of Part D premiums and deductibles and must either enroll with a PDP or MA–PD or be randomly assigned to a PDP or MA–PD.

(d) *Other low-income subsidy individuals.* Other low-income subsidy

individuals are subsidy eligible individuals who—

(1) Have income less than 150 percent of the FPL applicable to the individual's family size; and

(2) Have resources that do not exceed—

(i) For 2006, $10,000 if single or $20,000 if married (including the assets or resources of the individual's spouse).

(ii) For subsequent years, the resource amount allowable for the previous year under this paragraph (d)(2), increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of the previous year, rounded to the nearest multiple of $10.

§ 423.774 Eligibility determinations, redeterminations, and applications.

(a) *Determinations of whether an individual is a subsidy eligible individual.* Determinations of eligibility for subsidies under this section are made by the State under its State plan under title XIX if the individual applies with the Medicaid agency, or if the individual applies with SSA, the Commissioner of Social Security in accordance with the requirements of section 1860D–14(a)(3) of the Act.

(b) *Effective date of initial eligibility determinations.* Eligibility determinations are effective beginning with the first day of the month in which the individual applies, or January 1, 2006 if the application was taken in advance of that date, and remain in effect for a period not to exceed 1 year.

(c) *Redeterminations and appeals of low-income subsidy eligibility.* (1) *Redeterminations and appeals of low-income subsidy eligibility determinations—eligibility determinations made by States.* Redeterminations and appeals of low-income subsidy eligibility determinations by States must be made in the same manner and frequency as the redeterminations and appeals are made under the State's plan.

(2) *Redeterminations and appeals of low-income subsidy eligibility—eligibility determinations made by Commissioner.* Redeterminations and appeals of eligibility determinations made by the Commissioner must be made in the manner specified by the Commissioner.

(d) *Application requirements.* (1) In order for low-income subsidy applications to be considered complete, individuals applying for the low-income subsidy, or personal representatives applying on the individual's behalf, must—

(i) Complete all required elements of the application;

(ii) Provide any statements from financial institutions, as requested, to support information in the application; and

(iii) Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

(d)(2) [Reserved]

§ 423.780 Premium subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy individuals are entitled to a premium subsidy equal to 100 percent of the "premium subsidy amount," not to exceed the basic premium for coverage under the prescription drug plan selected by the beneficiary, and the greater of the low-income benchmark premium or the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the PDP region. (The premium subsidy determined in this way applies regardless of whether the individual enrolls in a PDP or MA–PD.) In the event the low-income benchmark premium is less than the lowest monthly beneficiary premium for basic prescription drug coverage offered by a PDP sponsor in a PDP region, in accordance with section 1860D–14(b)(3) of the Act, the premium subsidy will be equal to the lowest monthly beneficiary premium for basic prescription drug coverage offered by a PDP sponsor in the PDP region. The low-income benchmark premium amount for a region equals either—

(1) If all PDPs in the PDP region are offered by the same PDP sponsor, the weighted average of the monthly beneficiary premiums for basic prescription drug coverage; or

(2) If the PDPs in the region are offered by more than one PDP sponsor, the weighted average of the monthly beneficiary premiums for basic prescription drug coverage for all PDP and MA–PD plans in the region (excluding section 1876 cost plans, PACE plans, specialized MA plans for special needs individuals, and private fee-for-service plans) and the portion of the monthly beneficiary premium for alternative prescription drug coverage attributable to basic prescription drug coverage for all PDPs and MA–PD plans in the region. Fallback plans will be treated the same as risk-bid plans for the calculation of the low-income benchmark premium. The weighted average is determined based on enrollment in PDPs and MA–PDs in the region.

(b) *Other low-income subsidy eligible individuals—sliding scale premium.* Other low-income subsidy eligible individuals are entitled to a premium subsidy based on a linear sliding scale ranging from 100 percent of the amount described in paragraph (a) of this section, for individuals with incomes at or below 135 percent of the FPL applicable to their family size, to 0 percent for individuals with incomes at 150 percent of the FPL applicable to their family size.

(c) *Premium subsidy for late enrollment penalty.* Full subsidy eligible individuals who are subject to late enrollment penalties under § 423.46 are entitled to an additional premium subsidy equal to 80 percent of the late penalty for the first 60 months during which the penalty is imposed and 100 percent of the penalty thereafter.

§ 423.782 Cost-sharing subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy eligible individuals are entitled to the following:

(1) Elimination of the annual deductible under § 423.104(e)(1).

(2) Reduction in cost-sharing for all covered Part D drugs covered under the PDP or MA–PD plan below the out-of-pocket limit (under § 423.104), including Part D drugs covered under the PDP or MA–PD plan obtained after the initial coverage limit (under § 423.104(e)(4)), as follows:

(i) Except as provided under paragraphs (a)(2)(ii) and (a)(2)(iii) of this section, copayment amounts not to exceed the copayment amounts specified in § 423.104. This applies to those full benefit dual eligible individuals who are not institutionalized and who have income above 100 percent of the Federal poverty line applicable to the individual's family size.

(ii) Institutionalized individuals have no cost-sharing for covered Part D drugs covered under their PDP or MA–PD plans.

(iii) Non-institutionalized full benefit dual eligible individuals with incomes that do not exceed 100 percent of the Federal poverty line applicable to the individual's family size are subject to cost-sharing for covered drugs equal to the lesser of a copayment amount of $1 for a generic drug or preferred multiple source drug of $3 for any other drug, or the amount charged to other individuals with income below 135 percent of the FPL and resources not greater than 3 times the amount an individual may have and still be eligible for benefits under the SSI program. These amounts are increased each year beginning in 2007 by the percentage increase in CPI, rounded to the nearest multiple of 5 cents or 10 cents, respectively.

(iv) Non-institutionalized full benefit dual eligible individuals with incomes

that exceed 100 percent of the Federal poverty line applicable to the individual's family size are subject to cost-sharing for covered drugs equal to the lesser of a copayment amount of $2 for a generic drug or preferred multiple source drug or $5 for any other drug, or the amount charged to other individuals with income below 135 percent of the FPL and resources not greater than 3 times the amount an individual may have and still be eligible for benefits under the SSI program.

(3) Elimination of all cost-sharing for covered Part D drugs covered under the PDP or MA–PD plan above the out-of-pocket limit (under § 423.104(e)(5).

(b) *Other low-income subsidy eligible individuals.* Other low-income subsidy eligible individuals are entitled to the following:

(1) Reduction in the annual deductible under § 423.104 to $50. This amount is increased each year beginning in 2007 by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of $1.

(2) 15 percent coinsurance for all covered drugs covered under the individual's PDP or MA–PD plan obtained after the initial coverage limit (under § 423.104), up to the out-of-pocket limit (under § 423.104).

(3) For covered drugs above the out-of-pocket limit (under § 423.104), copayments not to exceed $2 for a generic drug or preferred multiple source and $5 for any other drug. These amounts are increased each year beginning in 2007 by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents.

§ 423.800 Administration of subsidy program.

(a) *Notification of eligibility for low-income subsidy.* CMS notifies the PDP sponsor offering the PDP or the MA organization offering the MA–PD plan, in which a subsidy eligible individual is enrolled, of the individual's eligibility for a subsidy and the amount of the subsidy.

(b) *Reduction of premium or cost-sharing by PDP sponsor or organization.* The PDP sponsor offering the PDP, or the MA organization offering the MA–PD plan, in which a subsidy eligible individual is enrolled must reduce the individual's premiums and cost-sharing as applicable, and provide information to CMS on the amount of those reductions, in a manner determined by CMS. The PDP sponsor and MA–PD organization must track the application of the low-income cost-sharing subsidies to be applied to the out-of-pocket threshold.

(c) *Reimbursement to sponsor or organization for the amount of the reductions.* CMS reimburses sponsors and MA organizations for reductions under paragraph (b) of this section, or, if a PDP sponsor or MA organization elects to be paid on a capitated basis under paragraph (e) of this section, the capitated amounts under paragraph (e) of this section, in the manner determined by CMS.

(d) *Reimbursement for cost-sharing on a capitated basis.* Reimbursement for cost-sharing subsidies may be computed on a capitated basis, taking into account the actuarial value of the subsidies and making appropriate adjustments to reflect differences in the risks actually involved.

(e) *Reimbursement for cost-sharing paid before notification of eligibility for low-income subsidy.* The PDP sponsor offering the PDP plan, or MA–PD organization offering the MA–PD plan, must reimburse low-income subsidy eligible individuals any out-of-pocket costs relating to excess premiums and cost-sharing paid before the date the individual is notified of subsidy eligibility and after the date subsidy eligibility is effective.

Subpart Q—Guaranteeing Access to a Choice of Coverage (Fallback Plans)

§ 423.851 Scope.

This section sets forth—the rights of beneficiaries to a choice of at least two sources of prescription drug coverage; requirements and limitations on the bid submission, review and approval of fallback prescription drug plans, and the determination of enrollee premium and plan payments for these plans.

§ 423.855 Definitions.

As used in this subpart, unless specified otherwise—

Eligible Fallback Entity or *Fallback Entity* means an entity that, with respect to a particular contract period—

(1) meets all the requirements to be a PDP sponsor except that it does not have to be a risk-bearing entity; and

(2) does not submit a bid under § 423.265 for any prescription drug plan for any PDP region for the first year of that contract period. An entity is treated as submitting a bid if the entity is acting as a subcontractor for an integral part of the drug benefit management activities of a PDP sponsor. An entity is not treated as submitting a bid if it is a subcontractor of an MA organization, unless that organization is acting as a PDP sponsor for a prescription drug plan.

Fallback Prescription Drug Plan means a plan offered by a fallback entity that—

(1) Offers only actuarially equivalent standard prescription drug coverage as defined in § 423.100;

(2) Provides access to negotiated prices, including discounts from manufacturers; and

(3) Meets other requirements as specified by CMS.

Qualifying Plan means a full-risk or limited-risk prescription drug plan, as defined in § 423.258, or an MA plan described in section 1851(a)(2)(A)(i) of the Act, that either provides basic prescription drug coverage, as defined in § 423.100, or provides alternative prescription drug coverage for no additional premium because it applies a premium rebate under Part C of Medicare as a credit against the supplemental coverage premium, as described under § 422.266(b)(1). An MA–PD plan must be open for enrollment and not operating under a capacity waiver to be counted as a qualifying plan.

§ 423.859 Assuring access to a choice of coverage.

(a) *Choice of at least 2 qualifying plans in each area.* Each Part D eligible individual must have available a choice of enrollment in at least 2 qualifying plans (as defined in § 423.855) in the area in which the individual resides. This requirement is not satisfied if only one entity offers all the qualifying plans in the area. At least 1 of the 2 qualifying plans must be a prescription drug plan.

(b) *Fallback service area.* (1) *For coverage year.* Before the start of each coverage year CMS determines if Part D eligible individuals residing in a PDP region have access to a choice of enrollment in a minimum of 2 qualifying plans, as described in paragraph (a) of this section. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, do not have available a choice of enrollment in a minimum of two qualified plans, CMS designates the region or portion of a region as a fallback service area. Each Part D eligible individual in a fallback service area is given the opportunity to enroll in a fallback prescription drug plan.

(2) *For mid-year changes.* If a contract with a qualifying plan is terminated in the middle of a contract year (as provided for in §§ 423.508, 423.509, or 423.510), CMS determines if Part D eligible individuals residing in the affected PDP region still have access to

a choice of enrollment in a minimum of 2 qualifying plans. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, no longer have available a choice of enrollment in a minimum of two qualifying plans, CMS designates the region or portion of a region as a fallback service area.

(c) *Access to coverage in the territories.* CMS may waive or modify the requirements of this part if—

(1) CMS determines that waiver or modification is necessary to secure access to qualified prescription drug coverage for Part D eligible individuals residing in a State other than the 50 States or the District of Columbia; or

(2) An entity seeking to become a prescription drug plan in a State other than the 50 States or the District of Columbia requests waiver or modification of any Part D requirement in order to provide qualified prescription drug coverage in a State other than the 50 States or the District of Columbia.

§ 423.863 Submission and approval of bids.

(a) *Submission of Bids.* (1) *Solicitation of bids.* Separate from the bidding process under § 423.265, CMS solicits bids from eligible fallback entities for the offering in all fallback service areas in one or more PDP regions of a fallback prescription drug plan during the contract period specified in § 423.871(c).

(2) *Timing of bids.* CMS will determine when to solicit bids for 2006 so that potential fallback plans will have enough time to prepare a bid. After that, bids will be solicited on three-year cycles, or annually thereafter as needed to replace contractors between contracting cycles.

(3) *Format of bid.* CMS specifies the form and manner in which fallback bids are submitted in separate guidance to bidders.

(b) *Negotiation and acceptance of bids.*

(1) *General rule.* Except as provided in this section, the provisions of § 423.272 apply for the approval or disapproval of fallback prescription drug plans. CMS enters into contracts under this paragraph with eligible fallback entities for the offering of approved fallback prescription drug plans in potential fallback service areas.

(2) *Flexibility in risk assumed and application of fallback plan.* In order to ensure access in an area pursuant to § 423.859(a), CMS may approve limited risk plans under § 423.272(c) for that area. If the access requirement is still not met after applying § 423.272(c), CMS provides for the offering of a fallback prescription drug plan in that area.

(3) *Limitation of 1 Plan for all fallback service areas in a PDP region.* All fallback service areas in any PDP region for a contract period must be served by the same fallback prescription drug plan.

(4) *Competitive procedures.* CMS uses competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5)) to enter into a contract under this paragraph. The provisions of section 1874A(d) of the Act apply to a contract under this section in the same manner as they apply to a contract under that section.

(5) *Timing of contracts.* CMS approves a fallback prescription drug plan for a PDP region in a manner so that, if there are any fallback service areas in the region for a year, the fallback prescription drug plan is offered at the same time as prescription drug plans are otherwise offered. In the event of mid-year changes and as required by § 423.859(b)(2), CMS approves a fallback prescription drug plan for a PDP region in a manner so that the fallback plan is offered within 90 days of notice.

(6) *No national fallback plan.* CMS may not enter into a contract with a single fallback entity for the offering of fallback plans throughout the United States.

§ 423.867 Rules regarding premiums.

(a) *Monthly beneficiary premium.* Except as provided in § 423.286(d)(3) (relating to late enrollment penalty) and subject to Subpart P (relating to low-income assistance), the monthly beneficiary premium under a fallback prescription drug plan must be uniform for all fallback service areas in a PDP region. It must equal 25.5 percent of CMS's estimate of the average monthly per capita actuarial cost, including administrative expenses, of providing coverage in the region based on similar expenses of prescription drug plans that are not fallback prescription drug plans.

(b) *Special rule for collection of premiums in fallback plans.* In the case of a fallback prescription drug plan, the provisions of § 423.293 (b) concerning payments of the late enrollment penalty do not apply and the monthly beneficiary premium is collected in the manner specified in § 422.262(f)(1) (or other manner as may be provided under section 1840 of the Act in the case of monthly premiums under section 1839 of the Act).

§ 423.871 Contract terms and conditions.

(a) *General.* Except as may be appropriate to carry out the requirements of this section, the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans are the same as the terms and conditions of contracts at § 423.504 for prescription drug plans.

(b) *Period of contract.* Except as may be renewed after a subsequent bidding process, a contract with a fallback entity for fallback service areas for a PDP region is in effect for a period of 3 years. However, a fallback prescription drug plan may be offered for any year within the contract period for a particular area only if the area is a fallback service area for that year.

(c) *Entity not permitted to market or brand fallback prescription drug plans.* An eligible fallback entity with a contract under this part may not engage in any marketing or branding of a fallback prescription drug plan.

(d) *Performance measures.* CMS issues guidance establishing performance measures for fallback prescription drug plans based on the following:

(1) *Types of Performance Measures.* Performance measures include at least measures for each of the following:

(i) *Costs.* The entity contains costs to the Medicare Prescription Drug Account and to Part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity through mechanisms such as generic substitution and price discounts, including discounts from manufacturers.

(ii) *Quality programs.* The entity provides the enrollees with quality programs that avoid adverse drug reactions and over utilization and reduce medical errors.

(iii) *Customer service.* The entity provides timely and accurate delivery of services and pharmacy and beneficiary support services.

(iv) *Benefit administration and claims adjudication.* The entity provides efficient and effective benefit administration and claims adjudication.

(2) *Development of performance measures.* CMS establishes detailed performance measures for use in evaluating fallback entity performance and determination of certain management fees based on criteria from historical performance, application of acceptable statistical measures of variation to fallback entity and PDP sponsor experience nationwide during a base period, or changing program emphases or requirements.

(e) *Payment terms.* A contract approved with a fallback entity includes terms for payment for—

(1) The actual costs (taking into account negotiated price concessions described in § 423.108(d) of covered Part D drugs provided to Part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity); and

(2) Management fees that are tied to the performance measures established by CMS for the management, administration, and delivery of the benefits under the contract as provided under paragraph (d) of this section.

(f) *Requirement for the submission of information.* Each contract for a fallback prescription drug plan requires an eligible fallback entity offering a fallback prescription drug plan to provide CMS with the information CMS determines is necessary to carry out this section, or as required by law. Officers, employees and contractors of the Department of Health and Human Services may use any information disclosed or obtained in accordance with the provisions of this part only for the purposes of, and to the extent necessary in, carrying out this part. This restriction does not limit OIG authority to conduct audits and evaluations necessary for carrying out these regulations.

(g) *Amendment to reflect changes in service area.* The contract may be amended by CMS at any time as needed to reflect the exact regions or counties to be included in the fallback service area(s).

§ 423.875 Payments to fallback plans.

The amount payable for a fallback prescription drug plan is the amount determined under the contract for the plan in accordance with § 423.871(e).

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

§ 423.880 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D–22 of the Act, as amended by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

(b) *Scope.* This section implements the statutory requirement that a subsidy payment be made to sponsors of qualified retiree prescription drug plans.

§ 423.882 Definitions.

For the purposes of this subpart, the following definitions apply:

Allowable retiree costs in accordance with section 1860D–22(a)(3)(C)(i) of the Act, means gross covered retiree plan-related prescription drug costs between the cost threshold and cost limit, as defined under § 423.886(b), that are actually paid by either the qualified retiree prescription drug plan or the qualifying covered retiree (or on the retiree's behalf), net of any manufacturer or pharmacy discounts, chargebacks, rebates, and similar price concessions.

Covered Part D drug has the same meaning as defined in § 423.100.

Retiree drug subsidy amount means the subsidy amount paid to sponsors of qualified retiree prescription drug coverage under § 423.886(a).

Employment-based retiree health coverage means coverage of health care costs under a group health plan based on an individual's status as a retired participant in the plan, or as the spouse or dependent of a retired participant. The term includes coverage provided by voluntary insurance coverage, or coverage as a result of statutory or contractual obligation.

Gross covered retiree plan-related prescription drug costs, or gross retiree costs means, for a qualifying covered retiree who is enrolled in a qualified retiree prescription drug plan during a plan year, non-administrative costs incurred under the plan for covered Part D drugs during the year, whether paid for by the plan or the retiree, including costs directly related to the dispensing of covered Part D drugs.

Group health plan has the same meaning as defined in section 607(1) of ERISA, 29 U.S.C. 1167(1). This definition also includes the following plans:

(1) *Federal and State governmental plan* means a plan established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision of a State, or by any agency or instrumentality or any of the foregoing, including a health benefits plan offered under chapter 89 of title 5, United States Code (the Federal Employee Health Benefit Plan (FEHBP)).

(2) *Collectively bargained plan* means a plan established or maintained under or by one or more collective bargaining agreements.

(3) *Church plan* means a plan established and maintained for its employees or their beneficiaries by a church or by a convention or association of churches that is exempt from tax under section 501 of the Internal Revenue Code of 1986 (26 U.S.C. 501).

Part D eligible individual is defined in § 423.4 of our proposed rule.

Qualified retiree prescription drug plan means employment-based retiree health coverage that meets the requirements set forth in § 423.884(a) through (d) of this chapter for a Part D eligible individual who is a participant or beneficiary under the coverage.

Qualifying covered retiree means a Part D eligible individual who is a participant under the qualified retiree prescription drug plan or the spouse or dependent of a participant under the qualified prescription drug plan, who is not enrolled in a Part D prescription drug plan or a Medicare Advantage-Prescription Drug (MA–PD) plan.

Standard Prescription Drug Coverage has the same meaning as defined in § 423.100.

Sponsor is a plan sponsor as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 (ERISA), except that, in the case of a plan maintained jointly by one employer and an employee organization and for which the employer is the primary source of financing, the term means the employer.

§ 423.884 Requirements for qualified retiree prescription drug plans.

A qualified retiree prescription drug plan must meet the requirements of this section.

(a) *Actuarial Attestation.* The sponsor of the plan (or a plan administrator designated by the sponsor) provides to CMS an attestation that the actuarial value of the retiree prescription drug coverage under the plan is at least equal to the actuarial value of the standard prescription drug coverage under Part D. The attestation must—

(1) Be provided annually, no later than 90 days prior to the start of the calendar year, except that for 2006, the attestation must be provided by September 30, 2005;

(2) Be provided no later than 90 days before the implementation of a material change to the drug coverage of the plan that impacts the actuarial value of the coverage;

(3) Certify that the values have been calculated according to established CMS actuarial guidelines based on generally accepted actuarial principles;

(4) Be certified by a qualified actuary who is a member of the American Academy of Actuaries. Applicants may use qualified outside actuaries.

(5) Be signed under the penalty of perjury;

(6) State that the information contained in the attestation is true and accurate to the best of the attester's knowledge;

(7) Contain an acknowledgement that the information being provided in the attestation is being used to obtain Federal funds.

(b) *Sponsor application for the subsidy payment.*

(1) *Deadlines.* The sponsor must submit an application for the subsidy,

signed by an authorized representative of the sponsor, to CMS by no later than for:

(i) The year 2006, September 30, 2005.

(ii) All other years, 90 days prior to the start of the year.

(iii) Plans that begin coverage in the middle of a year, 90 days prior to the date the coverage begins.

(iv) New plans that institute coverage after September 30, 2005, 150 days prior to the start of the new plan.

(2) *Required information.* The following information must be submitted with the application:

(i) Employer Tax ID Number (if applicable).

(ii) Sponsor name and address.

(iii) Contact name and email address.

(iv) Actuarial attestation and supporting documentation for each qualified retiree prescription drug plan for which the sponsor seeks subsidy payments.

(v) Full names of each qualifying covered retiree enrolled in each prescription drug plan (including spouses and dependents, if Medicare-eligible), and the following information:

(A) Health Insurance Claim (HIC) number (when available).

(B) Date of birth.

(C) Sex.

(D) Social Security number.

(E) Relationship to the retired employee.

(3) *Terms and conditions.* The application must specify acceptance of the terms and conditions of eligibility to receive a subsidy payment. The sponsor must—

(i) Agree to comply with all Federal laws and regulations, and the terms and conditions of eligibility for a subsidy payment, including those concerning auditing of claims for subsidy payments and combating fraud and abuse;

(ii) Acknowledge that the information is being provided to obtain Federal funds;

(iii) Require that all subcontractors, including administrators, acknowledge that information provided in connection with the subcontract is used for purposes of obtaining Federal funds;

(iv) Sign any further certification that CMS may require.

(4) *Signature by sponsor.* An authorized representative of the requesting sponsor must sign the completed application. The signed application constitutes an agreement between CMS and the sponsor.

(5) *Updates.* The sponsor (or the plan administrator designated by the sponsor) must provide updates to CMS of the information required in paragraph (b)(2) of this section in the manner and frequency specified by CMS.

(6) *Data match.* Once the full application for the subsidy payment is submitted, CMS—

(i) Matches the names of the qualifying covered retirees and the identifying information of each retiree with the Medicare Data Base (MBD) to determine which retirees are qualifying covered retirees.

(ii) Provides to the sponsor (or to a plan administrator designated by a sponsor) the names, and other identifying information if necessary, of the sponsor's qualifying covered retirees.

(c) *Disclosure of creditable coverage status.* The sponsor must disclose to all of its retirees and their spouses and dependents eligible to participate in its plan who are Part D eligible individuals whether the coverage is creditable coverage under § 423.4 in accordance with the notification requirements under § 423.56.

(d) *Audits, CMS access to records.* The sponsor must meet the requirements of § 423.888 (d).

§ 423.886 Retiree drug subsidy amounts.

(a) *Amount of subsidy payment.* For each qualifying covered retiree enrolled with the sponsor of a qualified retiree prescription drug plan in a plan year in which the retiree's gross covered retiree plan-related prescription drug costs (as defined in § 423.882) exceeds the cost threshold defined in paragraph (b)(1) of this section, the sponsor receives a subsidy payment in the amount of 28 percent of the allowable retiree costs (as defined in § 423.882) attributable to the gross covered prescription drug costs between the cost threshold and the cost limit defined in paragraph (b)(2) of this section.

(b) *Cost threshold and cost limit.* The following cost threshold and cost limits apply—

(1) Subject to paragraph (b)(3) of this section, the cost threshold under this section is equal to $250 for calendar year 2006.

(2) Subject to paragraph (b)(3) of this section, the cost limit under this section is equal to $5,000 for calendar year 2006.

(3) The cost threshold and cost limit specified in paragraphs (b)(1) and (b)(2) of this section, for years after 2006, is adjusted in the same manner as the annual Part D deductible and the annual Part D out-of-pocket threshold are adjusted annually under §§ 423.104(e)(1)(ii) and (e)(4)(iii)(B), respectively.

§ 423.888 Payment methods, including provision of necessary information.

(a) *Basis.* The provisions of § 423.301 through § 423.343, including requirement to provide information necessary to ensure accurate subsidy payments, govern payment under § 423.886.

(b) *Payment.* Payment under § 423.886 is conditioned on provision of accurate and truthful information in a form and manner specified by CMS. When directed by the sponsor of a qualified retiree prescription drug plan applying for payment under this section, the qualified retiree prescription drug plan (or an administrator or insurer of the qualified retiree prescription drug plan, if applicable) must submit in the form and manner CMS specifies, the information required to CMS.

(c) *Use of information provided.* Officers, employees and contractors of the Department of Health and Human Services, including the Office of Inspector General (OIG), may use information collected under paragraphs (a) and (d) of this section only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments and payment-related oversight and program integrity activities, or as otherwise required by law. This restriction does not limit OIG authority to conduct audits and evaluations necessary for carrying out these regulations.

(d) *Maintenance of records.* (1) The sponsor of the qualified retiree prescription drug plan and the qualified retiree prescription drug plan (or an administrator or insurer of the qualified retiree prescription drug plan), as applicable, must maintain, and furnish to CMS or the Office of Inspector General (OIG) upon request, the records enumerated in paragraph (d)(3) of this section. The records must be maintained for 6 years after the expiration of the plan year in which the costs were incurred for the purposes of audits and other oversight activities conducted by CMS to assure the accuracy of the actuarial attestation and the accuracy of payments.

(2) CMS or the OIG may extend the 6-year retention requirement in the event of an ongoing investigation, litigation or negotiation.

(3) The records that must be retained are:

(i) Reports and working documents of the actuaries who wrote the attestation submitted in accordance with § 423.884(a).

(ii) All documentation of costs incurred and other relevant information utilized for calculating the amount of the subsidy payment made in accordance with § 423.886, including the underlying claims data.

§ 423.890 Appeals.

(a) *Informal written reconsideration.* (1) *Initial determinations.* A sponsor is entitled to an informal written reconsideration of an adverse initial determination. An initial determination is a determination regarding the following:

(i) The amount of the subsidy payment.

(ii) The actuarial equivalence of the sponsor's retiree prescription drug plan.

(iii) If an enrollee in a retiree prescription drug plan is a qualifying covered retiree; or

(iv) Any other similar determination (as determined by CMS) that affects eligibility for, or the amount of, a subsidy payment.

(2) *Effect of an initial determination regarding the retiree drug subsidy.* An initial determination is final and binding unless reconsidered in accordance with this paragraph (a).

(3) *Manner and timing for request.* A request for reconsideration must be made in writing and filed with CMS within 15 days of the date on the notice of adverse determination.

(4) *Content of request.* The request for reconsideration must specify the findings or issues with which the sponsor disagrees and the reasons for the disagreements. The request for reconsideration may include additional documentary evidence the sponsor wishes CMS to consider.

(5) *Conduct of informal written reconsideration.* In conducting the reconsideration, CMS reviews the subsidy determination, the evidence and findings upon which it was based, and any other written evidence submitted by the sponsor or by CMS before notice of the reconsidered determination is made.

(6) *Decision of the informal written reconsideration.* CMS informs the sponsor of the decision orally or through electronic mail. CMS sends a written decision to the sponsor on the sponsor's request.

(7) *Effect of CMS informal written reconsideration.* A reconsideration decision, whether delivered orally or in writing, is final and binding unless a request for hearing is filed in accordance with paragraph (b) of this section, or it is revised in accordance paragraph (d) of this section.

(b) *Right to informal hearing.* A sponsor dissatisfied with the CMS reconsideration decision is entitled to an informal hearing as provided in this section.

(1) *Manner and timing for request.* A request for a hearing must be made in writing and filed with CMS within 15 days of the date the sponsor receives the CMS reconsideration decision.

(2) *Content of request.* The request for informal hearing must include a copy of the CMS reconsideration decision (if any) and must specify the findings or issues in the decision with which the sponsor disagrees and the reasons for the disagreements.

(3) *Informal hearing procedures.* (i) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The hearing are conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations.

(iii) If CMS did not issue a written reconsideration decision, the hearing officer may request, but not require, a written statement from CMS or its contractors explaining CMS' determination, or CMS or its contractors may, on their own, submit the written statement to the hearing officer. Failure of CMS to submit a written statement does not result in any adverse findings against CMS and may not in any way be taken into account by the hearing officer in reaching a decision.

(4) *Decision of the CMS Hearing Officer.* The CMS hearing officer decides the case and sends a written decision to the sponsor, explaining the basis for the decision.

(5) *Effecting of hearing officer decision.* The hearing officer decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (c) of this section.

(c) *Review by the Administrator.* (1) A sponsor that has received a hearing officer decision upholding a CMS initial or reconsidered determination may request review by the Administrator within 15 days of receipt of the hearing officer's decision.

(2) The Administrator may review the hearing officer's decision, any written documents submitted to CMS or to the hearing officer, as well as any other information included in the record of the hearing officer's decision and determine whether to uphold, reverse or modify the hearing officer's decision.

(3) The Administrator's determination is final and binding.

(d) *Reopening.* (1) *Ability to reopen.* CMS may reopen and revise an initial or reconsidered determination upon its own motion or upon the request of a sponsor:

(i) Within 1 year of the date of the notice of determination for any reason.

(ii) Within 4 years for good cause.

(iii) At any time when the underlying decision was obtained through fraud or similar fault.

(2) *Notice of reopening.* (i) Notice of reopening and any revisions following the reopening are mailed to the sponsor.

(ii) Notice of reopening specifies the reasons for revision.

(3) *Effect of reopening.* The revision of an initial or reconsidered determination is final and binding unless—

(i) The sponsor requests reconsideration in accordance with paragraph (a) of this section;

(ii) A timely request for a hearing is filed under paragraph (b) of this section;

(iii) The determination is reviewed by the Administrator in accordance with paragraph (c) of this section; or

(iv) The determination is reopened and revised in accordance with paragraph (d) of this section.

(4) *Good cause.* For purposes of this section, CMS finds good cause if—

(i) New and material evidence that was not readily available at the time the initial determination was made is furnished;

(ii) A clerical error in the computation of payments was made; or

(iii) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(5) For purposes of this section, CMS does not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the initial determination was made.

§ 423.892 Change in ownership.

(a) *Change of ownership.* Any of the following constitutes a change of ownership:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) *Asset sale.* Transfer of substantially all of the assets of the sponsor to another party constitutes a change of ownership.

(3) *Corporation.* The merger of the sponsor's corporation into another corporation or the consolidation of the sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception.* Transfer of corporate stock or the merger of another corporation into the sponsor's corporation, with the sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement.* A sponsor that has a retiree drug subsidy agreement in effect under this part and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change.

(d) *Assignment of agreement.* When there is a change of ownership as specified in paragraph (a) of this section, and this results in a transfer of the liability for prescription drug costs the existing sponsor agreement is automatically assigned to the new owner.

(e) *Conditions that apply to assignment agreements.* The new owner to whom a sponsor agreement is assigned is subject to all applicable statutes and regulations and to the terms and conditions of the sponsor agreement.

§ 423.894 Construction.

Nothing in this part must be interpreted as prohibiting or restricting—

(a) A Part D eligible individual who is covered under employment-based retiree health coverage, including a qualified retiree prescription drug plan, from enrolling in a prescription drug plan or in a MA–PD plan;

(b) A sponsor or other person from paying all or any part of the monthly beneficiary premium (as defined in § 423.286) for a prescription drug plan or MA–PD plan on behalf of a retiree (or his or her spouse or dependents);

(c) A sponsor from providing coverage to Part D eligible individuals under employment-based retiree health coverage that is—

(1) Supplemental to the benefits provided under a prescription drug plan or a MA–PD plan.

(2) Of higher actuarial value than the actuarial value of standard prescription drug coverage (as defined in § 423.104(e)); or

(d) Sponsors from providing for flexibility in the benefit design and pharmacy network for their qualified retiree prescription drug coverage, without regard to the requirements applicable to PDPs and MA–PD plans under § 423.104, as long as the requirements under § 423.884 are met.

Subpart S—Special Rules for States—Eligibility Determinations for Subsidies and General Payment Provisions

§ 423.900 Basis and scope.

(a) *Basis.* This subpart is based on sections 1935(a) through (d) of the Act as amended by section 103 of the MMA.

(b) *Scope.* This subpart specifies State agency obligations for the Part D prescription drug benefit.

§ 423.902 Definitions.

The following definitions apply to this subpart:

Actuarial value of capitated prescription drug benefits is the estimated actuarial value of prescription drug benefits provided under a capitated Medicaid managed care plan per full-benefit dual eligible individual for 2003, as determined using data as the Secretary determines appropriate.

Applicable growth factor for each of 2004, 2005, and 2006, is the average annual percent change (to that year from the previous year) of the per capita amount of prescription drug expenditures (as determined based on the most recent National Health Expenditure projections for the years involved). The growth factor for 2007 and succeeding years will equal the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals for the 12-month period ending in July of the previous year.

Base year Medicaid per capita expenditures is equal to the weighted average of:

(1) The gross base year (calendar year 2003) per capita Medicaid expenditures for prescription drugs, reduced by the rebate adjustment factor; and

(2) The estimated actuarial value of prescription drug benefits provided under a capitated Medicaid managed care plan per full-benefit dual eligible for 2003. The per capita payments for full benefit dual eligibles with managed care and non-managed care are weighted by the respective average monthly full dual eligible enrollment populations.

Full-benefit dual eligible individual means an individual who, for any month—

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA–PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus demonstrations.) It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) of the Act for any month if the individual was eligible for medical assistance in any part of the month. For the 2003 baseline calculations, the full-benefit dual eligibles are those individuals having Medicaid drug benefit coverage and Medicare Part A or Part B coverage.

Gross base year Medicaid per capita expenditures are equal to the expenditures, including dispensing fees, made by the State during calendar year 2003 for covered outpatient drugs, excluding drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1860D–2 of the Act, other than smoking cessation agents determined per full-benefit-dual-eligible-individual for the individuals not receiving medical assistance for the drugs through a Medicaid managed care plan. This amount is determined based on MSIS drug claims paid during the four quarters of calendar year 2003 and the associated dual eligibility enrollment status of the beneficiary.

Phased-down State contribution factor for a month in 2006 is 90 percent; in 2007 is 88 1/3 percent; in 2008 is 86 2/3 percent; in 2009 is 85 percent; in 2010 is 83 1/3 percent; in 2011 is 81 2/3 percent; in 2012 is 80 percent; in 2013 is 78 1/3 percent; in 2014 is 76 2/3 percent; or after December 2014, is 75 percent.

Phased-down State contribution payment refers to the States' monthly payment made to the Federal government beginning in 2006 to defray a portion of the Medicare drug expenditures for full benefit dual eligible individuals whose Medicaid drug coverage is assumed by Medicare Part D. The contribution is calculated by 1/12th of the product of the base year (2003) Medicaid per capita expenditures for prescription drugs (that is, covered Part D drugs) for full-benefit dual eligible individuals, and multiplied by the—

(1) State medical assistance percentage;

(2) Applicable growth factor;

(3) Number of the State's full-benefit dual eligibles for the given month; and

(4) Phased-down State contribution factor.

Rebate adjustment factor takes into account drug rebates and, for a State, is equal to the ratio for the State for the four quarters of calendar year 2003 of aggregate rebate payments received by the State under section 1927 of the Act to the gross expenditures for covered outpatient drugs.

State Medical Assistance Percentage means the proportion equal to 100 percent minus the State's Federal medical assistance percentage, applicable to the State for the fiscal year in which the month occurs.

§ 423.904 Eligibility determinations for low-income subsidies.

(a) *General rule.* The State agency must make eligibility determinations and redeterminations for low-income premium and cost-sharing subsidies in accordance with § 423.774.

(b) *Notification to CMS.* The State agency must inform CMS of cases where eligibility is established or redetermined, in a manner determined by CMS.

(c) *Screening for eligibility for Medicare cost-sharing and enrollment under the State plan.* States must—

(1) Screen individuals who apply for subsidies under this part for eligibility for Medicaid programs that provide assistance with Medicare cost-sharing specified in section 1905(p)(3) of the Act.

(2) Offer enrollment for the programs under the State plan (or under a waiver of the plan) for those meeting the eligibility requirements.

(3) Notify deemed subsidy eligibles of their subsidy eligibility in accordance with the requirements of § 423.34(d).

(d) *Application form and process.*

(1) *Assistance with application.* No later than July 1, 2005, States must make available—

(i) Low-income subsidy application forms;

(ii) Information on the nature of, and eligibility requirements for, the subsidies under this section; and

(iii) Assistance with completion of low-income subsidy application forms.

(2) *Completion of application.* The State must require an individual or personal representative applying for the low-income subsidy to—

(i) Complete all required elements of the application and provide documents, as necessary, consistent with paragraph (3) of this section; and

(ii) Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

(3) *The application process and States.*

(i) States may require submission of statements from financial institutions for an application for low-income subsidies to be considered complete; and

(ii) May require that information submitted on the application be subject to verification in a manner the State determines to be most cost-effective and efficient.

(4) *Other information.* States must provide CMS with other information as specified by CMS that may be needed to carry out the requirements of the Part D prescription drug benefit.

§ 423.906. General payment provisions.

(a) *Regular Federal matching.* Regular Federal matching applies to the eligibility determination and notification activities specified in § 423.904(a) and (b).

(b) *Medicare as primary payer.* Medicare is the primary payer for covered drugs for Part D eligible individuals. Medicaid assistance is not available to full benefit dual eligible individuals, including those not enrolled in a PDP or MA–PD, for—

(1) Covered Part D drugs; or

(2) Any cost-sharing obligations under Part D relating to covered Part D drugs.

(3) The effective date of paragraphs (b)(1) and (b)(2) of this section is January 1, 2006.

(c) *Non-covered drugs.* States may elect to provide coverage for outpatient drugs other than covered Part D drugs in the same manner as provided for non-full benefit dual eligible individuals or through an arrangement with a prescription drug plan or a MA–PD plan.

§ 423.907 Treatment of territories.

(a) *General rules.* (1) Low-income Part D eligible individuals who reside in the territories are not eligible to receive premium and cost-sharing subsidies under subpart P of this part.

(2) A territory may submit a plan to the Secretary under which medical assistance is to be provided to low-income individuals for the provision of covered Part D drugs.

(3) Territories with plans approved by the Secretary will receive increased grants under sections 1108 (h) and (g) of the Act as described in (c) of this section.

(b) *Plan requirements.* Plans submitted to the Secretary must include the following:

(1) A description of the medical assistance to be provided.

(2) The low-income population (income less than 150 percent of the Federal poverty level) to receive medical assistance.

(3) An assurance that no more than 10 percent of the amount of the increased grant will be used for administrative expenses.

(c) *Increased grant amounts.* The amount of the grant provided under sections 1108 (h) and (k) of the Act for each territory with an approved plan for a year shall be the amount in paragraph (d) of this section multiplied by the ratio of—

(1) The number of individuals who are entitled to benefits under Part A or enrolled under Part B and who reside in the territory (as determined by the Secretary based on the most recent available data for the beginning of the year); and

(2) The sum of the number of individuals in all territories in paragraph (c)(1) of this section with approved plans.

(d) *Total grant amount.* The total grant amount is—

(1) For the last three quarters of fiscal year 2006, $28,125,000;

(2) For fiscal year 2007, $37,500,000; and

(3) For each subsequent year, the amount for the prior fiscal year increased by the annual percentage increase described in § 423.104.

§ 423.908 Phased-down State contribution to drug benefit costs assumed by Medicare.

This subpart sets forth the requirements for State contributions for Part D drug benefits based on dual eligible drug expenditures.

§ 423.910 Requirements.

(a) *General rule.* Each of the 50 States and the District of Columbia is required to provide for payment to the Secretary a phased-down contribution to defray a portion of the Medicare drug expenditures for individuals whose projected Medicaid drug coverage is assumed by Medicare Part D.

(b) *State contribution payment.* (1) *Calculation of payment.* The State contribution payment is calculated by the Secretary on a monthly basis, as indicated in the chart below. For States that do not meet the quarterly reporting requirement for the monthly enrollment reporting, the state contribution payment is calculated using a methodology determined by the Secretary.

ILLUSTRATIVE CALCULATION OF STATE PHASED-DOWN MONTHLY CONTRIBUTION FOR 2006

Item	Illustrative value	Source
(i) Gross per capita Medicaid expenditures for prescription drugs for 2003 for full-benefit dual eligibles not receiving drug coverage through a Medicaid managed care plan, excluding drugs not covered by Part D.	$2,000	CY MSIS data.

ILLUSTRATIVE CALCULATION OF STATE PHASED-DOWN MONTHLY CONTRIBUTION FOR 2006—Continued

Item	Illustrative value	Source
(ii) Aggregate State rebate receipts in calendar year 2003	$100,000,000	CMS–64.
(iii) Gross State Medicaid expenditures for prescription drugs in calendar year 2003.	$500,000,000	CMS–64.
(iv) Rebate adjustment factor	0.2000	(2) ÷ (3).
(v) Adjusted 2003 gross per capita Medicaid expenditures for prescription drugs for full-benefit dual eligibles not in managed care plans.	$1,600	(1) × [1–(4)].
(vi) Estimated actuarial value of prescription drug benefits under capitated managed care plans for full-benefit dual eligibles for 2003.	$1,500	To Be Determined.
(vii) Average number of full-benefit dual eligibles in 2003 who did not receive covered outpatient drugs through Medicaid managed care plans.	90,000	CY MSIS data.
(viii) Average number of full-benefit dual eligibles in 2003 who received covered outpatient drugs through Medicaid managed care plans.	10,000	CY MSIS data.
(ix) Base year State Medicaid per capita expenditures for covered Part D drugs for full-benefit dual eligible individuals (weighted average of (5) and (6)).	$1,590	[(7) × (5) + (8) × (6)] ÷ [(7) + (8)].
(x) 100 minus Federal Medical Assistance Percentage (FMAP) applicable to month of state contribution (as a proportion).	0.4000	FEDERAL REGISTER.
(xi) Applicable growth factor (cumulative increase from 2003 through 2006)	50.0%	NHE projections.
(xii) Number of full-benefit dual eligibles for the month	120,000	State submitted data.
(xiii) Phased-down State reduction factor for the month	0.9000	Specified in statute.
(xiv) Phased-down State contribution for the month	$8,586,000	1/12 × (9) × (10) × [1 + (11)] × (12) × (13).

(2) *Method of payment.* State payment must be made in a manner specified by the Secretary that is similar to the manner in which State payments are made under an agreement entered into under section 1843 of the Act, except that all payments must be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

(3) *Failure to pay.* If a State fails to pay to the Secretary the required amount, interest accrues on the amount at the rate provided under section 1903(d)(5) of the Act. The amount so owed and applicable interest must be immediately offset against amounts otherwise payable to the State under section 1903(a) of the Act, in accordance with the Federal Claims Collection Act of 1996 and applicable regulations.

(c) *State Medicaid Statistical Information System (MSIS) Reporting.* Effective with calendar year (CY) 2003 and all subsequent MSIS data submittals, States are required to provide accurate and complete coding to identify the numbers and types of Medicaid and Medicare dual eligibles. Calendar year 2003 submittals must be complete and must be accepted, based on CMS' data quality review, by December 31, 2004.

(d) *State monthly enrollment reporting.* Effective January 2006, and each subsequent month, States must submit an electronic file, in a manner specified by the Secretary, identifying each full benefit dual eligible enrolled in the State for each month with Part D drug coverage who is also determined to be full benefit eligible by the State for full Medicaid benefits. The State will submit this file to CMS no later than 30 days after the end of each month.

(e) *Data match.* The Secretary performs those periodic data matches as may be necessary to identify and compute the number of full-benefit dual eligible individuals needed to establish the State contribution payment.

(f) *Rebate adjustment factor.* The Secretary establishes the rebate adjustment factor using total drug expenditures made and drug rebates received during calendar year 2003 as reported on CMS 64 Medicaid expenditure reports for the four quarters of calendar year 2003 that were received by CMS on or before March 31, 2004. Rebates include rebates received under the national rebate agreement and under a State supplemental rebate program, as reported on CMS–64 expenditure reports for the four quarters of calendar year 2003.

(g) *Annual per capita drug expenditures.* The Secretary notifies each State no later than October 15 before each calendar year, beginning October 15, 2005, of their annual per capita drug payment expenditure amount for the next year.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: July 23, 2004.

Tommy G. Thompson,

Secretary.

[FR Doc. 04–17234 Filed 7–26–04; 12:01 pm]

BILLING CODE 4120–01–P

Federal Register

Tuesday,
August 3, 2004

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 417 and 422

Medicare Program; Establishment of the Medicare Advantage Program; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417 and 422

[CMS–4069–P]

RIN 0938–AN06

Medicare Program; Establishment of the Medicare Advantage Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement provisions of the Social Security Act (the Act) establishing and regulating the Medicare Advantage (MA) program. The MA program was enacted in Title II of The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) on December 8, 2003. The MA program replaces the Medicare+Choice (M+C) program established under Part C of title XVIII of the Act, while retaining most key features of the M+C program.

The MA program attempts to broadly reform and expand the availability of private health plan options to Medicare beneficiaries. See the "Executive Summary" in the **SUPPLEMENTARY INFORMATION** section for an outline of the key features of the MA program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 4, 2004.

ADDRESSES: In commenting, please refer to file code CMS–4069–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on issues in this document to *http://www.cms.hhs.gov/regulations/ecomments* (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. *By 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–4069–P, P.O. Box 8018, Baltimore, MD 21244–8018.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (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 (410) 786–7195 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 could be considered late.

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. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public website.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Eligibility, Election, and Enrollment—Lynn Orlosky, (410) 786–9064 or Randy Brauer, (410) 786–1618.

Benefits and Beneficiary Protections—Frank Szeflinski, (303) 844–7119.

Quality Improvement Program—Tony Hausner, (410) 786–1093.

Submission of Bids, Premiums, and Plan Approval—Ann Hornsby, (410) 786–1181.

Payments to MA Organizations—Anne Hornsby, (410) 786–1181.

Special Rules for MA Regional Plans—Marty Abeln, (410) 786–1032.

Contracts with MA Organizations—Frank Szeflinski, (303) 844–7119.

Beneficiary Appeals—Chris Gayhead, (410) 786–6429.

General Information—(410) 786–1296.

SUPPLEMENTARY INFORMATION:

Executive Summary: Beginning in 2006, the Medicare Advantage program would:

- Provide for regional plans that would make private plan options available to many more beneficiaries, especially those in rural areas.
- Expand the number of kinds of plans provided for, so that beneficiaries can choose from Health Maintenance Organizations, Preferred Provider Organization plans (the most popular type of employer-sponsored plan), Fee-for-Service plans, and Medical Savings Account plans, if available where the beneficiary lives.
- Enrich the range of benefit choices available to enrollees, including not only improved prescription drug benefits, but also other benefits not covered by traditional Medicare, and the opportunity to share in savings where plans can deliver benefits at lower costs.
- Provide incentives to plans, and add specialized plans, to coordinate and manage care in ways that comprehensively serve those with complex and disabling diseases and conditions.
- Use Open Season competition among plans to provide continuing pressure on plans to improve service, improve benefits, invest in preventive care, and hold costs down in ways that attract enrollees. These improvements would be fostered through enhanced and more stable payments to organizations, improvements in program design, introduction of new flexibility for plans, and reductions in impediments to plan participation. At the same time, the traditional Medicare program will be enhanced by addition of a prescription drug benefit, and beneficiaries will retain the ability to remain in or return to this enhanced Medicare if they prefer it to a private health plan.
- Advance the goal of improving quality and increasing efficiency in the overall health care system. Medicare is the largest payer of health care in the world. As such, Medicare can drive changes in the entire health care system. For example, as providers and health plans implement innovations, such as e-prescribing, that can result in improved quality of care for Medicare beneficiaries, these improvements would be passed on to other public health programs and commercial health care markets. Similarly, competing Medicare health plans will seek efficient ways to provide health care to their beneficiaries, such as through prevention and disease management

strategies to avoid costly care in the future. These efficiencies will spill over into plans' commercial, Medicaid and other markets, driving changes in the overall health care system.

Throughout the preamble we identify options and alternatives. We welcome comments and ideas on our approach and on alternatives to help us design the Medicare Advantage program to operate as effectively, successfully, and efficiently as possible in meeting the needs of Medicare beneficiaries.

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–4069–P and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: Comments received timely will 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 (410) 786–7195.

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 (or toll-free at 1–888–293–6498) or by faxing to (202) 512–2250. The cost for each copy is $10. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access*, a service of the U.S. Government Printing Office. The Web site address is: *http://www.access.gpo.gov/fr/index.html.*

I. Background

A. Medicare Prescription Drug, Improvement, and Modernization Act of 2003

(If you choose to comment on issues in this section, please include the caption "Background—Medicare Prescription Drug, Improvement, and Modernization Act of 2003" at the beginning of your comments.)

Title II of MMA makes important changes to the current Medicare+Choice (M+C) program—it replaces M+C with a new Medicare Advantage (MA) program under Part C of Medicare. This title provides for additional opportunities for organizations to offer private plans to Medicare beneficiaries beginning in 2006. In an effort to increase beneficiary choice of plans across all regions of the country, including rural areas, Title II of the MMA establishes a MA regional contracting option. As discussed below, MA regional plans would be subject to somewhat different rules than MA local plans. MMA also provided extra incentives, such as a stabilization fund, bonus payments, and risk sharing to encourage organizations to participate as regional plans.

The MMA also increases payments to MA organizations beginning in 2004. The increased payments and other changes under MMA are intended to boost plan participation and thus offer more choice of plans to beneficiaries and improve health and overall health system efficiency. The MMA requires that increased payment amounts be used to increase benefits, reduce beneficiary costs, or enhance beneficiary access to services. As explained below, beginning in 2006, we would require MA organizations to submit "bids" for covering Medicare services, and if these bid amounts are below a benchmark amount established under the new law, this difference will be shared with enrollees. These provisions will potentially reduce Medicare costs.

One of the principal goals of the MMA is to provide beneficiaries with a choice in how they get their Medicare benefits. Under the MA program, to the extent that all parts of the country have at least one regional plan, all beneficiaries would have a choice in how they get their Medicare benefits, whether through a Medicare Advantage plan or the traditional fee-for-service program. Also, depending on plan offerings in the area in which they reside, beneficiaries would have the choice of a variety of types of local coordinated care plans, such as health maintenance organizations (HMOs), provider-sponsored organizations (PSOs), and preferred provider organization plans (PPOs) including both regional and local PPOs, as well as Medical Savings Account (MSA) plans and private fee-for-service (PFFS) plans. In addition, the MMA permits us to contract with specialized MA plans that create plans for enrollees with special needs, such as institutionalized or Medicaid-eligible individuals, or those with severe or disabling chronic conditions.

The competition among these various types of plan offerings in a region should improve health care quality for beneficiaries. Plans will have to compete not only on price but on quality to attract beneficiaries' enrollment and to keep them enrolled over time. Such competition based on quality should precipitate development and implementation of innovations to prevent chronic diseases and manage the care of diseases for Medicare enrollees and other enrolled populations.

With these new and improved choices, Medicare beneficiaries, like Federal employees and retirees in the Federal Employees Health Benefits (FEHB) Program, would have the opportunity to obtain improved benefits, improved services, and reduced costs. However, those who prefer would be able to remain in traditional Medicare, enhanced by the new Part D drug benefit. All would have the opportunity to switch among plans, or to or from traditional Medicare, during the annual election period (or "open season") in November and December. Over time, participating plans will be under continued pressure to improve their benefits, reduce their premiums and cost sharing, and improve their networks and services, in order to gain or retain enrollees. In addition, we would expect plans to use integrated health plan approaches such as disease prevention, disease management and other care coordination techniques. In doing so, integrated plans that combine the traditional Parts A and B of Medicare and the new Part D drug benefit and apply these innovative techniques may be able to pass on savings that may result from the care coordination to the enrollee through reduced premiums or additional benefits.

Beginning in 2006, payments for local and regional MA plans would be based on competitive bids rather than administered pricing. MA organizations would submit an annual aggregate bid amount for each MA plan. An aggregate plan bid is based upon their determination of expected costs in the plan's service area for the national average beneficiary for providing non-

drug benefits (that is, original Medicare (Part A and Part B) benefits), Part D basic prescription drugs, and supplemental benefits if any (including reductions in cost sharing). To determine an organization's payment, CMS would compare the non-drug portion of the aggregate bid to the local or regional plan benchmark, which is an average of county rates in the plan's service area. For a plan with a bid below its benchmark, CMS would pay the MA organization the total plan bid (for Parts A, B, and D benefits plus any supplemental bid amount), risk adjusted for the plan risk profile, plus the rebate amount. (The rebate amount is 75 percent of the difference between the plan bid and benchmark, and is used to provide mandatory supplemental benefits. The remaining 25 percent is retained by the Government.) For a plan with a bid equal to or above its benchmark, CMS would pay the MA organization the plan benchmark, risk adjusted.

We would be able to negotiate bid amounts with plans in a manner similar to negotiations conducted by the Office of Personnel Management with Federal Employees Health Benefits (FEHB) plans. In the spirit of the FEHB process, CMS would work with plans to ensure benefit packages meet the needs of our population and that information is made available to beneficiaries so that they can make decisions about which plans best meet their needs.

Finally, in conjunction with the new drug benefit required under Title I of MMA, which will be addressed in separate rulemaking, changes made in MMA to the M+C program (now called the MA program) are intended to bring about broad-based improvements to the Medicare program's benefit structure, including improved prescription drug coverage under the MA program. Organizations offering local and regional coordinated care MA plans must offer at least one plan with the Medicare prescription drug benefit or the actuarial equivalent.

We have identified many areas in which we believe we can prevent or reduce unnecessary burden, duplication, or complexity either in interpreting the new MMA provisions or in modifying existing rules to accommodate Medicare Advantage reforms. In addition to those specifically discussed, we request suggestions for other burden-reducing reforms or innovations we can incorporate in the final regulation that will improve the ability of plans to participate in the program without compromising quality or services.

B. Relevant Legislation

(If you choose to comment on issues in this section, please include the caption "Background—Relevant Legislation" at the beginning of your comments.)

1. Balanced Budget Act of 1997

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added sections 1851 through 1859 to the Social Security Act (the Act) establishing a new Part C of the Medicare program, known as the Medicare+Choice (M+C) program. Under section 1851(a)(1) of the Act, every individual entitled to Medicare Part A and enrolled under Medicare Part B, except for individuals with end-stage renal disease, could elect to receive benefits either through the original Medicare program or an M+C plan, if one was offered where he or she lived. The primary goal of the M+C program was to provide Medicare beneficiaries with a wider range of health plan choices through which to obtain their Medicare benefits. The BBA authorized us to contract with private organizations offering a variety of private health plan options for beneficiaries, including both traditional managed care plans (such as those offered by health maintenance organizations (HMOs)) that had been offered under section 1876 of the Act, and new options that were not previously authorized. Three types of M+C plans were authorized under the new Part C, as follows:

- M+C coordinated care plans, including HMO plans (with or without point-of-service options), provider sponsored organization (PSO) plans, and preferred provider organization (PPO) plans.
- M+C MSA plans (combinations of a high deductible M+C health insurance plan and a contribution to an M+C MSA).
- M+C private fee-for-service plans.

The BBA changed the payment methodology to Medicare health plans and initially afforded beneficiaries more choice of plans nationally. However, payment rates grew modestly in relation to costs health plans incurred, resulting in fewer health plans participating in the M+C program, decreased choice of plans available to beneficiaries, and fewer extra benefits available to enrollees. Although there were large payment increases in rural areas as a result of the BBA provisions, access to Medicare coordinated care plans declined significantly in rural areas after 1997.

2. Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. 106–113 (BBRA), amended the M+C provisions of the BBA. Many of these amendments were reflected in a final rule with comment period published in the **Federal Register** on June 29, 2000 (65 FR 40170). In addition, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. 106–554 (BIPA), enacted December 21, 2000, further amended the M+C provisions of the BBA and BBRA. A final rule containing BIPA provisions was published on March 22, 2002 (67 FR 13278).

These laws enacted subsequent to the BBA made incremental changes to M+C payments and provided financial incentives to plans to participate in the M+C program. While these efforts helped stabilize the M+C program, they did not generally improve plan participation in the M+C program nor did they increase overall beneficiary enrollment or access to plans in rural areas.

The specific sections of Part C of the Social Security Act that were impacted by the MMA are as follows:

Section 1851—Eligibility, election and enrollment.
Section 1852—Benefits and beneficiary protections.
Section 1853—Payments to MA organizations.
Section 1854—Premiums.
Section 1855—Organizational and financial requirements for MA organizations.
Section 1856—Establishment of standards.
Section 1857—Application procedures and contracts with MA organizations
Section 1858—Special rules for MA regional plans.
Section 1859—Definitions; Miscellaneous provisions.

This proposed rule addresses the new MA provisions in Title II of MMA. Subtitle B—Immediate Improvements, contained in Title II, requires immediate payment adjustments for 2004 to MA plans. These payment adjustments were implemented in 2004 and payment adjustments for 2005 will be implemented in 2005. The requirement in 1858(a)(2)(D) to conduct a market survey and analysis before establishing MA regions is occurring concurrent with the publication of this proposed

MA rule. Therefore, the announcement of the MA Regions will not be included in this proposed rule. As noted above, the provisions in Title I of the MMA will be set forth in a separate proposed rule.

Provisions of the MMA addressed in this proposed rule outside of Title II include Section 722—Medicare Advantage Quality Improvement Program, of Title VII. They may be found under Subpart D—Quality Assurance.

C. Codification of Regulations

(If you choose to comment on issues in this section, please include the caption "Background—Codification of Regulations" at the beginning of your comments.)

The proposed regulations set forth here are codified in 42 CFR Part 422—The Medicare Advantage Program. Note that the regulations for managed care organizations that contract with us under cost contracts will continue to be located in 42 CFR part 417, Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans.

D. Organizational Overview of Part 422

(If you choose to comment on issues in this section, please include the caption "Background—Organizational Overview of Part 422" at the beginning of your comments.)

MMA amends the existing provisions of the Medicare statute found in Part C of Title XVIII, sections 1851 through 1859 of the Act, and adds a new section 1858 to the Act. This proposed rule covers a wide range of topics included in the existing part 422, including eligibility and enrollment, benefits and beneficiary protections, payment, contracting requirements, and grievances and appeals. We have generally retained the organization of the sections from part 422, except for reordering subparts F and G to place the bidding and payment provisions in sequential order. Where the MMA did not amend existing statute, this proposed rule does not set forth unchanged regulations text from the previous part 422. Thus, this proposed rule contains only the necessary revisions to existing part 422. In some subparts of part 422, the only changes are in nomenclature, that is, the replacement of M+C references with MA references. The regulations in those subparts, H, L, and N are not set forth in this proposed rule. The subparts with substantive changes are as follows:

Subpart A—General provisions, establishment of the Medicare Advantage program, definitions, types of MA plans, and user fees.

Subpart B—Requirements concerning beneficiary eligibility, election, and enrollment and disenrollment procedures.

Subpart C—Requirements concerning benefits, access to services, coverage determinations, and application of special benefit rules to PPOs and regional plans.

Subpart D—Quality improvement program, chronic care improvement program requirements, and quality improvement projects.

Subpart E—Relationships with providers.

Subpart F—Submission of bids, premiums, and related information and plan approval.

Subpart G—Payments for MA organizations.

Subpart I—Organization compliance with State law and preemption by Federal law.

Subpart J—Special rules for MA regional plans, including the establishment of MA regions, stabilization fund, and risk sharing.

Subpart K—Application and Contract requirements for MA organizations.

Subpart M—Beneficiary grievances, organization determinations, and appeals.

Subpart O—Intermediate Sanctions

Each of these subparts is discussed below in section II of this preamble.

II. Provisions of the Proposed Rule

Part 417—Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans

Subpart J—Qualifying Conditions for Medicare Contracts Extension of Reasonable Cost Contracts (§ 417.402)

(If you choose to comment on issues in this section, please include the caption "Extension of Reasonable Cost Contracts (§ 417.402)" at the beginning of your comments.)

Authority for cost HMOs/CMPs (cost plans) had been due to expire on December 31, 2004. Section 234 of the MMA modified section 1876(h)(5) of the Act to extend authority for cost plans beyond the previous limit of December 31, 2004. Section 234 of the MMA provides an initial extension of cost plans through December 31, 2007. It also provides for a continued extension of cost plans beyond December 31, 2007, under specific conditions.

Effective for contract years beginning on or after January 1, 2008, cost plans may be extended where there are fewer than two coordinated care plan-model MA plans (as defined in section 1851(a)(2)(A)(i) of the Act) of the same type (that is, either two local or two regional plans) available to Medicare beneficiaries in the same service area. Both of the "competing" MA plans of the same type must meet minimum enrollment requirements for the entire previous year in order to trigger mandatory cost plan non-renewal or service area reduction. The minimum enrollment requirements of the "competing" MA plans that would trigger mandatory non-renewal or service area reduction for cost HMOs/CMPs are: (1) At least 5,000 enrollees for the portion of the service area that is within a metropolitan statistical area having more than 250,000 people and counties contiguous to such an area; and/or (2) at least 1,500 enrollees for any other portion of such service area.

We interpret the statute to require cost plan service area reduction where there are two or more MA plans of the same type meeting minimum enrollment requirements competing for Medicare members in a portion of the cost plan's service area. An alternative reading of the statute might permit a cost plan to continue operating in its entire service area until such time as all parts of the cost plan's service area are subject to MA competition meeting applicable thresholds. We believe the approach we have taken is consistent with the stated intent in the Conference Agreement that cost plans be required to operate under the same provisions as other private plans that enter the cost plan's service area. We invite comment on the approach we have taken.

We propose to permit existing cost plans to expand their service areas through September 1, 2006. Thereafter, service area expansion applications by cost HMOs/CMPs will be initially evaluated and accepted only when there are not two or more MA plans of the same type meeting minimum enrollment requirements in the area in which the cost plan proposes to expand.

We incorporate these changes into regulation by removing obsolete text and by revising other portions of § 417.402(b), and by adding a new § 417.402(c).

Subpart A—General Provisions (§ 422.1)

(If you choose to comment on issues in this section, please include the caption "Subpart A—General Provisions" at the beginning of your comments.)

1. Overview

Subpart A begins with a brief section (§ 422.1) that lists the statutory authority that is implemented in part 422 (sections 1851 through 1859 of the Act).

This proposed rule would amend § 422.1(a) by adding the new section 1858 of the Act, which would be implemented in proposed subpart J. Under § 422.2, we set forth new definitions for terms used in part 422 that we believe need clarification. These definitions provide the generally applied meaning for terms that are used throughout part 422. Where necessary, we have included in specific subparts of part 422 definitions for terms used primarily in those subparts. As discussed below, § 422.4 briefly describes the two new types of coordinated care MA plans provided for under section 1851(a)(2)(A) of the Act. The provisions formerly contained in § 422.6 and § 422.8 relating to application requirements and evaluation and determination procedures have been removed from subpart A and added as § 422.501 and § 422.502 of subpart K. Thus, prospective MA plans may find all applications and contracting information organized in one place. Section 422.6 (formerly § 422.10) describes the user fees associated with the Medicare Beneficiary Education and Information Campaign, required under section 1857(e)(2) of the Act.

2. Definitions (§ 422.2)

In § 422.2, we have included new definitions required under MMA and found under section 1859 of the Act. In addition, § 422.2 provides definitions that are not found in specific subparts of the regulation because they apply broadly to part 422. For example, in § 422.2, we provide the definition of "MA regional plans" as set forth in section 1859 of the Act because this term is used throughout part 422. However, a definition like "benchmark" found in section 1853 of the Act, that is specific to § 422.258 *et seq.*, is not described here but in that section. Finally, the statute specifies other new definitions under section 1859 of the Act, such as the definition of "specialized MA plans," and they are incorporated into this section.

We remove definitions for "ACR", "Additional benefits," "Adjusted community rate," and "M+C" as these terms will not apply after 2006. We also revise several existing definitions to make them consistent with the MMA statute. For example, Mandatory supplemental benefits are redefined to incorporate language reflecting that these benefits may be paid for through premiums and cost sharing or through the application of a rebate, or both. Therefore, mandatory supplemental benefits are defined as health care services not covered by Medicare that an MA enrollee must purchase as part of an MA plan. Such benefits may include reductions in cost-sharing for benefits under the original Medicare fee-for-service program—and are paid for in the form of premiums and cost-sharing, or by an application of the beneficiary rebate rule in section 1854(b)(1)(C)(ii)(I) of the Act, or both.

However, optional supplemental benefits retain the same definition as under the M+C program as health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. These services may be grouped or offered individually. Note that throughout the regulation, the phrase "supplemental benefits" refers to both mandatory and optional supplemental benefits. The terms "mandatory supplemental" and "optional supplemental" are used when referring specifically to one of the types of supplemental benefits.

We have removed "additional benefits" from the definition of "basic benefits" since MA plans will no longer offer additional benefits. In addition, we have replaced the word "ACR" process with the words "annual bidding" process in the definition of "benefits" to reflect the new bidding process for submission and approval of benefits. Finally, we have revised the definition of "service area" to incorporate the concept of the new MA regional plan's service area that consists of an entire region.

Under section 1851(a)(2)(A) of the Act, two new types of coordinated care plans are established—Regional MA plans, which are regional PPO plans, and specialized MA plans for special needs individuals. First, we define an "MA local area" as a county or other area specified by us because it is important to distinguish an MA local area from an MA region.

Next, we define an "MA regional plan" because it is a new type of coordinated care plan choice for beneficiaries. While PPOs first became a choice for beneficiaries under the BBA, they operated as "local" plans on a county (including multi-county) or partial county basis. The MA regional plan functions like a local PPO but must serve an entire region.

In all, CMS will establish between 10 and 50 regions, as described in § 422.455 (subpart J). A regional MA plan's service area is one or more entire MA regions. Thus, we define an "MA regional plan" as a private health plan that operates as a PPO, but serves an entire CMS-designated region. Like local PPOs that may offer MA plans under the MA program, the regional PPOs must have a network of contracting providers that have agreed to a specific reimbursement for covered benefits that are offered by the MA regional plan, and must also provide for reimbursement for all covered benefits regardless of whether the covered benefits are provided through the network providers or outside of the network. MA regional plans are further described in § 422.4 below, which describes types of contracting options under the MA program.

We define an "MA local plan" as one that is not an MA regional plan. Also defined under part 422 is the "Prescription Drug Sponsor," "Prescription Drug Plan (PDP)," and a "Medicare Advantage Prescription Drug (MA–PD) plan." A sponsor must be a private entity that meets our requirements and standards. PDP sponsors may offer multiple plans throughout the country or in a region, but sponsors must submit an individual bid for each plan.

An MA–PD plan is an MA plan that also provides qualified prescription drug coverage as found in Part D of the Act. An organization offering a coordinated care MA plan must have an MA–PD plan in each of the service areas in which it operates, as required under section 1860D–21(a)(1) and (2) of Part D of the Act.

The other new type of contracting option available is a specialized MA plan for special needs individuals, as provided for under section 231 of the MMA. Section 1851(a)(2)(A) of the Act is amended by adding a new clause (ii) providing for specialized MA plans for special needs beneficiaries. Those specialized MA plans are therefore to be treated as coordinated care plans. In section 1859(b)(6)(A) of the Act, specialized MA plans for special needs beneficiaries are defined to be MA plans that exclusively serve special needs individuals defined in section 1859(b)(6)(B) of the Act, described below.

Currently, MA plans may not selectively limit enrollment to a subgroup, for example, institutionalized individuals (except for areas in which an organization is permitted to limit enrollment to retirees obtaining their employer/union coverage through an MA plan, as permitted through waivers authorized under section 1857(i)(1) of the Act). The establishment of specialized MA plans would allow MA plans to exclusively enroll special needs individuals in MA plans that have targeted clinical programs for these individuals.

We may designate an MA plan as a specialized MA plan, if the plan "disproportionately" serves special needs beneficiaries. We will establish quantitative criteria to be able to designate MA plans that disproportionately serve special needs beneficiaries as specialized MA plans. For example, one possible criterion might consider the presence of four or more chronic conditions for an enrollee to represent a "complex" medical condition. Persons with complex medical conditions might be appropriately treated by a specialized MA plan. We may also establish criteria to validate that specialized MA plans have incorporated processes or clinical programs that are designed to address the unique needs of enrolled special needs beneficiaries. We expect to determine these criteria based on diagnosis data or other administrative data that we collect, such as diagnosis data for risk adjustment. In an effort to focus the care management on special needs individuals, a specialized MA plan may limit enrollment to special needs individuals beginning in January 2004 through December 2009, as described under § 422.52.

An issue related to specialized MA plans for special needs individuals is the availability of prescription drugs. Special needs individuals in particular need access to prescription drugs to manage and control their severe or disabling chronic conditions. From a disease management perspective, a non-prescription drug plan would not serve the interest of special needs individuals. Additionally, effective January 1, 2006, specific dual eligible individuals described in section 1935(c)(6)(A)(ii) of the Act are required to receive drug coverage solely through the Medicare Part D program. In other words, effective January 1, 2006, a full-benefit dual eligible who is also a Part D eligible individual will only be able to receive drug coverage through the Medicare Part D program. Eligibility for drugs under Title XIX will no longer be available for these individuals.

Therefore, we propose that effective January 1, 2006, all special needs plans, as defined in section 1859(b)(6)(B) of the Act, will need to provide Part D coverage. Again, for individuals with special needs enrolled in a special needs plan, this would be the only means for them to receive their Part D coverage as they cannot receive it through an MA plan that does not offer prescription drug coverage. We would welcome comments on this proposed requirement. The authority for such a requirement is found in our establishing requirements for special needs individuals under section 1859(b)(6)(B)(iii) of the Act. In addition, we also are interested in receiving comments on the development of an HIV/AIDS special needs plan that would address the special health needs, including prescription drugs, of the Medicare-eligible population living with HIV/AIDS.

Section 1859(b)(6)(B) of the Act identifies three types of special needs individuals as: Institutionalized individuals (as defined below); individuals entitled to medical assistance under a State plan under Title XIX; and such other individuals with severe or disabling chronic conditions as the Secretary determines would benefit from enrollment in such a plan.

For the purpose of defining a special needs individual above, "institutionalized" means to reside in a long-term care facility for more than 90 days as determined by the presence of a 90-day assessment in the Minimum Data Set (MDS). We are not at this time proposing a definition of "severe or disabling chronic condition." However, we welcome comments on whether we should set standards for the designation of an individual with severe or disabling chronic conditions and what criteria should be used. For example, does the individual need medical management by a specialist (for example, endocrinologist or cardiologist)? Does the individual have complex medical conditions? Does the individual qualify for the plan's disease or case management program? Are there specific benefits or interventions provided to these individuals that are not provided to the general MA population?

We would also welcome comments on whether we should allow specialized MA plans to exclusively enroll certain subgroups of Medicaid or institutionalized beneficiaries. If it were determined to be appropriate to enroll subgroups of either Medicaid or institutionalized beneficiaries, what would the appropriate subgroups be?

We note that MMA allows for the enrollment of End-Stage Renal Disease (ESRD) beneficiaries in specialized MA plans designed for this population. Thus, ESRD beneficiaries for whom an MA plan would receive payment at the ESRD rates would be considered special needs individuals who would benefit from enrollment in a specialized MA plan.

Finally, we would welcome comments on whether there are appropriate quality oversight mechanisms for specialized MA plans that would be appropriate to require to ensure that special needs individuals experience improved quality.

3. Types of MA Plans (§ 422.4)

The MA program is intended to provide beneficiaries access to a wider array of private health plan choices than the existing plans under the M+C program and to increase the number of areas in which private health care options are available to Medicare beneficiaries. As under the M+C program, entities can contract with us to provide three general categories or types of plans: MA coordinated care plans, MA MSA plans, and MA PFFS plans. However, the establishment of the MA program is designed to afford beneficiaries two additional types of plan choices within the coordinated care plan category—regional PPO coordinated care plans as defined in § 422.2 or specialized MA coordinated care plans, also defined in that section. These new MA coordinated care plan entities must conform to the contracting requirements described in § 422.504 *et seq.*

Section 520(a)(3) of the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) added section 1852(e)(2)(D) of the Act and defined Preferred Provider Organization plans (PPOs) under the MA program for purposes of quality assurance requirements. As we discussed in the preamble to the final rule with comment period titled, "Medicare Program; Medicare+Choice," published June 29, 2000 (65 FR 41070), the definition of PPOs at section 1852(e)(2)(D) of the Act was explicitly for purposes of applying quality assurance requirements in 1852(e)(2)(B) of the Act and was limited in its applicability to paragraph (2) of section 1852(e) of the Act. Before the BBRA, PPOs had been treated under the M+C statute and regulations in the same manner as all other M+C coordinated care plans for purposes of applying quality assurance requirements. In the June 29, 2000 final rule with comment period, we incorporated this new definition into the M+C regulations at § 422.4 and by revising § 422.152.

The PPO plan definition added by section 520 of the BBRA included three elements. They were: The PPO (1) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; (2) provides for reimbursement for all covered benefits regardless of whether those benefits are provided within the network of providers; and (3) is offered by an organization that is not licensed or organized under State law as a health maintenance organization.

Because the definition of PPO plan in section 1852(e)(2)(D) only applies for the limited purpose of eligibility for PPO quality improvement requirements, we do not believe that the limitations in this definition should have been set forth in a generally applicable definition of PPO plan in § 422.4, as is currently the case. We propose to clarify in regulation that it is solely for purposes of the application of the more limited quality assurance requirements in section 1852(e)(2)(B) of the Act that PPOs must be offered by MA organizations that are not licensed or organized under State law as a health maintenance organization. For PPO-type plans that are offered by MA organizations that are licensed or organized under State law as health maintenance organizations, the quality assurance requirements that apply to all other coordinated care plans in section 1852(e) of the Act also apply to those PPO type plans.

Section 722 of the MMA, which amends section 1852(e) of the Act effective January 1, 2006, is consistent with this interpretation insofar as it limits the applicability of the definition of PPOs in section 1852(e)(3)(A)(iv) of the Act (which is the same definition currently appearing in section 1852(e)(2)(D) of the Act) to subparagraph (A) of paragraph 1852(e)(3) of the Act. Effective January 1, 2006, MA organizations that offer MA local plans that are PPOs will only need to provide for the collection, analysis, and reporting of data that permit the measurement of health outcomes and other indices of quality insofar as services are furnished by providers that have contracted with the MA organization under those PPO plans. However, this exception to the normal rule in section 1852(e)(2) of the Act that data are to be collected from all clinical sources is afforded solely to PPOs that are offered by MA organizations that are not licensed or organized under State law as health maintenance organizations—section 1852(e)(3)(A)(iv)(III) of the Act. To the extent that a local PPO is offered by an MA organization that is licensed or organized under State law as a health maintenance organization, the normal data collection, analysis, and reporting requirements in clause (3)(A)(i) continue to apply. We propose to modify the definition of PPOs in § 422.4 to account for this more limited interpretation of State licensure requirements and to modify headings in § 422.152(b) and (e).

Another change in the type of MA plans authorized is the elimination of previous limits on enrollment in MA MSAs, described at § 422.56. As directed by section 233 of the MMA, MA organizations are authorized to offer medical savings account (MSA) plans as a permanent option. A Medicare MSA plan combines a high-deductible insurance policy and a savings account for health care expenses. The Medicare program pays premiums for the insurance policies and makes a contribution to the beneficiaries' medical savings account (MSA). The beneficiaries use the money in their MSAs to pay for their health care before the high deductible is reached. The sum of the premium and the contribution to the account would equal the payment made by Medicare to any other MA plan for a beneficiary.

By way of background, the Balanced Budget Act of 1997 (BBA) authorized a demonstration project for MSA plans when it created the Medicare+Choice program. MMA changes restrictive rules that governed the MSA demonstration. MMA eliminates the limits imposed on MSA plans by the BBA, including a time limit on enrollment and a limit on the number of beneficiaries who could enroll in such plans. It also exempted MSA plans from certain quality assurance requirements that the BBA applied to "network" MSA plans. The Congress made these changes in light of the fact that no MSA plans participated in the demonstration. We are particularly interested in comments on whether these changes are sufficient to attract MSA plan sponsors and beneficiary enrollment.

Finally, we delete the descriptions of M+C network MSA plan and M+C non-network MSA plan as different types of plans at § 422.4(a)(2)(B)(ii), since the distinction between network and non-network MSAs for the purpose of quality assurance requirements is no longer applicable.

4. Expansion of the Beneficiary Education and Information Campaign "User Fees" (§ 422.6, formerly § 422.10)

The last section of subpart A contains regulations implementing the user fees provided for in section 1857(e)(2) of the Act. MMA expands the user fee to include PDP sponsors as well as MA plans as contributors. The expansion of the user fee recognizes the increased Medicare beneficiary education activities that we would require around the new prescription drug benefit. In 2006 and beyond, user fees will help to offset the costs of educating over 41 million beneficiaries about the drug benefit through written materials such as a publication describing the drug benefit, internet sites, and other media. For example, CMS will develop a prescription drug price comparison Web site for beneficiary use. We may also provide information to beneficiaries on quality measures, networks, and other dimensions.

Additionally, as before, the user fee would pay for the ongoing costs of the national beneficiary education campaign that includes developing and disseminating print materials, the 1–800 telephone line, community based outreach to support State health insurance programs (SHIPs), and other enrollment and information activities required under section 1851 of the Act and counseling assistance under section 4360 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 103–66).

In fiscal year 2006 and thereafter, the MMA authorizes up to $200,000,000, reduced by the fees collected from MA organizations and PDP sponsors in that fiscal year (total amount is not indexed in any way). In each year, the total amount of collected user fees may not exceed the estimated costs in the fiscal year for carrying out the enrollment and dissemination of information activities in the MA and Part D prescription drug programs or the applicable portions (discussed below) of $200,000,000, whichever is less.

Finally, these user fee provisions establish the applicable aggregate contribution portions for MA organizations and PDP sponsors. The applicable portion of the user fee for MA organizations would be based on the total proportion of expenditures for Medicare Part C as well as for payments under Part D that are made to MA organizations as a percent of Title XVIII expenditures. The PDP sponsor's applicable portion is the estimate of the total proportion of expenditures under Title XVIII that are attributable to expenditures made to PDP sponsors for prescription drugs under Part D. The fees charged to individual MA plans and PDP sponsors would continue to be determined by CMS. These fees are calculated by a percent of plan's revenue to avoid over-burdening smaller plans.

The remaining portion of the costs of the beneficiary education campaign is the fee-for-service beneficiaries' portion of the campaign. It represents the portion of costs of fee-for-service informational materials, designed to enable beneficiaries to make informed choices among health plans and Medicare fee-for-service. This amount is funded through CMS' appropriations.

Subpart B—Eligibility, Election and Enrollment

(If you choose to comment on issues in this section, please include the caption "Subpart B—Eligibility, Election and Enrollment" at the beginning of your comments.)

1. Eligibility To Elect an MA Plan (§ 422.50)

The regulations contained in this subpart are largely the same as those now used in the M+C program. We have made the necessary terminology changes throughout subpart B to reflect the replacement of the M+C program with the MA program. Substantive changes are discussed below.

Under § 422.50 introductory text, we would clarify that, for this subpart, a reference to an "MA plan" should be read to include both MA local and MA regional plans, unless specifically noted otherwise in the text.

In addition, based on our experience with the M+C program, we believe that it is important to provide additional optional mechanisms for elections that take advantage of modern technology, such as allowing an individual to enroll at a secure Web site or at a health plan's customer service center. Section 1851(c) of the Act allows the Secretary to designate other enrollment mechanisms. These options promote a more efficient and simplified election process for beneficiaries as well as partner organizations. Therefore, we would revise § 422.50(a)(5) to allow other election methods as approved by us.

2. Eligibility To Elect a Special Needs MA Plan (§ 422.52)

We would include a new § 422.52 to describe the eligibility requirements for enrollment into specialized plans for special needs beneficiaries, which have been authorized under section 231 of MMA. Individuals would be eligible to enroll in these specialized plans if they are institutionalized, entitled to Medicaid ("dual eligible"), or have a severe and disabling condition and meet the requirements specified by CMS. We are considering including in this last category individuals with a disabling condition who are not in an institution but require a similar level of care. We invite comments on this approach. Specialized MA plans would be able to restrict enrollment solely to those individuals who are in one or more classes of special needs individuals.

In general, we believe that the new requirements regarding special needs MA plans primarily are intended to encourage more choices for certain populations by allowing plans that specialize in the treatment of beneficiaries with particular needs by providing and coordinating services for these individuals and to limit plan enrollment to such individuals. This provision could encourage plans to develop new products in the market place by giving them the opportunity to develop expertise in efficiently serving such specialized populations. We also have the authority to waive section 1851(a)(3)(B) of the Act, which precludes beneficiaries with ESRD from enrolling in MA plans. This authority grants us the discretion to permit people with ESRD to enroll in a special needs MA plan. We also are considering whether beneficiaries with ESRD should be considered to meet the requirements for special need status and invite comments on this idea.

We are permitted to apply to special needs plan enrollees a provision under section 1894(c)(4) of the Act that applies to enrollees in the Program of All Inclusive-Care for the Elderly (PACE). This provision provides for continued eligibility in certain situations. Specifically, this provision allows a PACE eligible individual to be deemed to continue to be enrolled even if the individual no longer meets the PACE eligibility requirements if, in absence of continued coverage under a PACE program, the individual reasonably would be expected to meet the requirements within the succeeding 6-month period. Similarly, we propose to allow special needs individuals who no longer meet the "special needs" criteria to remain enrolled in an MA special needs plan if it is reasonable to assume that, absent the continued special needs care available under the plan, they would again meet the eligibility criteria for that MA plan within the succeeding 6-month period.

We note that a special needs plan is described as "an MA plan that exclusively serves special needs individuals." We have considered the question of whether this means that the plan is exclusively offered to special needs individuals, and exclusively enrolls special needs individuals, or whether it means that it only provides care to special needs individuals, and has no enrollees who do not meet the definition of a special needs individual. In the latter case, if an existing plan were designated as a special needs plan, existing enrollees who did not meet the definition of a special needs individual would be required to terminate their enrollment.

We do not think that this was intended by the Congress, and therefore have interpreted "exclusively serves" special needs individuals to mean that the plan is only offered to special needs individuals, and only enrolls such individuals. Existing enrollees of such a plan, however, would be "grandfathered" and could remain enrolled. Therefore, we are providing in proposed § 422.52(e) that individuals who are enrolled in MA plans that are subsequently designated as "special needs plans" would be able to continue to be enrolled. Those individuals would be able to remain enrolled or choose to elect other MA plans during appropriate election periods provided to all MA eligible individuals.

We invite comment on the above approach, and on the alternative approach under which only special needs individuals could be enrolled and receive services through the plan, and any non-special needs individual would have to terminate enrollment involuntarily if his or her plan wanted special needs plan status. To ensure that the non-special needs individuals would be able to elect a new plan outside of an enrollment period, we intend to establish a special election period for these individuals. We have historically established SEPs for exceptional circumstances in our manual instructions rather than through regulation. Thus, we would establish such an SEP through that process.

We would distinguish the situation of a "grandfathered" plan enrollee who enrolled in the plan before it had special needs status from a case in which a new special needs plan was created that was designed to provide services only to people in a special needs category. For example, if a special needs plan was established to exclusively provide services to institutionalized individuals, and had no capacity to provide care to individuals not in a contracting institution, we would not expect the plan to allow an individual to remain enrolled in the plan if he or she no longer required institutional care.

In this case, unlike the grandfathered enrollees of an existing MA plan designated as a special needs plan, we would expect individuals to be informed before initial enrollment that they could only remain enrolled in this plan for so long as they remained institutionalized. If such a notice is given, we believe that a new special needs plan could require disenrollment when a person no longer had special needs status. Such a disenrollment would be pursuant to section 1851(e)(4)(B) of the Act, as the individual would "no longer be eligible" for that plan "because of a change in * * *circumstances. * *. *" (This would also be the basis for disenrollment of grandfathered

enrollees if we were to adopt the alternative reading of the word "serves," under which grandfathered enrollees could not remain enrolled because the plan could only provide services to special needs individuals.)

The statute also provides us with the authority to designate an MA plan to be a special needs plan if it "disproportionately serve[s] special needs individuals." Under our current interpretation of the word "serves," this would mean a plan that disproportionately enrolls special needs individuals. At a minimum, this would mean it enrolls special needs individuals in a proportion greater than such individuals exist in the area served by the plan. We invite comments on the question of whether this "minimum" definition would be appropriate, or whether there is another level of special needs enrollees (for example, 50 percent or more) that should be required in order to be considered a special needs plan under this "disproportionately serves" provision.

We note that under this provision as we are interpreting it, the plan would remain exempt from the requirement to enroll all MA eligible individuals, but would nonetheless enroll some MA individuals who are not special needs individuals. Operationally, this could be accomplished in a number of ways. For example, the plan could impose a cap on the number of non-special needs individuals enrolled at any point in time, or cap the number of special needs individuals served. It also might enroll two special needs enrollees for every one enrollee who does not meet the definition.

Other than the requirement that all MA eligible individuals be permitted to enroll, and—if we choose to waive it'the preclusion on enrolling individuals with ESRD, all other MA provisions would apply to specialized needs plans (for example, payment rules, appeal rights, quality assurance requirements, enrollment procedures).

3. Continuation of Enrollment for MA Local Plans (§ 422.54)

Section 1851(b)(1) of the Act is amended by section 222(l)(3)(A)(i) of the MMA to limit the offering of MA plan continuation areas to MA local plans only. We would revise § 422.54 to specify that this provision would apply only to local MA plans.

4. Enrollment in an MA MSA Plan (§ 422.56)

Section 1851(b)(4)(A) of the Act is amended by section 233 of the MMA to eliminate the cap on the number of individuals that may enroll in MA MSA plans and to make the program permanent by removing the enrollment cut-off date. While unchanged by the MMA, section 1851(b)(2) of the Act states that individuals enrolled in health benefit plans in the Federal Employees Health Benefit Plan, the Veterans Administration, or the Department of Defense may not enroll in an MSA until or unless the Director of OPM adopts policies to ensure that the enrollment will not result in higher government spending under these programs. While the existing exclusion of enrollees of other Federal programs is reflected in current regulations at § 422.56(b), the regulatory language does not provide for such individuals to be eligible following the adoption of new policies by OPM. We understand that the Office of Personnel Management's current policy is to encourage the creation of high deductible plans for Federal employees and retirees, and we will explore with OPM whether such a policy can now or in the future be certified to the Secretary. Therefore, we are revising the regulations to allow for that policy to be implemented in the future, as provided in the statute. We would revise § 422.56 to reflect these changes.

5. Election Process (§ 422.60)

We are proposing conforming changes throughout § 422.60, as in § 422.50(a)(5), to allow us to approve other election mechanisms in addition to paper forms. We are also streamlining § 422.60(e) to allow for notice options for MA plans other than the traditional mailing of a written document.

We are also proposing to clarify the regulation at § 422.60(b) to provide that MA organizations may submit requests to restrict enrollment for capacity reasons at CMS at any time during the year. There are several reasons why MA organizations may need to restrict enrollment for capacity reasons, especially those that are clearly outside of the MA organization's control. For instance, we have allowed capacity limits for certain organizations when a large competitor, in the same service area, has non-renewed its contract. The remaining contractor may not have the capacity to enroll a large percentage of its competitor's enrollees. Another example is a case in which an MA organization loses its contract with a large hospital system or physician group and thus can no longer handle the potential number of enrollees it previously estimated it could.

6. Election of Coverage Under an MA Plan (§ 422.62)

a. Annual Coordinated Election Period

Section 1851(e)(3)(B) of the Act is revised by sections 102(a)(2) and 102(a)(5) of the MMA to permanently establish the annual coordinated election period as November 15 through December 31 of each year. For 2006, the annual coordinated election period is extended through May 15, 2006.

b. Initial Coverage Election Period

Section 1851(e)(1) of the Act is amended to provide that, "if any portion of an individual's initial enrollment period under Part B occurs after the end of the annual, coordinated election period [for 2006, from November 15, 2005 to May 15, 2006], the initial enrollment period under this part shall further extend through the end of the individual's initial enrollment period under Part B."

We believe that this provision is intended to allow an individual who still has time to decide whether to enroll in Medicare Part B upon becoming eligible for Medicare to be able to enroll in an MA plan upon deciding to enroll in Medicare Part B. In using the words "further extend," we believe the Congress made clear that this new sentence was designed to expand upon the beneficiary's opportunity to choose to enroll in an MA plan by extending or lengthening the time the beneficiary has relative to the existing rules.

Accordingly, we are interpreting this sentence to apply only to the extent that its application would result in an extension of an initial enrollment period for an MA compared with the period that would apply if the sentence had not been added. Under the alternative interpretation, in which an MA initial enrollment period would end when the Medicare Part B initial enrollment period ends, individuals who defer Medicare Part B enrollment, such as those who decline enrollment while continuing to work, would be adversely impacted. The initial enrollment period for Medicare Part B is directly associated with an individual's eligibility for Medicare Part B, not with an individual's actual enrollment in Medicare Part B.

To ensure that an individual who is first eligible for MA has the full opportunity to elect an MA plan, we are interpreting the statute to provide for an initial coverage election period for MA that ends on the later of the day it would end under pre-MMA rules or the last day of the Medicare Part B initial enrollment period. The new sentence added to section 1851(e)(1) of the Act

accordingly would only extend an individual's MA initial election period, never reduce or eliminate it.

c. Open Enrollment Periods Through 2005

Section 1851(e)(2)(A) of the Act is amended to extend the open enrollment and disenrollment period through 2005, providing unlimited opportunities for MA eligible beneficiaries to enroll in, disenroll from, and or change enrollment in an MA plan. We would revise § 422.62(a)(3) to reflect this extension.

d. Open Enrollment Periods During 2006

Section 1851(e)(2)(B)(1) of the Act is revised to establish that the open enrollment period in 2006 will be the first 6 months of 2006. In addition, for individuals who first become eligible during 2006, an open enrollment period will be provided as the first 6 months the individual is MA eligible during 2006, but not to extend past December 31, 2006. After December 31st, 2006, all individuals are provided the 3-month open enrollment period from January through March, as provided in the next section.

e. Open Enrollment During 2007

Section 1851(e)(2)(C)(i) of the Act is changed to establish that the open enrollment period for 2007 and subsequent years will be the first 3 months of each year. In addition, for individuals who first become MA eligible during 2007 and subsequent years, an open enrollment period will be provided as the first 3 months the individual is MA eligible during the year, but not to extend past December 31, 2006. Although this specific period does not extend past December 31, it is important to remember that all individuals will be provided a 3 month open enrollment period from January through March, as discussed in this section.

A new clause is added to section 1851(e)(2)(C) of the Act that limits a change of election made during an open enrollment period in 2006 and later years to the same type of plan the individual making the election is already enrolled in. Specifically, an individual in an MA plan that does not provide drug coverage may only change to another similar MA plan, or to original Medicare, but may not enroll in an MA plan that provides Part D coverage, or enroll in a Part D plan. An individual enrolled in an MA plan that includes Part D coverage similarly may only enroll in another MA plan with Part D coverage, or change to original Medicare coverage with an election of a Part D plan. (We note that section 1851(e)(2)(C)(iii)(I) of the Act states that an individual who is "enrolled in an MA plan that does provide qualified prescription drug coverage," may only elect a plan that does not provide that coverage. A literal reading of this language would be in direct conflict with clause (II) of section 1851(e)(2)(C)(iii) of the Act, which says that an individual who is enrolled in an MA plan that provides qualified prescription drug coverage may not enroll in an MA plan that provides no Part D coverage.

This contradiction, plus (1) the fact that section 1851(e)(2)(C)(iii)(I) of the Act refers to a "another" MA plan that "does not" provide Part D coverage, (2) the fact that clause (I) is contrasted with clause (II) with the word "or", and (3) committee report language, make it clear that the word "not" was inadvertently omitted from the first clause of section 1851(e)(2)(C)(iii) of the Act.) Although the MMA and conference agreement are clear, we think that there may be some concern that the policy set forth in section 1851(e)(2)(C)(iii)(II) of the Act, as added by section 102(a)(6)(C) of the MMA, may be somehow inconsistent with the voluntary nature of the Part D program. Specifically, that policy would require a Medicare beneficiary who has changed their mind after initially electing Part D coverage through an MA plan to maintain drug coverage for the entire year, even if they decide during the open enrollment period that they do not want that coverage. (Of course, a Part D enrollee could always forego Part D coverage through a PDP by failing to pay premiums under the plan). We are soliciting comments from interested parties as to whether there is a way to interpret the statute, and whether it would be advisable, on a policy basis, to excuse the requirement that an enrollee who elects their option to disenroll from an MA–PD plan during an open enrollment period, enroll only in another MA plan with prescription drug coverage or enroll in fee-for-service Medicare with Part D coverage.

7. Coordination of Enrollment and Disenrollment Through MA Organizations (§ 422.66)

We would revise § 422.66 with conforming changes in keeping with our proposed clarification at § 422.50(a)(5) regarding election mechanisms other than, and in addition to, forms. As proposed in § 422.60(e), we are making similar changes in § 422.66(b) to provide for other notice mechanisms, as well as a more efficient notice process. This includes removing the requirement for MA plans to send a copy of the individual's disenrollment request back to the individual.

Section 1860D–21(b) provides the Secretary the authority to implement default enrollment rules at 1851(c)(3)(A)(ii) for the MA–PD program, which begins in 2006. If applied, these rules provide that an individual who is in a health benefits plan providing any prescription drug coverage will be deemed to make an election into an MA–PD offered by the same organization during the individual's initial election period surrounding Medicare entitlement. This statutory provision was originally created under The Balanced Budget Act of 1997 (BBA) for the Medicare+Choice (M+C) program. In developing regulations for the BBA, CMS decided *not* to default individuals to M+C plans offered by the same organization in which they were enrolled. Our rationale was that to implement such a process would require CMS to have access to information prior to the individual's initial coverage election period. Since we did not have access to the individual's information on health plans in which they were enrolled, we did not believe it would be feasible to implement a default process at that time.

Rather than implement a default enrollment process for these individuals who are enrolled in a health plan, we require (at section 422.66(d)(1) of our regulations) that an M+C plan offered by an M+C organization must accept any individual who is enrolled in a health plan offered by that M+C organization the month immediately preceding the month in which the individual becomes entitled to Part A and enrolled in Part B, as well as meeting the other M+C eligibility requirements. This requires an affirmative action by the individual; however it does not extend so far as to automatically enroll the individual (that is, "default") into the M+C plan.

In addition to our previous concerns regarding this provision, we are also concerned that, beginning in 2006, an individual's ability to choose his/her health care coverage will be limited to certain periods. Within these specified periods, an individual is limited to one election (either enrollment or disenrollment). If an individual makes an election of any type (including one by "default"), s/he is prohibited from making another choice until the next annual election period in November. Default enrollment may therefore limit an individual's choice by utilizing the individual's single election. In addition, automatically enrolling an individual assumes that the "default" plan would

be the plan that the individual would have chosen absent such a default process. This may not be the case. Given the variety of potential options available to these individuals, and the implications of choosing those options (including penalties for late enrollment in Part D), we must carefully consider the consequences of implementing a default enrollment process.

We must also carefully consider the implications a default enrollment process may have on individuals enrolled in employer groups. For example, such a process could conflict with the incentives that the MMA will provide to employers to encourage them to maintain creditable coverage for their employees. Such a provision could negatively impact married individuals enrolled in employer group plans if an individual has just become entitled to Medicare (and is enrolled in plan under default enrollment) while his or her spouse, who is already entitled to Medicare, receives coverage through the employer group in another health plan. On the other hand, we may learn from system processes we are establishing under the new Medicare-approved discount drug plan, such as data sharing with the States and other agencies. We could consider offering MA plans the option to establish a process with its employers to automatically enroll individuals, with an option for individuals to decline before enrollment. We recognize that any strategies to streamline and improve enrollment could lead to an overall reduction in costs. These are all important issues that must be carefully considered.

Since the Secretary has the discretion to not implement the default enrollment provision, we would continue to require affirmative elections by the individual upon becoming entitled to Medicare as provided under § 422.66. This ensures that individuals have the ability to remain with the organization that offers their health plan and protects beneficiary choice by requiring an individual to make an affirmative election. However, we encourage input from the public on this provision given the new Part D program, including the benefits, as well as the impact of implementing such a provision.

We would implement new rules for continuing MA coverage for individuals enrolled in MA plans as of December 31, 2005. Under section 1860D–21(b)(2), individuals enrolled in an MA plan that, as of December 31, 2005, provides any prescription drug coverage, would be deemed to be enrolled in an MA–PD plan offered by that same organization as of January 1, 2006. If an individual is enrolled with an MA organization that offers more than one MA plan that includes drug coverage, and is enrolled in one of those plans as of December 31, 2005, the individual would be deemed to have elected to remain enrolled in that plan on January 1, 2006 if it becomes an MA–PD plan on that date. An individual enrolled in an MA–PD plan on December 31 of a year would be deemed to elect to remain enrolled in that plan on January 1 of the following year (that is, the next day). We would revise § 422.66(e) to add language that incorporates these changes.

8. Effective Dates of Coverage and Change of Coverage (§ 422.68)

To coordinate the effective date of elections with the new special annual coordinated election period, section 1851(f)(3) of the Act is amended by establishing that the effective date of elections for the annual coordinated election period do not apply during the 2006 special annual election period, when enrollment will be effective on the first day of the month following the month in which an election is made. We propose to revise § 422.68(b) to provide for this coordination and make the effective date of elections in the annual coordinated election period for 2006 that are made in 2006 (that is, from January 1–May 15, 2006) the first day of the calendar month following the month in which the election is made.

9. Disenrollment by the MA Organization (§ 422.74)

We are clarifying the regulation at § 422.74(d)(1) regarding disenrollment for nonpayment of premium to provide more flexibility to MA plans in developing rules for those individuals who fail to pay their basic and supplementary premiums. Under the current regulations at § 422.74(d)(1), MA plans are required to provide, at minimum, a 90-day grace period before disenrolling individuals for failure to pay the premium. Thus, MA plans must maintain enrollment for individuals who do not pay their premiums for more than 90 days. We propose to provide greater flexibility to MA organizations by replacing the 90-day grace period in § 422.74(d)(1) with the approach taken in § 417.460(c)(1), which governs disenrollment from HMOs with cost contracts under section 1876. Cost HMOs must take certain actions before an individual may be disenrolled for nonpayment of premium, including demonstrating a reasonable effort was taken to collect the monies and providing the individual with written notice. While no specific timeframe dictates the process, certain steps must be taken. Generally, this process takes at least 30 days before a disenrollment is effective, given that disenrollments are effective the first of the month. Similarly, we propose to remove the mandatory timeframe before disenrollment would occur, focusing on the required and important steps that still must be taken. Such steps would continue to include requiring that proper notice be provided to individuals before that action is taken, and the MA organization would have to be able to demonstrate to us that it has made reasonable efforts to collect unpaid premium amounts. The notice would also inform the enrollee of his or her rights under the organization's grievance procedures. These revisions would not, however, preclude organizations from offering a more generous grace period than provided in the regulation, if they so choose.

Current regulations at § 422.74(d)(2) generally prevent an individual from being disenrolled from an MA plan if his or her behavior is related to "diminished mental capacity." While we originally intended this provision to protect the rights of individuals with mental illness, the language requiring that the individual's behavior not be related to diminished mental capacity has proven to be overly broad. The unintended impact of the current regulations has been to prohibit disenrollment of individuals whose violent and threatening behavior put the health and safety of enrollees, staff, and the public at risk. Therefore, we are amending the regulation by revising § 422.74(d)(2) to ensure due process and beneficiary protections, while at the same time protecting the health and safety of that individual as well as others. The changes include redefining disruptive behavior as "disruptive or threatening," as well as retaining the "unruly, abusive, or uncooperative" language. The revised provision would also require that the behavior be by an individual with "decision-making capacity," meaning someone with the ability to understand the consequences of his or her behavior. In addition, we are proposing limiting re-enrollment in the MA program he or she has been disenrolled from under this provisions, as well as a provision to provide for expedited disenrollment in cases where there is an immediate threat of health and safety to others.

M+C organizations and providers also have expressed concern regarding nonpayment of cost sharing, including co-payments, for health plan services. The statute specifically permits individuals to be disenrolled for non-payment of premiums, but it does not

provide for disenrollment due to nonpayment of cost-sharing. This has proven increasingly problematic since M+C organizations and providers have no effective mechanism to deal with individuals who repeatedly refuse to meet their cost-sharing responsibilities, potentially resulting in disruptions to the plan's ability to maintain its provider network. Thus, we are considering new regulatory language that would include nonpayment of cost sharing as "noncompliant" behavior under the disruptive behavior provisions because it limits the health plan's ability to provide services both to the individual and potentially to other enrollees. Although we are not proposing specific regulatory language at this time, we invite comments on adopting an interpretation of nonpayment of cost sharing as "disruptive behavior," as well as comments on the elements that we propose to include in language. As part of the regulation, we intend to require the policy be applied consistently, however, we would be clear that an exception would prohibit low-income individuals from being disenrolled under this provision. We would also indicate that the cost-sharing amount must represent a "significant" cumulative amount and that the MA plan would be expected to have an established threshold that would be approved by CMS. CMS envisions MA organizations would submit such thresholds at the time their annual payment rates are submitted to CMS for approval. In addition, we propose to include that the behavior must be based upon a repeated failure to pay cost sharing. Since the language for disenrollment for nonpayment of cost sharing would fall under the regulations for disruptive behavior, the process for disruptive behavior as provided in regulations and in manual instructions would be applied, including: required approval by CMS before such disenrollment is permitted and beneficiary notice requirements. This would also require plans to offer payment agreements with the beneficiary as part of the requirement under disruptive behavior to make a serious effort to work with the beneficiary. We may include guidance on this matter in a final regulation based upon comments received.

10. Approval of Marketing Materials and Election Forms (§ 422.80)

We have in place a program that recognizes consistent compliance with marketing guidelines by providing for streamlined approval of marketing materials submitted by organizations that have demonstrated compliance. Called the "File and Use" program, organizations that have demonstrated to us that they continually meet a specified standard of performance will have certain types of marketing materials (such as advertising materials or other materials that do not describe plan benefits) deemed to be approved by us if they are not disapproved within 5 days of submission to us for prior approval. Thus, under these circumstances, organizations only need to submit material for our approval 5 days befor its distribution.

The advantages of File & Use are that the organization can decrease the time it takes to begin using certain marketing materials and improve planning and budgeting for publication of these materials.

In addition, we are making the time frames under § 422.80(e)(5) consistent with those provided under § 422.80(a)(1). Currently, under § 422.80(a)(1), the review period for marketing materials is at least 45 days, unless using model materials provided by CMS, in which case the review period is decreased to no more than 10 days. However, the standards for M+C marketing under § 422.80(e)(1)(v) refer only to the 45-day period. Hence, we will now add a reference to the 10 day period in this section to be consistent with § 422.80(a)(1).

We are also making clarifying changes under those marketing activities the MA plans may not participate in, such as specifically using the term "targeted marketing" when discussing discriminatory activities and engaging in any marketing activity that CMS prohibits in its marketing guidance.

Finally, while all entities in which CMS does business with are required to adhere to all Federal laws, with regard to marketing, it is important to refer here to section 1140 of the Act prohibiting the misuse of symbols, emblems, or names in reference to Social Security or Medicare. While we have not reiterated this provision in our proposed rule, we believe that it is important to highlight this reference in the discussion of marketing requirements.

Subpart C—Benefits and Beneficiary Protections

(If you choose to comment on issues in this section, please include the caption "Subpart C—Benefits and Beneficiary Protections" at the beginning of your comments.)

In the areas of benefits and beneficiary protections, we are proposing regulatory reforms based on our program experience, as well as provisions implementing new requirements in the MMA. We have tried in these proposed rules to integrate new requirements in the MMA with existing regulations, while at the same time removing impediments in the existing rules that have tended to stifle innovation and, in some extreme cases, have caused Medicare+Choice organizations to nonrenew their contracts or reduce service areas in which they offer Medicare+Choice plans. We have done all this while keeping foremost in our consideration the paramount task of ensuring that beneficiaries continue to be fully informed and protected in their receipt of essential health care services under the Medicare program.

The regulatory reforms we are proposing include: (1) New beneficiary protections in cases in which an MA organization offers an "in-network" point-of-service (POS) option; (2) revisions to the rules limiting beneficiary cost sharing related to emergency episodes, (3) the elimination of administratively burdensome requirements on MA plans that are duplicative of activities already conducted by us, and (4) the elimination of a number of unnecessary, duplicative, or overly burdensome access to care provisions.

We also are proposing new rules that would apply only to MA regional plans, which are created under the MMA. These rules would afford specific additional protections to Medicare beneficiaries that enroll in those plans. For instance, MA regional plans must provide for catastrophic limits, or stop-loss, on beneficiary out out-of-pocket cost-sharing amounts related to original Medicare benefits received in and out of the MA regional plan's network of providers.

Finally, we propose regulations implementing incentives for MA regional plans to serve all areas. These incentives involve a new payment mechanism for "essential hospitals." We also provide for special access to care rights for enrollees in MA regional plans related to out-of-network cost sharing.

1. General Requirements (§ 422.100)

Section 233(c) of the MMA amended section 1852(k)(1) of the Act to include enrollees in MSA plans offered by an MA organization with MA coordinated care plans described in section 1851(a)(2)(A) of the Act as having protection from balance billing by non-contracting providers. A physician or other entity that does not have a contract with an MSA plan is now required to accept as payment in full,

for covered services provided to an MSA plan enrollee, the amount the physician or other entity could have collected had the individual not been enrolled in the MSA plan.

This provision applies to physicians and other entities, but not to providers of services. For purposes of this portion of the preamble discussion, "provider of services" has the same meaning as "provider of services" defined in section 1861(u) of the Act. Providers of services are covered by section 1866(a)(1)(O) of the Act related to charges they can impose on a Medicare Advantage plan enrollee when the provider of services does not have a contract with the Medicare Advantage organization sponsoring the plan in which the beneficiary is enrolled.

In cases in which participating physicians do not have an agreement in place governing the amount of payment, and treat beneficiaries enrolled in a coordinated care plan described in section 1851(a)(2)(A) of the Act or an MSA plan, they must accept the amount they would have received under fee-for-service Medicare as payment in full. Generally, the amount they would receive under fee-for-service Medicare is based on the participating physician fee schedule and includes both the amount paid by the Medicare carrier as well as the cost-sharing (generally 20 percent) due from the fee-for-service beneficiary or another source (that is, a Medigap plan).

In cases in which non-participating physicians do not have an agreement in place governing the amount of payment, and treat beneficiaries enrolled in a coordinated care plan described in section 1851(a)(2)(A) of the Act or an MSA plan, they also must accept the amount they would have received under fee-for-service Medicare as payment in full. Additionally, non-participating physicians are permitted to accept assignment on a case-by-case basis. If they do accept assignment on a claim, then the amount a non-participating physician must accept as payment in full is generally the non-participating fee-schedule amount. Non-participating physicians that do not accept assignment on a claim can generally balance bill up to, but no more than, 115 percent of the non-participating physician fee schedule amount. This limit on charges is known as the "limiting charge."

These fee-for-service billing limits have always applied to charges that providers and other entities could impose when providing covered services to enrollees in MA coordinated care plans where there is no agreement in place governing the payment amount. The MMA adds the same protections for MSA plan enrollees.

MSAs are "high deductible" MA plans and are defined at section 1859(b)(3) of the Act. Until the deductible is met, the MSA enrollee is generally responsible for payment of all covered services. Once the deductible is met, the MA organization offering the MSA plan is responsible for payment of 100 percent of the expenses related to covered services. In both cases, whether it is the enrollee or the MSA that assumes responsibility for payment, providers and other entities are required to accept the amount that fee-for-service would have paid as payment in full. We are also proposing to make conforming changes to § 422.214 to account for this new beneficiary protection for MSA enrollees.

To address this MMA requirement and other changes in the MMA and for purposes of administrative simplification and clarification, we propose the following provisions:

- We would delete the parenthetical "(other than an M+C MSA plan)" from the first sentence of § 422.100(b)(2) and replace it with "(and an MA MSA plan, after the annual deductible in § 422.103(d) has been met)."
- We would modify the reference to "additional benefits" in § 422.100(c), as those benefits are no longer applicable to MA plans offered on or after January 1, 2006.
- We would remove § 422.100(e), as it is duplicative of § 422.111(b)(2), and we would accordingly redesignate paragraphs (f) through (j) as paragraphs (e) through (i), respectively.
- We would remove the reference to operational policy letters in § 422.100(f), as instructions on benefit policy guidelines and requirements have been incorporated into the Medicare Managed Care Manual and other written instructions.
- We would add "or encourage disenrollment" to § 422.100(f)(2) after "discourage enrollment," as one of the prohibitions on the design of benefit packages.

2. Requirements Relating to Basic Benefits (§ 422.101)

Section 221 of the MMA adds a new section 1858 to the Act. Section 1858(g) of the Act provides for a special rule related to the way local coverage determinations (for example, "local medical review policies," or "LMRPs") will be applied by MA regional plans. MA regional plans are permitted to elect any one of the local coverage determinations that applies to original Medicare fee-for-service beneficiaries in any part of an MA region to apply to its enrollees in all parts of an MA region. Application of these local coverage determinations by an MA regional plan may be appealed under provisions of section 1869(f)(2) of the Act.

We interpret section 1858(g) of the Act to mean that the MA regional plan, if it chooses to exercise this option, must elect a single fee-for-service contractor's local coverage determination that it will apply to all members of an MA regional plan. The MA organization offering an MA regional plan may not select local coverage policies from more than one fee-for-service contractor that it will apply to all members of the plan. We invite comment on this interpretation and our proposed policy related to it.

We propose the following provisions:

- We would add a new § 422.101(b)(4) related to election of a local coverage determination by MA regional plans to provide for new language in section 221 of the MMA.
- We would remove reference to operational policy letters (OPLs) in § 422.101(b)(2), as all OPLs related to general coverage guidelines have been incorporated into the Medicare Managed Care Manual and other written instructions.

The MMA provides for new cost-sharing requirements in the statute at section 1858(b) of the Act related to MA regional plans. There are three specific requirements:

1. MA regional plans, to the extent they apply deductibles, are permitted to have only a single deductible related to combined Medicare Part A and Part B services. Applicability of the single deductible may be differential for specific in-network services and may also be waived for preventative services or other items and services.

2. MA regional plans are required to have a catastrophic limit on beneficiary out-of-pocket expenditures for in-network benefits under the original fee-for-service program (Medicare Part A and Part B benefits).

3. Regional MA plans are required to have an additional catastrophic limit on beneficiary out-of-pocket expenditures for in-network and out-of-network benefits under the original fee-for-service program. This second out-of-pocket catastrophic limit, which would apply to both in-network and out-of-network benefits under original Medicare, could be higher than the in-network catastrophic limit, but may not increase the limit applicable to in-network services.

We propose to make MA regional plans responsible for tracking these beneficiary out-of-pocket limits and for notifying members when they have been

met. We also propose to require MA regional plans to track and limit incurred rather than paid out-of-pocket expenses.

• We would add § 422.101(d) to account for these new cost-sharing requirements.

The MMA also adds new section 1859(b)(4) to the Act. MA regional plans are required to provide reimbursement for all covered benefits, regardless of whether the benefits are provided within or outside the network of contracted providers.

MA regional plans are preferred provider organizations (PPOs) and are defined at section 1859(b)(4) of the Act. (However, it should be noted that the statute does not preclude HMOs and other entities from offering other MA plan types on a region-wide basis, nor does it preclude other entities from offering MA regional plans as long as these plans meet statutory and regulatory requirements related to MA regional plans including, but not limited to, sections 1859(b)(4), 1851(a)(2)(A), and 1858(b) of the Act.) As PPOs, MA regional plans are permitted to impose differential cost sharing related to non-emergent services received from non-network providers. To the extent differential cost-sharing is part of the benefit package, the MA regional plan would generally be responsible for its portion of payment to a non-network provider and the enrollee would be responsible for the remainder—up to the limits discussed in item 2 and 3 of this part of the preamble.

In applying the actuarially equivalent level of cost sharing with respect to MA bids related to benefits under the original Medicare program option set forth under § 422.308, only the catastrophic limit on out-of-pocket expenses for in-network benefits (item 2 above) is to be taken into account.

We would accommodate these requirements related to MA regional plans by adding a § 422.101(e) to this section.

3. Supplemental Benefits (§ 422.102)

An MA plan may reduce cost sharing below the actuarial value specified in section 1854(e)(4)(B) of the Act as a mandatory supplemental benefit. Beginning in 2006, an MA plan can reduce the cost sharing that applies to plan members below the value that would apply to these members if they remained enrolled in the original Medicare program. This reduction in cost sharing can be included as a mandatory supplemental benefit. We propose the following provisions:

• We would add § 422.102(a)(4).

• We would remove the reference to "additional benefits" in § 422.102(a)(1), as those benefits are no longer applicable to MA plans offered on or after January 1, 2006.

• We would remove the reference to operational policy letters (OPLs) in § 422.102(a)(3), as guidelines related to benefits that had been contained in OPLs have been incorporated into regulation, into the Medicare Managed Care Manual, or into other instructions.

4. Benefits Under an MA MSA Plan (§ 422.103)

We would remove the extraneous word "under" from the second sentence of paragraph (a).

5. Special Rules for Point of Service Option (§ 422.105)

"Point of Service" (POS) is an option in some plans that allows enrollees to use providers who are not preferred, on a fee-for-service basis. To clarify an issue that has created confusion for both beneficiaries and MA organizations, we propose to include the following statement as introductory text to § 422.105 of the regulation:

"If an MA organization does not offer a POS benefit to members of a plan, or if it offers a POS benefit as an optional supplemental benefit and the member has not selected that benefit, then when those members receive what is a covered item or service from contracted providers of that plan, the member cannot be financially liable for more than the normal in-plan cost sharing, if the member correctly identified himself or herself as a member of that plan to the contracted provider before receiving the covered item or service."

We believe that indemnifying the Medicare member in such a situation conforms with normal industry practice and also clarifies our long-standing policy that members cannot be held financially liable when contracting providers fail to follow or adhere to plan referral or pre-authorization policies before providing covered services. If a plan member insists on receiving what would otherwise be covered services from a contracted provider (but for the lack of a referral or pre-authorization), then the contracted provider would be required to inform the member that those services will not be covered under the plan. The provider would also be required to document the medical record as to why the services are medically necessary but not available through the plan.

In addition, an MA regional plan might choose to provide for a POS–LIKE benefit where beneficiary cost sharing would be less than it would otherwise be for non-network provider services, but where it still might be greater than it would be for in-network provider services. We propose the following provisions:

• We would remove the extraneous word "only" from § 422.105(a)(1) and § 422.105(a)(2), and we would modify § 422.105(a)(1) to account for the fact that beginning January 1, 2006, there will no longer be any additional benefits under the MA program.

• We propose to add § 422.105(a)(4) to clarify that although an MA regional plan may offer a POS–LIKE benefit to members, it still may not deny reimbursement for *any* covered benefit, regardless of whether such benefit is provided within the network of contracted providers.

6. Coordination of Benefits With Employer Group Health Plans and Medicaid (§ 422.106)

Section 222(j) of the MMA revised section 1857(i) of the Act in order to facilitate employer sponsorship of MA plans. Specifically, section 222(j)(1) of the MMA redesignated existing section 1857(i) of the Act as section 1857(i)(1) of the Act and adds a new sub-heading—"Contracts with MA Organizations." Section 222(j)(2) of the MMA created a new section 1857(i)(2) of the Act with a sub-heading of "Employer Sponsored MA Plans."

Section 222(j)(2) of the MMA allows us to waive or modify requirements that hinder the design of, the offering of, or the enrollment in an MA plan offered by an employer, a labor organization, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof), or members or former members (or combination thereof) of labor organizations. Section 222(j) of the MMA further states that the MA plan may restrict enrollment to individuals who are beneficiaries and participants in such a plan.

We propose a new paragraph (d) to account for this new statutory authority, which is effective for plan years beginning on or after January 1, 2006. We would also revise the paragraph heading for existing paragraph (c) to "Waiver or modification of contracts with MA Organizations." In addition, we make editorial corrections to the first sentence of paragraph (c)(2) and to remove the second sentence. We remove the second sentence of paragraph (c)(2) because we believe that instructions related to the specific manner in which ACRs or bids are to be filed and specific requirements related to the filings are

better suited to manual instructions and other written instruments.

- We would revise the paragraph (c) heading.
- We would make editorial corrections to paragraph (c)(2).
- We would add a new paragraph (d) to allow for employer sponsored MA plans effective January 1, 2006.

7. Medicare Secondary Payer (MSP) Procedures (§ 422.108)

Section 232 amended section 1856(b)(3) of the Act to remove all ambiguity related to State authority over the MA program. Congressional intent is now unambiguous in prohibiting States from exercising authority over MA plans in any area other than State licensing laws and State laws relating to plan solvency. Therefore, we would amend paragraph (f) to remove language that suggests States can limit the amount an MA organization can recover from liable third parties under Medicare secondary payer procedures. Consistent with specific preemption authority now provided by section 1856(b)(3) of the Act, MAs are permitted by section 1852(a)(4) of the Act to *fully* recover from liable third parties according to section 1862(b)(2) of the Act.

We would amend paragraph (f) of § 422.108 to account for enhanced preemption authority provided by section 232 of the MMA.

8. Effect of National Coverage Determinations (NCDs) (§ 422.109)

Section 1853(c)(7) of the Act requires us to "adjust" MA payments when a national coverage determination (NCD) or legislative change in benefits will result in a significant increase in costs to MAs. We have historically interpreted what constituted "significant" costs in regulation at § 422.109, where the costs of a coverage change are considered "significant" if either the average cost of providing the service exceeds a specified threshold, or the total cost for providing the service exceeds an aggregate cost threshold.

In a final rule published on August 22, 2003, at 68 FR 50839, we amended § 422.109 to refine the definition of "significant" cost to include a new test. By adding a new paragraph at the end of § 422.109(a)(2), we provided that, for purposes of determining whether to make an additional payment adjustment under § 422.256, the tests for reaching the "significant" cost threshold were to include the aggregate costs of all NCDs and legislative changes in benefits made in the prior contract year.

Under this new test, the "average cost" of every NCD and legislative change in benefits for the contract year would have been added together. If the sum of all these average amounts exceeded the threshold under § 422.109(a)(1), then an adjustment to payment would have been made in the following contract year under § 422.256 to reflect this "significant" cost. Alternatively, if the costs of the NCDs and legislative changes in benefits, in the aggregate, exceeded the level set forth in § 422.109(a)(2), an adjustment to payment would also have been made under § 422.256 on that basis.

Among the reasons for the above change, as noted in the preamble to the August 22, 2003 final rule, was that even when the "significant" cost threshold had been met under the existing definition, the methodology then employed for making a payment adjustment under section 1853(c)(7) of the Act did not result in an adjustment in the capitation rate in those counties with the "minimum" update rate (the so-called "2 percent minimum update" counties paid under section 1853(c)(1)(C)) of the Act. In accordance with section 1853(c) of the Act, the CMS Office of the Actuary used the annual growth rate to update only the floor and blended rates, so the "minimum" 2 percent update rate, which was 102 percent of the prior year's rate, did not reflect the costs of new benefits effective in the middle of the previous payment year. Therefore, we decided that payments in counties in which payment was based on the "minimum" 2 percent update rate were not appropriately adjusted to reflect new coverage costs as required by section 1853(c)(7) of the Act.

The MMA has changed the "minimum" percentage payment prong of the former M+C payment methodology by adding a new basis for a minimum update. The "minimum" percentage increase rate is changed, effective January 2004, as follows: Instead of being set at 102 percent of the prior year's rate, the minimum increase rate will now be the *greater of* 102 percent of the prior year's rate, or the annual MA growth percentage. This means that under the MMA, the minimum percentage increase rate (the so-called "minimum 2 percent rate") will now reflect the cost of mid-year NCDs and legislative changes in benefits. These costs are now automatically built into the annual MA growth percentage and will no longer require an additional adjustment under § 422.256.

Therefore, we are proposing to revise the regulatory change established in the August 22, 2003 final rule, in order to implement this new MMA payment provision that became effective January 1, 2004. Specifically, the changes to § 422.109 and § 422.256, which established a new "NCD adjustment factor" effective CY 2004, which was to be added to the county rates in counties receiving the "minimum" 2 percent update, will be eliminated. We propose the following provisions:

- We would remove the final paragraph of § 422.109(a)(2).
- We would amend § 422.109(a)(2) to remove "all" from the first clause of the first sentence.

The "national standardized annual capitation rate" described in § 422.254(f) is already an average and does not need to be further "normalized" by multiplication "by the total number of Medicare beneficiaries for the applicable calendar year."

- We would remove the portion the first sentence of § 422.109(a)(2) to remove all language after "§ 422.254(f)."
- We would revise § 422.109(c)(3) to read: "Costs for significant cost NCD services or legislative changes in benefits for which our fiscal intermediaries and carriers will make payment are those Medicare costs not listed in paragraphs (c)(2)(i) through (c)(2)(iv) of this section."
- We would remove paragraphs (c)(3)(i) and (c)(3)(ii).

9. Discrimination Against Beneficiaries Prohibited (§ 422.110)

We would make the following correction to this section, to bring it into conformance with § 422.50(a)(3)(ii). We would modify paragraph (b) to say that if an MA organization chose to apply the rule in § 422.50(a)(3)(ii) and allowed individuals who are enrolled in a health plan offered by the organization at the time of first entitlement to Medicare, but residing outside the MA plan's service area, to remain enrolled that such an allowance would also need to be applied to individuals with end-stage renal disease.

The new paragraph (b) would read:

(b) *Exception.* An MA organization may not enroll an individual who has been medically determined to have end-stage renal disease. However, an enrollee who develops end-stage renal disease while enrolled in a particular MA organization may not be disenrolled for that reason. An individual who is an enrollee of a particular MA organization, and who resides in the MA plan service area at the time he or she first becomes MA eligible, or, an individual enrolled by an MA organization that allows those who reside outside its MA service area to enroll in an MA plan as set forth at § 422.50(a)(3)(ii), then that individual is considered to be "enrolled" in the MA

organization for purposes of the preceding sentence.

We would remove paragraph (c), as it is duplicative of a requirement appearing in § 422.502(h) of the current MA regulation. In the subpart K section of this preamble related to § 422.502(h) (redesignated as § 422.504(h)), we explain why we are proposing to modify the language currently found there.

10. Disclosure Requirements (§ 422.111)

When the Balanced Budget Act of 1997 introduced the M+C program, the Annual Coordinated Election Period was established as the month of November. In subsequent legislation, the Annual Coordinated Election Period for years after 2001 was changed to November 15 through the end of December. We propose that rather than changing the date in § 422.111(d)(2) to a "date certain," we would leave the date flexible—should the Congress again decide to change the date on which the Annual Coordinated Election Period begins. Additionally, this proposed change is consistent with section 1851(d)(2)(A) of the Act, the authority for this regulatory requirement. The intent of section 1851(d)(2)(A) of the Act and § 422.111(d)(2) of the regulation is simply to provide notice to plan members of impending changes to plan benefits, premiums, and copays in the coming year. That notice is to be provided at least 2 weeks before the onset of the Annual Coordinated Election Period as a means of ensuring that plan members will be in the best possible position to make an informed choice on continued enrollment in or disenrollment from that plan.

Section 422.111(d)(2) would be modified to say that plan members need to be notified of January 1 changes at least 15 days before the Annual Coordinated Election Period defined in section 1851(e)(3)(B) of the Act.

Section 422.111(c)(1) states that an MA plan must disclose the information in § 422.111(f) upon request to individuals eligible to elect an MA plan.

We would remove § 422.111(f)(4), as the requirement to provide information on Medigap and Medicare Select as a Secretarial responsibility under section 1851(d)(2)(A)(i) and (d)(3)(D) of the Act and is to occur as part of the "open season notification" required by section 1851(d)(2)(A) of the Act.

In addition to an "open season" notification, information on Medigap and Medicare Select is available year-round from the Federally funded State Health Insurance Assistance Program (SHIP) and the 1–800 MEDICARE telephone number. Both the local SHIP and the 1–800 MEDICARE telephone numbers are prominently displayed in MA plan literature. In addition, we will continue to require MA plans to publicize the availability of information on Medigap, Medicare Select, and other MA plans through appropriate CMS information channels. This will not only remove unnecessary administrative burden, but it will also ensure that reliable, accurate, and complete information is made available to those seeking it.

Since the introduction of *http://www.medicare.gov* in 1998, we have substantially increased the amount of personalized information available to Medicare beneficiaries, making it one of the government's most comprehensive and customer-oriented sites available to the public. The web site hosts twelve separate database applications to help individuals make their own health care decisions. The most significant ones are: the Medicare Personal Plan Finder (which contains costs, benefits, quality, satisfaction and disenrollment measures), Nursing Home Compare (which contains basic characteristics, staffing information and inspection results), the Prescription Drug and Other Assistance Programs application (which contains the most extensive, nationally complete listing of the Medicare-approved discount drug cards, including price comparisons, as well as other government and private programs designed to help with prescription drug costs), and the Medicare Eligibility Tool (which assists users in determining when they are eligible, how to enroll and what they need to consider when joining Medicare). Other tools providing customized results include: the Participating Physician and Supplier Directories, Home Health and Dialysis Facility Compare, Your Medicare Coverage, Helpful Contacts, Publications, and Frequently Asked Questions. By updating all information on the web site at least once a month, the information provided to Medicare beneficiaries via *http://www.medicare.gov* is the most reliable and consistent information available.

Much of the information available through *http://www.medicare.gov* is also available via the 1–800 MEDICARE helpline. 1–800 MEDICARE is a major information channel for providing the most personalized and reliable information to people with Medicare. As a result of the MMA, we are receiving the largest call volume ever for 1–800 MEDICARE. The beneficiary can call 1–800 MEDICARE to find out the most reliable information on public and private programs that offer discounted or free medication, programs that provide help with other health care costs, and Medicare health plans that include prescription coverage. The caller can always talk to a live person at 1–800 MEDICARE to get the facts they need. When a beneficiary calls 1–800 MEDICARE, we can send them a personalized brochure that allows them to look at discount cards based on their drug needs and their preferences about how to get their medicines, and their enrollment forms. We can also give the beneficiary personalized brochures containing information on their health plan choices, nursing homes and Medicare participating physicians in their area.

1–800 MEDICARE is available 24 hours a day, 7 days a week, to provide the one-on-one service that our Medicare beneficiaries need to make appropriate health care decisions.

We would also remove § 422.111(f)(6), since this is also a Secretarial responsibility under section 1851(d)(2)(A)(ii) of the Act and is also to occur as part of the Secretarial "open season notification." We propose the following provisions:

- We would redesignate paragraph (f)(5) as paragraph (f)(4), and we would redesignate paragraphs (f)(7) through (f)(11) as paragraphs (f)(5) through (f)(9).
- We would remove a portion of the existing paragraph (f)(7)(iv) and all of paragraph (f)(7)(v) (the new paragraphs (f)(5)(iv) and (f)(5)(v)) to remove the requirement that MAs and MSAs provide comparative information related to other MA plans. The new paragraph (f)(5)(iv) would read, in full: "In the case of an MA MSA plan, the amount of the annual MSA deposit." The new paragraph (f)(5)(v) would be deleted. The existing paragraphs (f)(7)(vi) through (f)(7)(viii) would be redesignated as paragraphs (f)(5)(v) through (f)(5)(vii).
- We would change "contracted is terminating" to "contract is terminating" in the second sentence, just before the comma, in § 422.111(e).

To prevent what might otherwise be the unreasonable result that MA regional or national plans would be required to provide comprehensive lists of contracting providers to all enrollees, we propose to modify paragraph (b)(3) in this section. We will, however, specifically require MA organizations to provide information on contracted providers in other geographic areas to enrollees who plan to travel (for instance) by adding a new paragraph (f)(10), requiring MA organizations to provide detailed information on contracted providers in other areas upon request.

- We would modify paragraph (b)(3) by inserting "reasonably be expected to"

between "may" and "obtain" in the first sub-clause of the first full sentence, so it would read: "The number, mix, and distribution (addresses) of providers from whom enrollees may *reasonably be expected to* obtain services;"

- We would add a new paragraph (f)(10), which would read: "The names, addresses, and phone numbers of providers from whom the enrollee may obtain in-network coverage in other areas."

Section 1851(d)(3)(F) of the Act, as modified by the MMA, would require MA regional plans to provide members an annual description (at the time of enrollment and annually thereafter) of the catastrophic stop-loss coverage and single deductible (if any) applicable under the plan. We would add a new paragraph (b)(11) to account for this.

- We would change the existing paragraph (f)(11) (the new paragraph (f)(9)) related to supplemental benefits to read: "*Supplemental benefits.* Whether the plan offers mandatory and optional supplemental benefits, including any reductions in cost sharing offered as a mandatory supplemental benefit as permitted under section 1852(a)(3) of the Act (and implementing regulations at § 422.102) and the terms, conditions, and premiums for those benefits."
- In § 422.111(c)(1), we would insert "in" between "required" and "paragraph."

The Internet has proven to be an inexpensive and widely available source of information on health plans. Almost all FEHB insurance plans, most large employer plans, and commercial HMOs maintain websites for the convenience of enrollees. Many MA organizations also currently provide information on the MA plans they offer on websites available through the Internet.

We currently require MA plans to communicate with us via electronic media—§ 422.502(b) (redesignated as § 422.504(b)). Finally, all MA coordinated care plans would be required to offer Part D drug benefits to the enrollees of at least one of their plans and as part of that offering will be required to maintain formulary and other information on an Internet Web site.

Therefore, pursuant to our authority under section 1856(b) of the Act to establish standards by regulation, we are considering imposing a requirement that all MA plans set up an Internet Web site that will make basic MA plan information and materials available to interested Medicare beneficiaries and other parties. The basic information and materials could include the Evidence of Coverage, the Summary of Benefits, and information (names, addresses, phone numbers, specialty) on the network of contracted providers. Those Internet materials and information would duplicate materials already produced in print format and made available by MA organizations relative to the MA plans they offer. We are interested in receiving comments on whether or not such a requirement should become part of the MA regulation.

11. Access to Services (§ 422.112)

There are no new access standards for MA regional plans, and existing MA standards will generally apply. An important provision (discussed below) will likely improve access to hospital services for MA regional plan enrollees. In attempting to create region-wide networks, MA regional plans will be forced to bargain with hospitals, that are, in effect, the only hospital (or the only hospital with a particular service or services) in a broad area. Such a hospital would have what some call "monopoly power" in negotiating with plans that are, in effect, forced to contract with it in order to secure an adequate network of contracted providers with which to serve anticipated Medicare enrollees. The MMA attempts to address this situation through a provision that would make limited funds available to supplement payments to such hospitals.

While we reviewed our existing regulatory requirements related to network adequacy and propose to remove some that are either duplicative or, in our view, overly onerous without a resultant payoff in beneficiary protections, we have retained our core requirements. We expect competition to be the best method for ensuring network adequacy, as enrollees will favor and enroll in plans with more extensive networks and tend to avoid those without. Note that we will continue to require MA organizations to make a list of network providers available to prospective enrollees prior to enrollment. Finally, Medicare beneficiaries can simply choose to remain in the original Medicare fee-for-service program, if they cannot find an MA plan that meets their needs.

We note that the Office of Personnel Management does not mandate specific access standards while it serves nearly 2 million retirees who are located around the country in a manner similar to Medicare beneficiaries. Yet, "An Analysis of the Availability of Medicare+Choice, Commercial HMO, and FEHBP Plans in Rural Areas: Implications for Medicare Reform" by the Rural Policy Research Institute (*at http://rupri.org/healthpolicy/*) shows that 98 percent of rural counties demonstrate usage of three or more FEHB plans, which is in sharp contrast to the 16 percent of rural counties showing access to even a single M+C coordinated care plan. We expect the Medicare Advantage program to produce a pattern of plan availability more like the FEHB program than to the current M+C program.

In order to encourage MA organizations to offer MA regional plans covering rural areas, we are considering one new requirement related to an exception process for enrollees in an area without a preferred provider for a specific medically-necessary service. We discuss this requirement and the exception process later in this section of the preamble. We welcome comment on this possible change and on any of the other changes we propose to make to our access to care standards.

We propose to make three technical corrections to this section of the regulation. By removing unnecessary administrative burden, and in light of protections afforded by the MMA, which makes certain access requirements redundant, we hope to facilitate participation by MA organizations in the new Medicare program. We would remove or modify three current requirements from § 422.112 of the regulation. None of these requirements are based on statutory authority, and many of them become unnecessary as they are replaced or superseded by requirements in the MMA.

Effective January 1, 2006, the MMA—section 1852(e) of the Act—requires all MA coordinated care plans to focus quality assurance activities on "chronic care improvement programs." We note that MA private fee-for-service plans and MSA plans are already exempt from this requirement. We also note in section 1852(e)(3)(A)(iii) of the Act, that to the extent that MA local PPOs have a contracted network, they must also meet the same quality assurance requirements as do all other MA coordinated care plans. To the extent that all coordinated care plans will be required to focus on quality improvement activities on identifying and monitoring enrollees with multiple or severe chronic conditions, and also to measure and improve the health outcomes of those enrollees, it would be redundant and to a degree unnecessarily proscriptive to suggest a specific approach to those quality improvement activities in the context of and as a means of ensuring enrollee access to care. We would delete § 422.112(a)(4)—serious and complex medical conditions.

Written standards are simply one tool MA coordinated care plans can use to ensure adequate access to medically necessary health care items and services.

The three items enumerated in § 422.112(a)(7) are redundant of other parts of the regulation. Section 422.112(a)(7)(i), related to written standards for access to care, is duplicative of § 422.112(a)(1). Sections 422.112(a)(7)(ii) and (a)(7)(iii), related to written standards that allow for medical necessity determinations and patient input into treatment plans, are duplicative of § 422.206—Interference with health care professionals' advice to enrollees prohibited, § 422.202(b) Participation procedures—Consultation, and § 422.152(b)(3)(paragraph new (b)(2)). We would delete paragraph (a)(7)—written standards.

Section 422.112(b) requires all MA organizations for all MA plans they offer to ensure continuity of care through integration of health care services. Additional requirements in § 422.112(b)(1) through (b)(6) require specific methods by which MA organizations are to ensure an effective continuity and integration of health care services. While all of the enumerated services and processes are clearly desirable, it is not as clear that the responsibility for them is appropriately or reasonably placed on organizations whose business is primarily insurance coverage. While it may be reasonable to expect coordinated care plans to undertake these coordination, continuity, and integration requirements, it is less clear that MA private fee-for-service plans, MSAs, and (to a lesser extent) local PPO plans and MA regional plans (which will be offered as PPOs) should also be expected to. One might argue that continuity of care rules cannot apply in the same manner to MA plans in which the enrollee is free to choose his or her own providers without restraint—such as MSAs and private fee-for-service plans. We are therefore considering eliminating most of the requirements in § 422.112(b) for MSAs and private fee-for-service plans. We are also considering eliminating or modifying many of the requirements in § 422.112(b) for local PPOs and regional MA plans. Finally, we are considering the continued appropriateness of these continuity of care standards for all other coordinated care plans. We are seeking comment on this proposal. We would specifically welcome input on the extent to which requirements similar to those in § 422.112(b)(1) through (b)(6) are established for commercial health insurers offering HMOs, PPOs or indemnity plans.

Special access requirements apply to MA regional plans beginning in 2006 based on section 221(c) of the MMA, which created a new section 1858 of the Act. Specifically, section 1858(h) of the Act creates special access rules for MA regional plans as a means of enabling MA organizations that offer MA regional plans to meet provider access requirements under section 1852 of the Act and thus under § 422.112 of the regulation.

Beginning for benefits offered to MA enrollees of an MA regional plan for contract year 2006, if an MA organization certifies that it was unable to reach an agreement with an "essential hospital" paid under subsection (d) of section 1886 of the Act, under specific circumstances we are authorized to pay additional amounts to that hospital from the Federal Hospital Insurance Trust Fund. This additional payment to the "essential hospital" is in addition to and does not affect the normal monthly MA payment amount that we would make to the MA organization.

An "essential hospital," for purposes of this section, means a general acute care hospital as defined in section 1886(d) of the Act that we determine the MA regional plan must have under contract in order to meet our access requirements. The determination of "essential hospital" status is only conferred after application to us by an MA organization offering an MA regional plan. Additionally, as part of its application to establish the hospital as an "essential hospital," the MA regional plan must also certify that it made a good faith effort to contract with the hospital. The MA organization must also provide assurances that it will make payment to the hospital for inpatient hospital services in an amount not less than the amount that would be payable under section 1886 of the Act. Finally, in order to qualify for the additional payment, the "essential hospital" must demonstrate to our satisfaction that the amounts normally payable under section 1886 of the Act are less than the hospital's costs for providing services to MA regional plan enrollees.

The intent of the additional payment to the section 1886(d) "essential hospital" is to facilitate an MA regional plan's ability to meet network adequacy requirements across large geographic areas—an MA region. Such an "essential hospital" would become part of the contracted network of providers of the MA regional plan and in-network enrollee cost-sharing rules would apply.

Payments under this new authority, however, are limited to a total of $25 million for 2006, and the prior year's amount updated by the market basket percentage increase under section 1886(b)(3)(B)(iii) of the Act for future years.

We invite comment from the public as to how we can ensure that payments are limited to the amount specified. We also invite comment on how we can best ensure that a "good faith effort" to contract has actually occurred. For instance, should we require negotiations to occur before the admission of an MA regional plan patient? Or, in the case of an emergency admission, should we permit negotiations between the MA regional plan and the hospital to occur after admission, or perhaps even after discharge?

Additionally, we invite comment on the best way to determine that a hospital's actual costs for services provided to an MA regional plan enrollee actually exceeded the amount that would normally be payable to that hospital under section 1886 of the Act with respect to those services. Total additional payments under this section are limited to $25 million in 2006 and in subsequent years, $25 million increased by the market basket percentage increase as specified in statute. In a specific case, the actual payment to an "essential hospital" from the Federal Hospital Insurance Trust Fund would be the sum of the difference between the amount that would have been paid to the hospital under section 1886 of the Act and the amount of payment that would have been paid for those services under fee-for-service Medicare had the "essential hospital" been a critical access hospital. We would like input on how to best minimize the administrative burden associated with implementing this statutory provision, while still ensuring the accuracy and integrity of the process.

We would add a new paragraph (c) to account for the special access requirements related to MA regional plans beginning in 2006 based on "essential hospitals."

Instead of always requiring comprehensive, contracted provider networks in all cases, we propose to require MA regional plans to offer beneficiaries reasonable access to in-network cost-sharing, even if there are no contracted providers of a specific type available in a geographic location within the service area. This is the exception process mentioned earlier in this section of the preamble. We also propose a new requirement related to this exception process, which is similar

to a United States Office of Personnel Management (OPM) requirement imposed on the FEHB Blue Cross and Blue Shield Basic Option plan to address similar circumstances.

We propose to permit relaxation of comprehensive network adequacy requirements for MA regional plans, but only to the extent that beneficiaries are not put "at risk" for high cost sharing related to services received from non-network providers. This new tolerance that we propose to afford MA regional plans need not be applied on a plan-wide basis, but rather can be applied in a county or portion of a region where, for example, the MA regional plan is unable to secure contracts with an adequate number of a specific type of provider or providers to satisfy our comprehensive network adequacy requirements.

Such an exception process might require the MA regional plan enrollee to contact the sponsoring MA organization when seeking a specific service that is not otherwise available from a contracted provider. The MA organization, in such a case, could designate a non-contracted provider from whom (or from which) the enrollee could obtain the service at in-plan cost sharing levels. Or, the MA organization could allow the enrollee to seek the service from any provider and guarantee that in-plan cost sharing limits would apply.

In applying the above principle, we need to consider two forms of beneficiary cost sharing. One is the cost sharing related to a specific item or service—for instance, a hospital coinsurance charge. Another is the "catastrophic limits" that MA regional plans must apply to benefits under the original Medicare fee-for-service option. MA regional plans are required to provide reimbursement for all covered benefits regardless of whether those benefits are received from network providers—section 1859(b)(4)(B) of the Act and the new § 422.101(e)(1). MA regional plans are also required to apply a catastrophic out-of-pocket limit on beneficiary cost sharing for covered in-network services and another on all covered services (in and out of network)—section 1858(b)(2)(B) of the Act and the new § 422.101(d)(2) and (d)(3).

We propose to permit MA regional plans with lower out-of-network cost sharing to have less robust networks of contracted providers. While we propose to permit MA regional plans with more robust networks of contracted providers to impose higher cost sharing charges on individuals going out-of-network. This is because if the plans' networks were robust, we would not expect beneficiary access to be unduly limited by higher cost-sharing requirements when they seek care from out-of-network providers. However, for plans with less robust networks, we propose to limit those plans' ability to impose higher cost-sharing requirements for out-of-network care. We believe that higher cost-sharing requirements imposed by plans with limited provider networks could unduly limit access and that more equitable cost-sharing requirements would serve as a safety valve to ensure that beneficiary access is not compromised. For instance, we could require MA regional plans that have less than 20, 50, or 70 percent of hospital beds in the service area (or portion of the service area) under contract to charge lower out-of-network cost sharing to individuals accessing non-network hospitals. In other words, in such a case, we would require the MA regional plan to charge lower coinsurance for out-of-network hospital care as a means of ensuring adequate access to hospital services.

Similarly and related to the "catastrophic limits" on out-of-pocket expenditures, to the extent that an MA regional plan had a less robust network of contracted providers, we would require a convergence in the cost sharing limits that apply to network and all (network and non-network) services. While for plans with more robust contracted networks, we would allow the "catastrophic limits" to diverge.

We ask for comment on the measures we should adopt to assess the robustness of contracted provider networks. We also seek comment on the thresholds we should adopt relative to the cost-sharing limits (related to both individual services and the catastrophic limits on out-of-pocket costs that regional MA plans must provide related to in-network and all services) that should apply to services when contracted provider networks are less than robust. For instance, would it be adequate to adopt fee-for-service cost sharing limits for individual services as a means of ensuring adequate access, or should a different standard apply, and why? We specifically ask for comments in this area. Finally, related to out-of-pocket cost-sharing limits for in-network and all services, is there a formula that we should apply that rationally expresses the maximum out-of-pocket cost sharing that we should permit? Is there a means of quantifying how the two out-of-pocket cost-sharing limits should converge, or how much we should allow divergence, based on the robustness of the contracted provider network?

The preceding discussion is from the perspective of an MA regional plan establishing compliance with our access requirements at the time of initial application or on a continuing basis. From a beneficiary perspective, the MA regional plan would always need to provide an accessible and available source of treatment at network cost sharing levels. Our normal access standards would apply. For instance, where community patterns of care call for travel of no more than 30 minutes or 30 miles to access hospital services, then MA regional plans would need to ensure comparable access to a contracted hospital. To the extent that an MA regional plan did not actually have a contracted hospital within 30 minutes or 30 miles, then the MA regional plan would need to designate a non-contracted hospital from which the member could receive care at network cost sharing levels. Such a requirement would be similar to a requirement imposed by OPM related to the Basic Option plan offered to Federal employees and annuitants under the FEHB program where normal OPM access standards are not met.

We provide for this exception to the normal access requirements related to MA regional plans by proposing to add a new paragraph (ii) to § 422.112(a)(1). We invite comment on the access standards we should establish for primary care, specialty, and institutional providers.

12. Special Rules For Ambulance Services, Emergency Services, and Urgently Needed Services, and Maintenance and Post-Stabilization Care Services (§ 422.113)

Policies on enrollee cost-sharing for emergency care are historically a point of contention. Cost-sharing limits for emergency care are important to ensure that there is no disincentive to receive emergency care that is critical to a beneficiary's health.

On the other hand, since the proposed M+C regulation was published in June 1998, when the cost-sharing limit of $50 on out-of-network emergency services was initially established, there have been unforeseen consequences that have tended to increase confusion rather than contribute to the goal of appropriate access. Additionally, the $50 emergency services cost-sharing limit has not increased since 1998, despite changing market conditions. For instance, in recent years, some M+C plans have established inpatient hospital copays of $200 per day and fee-for-service Medicare coverage has a per-hospital stay deductible of $840 in 2004. These hospital copays, combined with the

regulatory definition of "emergency services" that includes inpatient care "until stabilized," requires a review of § 422.113(b)(2)(v).

Section 422.113(b)(2)(v) reads: "[The M+C organization is financially responsible for emergency and urgently needed services—] With a limit on charges to enrollees for emergency services of $50 or what it would charge the enrollee if he or she obtained the services through the M+C organization, whichever is less."

The regulation states that emergency services continue until the enrollee is stabilized. Hence, a strict (and unintended) reading of the current regulation could require an assessment of the exact time that stabilization occurred in order to determine when the $50 "emergency services" cost-sharing limit ends and when inpatient "post-stabilization" cost sharing can begin. A detailed review of the member's medical record is needed to make a stabilization assessment in order to assess cost-sharing liability. This review of the medical record is an administrative burden on plans as well as appeal review entities—our reconsideration contractor and Administrative Law Judges. All are required to spend considerable amounts of time determining when stabilization occurred for purposes of properly assigning enrollee cost sharing. This is contrary to medical practice, which does not generally identify when a patient is stabilized.

We propose to modify the regulation to clarify that the $50 limit for "emergency services" at § 422.113(b)(2)(v) applies only to the emergency department, and that while the limit on cost-sharing for "post-stabilization" care at § 422.113(c)(2)(iv) continues to apply, its application would always begin upon admission. Thus, emergency cost-sharing limits would shift from being tied to the *type* of service (emergency services) to being tied to the *site* of service (emergency department). Making this clarification would retain cost-sharing limits for both emergency services and post-stabilization care, while eliminating the unanticipated complexities and administrative burden associated with this section of the regulation.

We believe that final regulations published on September 9, 2003, and effective November 10, 2003 (68 FR 53222), provide support for this change. These regulations establish the rule that requirements related to the Emergency Medical Treatment and Labor Act (EMTALA) *end* at the time a patient is admitted. We recognize that EMTALA rules related to patients who present to hospitals with emergency medical conditions and our rules related to allowable cost sharing in the MA program are not a perfect fit; however we do believe that similar administrative difficulties warrant similar administrative solutions. In addition to the consonance this change would have with our EMTALA rules, we also believe that this clarification will allow the MA program to reflect current commercial practices. Finally, the clarification is consistent with our intent. We propose the following provisions:

We propose to change "emergency services" to "emergency department services" in § 422.113(b)(2)(v).

13. Access to Services Under an M+C Private Fee-For-Service Plan (§ 422.114)

Section 211(j) of the MMA allows MA private fee-for-service plans that have a contracted network of providers through which the plan entirely meets access and availability requirements (for a specific category of health care professional or provider) to provide for a higher beneficiary copayment in the case of health care professionals and providers of that category who do not have contracts with the plan. Generally, this would permit a private fee-for-service plan to charge higher co-pays to members who opt out of a private fee-for-service plan's contracted network. This provision does not apply to private fee-for-service plans that meet access requirements solely through "deemed" networks as defined in § 422.114(a)(2)(i). We proposed to add a new paragraph (c) to account for section 211(j) of the MMA.

14. Return to Home Skilled Nursing Facility (§ 422.133)

Under our authority under section 1856 of the Act to establish MA standards by regulation, we are proposing to extend the provisions in § 422.133 to SNF services provided in cases in which an MA organization elects, under § 422.101(c), to provide Medicare covered SNF care in the absence of a prior qualifying hospital stay. Note that our policy to waive the 3-day hospital stay requirement for MA plans does not require MA plans to cover SNF stays without a 3-day hospitalization. The policy simply allows such SNF stays to be considered Medicare-covered if the MA plan chooses to cover them. In such an instance, we are proposing to require by regulation that an individual who would be eligible under section 1852(l) of the Act for admission to a "home SNF" upon discharge from a hospital stay, would nonetheless retain his or her right to receive "home SNF" benefits in the absence of such a stay. We propose to deem that a hospital discharge has occurred prior to an admission for SNF services, and provide the MA enrollee full rights to the "home SNF" benefit. For example, the reference in § 422.133(b)(3) to the SNF "in which the spouse of the enrollee is residing at the time of discharge from the hospital" would be deemed to refer to the SNF in which the spouse of the enrollee is residing at the time covered extended care services are initiated. We propose to add a new paragraph (b)(4).

Subpart D—Quality Improvement Program

(If you choose to comment on issues in this section, please include the caption "Subpart D—Quality Improvement Program" at the beginning of your comments.)

1. Overview

The MMA amended section 1852(e) of the Act in a number of significant ways. First the heading of the section was changed from quality assurance to quality improvement. It also deleted the sections of the Act that provided a list of "elements" that an MA plan's quality assurance program was required to address. These provisions were removed and replaced with several new provisions, including the following:

- Each MA plan (other than an MA private fee-for-service plan or an MSA plan) must have an ongoing quality improvement program.
- Each ongoing quality improvement program must have a chronic care improvement program.
- Each MA plan must provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality, such as HEDIS, CAHPS, and HOS, as discussed below. PPOs however, are only required to collect, analyze, and report data that are furnished by providers that have a contract with the PPO. The MMA also provides for the Secretary to establish separate rules for implementing this requirement with respect to MA regional plans. (See § 422.152(e).)

In response to these amendments, we would change the heading and all references in the section from "quality assurance" to "quality improvement." In addition, we would modify many of the provisions in § 422.152 that address quality assurance and performance improvement programs. We would also delete the provisions of § 422.154 that address external review, and add requirements related to MA–PD benefits to those that can be "deemed" to be met

based on accreditation under § 422.156(b).

The key provisions of this subpart form the cornerstone for a competition based program in quality of care. We already place information from these systems on the Medicare.gov web site, such as Health Plan Employer Data Information Survey (HEDIS), and Consumer Assessment of Health Plans (CAHPS). We will be exploring additional ways to enhance the use of quality of care systems as part of a competition based program.

2. Quality Improvement Program (§ 422.152)

To reflect the congressional intent to refocus the section on quality improvement, rather than quality assurance, we would change the heading of § 422.152 from "quality assessment and performance improvement program" to "quality improvement program." The revised section 1852(e)(1) of the Act excludes MA private fee-for-service (PFFS) and MSA plans from the requirement to have an ongoing quality improvement program. This exclusion is, in part, because enrollees of MA PFFS and MSA are not restricted to seeking care from a network of providers. In addition, some believe MA PFFS and MSA plans lack the ability to influence the behavior of providers and enrollees. We would modify § 422.152(a) to reflect that each plan (except MA private-fee-for-service and MSA plans) offered by a MA organization must have an ongoing quality improvement program. As required under section 1852(e)(2) of the Act, we would require MA plans to have a chronic care program in place as part of their quality improvement program. As discussed below, we are proposing that this program be required to meet requirements set forth in § 422.152(c).

Under our authority in section 1856(b)(1) of the Act to establish standards by regulation, we are proposing to require that the quality improvement program required under section 1852(e)(1) of the Act include quality improvement projects that could be expected to have a favorable effect on health outcomes and enrollee satisfaction, and that meet regulatory requirements set forth in proposed § 422.152(d).

We believe that the broad requirements in proposed § 422.152(d) will not present an undue burden for MA organizations, which have years of experience in carrying out performance improvement projects under the current version of § 422.152(d), which, as discussed below, is more prescriptive than the revised version we are proposing in this rule.

In light of the substantially revised quality requirements under this proposed rule, we believe that it is reasonable to expect all MA plans, including regional and local PPOs, to meet the quality improvement project requirements in proposed § 422.152(d). MSAs are excluded from this requirement altogether. We would also require an organization offering an MA plan to encourage its providers to participate in CMS and HHS quality improvement initiatives. Also, MA organizations are encouraged to seek technical assistance from the State quality improvement organization in designing and implementing quality improvement initiatives. By encouraging this participation, MA organizations are facilitating quality improvement in a variety of health care settings.

Our previous quality improvement efforts for M+C coordinated care plans focused on requiring improvement in specific clinical topics and included specific performance measures to be improved. Thus, while we propose to retain regulatory requirements for quality improvement programs, we would revise the requirements in the current § 422.152(b) to enhance plans' ability to target quality improvement efforts to their enrollees' needs by deleting, modifying, and renumbering most of the requirements in this paragraph. Similar to the existing requirements, this paragraph would provide quality requirements for MA coordinated care plans, but would no longer refer to MSA plans. We would also address certain local PPO and all regional MA plan quality requirements in another paragraph—§ 422.152(e) of this section. We are interested in comments on whether or not we should require plans to use comparable measures across plans and making QI program size/scope proportionate to plan size.

The requirements in the existing § 422.152(b)(1) and § 422.152(b)(2) would be retained, as we believe these standards are integral to any plan's quality improvement program, and are consistent with the requirements of private accrediting organizations. Section § 422.152(b)(1), for example, would require that in processing a request for initial or continued authorization of services, MA plans would need to follow written policies and procedures that reflect current standards of medical practice. Section 422.152(b)(2) would require MA plans to have mechanisms in place to detect both under utilization and over utilization of services.

We are directed in section 1852(e)(3)(B)(i) of the Act to require the collection of only the types of data that we collected as of November 1, 2003. We address this requirement in § 422.152(b)(3). We interpret section 1852(e)(3)(B)(i) of the Act to mean that we can continue to require MA coordinated care plans to collect, analyze, and report their performance by using the measurement systems that are currently required, such as HEDIS, Health Outcomes of Seniors (HOS), and CAHPS, as appropriate for the type of plan. We believe that, consistent with private sector practices, we would be allowed to add, delete, or modify measures within these systems. Changes to these measurement systems are generally reviewed and approved by a committee with representatives from managed care plans, beneficiary advocacy groups, private and public health care purchasers.

We are interested in comments on the following options. There are two basic ways to go (1) use the same metrics across all plan types which allows consumers to compare all plans (both groups of plans (for a specific plan type), or specific plans (across or within plan types)) for a larger set of metrics, or (2) tailor the metrics to specific plan types, which limits the dimensions upon which consumers would be able to compare plans.

If, in the future, we believe that a new measurement system should be used to assess MA plans' performance, we are required under section 1852(e)(3)(B)(ii) of the Act to submit a report to Congress that is prepared in consultation with MA organizations and private accrediting organizations. Thus, we have proposed to remove the provisions in § 422.152(c) that address measuring and reporting performance. We also would remove all the requirements relating to minimum performance levels and requirements that address clinical and non-clinical areas.

We will continue to look for cost-effective ways to measure quality for MA plans and will use a variety of procedures to get input from the public, MA organizations, private accrediting organizations, and seek Congressional review.

Proposed § 422.152(b)(3)(ii) would require MA plans to make available to us the information on quality and outcomes measures that will enable beneficiaries to compare health coverage options and select among them, as provided in § 422.64(c)(10).

Section 422.152(b)(4) would require MA local PPO plans that are offered by

an organization that is licensed or organized under State law as a health maintenance organization to follow the same quality improvement requirements as other MA coordinated care plans. Quality improvement requirements for local PPOs that meet the definition of a local PPO that is specified in § 422.152(e)(1) (local PPOs that are not offered by organizations that are licensed or organized under State law as HMOs) are addressed in that paragraph.

3. Chronic Care Improvement Program Requirements (§ 422.152(c))

We would replace the provisions in § 422.152(c) with requirements for MA plans' chronic care improvement programs. As directed by MMA, we would require MA plans to develop criteria for participating in a chronic care improvement program. The criteria must include methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions who would benefit from participating in a chronic care improvement program. The criteria must also provide mechanisms for monitoring MA enrollees that are participating in the chronic care improvement program. We invite comments on these requirements to help us provide additional guidance to MA plans on additional criteria and mechanisms that might be useful to help them identify and monitor MA enrollees that are participating in their chronic care improvement program. For example, are there data or approaches used to identify special needs individuals with severe or disabling chronic conditions who might benefit from enrollment in specialized MA plans that could also be used in the identification of MA enrollees who would benefit from participating in a chronic care improvement program because of their severe chronic conditions?

4. Quality Improvement Projects (§ 422.152(d))

As noted above, we have proposed to delete many of the prescriptive requirements for quality improvement projects that appear in the current § 422.152(d). While MMA has resulted in the deletion of a number of the more prescriptive requirements of quality improvement programs, it still retained the basic requirements of such projects. The MMA retained the requirements of the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality, for example, HEDIS, HOS, and CAHPS. Furthermore, it added the chronic care improvement program. As mentioned, these aspects of the program provide the cornerstone for a competition based program in quality of care. We already place information from these systems on the Medicare.gov Web site. We will be exploring additional ways to enhance the use of quality of care systems as part of a competition based program. We propose deleting the list of clinical and non-clinical topic areas because it is our intention that MA plans select the topic area for a quality improvement project based on the needs of their enrolled population. It is our intention, however, that MA plans would select topic areas that are relevant to a Medicare population.

We would delete the requirement of including the entire relevant population in the measurement because it has been proven that sampling is an approved method for assessing the performance of providing care and services to a population. Since MA plans conduct quality improvement projects for both the Medicare program and private accreditation organizations, we feel that it is appropriate for them to conduct projects that include both Medicare and non-Medicare enrollees. Thus, they would be allowed to conduct a study of persons with Coronary Artery Disease that includes enrollees that are both over and under 65. However, the sample of enrollees that are studied must be appropriately representative of Medicare beneficiaries. Since the MA plans would be selecting their own topics, it is not necessary for us to ensure that the entire spectrum of clinical and non-clinical areas are addressed by an MA plan. Similarly, we propose deleting the requirement that addresses national and statewide projects because MA plans would be selecting their quality improvement project topics by assessing the needs of their population. Thus, we would delete the following requirements:

- The lists of required clinical and non-clinical areas (§ 422.152(d)(4), § 422.152(d)(5)).
- The requirement that an entire relevant population must be included in the measurement set (§ 422.152(d)(2)).
- The provision authorizing us to ensure that the entire spectrum of clinical and non-clinical areas are addressed by establishing the number and distribution of projects (§ 422.152(d)(3)).
- The requirement for participation in national or site-wide projects (§ 422.152(d)(6)(ii))).

In § 422.152(d)(1), we would require that quality improvement projects be initiatives that include the entire organization and focus on clinical and non-clinical areas. The projects would need to follow the regular quality improvement process (measure, intervene, and then remeasure to determine if the intervention resulted in improvement). We have retained the provisions that quality improvement projects must measure performance, and the interventions must be system-wide and include the establishment or alteration of practice guidelines. In addition, the projects must focus on improving performance and involve systemic and periodic follow-up on the effect of the interventions.

To ensure that the measures (or quality indicators) used in quality improvement projects are reliable and relevant for improving the health care and services furnished to MA enrollees, we would require in § 422.152(d)(2) that the quality indicators be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research. The measures must also be capable of measuring outcomes, such as changes in health status, functional status, and enrollee satisfaction, or valid proxies of those outcomes.

Likewise, in § 422.152(d)(3), we would require that the data used in an MA plan's quality improvement projects be valid and reliable and based on systemic ongoing collection and analysis of information. We would also require in § 422.152(d)(4) that the interventions achieve measurable and sustained improvement. We would not define what constitutes measurable and sustained improvement in the regulation, but we mean some movement in the quality indicator in an upward or downward direction as appropriate.

Finally, in § 422.152(d)(5), we would retain the requirement that MA plans report the status and results of their projects when requested by us. At this time, we believe that because of the various changes just described, the reporting and review burden would be much less than the current process used in the M+C program. We are considering using a model similar to the one used by private accrediting organizations, where quality projects would be submitted before an onsite monitoring review. For plans selecting MA deeming, their quality improvement projects would be collected and evaluated by the accrediting organization that would be conducting the deeming review.

5. Requirements for MA Regional Plans and MA Local Plans That Are PPOs as Defined in § 422.152(e)

As noted above, section 1852(e)(3)(A)(ii) of the Act provides for us to establish separate regulatory

requirements for MA regional plans relating to the collection, analysis, and reporting of data that permit the measurement of health outcomes and other indices of quality for MA regional plans. Section 1852(e)(3)(A)(ii) of the Act further provides that these requirements for MA regional plans could not exceed the requirements established for MA local plans that are PPO plans as defined in section 1852(e)(3)(A)(iv) of the Act—local PPO plans that are offered by an organization that is not licensed or organized under State law as an HMO. We propose to apply these same principles in applying general quality requirements, beyond those relating to the collection, analysis, and reporting of data. Thus, as noted above, and as provided in the current regulations, we propose a separate set of requirements for these specific PPOs, which we would also apply to regional MA plans.

In § 422.152(e)(1), we would provide a definition for the term "local PPO plan" as used in this section. The other requirements in this paragraph are the requirements that apply to PPOs under current regulations. We are aware that some organizations that offered PPO plans felt that some of the performance measures required of PPO plans in the M+C program were difficult to collect in a PPO environment. To address this concern, we will assess all the performance measurement and reporting requirements and make the necessary adjustments. We anticipate that PPOs will not be required to collect data such as medical records, because they have difficulty in obtaining such records. We will work with outside experts, the public, MA organizations, and private accrediting organizations on developing HEDIS measures appropriate to PPOs and welcome comments on these issues. We anticipate that in early 2005 that we will finalize the reporting requirements for PPOs.

In § 422.152(f), we retain the provisions that address health information systems, quality improvement program review, and remedial action. MA organizations would be required, for all the MA plans they offer, to maintain a health information system that collects, analyzes, and integrates the data necessary to implement their quality improvement program. The organization would also be required to ensure that the information it receives from providers of services is reliable and complete. In addition, for each plan, there would have to be in effect a process for formal evaluation, at least annually, of the impact and effectiveness of its quality improvement program.

Finally, for each plan it offers, an MA organization would be required to correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms.

MMA removed the provision that each MA organization's quality assurance program include a separate focus on racial and ethnic minorities. Thus, we would remove the current § 422.152(f)(4) addressing this issue. It should be noted that CMS specified that the 2003 national projects for M+C plans be Clinical Health Care Disparities or Culturally and Linguistically Appropriate Services. Thus, this requirement has already been initiated by the plans.

MMA removed the requirement that for each plan it operated the MA organization would have an agreement with an external quality review and improvement organization. Thus, we would remove the corresponding regulatory requirements in § 422.154.

MMA provided that all the part D (Voluntary Prescription Drug Benefit) requirements are to be included as among those that could be deemed to be met through accreditation, and we accordingly have added this provision to the list of deemable requirements in § 422.156(b).

Subpart E—Relationships With Providers (§ 422.210)

(If you choose to comment on issues in this section, please include the caption "Subpart E—Relationships with Providers" at the beginning of your comments.)

MMA has not changed most existing MA program requirements concerning MA organization relationships with providers. Since these aspects of the program have worked well, we generally have proposed to keep the existing provisions of subpart E as they are. The only exceptions, which are discussed below, are modifications to the physician incentive plan requirements to reflect changes made by MMA to section 1852(j)(4) of the Act.

Section 222(h) of MMA revised section 1852(j) of the Act to eliminate requirements that were set forth in section 1852(j)(4)(A)(ii)(II) and (iii) of the Act and to require only that an MA organization "provide assurances satisfactory to the Secretary" that it meets certain stop loss protection requirements that were in what was section 1852(j)(4)(A)(ii)(I) of the Act, and that remain in the revised version of section 1852(j)(4) of the Act. Section 1852(j)(4)(A)(ii)(II) of the Act had required that, where a physician incentive plan places physicians at substantial financial risk, MA organizations conduct "periodic surveys of both individuals enrolled and individuals previously enrolled with the organization to determine the degree of access of such individuals to services provided by the organization and satisfaction with the quality of such services." This requirement was deleted. We have proposed to delete this requirement in § 422.208(h). We are redesignating existing paragraph § 422.208(i) as § 422.208(h).

We note that the surveys that were previously required under this section were covered for the most part by our administration of the CAHPS survey, which will be continued.

Section 1852(j)(4)(A)(iii) of the Act contained a requirement that descriptive information be provided to the Secretary to permit the Secretary to determine compliance with the requirements in section 1852(j) of the Act. This requirement was also deleted by section 222(h) of MMA. We note that in a final rule published on August 22, 2003, at 68 FR 50840 through 50859, we had deleted a regulatory provision that had previously implemented this reporting requirement by requiring routine reporting of data to us. This final rule proposed that the information only be made available to us upon request. Given the MMA amendment providing that the MA organization will now only be providing "assurances," the need to gather data to make an independent determination no longer exists. Moreover, the Congress repealed the statutory basis for requiring that the information be provided. We therefore propose to revise § 422.210 to eliminate the requirement that information on physician incentive plans be disclosed to us.

Subpart F—Submission of Bids, Premiums, and Related Information and Plan Approval

(If you choose to comment on issues in this section, please include the caption "Subpart F—Submission of Bids, Premiums, and Related Information and Plan Approval" at the beginning of your comments.)

Under the current MA regulations, subpart F addresses payments to MA organizations, and subpart G discusses beneficiary premiums and cost sharing. Given the substantial revisions that MMA makes to pricing and payment rules for MA organizations, we propose to replace these subparts with new subparts F and G. In doing so, we will reverse the order of provisions to reflect the chronology of events in the new MA

bidding system more accurately. In this proposed rule, provisions addressing bid submissions and CMS review of bids come first in subpart F, and a description of the methodology and process for CMS' payment to MA organizations follows in subpart G.

The proposed rules in the new subpart F set forth the annual bid submission process for organizations intending to offer MA local and regional plans in the upcoming year. In particular, they address the basis for bids, what must be included in the bid, and other information MA organizations must submit by law for each plan, such as the actuarial bases for the bid. The proposed rules set forth general rules that apply to all MA organizations, and special rules for certain types of plans. They contain authority to review the submitted bids and the standards for reviewing those bids, including the actuarial analyses that are mandated by the MMA, and describe the negotiation process between MA organizations and us.

After provisions addressing submission, review, and approval of bids, the proposed regulations address "bid-to-benchmark" comparisons, including how local and regional benchmark amounts are determined and how beneficiary premiums and savings are calculated. The rules also set forth how beneficiary savings are used for beneficiary rebates and Government savings, and distinguish between calculations for regional MA plans and local MA plans. The proposed rules also describe the various premium payment options available to beneficiaries, and require that beneficiary premiums and cost-sharing be uniform within a service area (or service area segment). Finally, the new subpart F describes the options for distributing the beneficiary portion of the rebate.

We propose to replace the previous MA provisions from the old subpart G (now subpart F) almost in their entirety, with the exception of the following proposed provisions, which largely retain existing language:

§ 422.262(d), *monetary inducement prohibited,* which precludes an MA organization from providing cash or other monetary rebates as an inducement for enrollment or for any other reason or purpose.

§ 422.262(e), *timing of payments,* which gives beneficiaries the right to make premium payments on a monthly basis, and protects them from a termination of coverage for failure to make these payments except as provided in § 422.74(b). The only change to this provision is the addition of the prescription drug premium to the list of beneficiary premiums.

§ 422.270, *incorrect collection of premiums and cost sharing,* which addresses cases in which an MA organization collects more than the amount of beneficiary premium allowed. Under this provision, the organization is required to refund these over-collections through an adjustment to current and future premiums. This language is identical to the current MA regulation now in subpart G at § 422.309.

1. Basis and Scope (§ 422.250)

Proposed § 422.250 sets forth the basis and scope of the revised subpart F, noting that it is based largely on section 1854 of the Act, but includes provisions from sections 1853 and 1858 of the Act. Section 422.250 notes that subpart F addresses the bidding methodology upon which MA payments will be based beginning in 2006 and provisions for CMS' negotiation and approval of organizations' bids.

2. Terminology (§ 422.252)

There are several general terms defined in parts of section 1853 and section 1854 of the Act that apply to both bidding rules (subpart F) and payment calculations (subpart G), so we define these terms in the regulatory text for this part. The proposed definitions throughout both subparts F and G are intended to reflect the statutory definitions they implement in a simplified manner. We will identify clearly those cases in which we propose independently to define a term that is not defined in the statute. In this preamble, we provide an overview of rate terms used in both subparts F and G.

Mandatory and optional supplemental benefits are defined at § 422.102. In subparts F and G the phrase "supplemental benefits" refers to both mandatory and optional supplemental benefits. The terms "mandatory supplemental" and "optional supplemental" are used when referring specifically to one these types of supplemental benefits.

The MMA introduces regional MA plans, thus revising section 1853(d) of the Act to define two types of payment areas. For MA regional plans, the payment area is an MA region, and for MA local plans, the payment area is a county (called an "MA local area").

Under the rate setting method for the previous M+C program, the general rule was that an annual capitation rate was the rate for a county, and an MA payment area was a county. Under the MMA, the "annual MA capitation rate" continues to be the county rate. As set forth at section 1853(c)(1) of the Act, capitation rates are called "MA local area" rates, and references throughout the MMA to capitation rates are to county rates (or in the case of ESRD enrollees, to State-level rates). Note, however, that section 1858 of the Act does require us to calculate a regional per capita rate, described in proposed § 422.262(b)(3) as the "statutory region-specific non-drug amount." We chose to not define this term separately in proposed § 422.252, however, because it is an intermediate product that we would use to arrive at the administrative pricing component of the region-specific benchmark amount (discussed below).

Proposed § 422.252 also includes a definition of "MA–PD plan," which means an MA local or regional plan that offers prescription drug coverage under Part D. We would note that MSA plans are not allowed to offer Part D prescription drug coverage, and private fee-for-service plans may but do not have to offer Part D coverage.

The following terms are also defined in proposed § 422.252:

"Unadjusted MA statutory non-drug monthly bid amount" is defined as the plan's estimate of its monthly required revenue for Part A and Part B original Medicare benefits.

"Monthly aggregate bid amount" is defined as the total monthly plan bid for coverage of an MA eligible beneficiary with a nationally average risk profile. This bid is composed of: the unadjusted MA statutory non-drug monthly bid amount; an amount for coverage of basic prescription drug benefits under Part D (if applicable), and an amount for provision of supplemental benefits, if any.

In the preambles to subparts F and G, the term "basic A/B bid" is used to refer to the unadjusted MA statutory non-drug monthly bid amount. The term "bid" refers to the aggregate monthly bid amount unless otherwise indicated.

"Plan basic cost sharing" means cost sharing that would be charged by a plan for benefits under the original Medicare fee-for-service program option before any reductions resulting from mandatory supplemental benefits.

"Unadjusted MA area-specific non-drug monthly benchmark amount" is defined, for local MA plans serving one county, as the county capitation rate. For local MA plans serving multiple counties it is the weighted average of county rates in a plan's service area, where the weights are by the plan's projected enrollment per county.

"Unadjusted MA region-specific non-drug monthly benchmark amount" is the sum of two components: the

statutory component (based on a weighted average of capitation rates in the region) and the plan bid component (based on a weighted average of plan bids in the region).

"MA monthly basic beneficiary premium" is the amount that an MA plan (other than an MSA plan) charges an enrollee for original Medicare benefits if its bid is above the benchmark.

"MA monthly prescription drug beneficiary premium" is the base beneficiary premium, adjusted to reflect differences between the plan bid and the national average bid, less the amount of rebate the MA–PD plan elects to apply toward a reduction of the base beneficiary premium, as described in proposed § 422.266(b).

"MA monthly supplemental beneficiary premium" is the portion of the plan bid attributable to mandatory and/or optional supplemental health care benefits described in § 422.102, less any rebate applied to a mandatory supplemental benefit under § 422.266(b)(2).

"MA monthly MSA premium" is the amount of the plan premium for coverage of benefits under the original Medicare program through an MSA plan, as described in proposed § 422.254(e).

3. Submission of Bids (§ 422.254)

General rule. Section 1854 of the Act was amended by the MMA to replace the adjusted community rate (ACR) proposal system currently in effect under the MA program with a bid submission process. No later than the first Monday of June each year, beginning for contract year 2006, MA organizations must submit bids for each plan that they intend to offer in the following year. Plan bids would be required to meet the requirements specified at proposed § 422.254(b), and bid submissions would be required to include the information listed in proposed § 422.254(c), discussed below.

Section 1853(a)(1)(H) of the Act, as proposed in § 422.254(a)(2), gives us the authority to determine if ESRD MA enrollees should be included in the MMA bidding process. We propose that ESRD enrollees be fully incorporated into the plan's aggregate bid for contract year 2007 and succeeding years. However, for contract year 2006, we are concerned that MA organizations would have to submit bids in June 2005, and at that time they would have very little experience with the impact on their payments of the new ESRD risk adjustment model, which is effective January 1, 2005. Therefore, we propose three options for handling the costs of ESRD enrollees in the June 2005 bid submission. We invite comment on these approaches.

One option for contract year 2006 only is that MA organizations would not include costs for ESRD enrollees in their basic A/B bids and supplemental bids. We would pay MA organizations for ESRD enrollees using the MMA rate setting methodology, as discussed at proposed § 422.304(c)(1)(i). A second option for 2006 only is that MA organizations would not include costs for ESRD enrollees in their basic A/B bids, but would include costs for ESRD enrollees in the supplemental portion of the bid in order to determine the appropriate price of supplemental benefits other than Part B premium reductions. The third option would be that MA organizations fully incorporate ESRD enrollees in the pricing of both basic and supplemental benefits for contract year 2006 and succeeding years. That is, we would not delay full incorporation until 2007.

Under all three options, ESRD enrollees would be included in plan estimates of the amount it would cost to provide qualified prescription drug coverage under Part D for 2006.

Regardless of whether a plan's ESRD enrollees were excluded from the basic A/B bid or from both basic and supplemental bids for 2006, they would still be subject to the same premium and cost sharing as other plan enrollees under the uniformity of premiums provision in proposed § 422.262(c). Accordingly, for any plan offering a Part B premium reduction to MA plan enrollees, we would adjust our payments for ESRD enrollees to reflect that part of the plan benefit package is payment of all or a portion of the enrollee's Part B premium. For further discussion of payments to MA organizations for ESRD enrollees, see the subpart G preamble discussion of § 422.304(c)(1)(i).

Bid requirements. Proposed § 422.254(a) and (b) would implement section 1854(a)(1)(A) and section 1854(a)(6)(A) of the Act, which set forth requirements for plan bids. MA organizations must submit an aggregate monthly bid amount for each MA plan the organization intends to offer.

Each bid submission for an MA plan represents the MA organization's estimate of its average monthly estimated required revenue to provide coverage in the service area of the plan for an MA eligible beneficiary with a nationally average risk profile for the risk adjustment factors (that is, the aggregate bid is a standardized bid). This aggregate bid is the sum of several amounts the plan estimates are its revenue requirements: (1) The "unadjusted MA statutory non-drug monthly bid," to provide original Medicare benefits; (2) the amount to provide basic prescription drug coverage; and/or (3) the amount to provide supplemental coverage, if any.

We state in proposed § 422.254(b)(2) that each bid would be for a uniform benefit package for the service area (or service area segment, if applicable, for local plans). Plan premiums and all applicable cost sharing would also be uniform.

We state in proposed § 422.254(b)(3) that the bid submission would contain all estimated required revenue, including administrative costs and return on investment (profit, retained earnings). We state in proposed § 422.254(b)(4) that the bid amount is for plan payments only but must be based on plan assumptions about the amount of estimated revenue required from enrollee cost sharing.

When estimating required revenue, a plan would include adjustments for the effect that providing any non-Medicare benefit has on utilization. This method of pricing supplemental coverage would apply to both mandatory and optional supplemental benefits.

To the extent that the provision of reductions in Part A, Part B, and/or Part D cost sharing results in higher utilization of these benefits, the additional expenditures attributable to the change in cost sharing structure are categorized as mandatory supplemental benefits. That is, when a plan offers a benefit package that includes reductions in cost sharing, the pricing of such a mandatory supplemental benefit would include not only the cost of "buying down" the cost sharing (that is, the estimated revenue needed to cover the amounts enrollees would have otherwise paid as cost sharing), but also the cost of financing the expenditures associated with the additional utilization resulting from offering the cost sharing benefits.

The basic A/B bid should assume a utilization pattern consistent with Medicare cost-sharing. The portion of the aggregate bid related to the provision of basic prescription drug coverage should assume a utilization pattern consistent with defined standard cost sharing. Since the basic A/B bid is used to determine rebates and the portion of the bid related to Part D basic benefits is used to determine the monthly prescription drug beneficiary premium, these amounts cannot reflect the utilization effect of cost-sharing reductions provided through supplemental benefits.

Plans would make an actuarial projection for their populations concerning the expected utilization of each supplemental benefit (both mandatory and optional supplemental benefits) and the appropriate pricing of such benefits. We would verify the reasonableness of these projections as part of the bid review process (in the same way that we would verify the reasonableness of plans' projections of enrollment numbers and enrollment mix for an optional supplemental product). A determination that supplemental benefits are appropriately priced is essential for the integrity of the bidding process. A plan could overstate its revenue needs for covered services with the intention of maximizing payments not subject to rebates while under-pricing supplemental benefits to make the offering attractive to enrollees. To prevent this kind of strategy, the accurate pricing of Part A, Part B, and Part D benefits and supplemental benefits have equal importance in the bidding process.

We propose to exercise our authority under section 1856(b) of the Act (allowing CMS to establish MA standards by regulation) to establish a rule prohibiting MA organizations from offering, as optional supplemental benefits, reductions in Part A, Part B, and Part D cost sharing, or enhancements to Medicare Parts A and B benefits. Under such a rule, MA organizations would still be permitted to offer non-Medicare benefits such as dental and optical services as optional supplemental benefits. We are concerned about the effects of allowing a benefit that affects the level of cost-sharing and utilization of benefits to be offered at the enrollee's option. Allowing MA organizations to offer cost sharing-reductions and enhancements to Part A and Part B Medicare benefits as optional supplemental benefits arguably would be inconsistent with a multi-component bid, where one component is a bid amount for all of the supplemental benefits a plan intends to offer, both mandatory and optional. Costs for part of the supplemental bid amount would be carried by all enrollees, while costs for part would be carried by those who choose the benefit. Also, optional supplemental benefits do not exist under Part D. We are exploring the issue of whether allowing MA–PD plans to include drug coverage in an optional supplemental benefit would require a request for a waiver under section 1860D–21(c)(1) of the Act.

If we were to implement this restriction on optional supplemental benefits, MA organizations would still be able to provide choice by offering multiple plans within the same service area that have different mandatory supplemental benefits. We invite comments on this issue.

The MMA does not alter the percentage of the amount paid to MA organizations in 2006 that is adjusted by the CMS–HCC risk adjustment model. As previously provided, 75 percent of the payment will be subject to risk adjustment, and the remaining 25 percent will be based on the demographic model. Since the statute requires us to combine different approaches to adjusting capitation rates in 2006, we believe this raises the issue of whether MA organizations should be required to submit one or two different bids for each plan in order for each portion of the payment to be based on an appropriately standardized bid.

We propose that since we must make blended payments in 2006 for MA organizations, that MA organizations submit a blended bid for 2006, with one portion being based on a beneficiary with a nationally average risk profile (that is, the "1.0 beneficiary") and the second one being based on a beneficiary with a nationally average demographic profile. We invite comment on this approach or others that may be feasible. Note that some demonstrations have an alternative transition schedule to 100 percent risk adjusted payments, so these organizations would have to submit a blended bid for 2006 and 2007.

Proposed § 422.254(b)(4) would implement section 1854(a)(6) of the Act and would address an issue arising from section 1852(a)(1)(B) of the Act, which warrant a full discussion. Section 1854(a)(6) of the Act requires organizations to submit, for each MA plan, a bid consisting of three components, along with a statement of the actuarial basis for each of those components: (1) The original Medicare fee-for-service benefit package; (2) basic prescription drug coverage; and (3) any coverage beyond the first two components (supplemental health care benefits).

In the case of the first component, the health plan's basic A/B bid is the statement of the expected revenue the bidder requires to provide the Medicare-covered benefit package. This component of the aggregate bid may not include services not covered by Medicare. A simple example of what must be included as supplemental coverage rather than basic Medicare coverage would be routine physician services provided outside of the United States. The physician services would have to be included in the bid component referred to as "the provision of supplemental health care benefits" (section 1854(a)(6)(A)(ii)(III) of the Act), not in the component for the "provision of benefits under the original Medicare fee-for-service program" (section 1854(a)(6)(A)(ii)(I) of the Act). Medicare does not cover these services, but an MA plan may cover them as supplemental services.

A more complicated example would be that the "original Medicare" component of the bid may not include any inpatient hospital days that a health plan covers where such services would not be covered under original Medicare solely because an individual has exhausted the Medicare lifetime reserve days. To the extent that the care is "bundled" as part of a benefit package that a particular MA plan offers to Medicare enrollees, in order to use the plan cost and utilization data as the basis of its bid, the health plan must disaggregate the hospital benefit to determine costs (revenue needs) attributable to covered versus non-covered care. As part of the bid review process, we would ensure that only Medicare-covered services are included in a plan bid. (Note that under the prior M+C program we required "unlimited hospital days" to be shown on the Adjusted Community Rate Proposal as an additional benefit.)

Requiring that the "original Medicare" bid component only include covered care enables a fair comparison to determine the extent to which a plan can save money (or will cost more) in relation to a benchmark that consists primarily of Medicare fee-for-service expenditures for covered services in a given area. With a correct bid for this component, rebate dollars can be correctly calculated. If a health plan includes non-covered care in the basic A/B bid and this bid amount is below the benchmark, dollars that should have been returned to beneficiaries as rebate dollars will not be available to finance rebates (and dollars that should have been returned to the Government will not be available). Instead, the health plan will use those funds received from the Government to finance benefits that should have been classified as mandatory supplemental (non-covered) benefits. Those non-covered benefits included in the basic A/B bid would be financed at 100 percent of their cost to the plan, rather than having only 75 percent of the rebate dollars available to finance the benefit as a mandatory supplemental benefit (for example). Another health plan in the exact same situation that had correctly classified the services as non-covered services and had priced them as a mandatory supplemental benefit will appear more expensive to prospective enrollees

because 25 percent of the cost of the benefit becomes a "cost" to the beneficiary.

Actuarial equivalence of cost sharing. In connection with the "original Medicare" component of the bid, section 1852(a)(1)(B) of the Act states that "the term 'benefits under the original Medicare fee-for-service program option' means those items and services (other than hospice care) for which benefits are available under Medicare Parts A and B to individuals entitled to benefits under Medicare Part A and enrolled under Medicare Part B, *with cost-sharing for those services as required under Parts A and B or an actuarially equivalent level of cost sharing as determined in this part*". The provision regarding cost sharing is necessary because it reflects a feature of the structure of the Medicare program which provides that a certain share of the cost of covered care is to be borne by beneficiaries (or third parties paying on behalf of beneficiaries). Those costs, in original Medicare fee-for-service, are not financed by Government funds, and the costs would not be financed by Government funds in the bidding system (unless rebate dollars are available).

We have examined a number of ways to incorporate this Part A/B cost sharing provision in the bidding process, and in particular how to determine whether a bid incorporates cost sharing that would be considered actuarially equivalent to the cost sharing of original fee-for-service Medicare. As a starting point, we discuss the concept of actuarially equivalent cost-sharing by describing a hypothetical plan with the original Medicare cost-sharing rules. We then discuss three methods of implementing the MMA provision for determining what level of plan cost sharing is actuarially equivalent to original Medicare: (1) The current method that defines original Medicare cost sharing as a national average per capita uniform dollar amount, and a possible variation on this approach, the localized uniform dollar amount; (2) the plan-specific approach; and (3) the proportional approach (including national, regional, or local proportions).

One way in which a health plan could have a basic A/B bid for Medicare services that conforms to the provision in section 1852(a)(1)(B) of the Act is to design a plan that covers only Medicare-covered services and uses the same cost-sharing rules as Medicare (the hospital deductible, 20 percent coinsurance for outpatient services, etc.). For such a plan, there is no issue of actuarial equivalence since the plan has "cost sharing as required under Parts A and B" of Medicare, as specified in 1852(a)(1)(B) of the Act. For this hypothetical plan, the actual dollar amount of the basic A/B bid may be quite different from the local Medicare fee-for-service expenditures, and from the dollar amount of cost sharing beneficiaries face in fee-for-service Medicare—for a number of possible reasons.

Among the possible reasons for variation are that local fee-for-service cost sharing amounts reflect a mix of types of supplemental coverage that Medicare beneficiaries may have. It is well known that beneficiaries with generous supplemental coverage (Medigap, Medicaid, some employment-based coverage) who do not directly face the expense of cost sharing have higher Medicare expenditures, and consequently higher cost sharing (though paid for by a third party). Individuals with only Medicare coverage have much lower expenditures and lower cost sharing. Expenditures of enrollees in the hypothetical plan with Medicare cost sharing may be closer to the level of expenditures for beneficiaries with no supplemental coverage. The private plan may also have lower expenditures overall because it has secured discounts below the Medicare rates from its network of providers, and the plan is likely to have utilization controls that reduce certain types of care or which shift care to a different setting or type of provider. This hypothetical plan's basic A/B bid for the coverage of Medicare services, and the associated cost sharing, would reflect the unique features of the private plan, and when expressed as a dollar amount there would most likely not be a match between the plan cost sharing amount and the amount in fee-for-service Medicare for the service area in which the plan is operating.

In reality, it is unlikely that there would be any plan meeting the requirement in section 1852(a)(1)(B) of the Act by imposing exactly the cost-sharing structure that Medicare uses. Hence, the law permits the use of an actuarial equivalence approach to determine the appropriate cost-sharing component of a basic A/B bid that would actuarially equal the "cost sharing as required under Parts A and B." Three methods of implementing the actuarial equivalence standard are discussed below: the uniform amount, plan-specific amount, and proportional methods.

Uniform Amount Method. The new section 1852(a)(1)(B) of the Act is similar to a provision in the law that continues to apply to MA plans through 2005, dealing with the determination of "excess amounts" used to fund extra benefits. When Medicare payments exceed the revenue a plan needs for providing the Medicare benefit, the plan must "return" the excess amount to enrollees in the form of extra benefits (or cost sharing reductions). Section 1854(f)(1)(B) of the Act provides that:

For purposes of this paragraph, the excess amount, for an organization for a plan, is the amount (if any) by which—

(i) The average of the capitation payments made to the organization under section 1853 for the plan at the beginning of contract year, exceeds

(ii) The actuarial value of the required benefits described in section 1852(a)(1)(A) under the plan for individuals under this part, as determined based upon an adjusted community rate described in paragraph (3) *(as reduced for the actuarial value of the coinsurance, copayments, and deductibles under parts A and B).* [Emphasis added.]

The way in which this provision is currently implemented is through the determination of a uniform national dollar amount representing our projection of the monthly actuarial value of Medicare coinsurance and deductibles (that is, the amount, on average, of cost-sharing expenses beneficiaries incur in receiving Medicare services). All plans are required to use this national average amount as the "the actuarial value of the coinsurance, copayments, and deductibles under parts A and B," to comply with section 1854(f)(1)(B) of the Act. There are a number of drawbacks with this uniform dollar approach, including the sources of variation in cost sharing noted above (as well as regional variation in cost sharing). In the context of a bidding system, this national uniform dollar approach does not adequately recognize differences among private health plans and differences between private plans and fee-for-service Medicare.

The uniform amount approach could create distortions in the MA plan bids and have a negative impact on plans and on beneficiaries. In a situation in which the national dollar value of Medicare cost sharing (currently $113.07 per month for CY 2004) exceeds the appropriate amount for a particular health plan because the plan is very efficient and its expenditures are low in relation to those of Medicare, the plan bid would be depressed because of the assumption that $113 per month in revenue is collectible from enrollees. This would result in a greater difference between the plan bid and the benchmark, with 75 percent of that difference required to be rebated to

beneficiaries. Some or all of that rebate money can be used to fund the cost sharing that beneficiaries would face, which in this case the Government has deemed to be $113. This plan would be forced to fund a portion of the plan's own cost of providing the Medicare benefit with beneficiary dollars that otherwise would have been available for extra benefits.

For example, a plan could determine that its total revenue needed for providing the Medicare benefit is $500 per person per month—including $80 received as enrollee cost sharing revenue. Assume that the plan is operating in a county in which the benchmark is $600 (exactly equal to local fee-for-service expenditures, and with cost sharing in the area at exactly the $113 national level). Rather than state that its estimated required revenue for the Medicare package, after cost sharing, is $420 ($500 less $80), the plan is obligated to state its bid as $387 ($500 less $113). This affords the plan 75 percent of $213 (or $160) for rebates. In order to "make itself whole" the plan needs $33 to fully fund its Medicare benefits, yet it will receive only $25. This $33 amount would be identified under the uniform amount approach as a reduction in enrollee cost sharing (in relation to the $113 level), and a net amount of $127 will remain for other rebate financing. If the plan reduces cost sharing to 0, $47 is left for other benefits (because $80 is the actual cost sharing liability for enrollees that needs to be "bought down"). Had the plan been allowed to correctly state its bid for its particular circumstances, the plan would have had 75 percent of $180 (or $135) for rebate purposes. If the plan reduces cost sharing to 0, a net of $55 is left for other benefits (or $8 per person per month more than under the uniform amount approach). (Distortions also occur when less efficient plans are required to understate their cost sharing level.)

We believe the current uniform amount method creates distortion under the MA bidding system both in the bids and levels of savings returned to the enrollee and to the Government, and limits the flexibility of MA plans to provide competitive benefits and to pass on cost savings to beneficiaries.

A more feasible version of the current national approach would be to use a localized uniform amount. Under this method, we would publish localized (for example, county-level or MSA-level) cost-sharing values to be used for purposes of actuarial equivalence. The values would be based on actual per-beneficiary FFS cost sharing, projected to the contract year and standardized to a 1.0 risk score.

In addition to the localized uniform dollar amount approach, there are two other methods we are considering: the plan-specific amount and the proportional approach. The plan-specific method for determining the PMPM amount of beneficiary cost sharing is based on the MA organization's pricing and utilization estimates. The organization would also use these estimates to generate its basic A/B bid. In contrast, the proportional method is based on fee-for-service pricing and utilization experience, either national, regional, or local proportions.

Plan-Specific Amount Method. A second approach eliminates the distortions caused by the uniform amount approach by allowing an MA organization to use actuarial assumptions and projections to determine the level of cost sharing that beneficiaries would face if the plan imposed the Medicare cost sharing structure or an actuarially equivalent structure. That is, whether an MA organization intends to offer a basic package or, through the use of mandatory supplemental benefits, intends to offer a plan with reduced cost-sharing, the organization would determine the basic A/B bid as if it were offering a plan that consists of Medicare-only benefits offered under Medicare cost sharing rules or an actuarially equivalent structure. A cost-sharing structure would be actuarially equivalent if the projected average cost-sharing as percent of the sum of average cost-sharing and projected average plan payout equals the percentage using Medicare's cost sharing rules, based on the projected experience of the same group and using the same pricing assumptions.

The average amount of cost-sharing and the average plan revenue requirements for the assumed basic A/B package would then be adjusted so as to reflect cost-sharing and plan requirements based on an enrollee with a national average risk profile. The adjusted plan revenue requirements would serve as the organization's basic A/B bid. Thus, under a plan specific approach, the cost-sharing estimate and the basic A/B bid would be the result of the same estimating process enabling the organization to factor in any discounts it receives from providers, any utilization controls that influence services received, and any other plan-specific factors that should be considered in determining a fair and accurate bid.

To the extent that a plan does intend to use mandatory supplemental benefits, the question arises as to the relationship between the estimate of cost-sharing and plan revenue requirements for the assumed basic A/B package to the estimate of cost-sharing and revenue requirements under the integrated package that the plan intends to offer. Assume, for example, that the bidding organization, through the use of mandatory supplemental benefits intends to have no cost sharing at all in its plan and will rely on provider discounts and good utilization management to offer an efficient Medicare product. Because the basic A/B bid involves significant levels of cost sharing, utilization and hence plan revenue needs would increase from the estimate of plan revenue needed for basic A/B coverage to that for the planned integrated package (that is, basic A/B plus mandatory supplemental benefits). As previously discussed, this additional utilization resulting from reduced cost sharing would be included in the costs of mandatory supplemental coverage as part of the bid component for supplemental benefits. (Note that under the provisions of section 1854(a)(6)(A) of the Act, bids are for an "enrollee with a national average risk profile." The actuarial determination of cost sharing would also be for an enrollee with a national average risk profile.)

This method of determining the Medicare cost sharing amount is more complicated than the uniform amount method. However, we would not expect the calculation to be burdensome to MA organizations, since they would have to develop plan-specific estimates of cost sharing in order to price cost-sharing reductions provided as mandatory supplemental benefits. These kinds of actuarial estimates are necessary in connection with the design of any type of plan benefit package an MA organization offers or considers offering. While the Medicare cost sharing structure is complicated and varies by type of service provided, we would note that current MA plans have equally varied cost sharing applied to different services in the plans offered to Medicare enrollees. The plan-specific approach is also consistent with our position that additional utilization arising from reduced cost sharing must be priced as part of the mandatory supplemental component of the plan bid.

Proportional Method. Another method of determining a Medicare level of cost sharing is to use a proportional approach. Actuarial equivalence under this approach would be met if the ratio of a plan's cost sharing amount for the

basic A/B bid to the total cost of plan benefits equals this proportion under original Medicare. For example, if the national average actuarial value of cost sharing under original Medicare in a year were 16.8 percent of the total (value of cost sharing plus value of benefits, using the actual 1999 figure for Medicare), then an MA plan would have to offer a basic A/B bid based upon a plan basic cost-sharing amount that is 16.8 percent of total costs. We would announce the projected percentage of total expenditures that represent cost sharing in the same way that we currently announce the national average actuarial value of Medicare cost sharing as part of the rate announcement for private health plans.

Using a fixed national proportion is a variation on the uniform national dollar method, but it recognizes variation in expenditures at the health plan level. However, even within fee-for-service Medicare, there is significant variation by area in the cost-sharing proportion, ranging from 13 percent in Maryland to 20 percent in Nebraska in 1999 (compared to the national average of 16.8 percent). To address the issue of geographic variation in cost sharing, which also became a concern in the Medicare+Choice program, we are considering the development of regional or local cost-sharing proportions.

Using a proportional approach, plan pricing assumptions are built into the total value of the benefit package. However, any utilization effect within the plan of a Medicare-like cost-sharing structure is not factored in. Another factor that is not recognized in a straight national or local proportional method is that the mix of services within a health plan, and the costs associated with each category of services, may be different from the mix in fee-for-service Medicare. For example, plans may tend to favor post-acute care over acute care, which, if fee-for-service Medicare were to do the same, would alter the total cost sharing and the distribution of the cost sharing in relation to the types of services from which cost-sharing revenue is derived.

To refine the proportional method, and to attempt to be more consistent with the letter of the law ("cost sharing for * * * services as required under A and B"), we could develop service-specific proportions of cost sharing applied to the different categories of expenditures health plans would have (for example, a proportion would be stated for inpatient hospital care, a proportion for physician services, etc.). In order to further refine this approach, we would also incorporate assumptions about how health plans generally use services. We would then announce the (local area) service-by-service proportions plans would use to determine their actuarial equivalent of Medicare cost sharing. Such a local, adjusted proportional approach would be relatively easy for plans to implement, but it would involve an additional burden on us to develop varying percentages by area and by service category. Assumptions made about the distribution of services provided by private plans may not be consistent with the experience and practices of individual plans.

We invite comment on each of the alternatives we are considering to replace the national uniform amount method: localized uniform dollar amounts; plan-specific amounts; and proportions (national, regional, or local). We would have liked to provide a comparison of the effects on plan bids of these three methods for determining a level of beneficiary cost sharing that is actuarially equivalent to original Medicare. This is not possible at this time, however, because we have not fully developed these options. To specify impacts we would need to know exactly what data elements we would collect and what formulas we would use. We invite comment on the details of these alternatives methods and how best to implement them.

PACE organizations and the MMA bidding methodology. We believe, based on conference report language, that the Congress intended to exempt PACE organizations from the Title II bidding process, so payments for PACE plans would be based on MA capitation rates. However, this exemption does not apply to PACE organizations intending to offer Part D drug coverage to PACE enrollees. We expect that PACE plans would be required to submit bids to provide Part D drug benefits under Title I of the MMA, addressed in a separate rulemaking.

Information required. Sections 422.254(c) and (d) implement section 1854(a)(6)(A) of the Act by setting out the information MA organizations must submit for coordinated care plans (including regional MA plans and specialized MA plans) and private fee-for-service plans. Proposed § 422.254(e) specifies information that must be submitted for MSA plans.

In addition to submitting an aggregate bid amount, MA organizations must submit the proportions of the aggregate bid attributable to coverage of Part A and Part B benefits, Part D basic benefits, and supplemental coverage. They must also identify the plan type, projected enrollment, and any capacity limits, the actuarial bases for determining the bid amounts and proportions, and information on the plan's cost sharing, including the actuarial values of deductibles, coinsurance, and co-payments. Additional information required on drug coverage is specified at section 1860D–11(b) of the Act.

Under proposed § 422.254, for MA organizations required to provide a monthly rebate because the plan bid is less than the plan benchmark, the organization must submit information to us about how this rebate would be allocated across the options specified by the statute for a mandatory supplemental benefit: (1) Provision of supplemental health benefits, including additional health care benefits, reduction of cost sharing for original Medicare benefits and/or Part D benefits; and/or (2) reduction of the Part B, Part D, and/or mandatory supplemental benefit premium(s). For further discussion of requirements for rebates, see § 422.266.

Since MA regional plans may serve multiple regions, and each region is a separate service area, we will develop procedures to allow MA organizations to file consolidated bid information for multi-region MA plans (including national plans), in order to encourage the offering of regional plans, in accordance with section 1854(a)(1)(C) of the Act.

In addition to the information cited above, in 2006 and/or 2007, MA organizations offering regional plans must submit as a part of the bid package sufficient information for us to calculate risk corridor amounts. This information includes projected allowable costs (see discussion of subpart J) and the portion of the allowable costs attributable to administrative expenses incurred in providing these benefits. In addition, the plan must provide the total projected costs for providing rebatable integrated benefits as well as the portion of rebatable integrated benefits that are attributable to administrative expenses.

Finally, section 1854(a)(6)(A)(iii) of the Act gives us the authority to require information in addition to that listed above to allow us to verify the actuarial bases for plan bids. We have not yet determined the format for initial bid submission, and we will provide future guidance on these requirements.

Special rules for MSA plans. Section 422.254(e)(2) implements section 1854(a)(3) and section 1854(b)(2)(D) of the Act by indicating that bids are not required for MA MSA plans. However, for MSA plans MA organizations must submit the enrollment capacity, the monthly MSA premium amount, which is the amount of revenue the plan

requires to offer original Medicare benefits, analogous to the basic A/B bid for other MA plans. MA organizations must also submit the amount of the deductible, and the beneficiary supplemental premium, if any. MSAs are prohibited from offering Part D coverage (although MSA enrollees may choose to enroll in a prescription drug plan).

A supplemental benefit for an MSA plan cannot cover the MSA deductible. Health insurance policies for benefits described in section 1882(u)(2)(B) of the Act must not be treated as covering such a deductible.

Our goal is to maximize the diversity of plans available in the MA program, and to this end we welcome any comments that would help us improve our payment methodology for MSA plans.

4. Negotiation and Approval of Bids (§ 422.256)

Authority to review and negotiate bids. The provisions in proposed § 422.256 implement section 1854(a)(6)(B) of the Act, which provides us with the authority to negotiate the monthly aggregate bid amount and the proportions of the aggregate bid attributable to basic benefits, supplemental benefits, and prescription drug benefits. The MMA grants us the authority to negotiate bids that is "similar to" the statutory authority given the Office of Personnel Management (OPM) to negotiate with health benefits plans under the FEHBP program. Chapter 89 of title 5 gives OPM broad discretion to negotiate prices and levels of benefits. We believe that the Congress used "similar to" in the statute to recognize the differences between the two programs. For example, the OPM authority applies to negotiating the level of plan benefits, while Medicare benefits under Parts A and B are defined in law. Also, the authority to negotiate payment rates would seem to be limited for the MA program by other provisions of the MMA (for example, statutory formulas for determining benchmarks, premium and rebate amounts, and payments to plans).

However, plans are able to modify the cost sharing for Medicare Parts A and B benefits via supplemental benefits. We have the authority to negotiate the level of the supplemental benefits as part of ensuring that the bid is not discriminatory, as described in section 1852(b)(1) of the Act. Further, in situations where we have questions about the assumptions used for a plan bid, we will negotiate with the MA organization regarding the appropriate assumptions and the resulting rebate and/or supplemental premiums.

As provided under § 422.256(a)(2) and in accordance with section 1854(a)(6)(B)(iii) of the Act, we may not require: (1) Any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services under the Act; or (2) a particular price structure for payment under such a contract to the extent consistent with our authority. Also, as under current law, we do not have the authority to review or negotiate bids for private fee-for-service plans or any amounts submitted by MSA plans.

Standards of bid review. Section 422.256(b) implements section 1854(a)(6)(B)(ii) and (iii) and section 1854(e)(4) of the Act, which together establish three standards for our review of bids. First, the bid and proportions must be supported by the actuarial bases, which we determine based on information provided by the MA organization.

Second, the bid amount and proportions must reasonably and equitably reflect the plan's revenue requirements for providing the benefit package, as the term revenue requirements is used in section 1302(8) of the Public Health Service Act. We interpret this reference to mean that the Congress intends for a plan bid to reflect the plan's estimated required revenue in providing coverage, and not other factors such as the relative lack of competition in the plan's market area or the level of annual capitation rates and benchmarks in the service area.

Third, proposed § 422.256(b)(3) implements section 1854(e)(4) of the Act by providing for a limitation on applicable cost-sharing for coordinated care and private fee-for-service plans: the actuarial value of plan cost sharing "applicable on average" to plan enrollees cannot exceed the actuarial value of cost sharing "applicable * * * on average" under original Medicare.

We are interpreting "applicable" to mean the level of cost-sharing in effect *after any reductions to the level of cost sharing that a plan can make by offering a mandatory supplemental benefit, as specified under section 1852(a)(1)(B) of the Act.* That is, we apply this third standard of review, as specified under section 1854(e)(4) of the Act, in light of both the basic A/B bid and the application of any rebate toward reduced cost sharing of Medicare Parts A and B benefits included in the supplemental bid. Essentially, the requirement in section 1852 of the Act (discussed in connection with proposed § 422.254(b)(4)) that the actuarial value of MA plan cost sharing for Medicare Part A and Part B benefits assumed in constructing the basic A/B bid must equal the actuarial value of original Medicare cost sharing would affect how MA organizations develop their basic bids. Section 1854 of the Act places a cap on *actual* enrollee cost-sharing liability for Medicare Parts A and B benefits in relation to average cost sharing in fee-for-service Medicare in the service area as estimated by us. This means that if a plan's *aggregate* bid includes a mandatory supplemental benefit, the plan can have an actuarial value of cost sharing that is less than that under original Medicare because the plan rebate has been applied to a buy down plan cost sharing.

There has been some confusion about whether an MA plan can substitute a premium for some portion of the cost sharing under original Medicare. Section 1854(b)(2)(A)(i) of the Act (which would be implemented at proposed § 422.262(a)(1)) mandates that for plans with bids less than benchmarks, the premium for original Medicare benefits must be zero. Our understanding is that congressional intent was to have the basic A/B bid be for a standardized package. This means MA organizations able to offer plans with Medicare-covered benefits at a lower cost to the beneficiary than the benchmark will have a plan with zero premium for coverage of benefits under original Medicare.

However, any MA organization can choose to structure the benefit package with a mandatory supplemental benefit that includes a reduction in Medicare Part A and B cost sharing. The premium for this supplemental package, as well as the Part D or Part B premium, can be offset by any rebates for which the plan is eligible. Thus, the aggregate bid would consist of: (1) A basic A/B bid amount for benefits available for either zero premium or a basic premium depending on whether the plan's bid is above or below the benchmark; (2) a mandatory supplemental bid amount for benefits available for a premium or no premium depending on the plan's use of rebates (and an optional supplemental benefit if offered); and (3) a drug bid amount for basic benefits, also available at a premium or no premium depending on use of rebates.

Under the previous M+C program, we allowed M+C organizations to reduce beneficiary basic premium amounts as a part of the ACRP process, that is, they were allowed to take a negative adjustment on their additional revenues. Under the MMA, this type of adjustment is no longer permitted for the basic bid for benefits under the original Medicare

program. In accordance with section 1854(a)(6)(B)(ii) of the Act, plan bids must reasonably and equitably reflect plan expected revenue requirements. MA organizations cannot submit plan bids that understate their revenue requirements for the basic A/B bid. When the basic A/B bid amount exceeds the benchmark amount, the difference is required to be charged as a basic beneficiary premium. If an MA organization were able to waive the plan's basic beneficiary premium, this would suggest that the MA organization had overstated the plan's expected revenue requirements for basic benefits. In essence, we do not have the authority under the statute to allow MA organizations to waive basic beneficiary premiums for plans with basic A/B bids greater than benchmarks.

Negotiation process. Section 422.256(a) implements section 1854(a)(6)(B)(i) of the Act, which provides us the authority to negotiate with MA organizations. As mentioned above, we have the authority to negotiate to ensure that the bid is not discriminatory; and in situations where we have questions about the assumptions used for a plan bid, we will negotiate with the MA organization regarding the appropriate assumptions and the resulting rebate and/or supplemental premiums.

At this time, we have not completed development of the bidding and approval process. We expect to revise the current Adjusted Community Rate Proposal tool (both the Plan Benefit Package and the ACR spreadsheet) to align with MMA provisions for bid submission. We expect that the process of bid negotiation between between CMS and an MA organization could result in an agreement to adjust the bid's pricing, utilization, and/or enrollment assumptions. The MA organization would resubmit the bid information for the plan.

In addition, MA organizations may need to adjust the allocation of rebate dollars in a plan bid (see discussion below), so would also need to resubmit the bid.

Rules for adjustment of rebate dollar allocation. As required by section 1860D–13(a)(4) of the Act, CMS must publish a national average monthly bid amount for Part D based on an average of plan bid amounts. This means MA organizations must submit their plan bids (including the estimated drug premium amount) before knowing the national average monthly bid amount for basic coverage. Since section 1854(b)(2)(A) of the Act requires that organizations with basic A/B bids below benchmarks charge a zero basic beneficiary premium, in their initial bid submission MA organizations will allocate rebate dollars to mandatory supplemental benefit packages (to ensure that all beneficiaries receive the full value of their rebate amount, which may include the provision of a Part D premium reduction. For example, a plan may have an estimated Part D monthly premium of $35, and offer a mandatory supplemental package that applies $35 of its rebate to "buy down" the Part D premium to zero.

Given the preliminary nature of MA organizations' Part D premium submission, we expect that some rebate allocations to Part D premium reductions will be overestimated (excessive allocation) or underestimated (insufficient allocation). These misestimates will mean some portion of the beneficiary rebate has been credited where it is not needed or not enough has been credited to achieve the premium desired. For example, if a plan's monthly drug premium is determined to be $34, which is less than the projected premium of $35 in its initial bid submission, there was an excessive allocation of $1 of the rebate to fund the Part D premium reduction. We would require the MA organization to amend its bid submission to reallocate the excessive $1 of rebate credit to other mandatory supplemental benefits. On the other hand, if the plan monthly drug premium is determined to be $36, which is greater than the projected monthly premium of $35 in the initial bid submission, there is an insufficient allocation of $1. We would give the MA organization the option of reallocating $1 of rebate from another mandatory supplemental benefit toward the Part D premium reduction in order to eliminate the $1.00 Part D premium and return to the zero premium in the initial bid submission.

For this reason, we anticipate that some MA organizations will make minor technical adjustments to the benefit structures of their non-prescription drug bids. The adjustments would consist of reallocation of beneficiary rebate dollars in the mandatory supplemental benefit among the different categories allowed by law: Additional benefits, reductions in Part A/B cost sharing, reduction to the mandatory supplemental premium, and reductions in Part B and Part D beneficiary premiums. Modifications to Part D cost sharing could not be made, however, given the implications that such modifications would have on projected reinsurance dollars which then impacts the pricing of the bid for basic Part D benefits. Changes to the basic Part D portion of the bid would have implications for the national average monthly bid amount and, hence, the basic beneficiary premium that we would have just previously calculated for the year.

Note that the bid cannot be changed unless mutually agreed upon by CMS and the MA organization representatives as a result of our review and negotiation process. An example of an appropriate change would be if an MA organization elects to allocate rebate dollars to reduce its estimated Part D premium to zero in its initial June bid submission, and the outcome of the national average premium calculation is that the plan has an excessive allocation of rebate dollars so that the Part D premium has become a negative amount, such as –$3.25, this plan would have to reallocate $3.25 to other mandatory supplemental benefits to ensure enrollees receive the full amount of the rebate. Conversely, if another MA organization also elects to allocate rebate dollars to have a zero Part D premium, and the comparison with the national average drug premium results in an insufficient allocation of rebate dollars so that the Part D premium has become $1.42, this plan would have the option of reallocating the $1.42 of beneficiary rebate dollars to return to a zero premium, as submitted in the original June bid. (Bid amounts must be submitted no later than the first Monday of June each year, beginning for contract year 2006).

We also recognize that the June bid submission for regional MA plans will be based on unknown benchmarks not only for the drug premium but also for Medicare Parts A and B benefits. As discussed in § 422.258(c), the region-specific benchmark amount is based, in part, on a weighted average of the plan bids for Medicare Part A and Part B benefits, which we cannot calculate until after the June bid submission. This means that the exact amount of a plan's rebate is unknown and will shift to the extent that the estimated benchmark a plan uses to create its June basic A/B bid amount differs from the region-specific non-drug benchmark we establish based on plan bids. Therefore, regional MA plans will also be allowed to modify cost sharing (that is, increase or decrease reductions in the initial June bid submission), other than for Part D benefits, and certain premiums to arrive at the supplemental, Part B, and Part D premiums originally submitted.

We propose the following rules for the negotiation process concerning reallocation of rebate dollars due to excessive or insufficient allocation.

(1) Local MA plans with overestimated allocations to Part D premium reduction must reallocate

beneficiary rebate dollars to other mandatory supplemental benefits and can do so only for the purpose of achieving the original Part D premium in their initial bid submission.

(2) Local MA plans with underestimated allocations to Part D premium reduction have the option of reallocating beneficiary rebate dollars to other mandatory supplemental benefits. However, the plan could only reallocate rebate dollars for the purpose of achieving the Part D premium in the initial bid submission. In this circumstance, plans could choose to not adjust the new premium or reallocate the appropriate amount to achieve the initial premium submitted.

(3) Regional MA plans may reallocate beneficiary rebate dollars to achieve the supplemental, Part B, and Part D premiums in their initial bid submission.

(4) Local MA plans not offering Part D benefits (these would only be private fee-for-service plans who have elected this option) would have all the necessary information upon which to estimate their bid amounts for their initial June bid submission, and, therefore, the MA organizations would not be allowed to modify their plan benefit structures.

We believe that it is appropriate for MA organizations to only make technical adjustments or modifications during the negotiation process initiated by CMS in order to create a bidding process with integrity, to ensure that bids are meaningful, and to avoid the endless cycle of CMS benchmark calculation-plan benefit adjustment-CMS benchmark calculation. We invite comments on this issue.

5. Calculation of Benchmarks (§ 422.258)

Proposed § 422.258 would implement the new section 1853(j) of the Act (added by the MMA) by providing a description of how benchmarks for local MA plans are calculated. We will calculate benchmarks for each county, that is, MA local area. For a service area that is entirely within an MA local area, the MA area-specific non-drug monthly benchmark amount is equal to the monthly MA capitation rate for the local area. For a service area that is in more than one MA local area, the benchmark amount is calculated as a weighted average of the local MA monthly capitation rates. The monthly capitation rate for each local area is multiplied by the plan's projection of the proportion of its enrollees that will reside in each local area. These enrollment projections would be based on information submitted by the local plans for bidding purposes, as mandated under section 1854(a)(6)(A)(iii) of the Act. These products would be summed to yield the local area benchmark amount for that MA plan.

For all calculations that follow, CMS will determine the number of MA eligible individuals in each local area, in each region, and nationally as of the reference month, which is a month in the previous calendar year CMS identifies as the most recent month for which data is available.

Proposed § 422.258(b) and (c) would implement section 1858(f) of the Act by providing a description of how regional MA plan benchmarks are calculated. We would calculate benchmarks for the MA regional area. The benchmark amount for regional plans would be a blend of two components, the MA area-specific benchmark amounts and the plan bid amounts. The purpose of the blend would be to be more responsive to market conditions in the region by allowing plan bids to influence the final benchmark amount. This blending would allow a more accurate reflection of the actual revenue needs of the plans to be included in the bidding process.

Proposed § 422.258(b)(1) would implement section 1858(f)(2) of the Act by describing the two components of the MA regional benchmark, the statutory component and the plan bid component.

The statutory component would be based on the local area capitation rates. For each local area, the capitation rate would be multiplied by the ratio of the number of MA eligibles (based on the reference month), residing in the area to the number of MA eligibles (based on the same reference month) residing in the region. These products would be summed across all local areas in the region to yield the statutory component.

The plan-bid component would be based on the bids of all MA plans in the region. For each plan offered in a region, we will multiply the plan's unadjusted region-specific non-drug bid amount by the plan's share of enrollment (as determined under paragraph (c)(5)) and then sum these products across all plans offered in the region. We then multiply this by 1 minus the statutory market share to determine the plan-bid component of the regional benchmark.

The weighted average of plan bids for a region would be determined based on the number of regional plans offered in the region in a given year and the number of regional plans offered in the reference month. Section 1858(f)(5) of the Act, which we would implement in proposed § 422.258(c)(4) and (c)(5), addresses how to account for varying numbers of plans and different size plans in a region when determining the regional benchmark amount. If two or more regional plans were offered in the region in the reference month, the plan-bid component would be based on the weighted average of the plan bids, unadjusted for risk adjustment. Each plan's bid would be multiplied by the ratio of the number of MA eligibles in the reference month enrolled in the plan to the number of MA eligibles in the reference month enrolled in all the plans in the region. These products would be summed across all plans in the region to yield the plan-bid component.

If only a single regional plan is offered in the region in a year, the plan-bid component would be this plan's bid. If there were no regional plans offered in the reference month, but two or more new regional plans are offered in the region in a year, we may give equal weight to each plan's bid in determining the plan-bid amount. Alternatively, we may weight the bids based on each plan's estimate of its projected enrollment, with the reasonableness of the projections subject to our approval.

The MA regional benchmark would be the weighted average of the statutory component and the plan-bid component. The statutory component would be multiplied by the statutory national market share, which is the number of MA eligibles in the nation who were not enrolled in an MA plan during the reference month divided by the total number of MA eligibles in the nation. The plan-bid component would be multiplied by the non-statutory market share, which is the number of MA eligibles in the nation who were enrolled in an MA plan during the reference month divided by the total number of MA eligibles in the nation. These components would be added to yield the MA regional benchmark.

6. Beneficiary Premiums (§ 422.262)

Proposed § 422.262(a) would implement section 1854(b)(2)(A) of the Act, and would describe the new methodology for calculating the MA monthly basic beneficiary premium. This premium will now be determined by comparing the unadjusted plan bids to unadjusted benchmark amounts.

(1) For an MA plan with an unadjusted statutory non-drug bid amount (basic A/B bid) that is less than the appropriate unadjusted non-drug benchmark amount, the basic beneficiary premium is zero.

(2) For an MA plan with an unadjusted statutory non-drug bid amount (basic A/B bid) that is equal to or greater than the unadjusted non-drug benchmark amount, the basic

beneficiary premium is the amount by which (if any) the bid amount exceeds the benchmark amount. All approved premiums must be charged—that is, plans are not allowed to waive premiums.

Proposed § 422.262(b) would implement section 1854(d)(4) of the Act, which specifies that MA enrollees must be charged consolidated monthly premiums. As intended by the Congress and as a part of our efforts to simplify the process for beneficiaries, proposed § 422.262(b) states that an MA enrollee will pay a single premium consisting of the sum of all premiums a particular plan charges its enrollees, which will be one or more of the following: (1) The monthly basic beneficiary premium; (2) the monthly supplemental premium; and (3) the MA monthly prescription drug premium. In the case of an MSA plan, there are no basic beneficiary premiums since we instead make a deposit to the enrollee's MSA. MSA plans are high deductible insurance policies, not managed care plans. This means the only beneficiary premium for an MSA plan would be a supplemental premium.

Uniformity of premiums and cost-sharing. The MMA continues current MA regulations now in subpart G at § 422.304(b) regarding uniformity of beneficiary premiums and cost sharing within MA plans.

MA organizations offering local MA plans within segments of service areas must submit separate bids for those segments that will have different premiums and cost sharing. Section 1858(a)(1) of the Act mandates that regional MA plans must provide uniform premiums and cost sharing within a region, specifying that section 1854(h) of the Act (allowing segmented service areas) does not apply to regional MA plans.

Section 1854(d)(1) of the Act would be implemented in proposed § 422.262(e), describing the rules on the timing of payments by MA enrollees of their beneficiary premiums.

Proposed § 422.262(f) would implement section 1854(d)(2) of the Act on beneficiary payment options. This provision gives enrollees the option, at their discretion, of paying their MA consolidated premium by: (1) Having it deducted directly from their Social Security benefits in the same manner that Part B premium reductions are handled; (2) setting up an electronic funds transfer; or (3) through other appropriate means we may identify. The Congress provided for other beneficiary payment options including payment by an employer. Under employment-based retiree coverage, payment could be made on behalf of an employee, a former employee, or a dependent. All premium payments deducted from Social Security benefits would be credited to the appropriate Trust Fund as we specify, and will be paid to the appropriate MA organization. We would consult with the Commissioner of Social Security and the Secretary of the Treasury to determine which Trust Funds are the appropriate ones to credit. The MA organization must not impose a charge for individuals electing to pay their premiums through a deduction from their Social Security payments.

We would transmit the appropriate information (for example, name, social security number, consolidated monthly beneficiary premium owed by each beneficiary for each month in the year), and other information to the Commissioner of Social Security (SSA) as agreed to with SSA. We would consult with the Commissioner of Social Security about what information is appropriate to transmit. We would update this information, as necessary, during the year. We invite comments on the additional appropriate beneficiary payment options that we could institute as well as uses for and development of electronic funds transfer mechanisms to help beneficiaries pay their premiums.

7. Calculation of Savings (§ 422.264)

Under section 1854(b)(3)(A)(iii) of the Act, in calculating the monthly savings as a step in determining beneficiary rebate amounts for MA local plans beginning in 2006, the Congress gave the Secretary the flexibility to determine whether the risk adjustment factors to be applied to the local benchmarks and bids are determined on a State-wide basis, a plan-specific basis, or some other basis.

The advantage of applying a State-wide risk adjuster to benchmarks and basic A/B bids is that it ensures savings (and rebates) are uniform for beneficiaries in local plans in the same State. That is, plans with equal basic A/B bids (below the benchmark) within a State would have equal savings and rebates. This means that beneficiaries in equally efficient plans would not be either rewarded or penalized because they chose a plan with less healthy enrollees or a plan with healthier than average enrollees.

However, equally efficient plans with less healthy populations (as compared to the State-wide average) would be disadvantaged by a State-wide risk adjuster because it would be more costly for those plans to provide supplemental benefits with the same value as provided by healthier plans. The use of rebate dollars to reduce premiums (which is a dollar-for-dollar reduction in any kind of plan) is different than the use of rebate dollars to finance extra benefits, which cost more for a plan with less healthy enrollees. The cost difference for plans with a less healthy enrollee population is based on the assumption that enrollees in plans with a higher than average risk profile would use more services than enrollees in plans with lower risk profiles.

An additional practical complication of applying a State-wide risk adjustment factor might arise in situations where plans serve health care markets that cross State lines, since enrollees in the same plan who live in different States would be subject to different risk adjustment factors.

Section 1854(b)(3)(A)(iii) also provides the option of applying a plan-specific risk adjuster to the calculation of savings. This approach would address the above problem, in that among plans with equal basic A/B bids (below the benchmark), plans with less healthy enrollee populations would receive more rebate dollars and thus would be able to offer mandatory supplemental benefits that have close to the same value as plans with healthier enrollee populations. However, this would mean that plans operating at similar levels of efficiency, but with different risk profiles, would not have uniform beneficiary savings and rebates.

We are reviewing options for this adjustment and request comments on these two approaches.

In the case of States or other areas in which no local plans have been offered in the previous year, we may use average risk adjustment factors applied to comparable States or applied on a national basis.

Under section 1854(b)(3)(B) of the Act, we would apply an average risk adjustment factor (State-wide or some other applicable risk adjustment factor) to determine the risk-adjusted basic A/B bid and benchmark amounts for each local plan offered.

Section 1854(b)(3)(C) of the Act addresses how to determine the amount of savings for each local MA plan, if any, by calculating the amount by which the risk-adjusted benchmark amount exceeds the risk-adjusted bid amount. This provision would be implemented in proposed § 422.264(d).

Under section 1854(b)(4)(A)(iii) of the Act, for regional MA plans, the Congress provided us the flexibility to determine the basis for the risk-adjustment factors to be applied to regional benchmarks and bids. These could include average risk factors calculated on a regional or other geographic area or on a plan-specific basis.

Under section 1854(4)(B) of the Act, we would apply an average risk-adjustment factor (region-wide or some other applicable risk-adjustment factor) to determine the risk-adjusted bid and regional benchmark amounts for each regional plan offered.

Section 1854(b)(4)(C) of the Act addresses how to determine the amount of savings for each regional plan, if any, by calculating the amount by which the risk-adjusted benchmark amount exceeds the risk-adjusted bid amount.

The foregoing provisions would be implemented in § 422.264(d) and (e).

8. Beneficiary Rebates (§ 422.266)

Beneficiary rebate rule. Section 1854 (b)(1)(C) of the Act states that an MA plan with savings (because the basic A/B bid is less than the benchmark) must provide to the enrollee a monthly rebate equal to 75 percent of the savings amount for that plan for the year. The remaining 25 percent of the savings would be retained by the Medicare Trust Funds. If the plan basic A/B bid is equal to or greater than the benchmark, the plan has no savings and, thus, no rebate.

Proposed § 422.266(b) would provide, as set forth in section 1854(b)(1)(C)(ii) of the Act, that the beneficiary rebate could be provided in the following forms: Some part or all of the rebate can be credited toward the provision of supplemental health care benefits (including additional health benefits not covered under original Medicare, a reduction in cost sharing for Parts A, B, and D benefits, and/or a reduction in the premium for the mandatory supplemental benefits); or credited toward the prescription drug premium or Part B premium.

Proposed 422.266(b)(1) provides that all rebate dollars must be applied to a mandatory supplemental benefit. We interpret the provision at section 1854(b)(1)(C)(i) of the Act that an MA plan must provide to enrollees a rebate equal to 75 percent of savings to mean that rebate dollars must be provided to all enrollees in a plan. Therefore, rebate dollars could not be used to fund optional supplemental benefits because this would not guarantee that the plan is providing every enrollee with the rebate dollars.

Although rebate dollars can only be used to fund a mandatory supplemental benefit, a mandatory supplemental benefit may also be funded by beneficiary premium dollars. That is, a plan with a rebate may fund a mandatory supplemental benefit with rebate dollars only or with a mixture of rebate and premium dollars.

The MA plan would be required to inform us about the form and amount of the rebate and/or the actuarial value of the supplemental health care benefits. Adjustments to the structure of the benefit package would occur during the process of negotiating and approving bids detailed in proposed § 422.256.

If an MA organization elects to provide a rebate in the form of a reduction in the beneficiary Part B premium for beneficiaries in a particular plan, we would work with the Commissioner of Social Security to provide the necessary information to the Commissioner to apply a credit (as provided for under section 1840 of the Act) to reduce the amount of the Part B premium to be charged under section 1839 of the Act for each enrollee in that MA plan.

Under the previous M+C program, we permitted M+C organizations to offer new plans mid-year and to offer mid-year benefit enhancements to existing benefit packages. However, in order to maintain the integrity of the bidding process, we believe that it is no longer appropriate to allow MA organizations to enter the program with a new plan or to offer mid-year enhancements to an existing plan. Allowing an MA organization to offer a new plan after the June bidding cycle would not comply with section 1854(a)(1)(A) of the Act, which requires MA organizations to submit a bid for any plan it intends to offer in its service area (or segment of service area for local plans). Any mid-year benefit enhancements would be *de facto* adjustments to benefit packages for which bids were submitted earlier in the year based on their organization estimated revenue requirements. In essence, allowing mid-year benefit enhancements by an organization for a plan for which it submitted a bid in the previous June could render the bid meaningless.

9. Incorrect Collection of Premiums and Cost-Sharing for All Years (§ 422.270)

This section, which is identical to the previous language in the current MA regulations in subpart G at § 422.309, sets out procedures for situations in which an MA organization collects more than the amount the plan is allowed to charge its enrollees. The MA organization is required to refund the over-collections, and if the amounts incorrectly collected were premiums or included premiums, the MA organization may refund the enrollees through an adjustment to future premiums for all MA plan enrollees or a combination of a premium adjustment and a lump sum payment. An MA organization that collects amounts in excess of those permitted is subject to intermediate sanctions and civil money penalties under subpart O.

Subpart G—Payments to Medicare Advantage Organizations

(If you choose to comment on issues in this section, please include the caption "Subpart G—Payments to Medicare Advantage Organizations" at the beginning of your comments.)

As discussed above in connection with subpart F, we have proposed to revise subparts F and G in their entirety, and to reverse the order of the subjects addressed in these subparts. The current subpart F deals with payment rules while the current subpart G contains provisions relating to MA organizations' submission of benefit information and premium rules. Proposed subpart F addressed the provisions for MA organizations to submit bids for contract years after 2005, as well as provisions governing beneficiary premiums. In proposed subpart G, we would implement new MMA provisions governing payments to MA organizations.

The proposed regulations address how MA organizations continue to be paid on a monthly basis, but now based on the new methodology of plan bids established by the MMA. The proposed rules specifically provide that the specific amount of the payment for MA organizations (except MSA plans) depends upon the plan bid-to-benchmark comparison. The rules provide for an exception that payments for ESRD enrollees may be made outside of the MMA bidding methodology, but will be based on the new MMA capitation rates.

Further, the proposed text sets forth the calculations for the annual capitation rates established by the MMA and details the adjustments that will be made to capitation rates, benchmarks, bids, and MA organization payments. The regulations in this subpart describe the risk adjustment methodology and data requirements that must be met in order to properly adjust payment and benchmark amounts for the health status of enrollees, and then include the new date for publication of annual capitation rates, regional benchmarks, and payment methodology changes. Finally, they set forth a variety of special rules, including payments for enrollees electing hospice, and rates for payments to Federally qualified health centers (FQHCs).

1. Basis and Scope (§ 422.300)

Proposed § 422.300 sets forth the basis and scope for the revised subpart G, stating that it is based on sections 1853,

1854, and 1858 of the Act. It also indicates that the regulations in this subpart set forth the requirements for making payments to Medicare Advantage (MA) organizations offering local and regional MA plans, including calculation of MA capitation rates and benchmarks, conditions under which payment is based on plan bids, adjustments to capitation rates (including risk adjustment), and other payment rules. Since we are only able to share risk with regional MA organizations, see subpart J, § 422.458 for a description of risk corridors to be used by regional MA organizations in 2006 and 2007 only.

2. Monthly Payments (§ 422.304)

Under the current MA program, as set forth at section 1853(a)(1)(A)(i) of the Act, an MA organization is paid a fixed statutorily determined administrative amount each month, regardless of its actual revenue needs of providing services to the Medicare population enrolled in its plan(s). The MMA replaces this methodology beginning in 2006. We provide in proposed § 422.304(a) that, with the exception of payments to MSA plans and payments for ESRD enrollees in all other plans (discussed below), we would make advance monthly payments to an MA organization for each enrollee for coverage of original fee-for-service benefits in the plan payment area for a month, using the new bidding methodology described here and in the proposed subpart G regulations text.

The amount of our payment for an MA plan (except an MSA plan) depends on the relationship of the plan basic A/B bid to the benchmark amount. Section 422.304(a) describes two payment tracks. If the plan's risk-adjusted basic A/B bid is less than the risk-adjusted benchmark, the plan's average per capita monthly savings equals 100 percent of that difference, and the beneficiary is entitled to a rebate of 75 percent of this plan savings amount. The other 25 percent of savings remains in the Trust Funds (except for regional MA amounts used for the regional plan stabilization fund). We pay plans that have beneficiary rebates the amount of their aggregate bid (adjusted both for risk using the appropriate enrollee risk factor determined under our risk adjustment model and for intra-area payments variations) and the amount of the rebate (less any reduction in the Part B premium.

If the risk-adjusted plan basic A/B bid is equal to or greater than the risk-adjusted benchmark, the plan has no savings and thus no rebate, and we pay plans without rebates the benchmark for the geographic service area. This amount is adjusted for risk using the appropriate enrollee risk factor, for intra-area payment variations, and for the effects of risk adjustment on the enrollee basic premium. We apply a further adjustment to all plan payment amounts for variations among local payment rates

Under section 1853(a)(1)(D) of the Act, which would be implemented in proposed § 422.304(b), MA plans offering qualified prescription drug coverage also receive payments for the direct and reinsurance subsidy payments for basic prescription drug coverage and reimbursement for premium and cost sharing reductions for low-income individuals, described at sections 1860D–14 and 1860D–15 of the Act.

Special rules for enrollees with end-stage renal disease

Proposed § 422.304(c)(1)(i) would implement section 1853(a)(1)(H) of the Act, which instructs us to continue using the ESRD methodology we applied before the enactment of the MMA, specifically to establish special rates that are actuarially equivalent to rates in effect before the enactment of the MMA. We believe the MMA provided us with flexibility for determining ESRD payments because the cost and utilization patterns for ESRD beneficiaries are distinct from aged and disabled beneficiaries. We propose to continue paying MA organizations for their ESRD MA enrollees based on the State ESRD capitation rates. We would use the State ESRD rates calculated under the MMA rate setting methodology set forth in proposed § 422.306. We would continue to risk adjust the State payment rates, as provided at § 422.308(c). We also would continue to reduce payments for ESRD enrollees for the ESRD network fee, as provided in § 422.208(c)(4), as set forth at section 1881(b)(7) of the Act.

However, the mandate to pay using pre-MMA payment rates raises a payment issue regarding ESRD enrollees. Under the previous M+C program, an M+C plan could offer as an additional benefit the reduction of some or all of the standard Part B premium. CMS reduced the monthly payment to the M+C organization, and 80 percent of this reduction was applied to reduce the enrollees' Part B premiums. Twenty percent of this payment reduction was savings to the M+C program. This 80–20 split, which was in effect before the MMA, applied to all M+C plan enrollees, including those with ESRD. It is analogous to the MMA requirement that 25 percent of the difference between basic A/B bid and benchmark be returned to the government as savings.

Therefore, one option is for CMS to pay the risk-adjusted State rate per enrollee, which would be analogous to paying the benchmark to all plans, even those with basic A/B bids below the benchmark. Since the concept of splitting a payment reduction into government savings and plan benefit existed prior to the MMA, 75 percent of any reduction in CMS's payments for a plan would be applied to the Part B premium for plan enrollees.

Another option would be to consider the use of the State capitation rates in calculation of plan benchmarks as sufficient implementation of section 1853(a)(1)(H) of the Act. Accordingly, ESRD enrollees would be fully incorporated into the bid process, and payments for all enrollees would be either the risk adjusted aggregate bid plus rebate and other relevant adjustments discussed below or the risk adjusted benchmark. (Both bid and benchmark amounts would reflect the plan's relative weights of ESRD enrollees costs versus aged/disabled enrollee costs.) See the discussion in the Subpart F preamble on when to incorporate ESRD enrollees into the bid amount. We invite comments on these and other feasible payment approaches.

Special rules for payments to MSA plans. Section 422.304(c)(2) would implement section 1853(a)(1)(B)(iii) of the Act, which contains the same rules for MSA plans that existed under the previous M+C program. The only MMA change in payment provisions is that MSA plans become local MA plans, and we would make payments to MA organizations for MSA enrollees based on the non-drug benchmark amount (instead of county rates), less 1/12 of the annual lump sum amount (if any) we deposit to the enrollee's MA MSA, as determined under § 422.314(c). This payment amount is adjusted for enrollee risk, as set forth at § 422.308(c).

Our goal is to maximize the diversity of plans available in the MA program, and to this end we welcome any comments that would help us improve our payment methodology for MSA plans.

RFB plans. Section 422.304(c)(3) on special rules for religious and fraternal benefit (RFB) society plan enrollees is unchanged from the current MA regulation, now in subpart F at § 422.250(a)(2)(iii), allowing us to make payment adjustment reflecting the actuarial characteristics and utilization patterns of enrollees.

Payment areas. Proposed § 422.304(d) would implement section 1853(d) of the

Act, which changes the definition of payment area to account for the new MA regional plan program. Under the previous M+C program, a payment area was defined as a county or equivalent area defined by the Secretary (with the exception of ESRD enrollees, for whom the payment area was a State). The MMA establishes two general types of payment areas: (1) For MA local plans, the payment area is an MA local area (defined as a county or equivalent specified by CMS); and (2) for MA regional plans, the payment area is an MA region. The payment area for ESRD enrollees continues to be a State.

Section 422.304(e) implements section 1853(d)(4) of the Act, which permits a State's chief executive to request that we use alternative payment areas. This provision retains the same language as the previous M+C provision, with the exception that the statute specifies this option applies only to local MA plans. No State has availed itself of this option since its enactment in 1998. (Note that the terminology used in the statute to refer to statistical areas is inconsistent with new definitions and designations of metropolitan areas published by the Office of Management and Budget in June of 2003. The terms "consolidated metropolitan statistical area" and "primary MSA" are no longer used. There are now metropolitan statistical areas and metropolitan divisions of such areas, a change which is reflected in the text of the proposed rule.)

3. Annual MA Capitation Rates (§ 422.306)

For years before 2004, payments to MA organizations were based on the highest of three amounts: (1) A "blended rate" based on a blend of national and local data on Medicare's costs for providing services to beneficiaries not enrolled in an MA plan, (2) a "floor amount," based on an amount specified in statute, subject to an update factor, and (3) an amount representing the previous year's rate updated by a minimum percentage increase. The MMA replaces the "highest of three rates" methodology in several phases. For 2004, the MMA specified a transitional methodology, where the county and State rates were the "highest of four rates": the floor amount rate, blend rate, minimum percentage increase rate (which was redefined to be the higher of 102 percent of the previous year's rate or the previous year's rate increased by annual MA growth percentage), and the 100 percent of fee-for-service (FFS) costs rate introduced by the MMA. For the next phase, the MMA specified that beginning with 2005, annual capitation rates will be minimum increase rates except for years when we rebase the FFS rate; in rebasing years, the rate is the higher of the minimum increase rate and the FFS rate. The MMA requires us to rebase the FFS rates no less than every 3 years; that is, at least every 3 years a "higher of two rates" methodology is in effect.

Hence, proposed § 422.306(a) would implement the revised version of section 1853(c)(1)(C) of the Act, which defines the minimum percentage increase rate. As noted above, the minimum percentage increase rate is modified to be the greater of 102 percent of the prior year's rate or the prior year's rate increased by the national per capita MA growth percentage.

The MMA also provides that no less than every 3 years, we must assign 100 percent of local per capita FFS costs as the county rate in those counties where this amount is higher than the minimum percentage increase rate. The new FFS rate is defined as the adjusted average per capita cost (AAPCC) for the MA local area, as determined under section 1876(a)(4) of the Act, based on 100 percent of FFS costs for individuals who are not enrolled in an MA plan for the year, with the following adjustments: (1) Standardized for the county risk profile relative to the nationally average beneficiary; (2) adjusted to exclude costs of direct graduate medical education; and (3) adjusted to include our estimate of costs for VA and DOD military facility services to Medicare-eligible beneficiaries.

We must recalculate the AAPCC rate no less than once every 3 years. The statute gives us the authority to determine how often to "rebase" the rate book within this 3-year window. We intend to announce our intention annually in the 45-Day Advance Notice regarding whether we will rebase the rate book for the upcoming year.

4. Adjustments to Capitation Rates, Benchmarks, Bids, and Payments (§ 422.308)

The annual capitation rates described above will be adjusted under provisions set forth in proposed § 422.308.

Language in proposed § 422.308(a) remains the same as that currently in subpart F of the current regulations governing MA payments. Under section 1853(c)(1)(C) of the Act, the MMA makes only one change to how we must apply the national growth percentage each year to increase the minimum percentage increase rate. As we provide in proposed § 422.308(b), no adjustment can be made for changes in prior years' estimates of the national growth percentage for years before 2004.

Risk adjustment. Proposed § 422.308(c) would implement section 1853(a)(1)(C) of the Act, which requires us to adjust the payment amount for an MA plan to take into account the health status of the plan's enrollees. In order to ensure that MA organizations are paid appropriately for their plan enrollees (less or more healthy), we would apply these adjustment factors to all types of plans (with the exception of MA RFB plans, discussed at § 422.304(c)(3)). In 2006, 25 percent of our payment to MA organizations for aged and disabled enrollees will be based on current demographic factors, and 75 percent based on the CMS–HCC risk adjustment model. In 2007 and succeeding years, 100 percent of payment will be risk-adjusted. Note that for ESRD MA enrollees, payments to MA organizations are 100 percent risk adjusted under the CMS–HCC ESRD risk adjustment model, effective January 1, 2005. Also, for PACE organizations, the transition blends are one year behind that for MA organizations. Therefore, PACE organizations will receive 100 percent risk adjusted payments in 2008 and succeeding years.

The demographic adjustment factors for aged and disabled enrollees are age, sex, institutional status, Medicaid status, and working aged status. The demographic adjustment factors for ESRD enrollees are age and sex factors. Under the CMS–Hierarchical Condition Category (HCC) risk adjustment payment methodology, there are CMS–HCC models for three different populations: community-based, long-term institutionalized, and ESRD beneficiaries. Currently, the CMS–HCC factors in these models include age, sex, original reason for entitlement, Medicaid status, and disease factors. A plan-level working aged adjustment is applied to the risk-adjusted portion of the payment. The statute continues to provide us the authority to add to, modify, or substitute for risk adjustment factors if the changes will improve the determination of actuarial equivalence. Additional factors would enable us to pay more accurately for different types of beneficiaries, that is, the healthier and less healthy MA enrollees.

Adjustment for intra-area variations. Proposed § 422.308(d)(1) would implement section 1853(a)(1)(F)(i) of the Act, which requires us to adjust payments for local and regional MA plans to account for variations in "local payment rates" within each region the plan is serving.

Proposed § 422.308(d)(2) would implement section 1853(a)(1)(F)(ii) of the Act, which requires us to adjust payments for a local MA plan serving

more than one county to account for variations in "local payment rates" within the plan's service area.

This adjustment relating to risk adjustment recognizes that costs in some portions of a plan's service area could be higher than those in lower-cost areas covered by the plan. Plans serving both low-cost and high-cost areas will have bids and benchmarks reflecting costs averaged across these areas, since these are weighted by a plan's projected enrollment. Those plans whose actual enrollment reflects a greater proportion of residents in higher-cost areas than was projected for enrollment when calculating the plan bid may see payments coming in below cost projections.

Although the statutory language referring to adjustments for intra-area variations is similar for regional plans (section 1853(a)(1)(F)(i) of the Act) and local plans (section 1853(a)(1)(F)(ii) of the Act), we are interpreting the phrase "variation in local payment rates" to mean that there could be different reasons for the variation in payment rates in regional versus local plans. For example, regional MA plans could have significant variation in their payment areas because they are required to cover at least one State, thereby being compelled to include urban and rural areas in one region. These areas could have significantly different provider practice and beneficiary utilization patterns, wage indices, and other factors that affect the cost of providing services to plan enrollees.

Therefore, we may apply different methodologies to regional and local plan payments to adjust for rate variations within a plan's service area. Also, we are assuming the statutory language would allow approaches other than adjusting back to county capitation rates.

We are reviewing options for this adjustment other than making adjustments based on county rates. One option would be to apply an index based on local fee-for-service rates compared to the national fee-for-service average. Another possibility is an index that reflects input price differences, such as some indicator of local wage rates to a national average. We may apply separate adjustments to regional and local plans.

In deciding how to proceed, we will review Medpac's upcoming study on MA payments, required by the MMA, which will include an analysis of the bases for variation in costs among different areas, including differences in input prices, utilization, and practice patterns. We also invite public comments on the best approach to this adjustment.

Adjustment relating to risk adjustment. Proposed § 422.308(e) would implement section 1853(a)(1)(G) of the Act, which requires us to adjust payments to plans with basic A/B bids above their benchmarks to ensure that plans are not advantaged or disadvantaged by the method of paying based on bid-to-benchmark comparisons. Under the bidding method, the beneficiary basic premium is the difference between unadjusted ("1.0 beneficiary") bid and benchmark, yet the payment is the risk adjusted benchmark. If the MA organization received this premium and its risk adjusted payment from CMS, the combined payments would not match its revenue needs since the basic premium is not risk adjusted. Therefore, the impact that risk adjustment would have had on the basic premium will be incorporated into our payment to the organization. Without this adjustment, a plan with a higher-than-average risk score would receive a total payment (beneficiary premium plus Government contribution) that was less than the plan's bid, which represents the plan's estimated revenue requirements (in addition to member cost sharing). Conversely, a plan with a lower-than-average risk score would receive a total payment that exceeded its bid.

Proposed § 422.308(e)(1) specifies that for each regional plan, payments are adjusted so the sum of the monthly payment and any basic beneficiary premium equals the bid adjusted for enrollee risk factors and the adjustment for intra-area variations in payments in proposed § 422.308(d)(1). Note that the formula as stated at section 1853(a)(1)(G)(ii) of the Act also references the adjustment discussed in the previous paragraph—for intra-regional variations in local payment rates.

Proposed § 422.308(e)(2) specifies that for each local plan, payments are adjusted so the sum of the monthly payment and any basic beneficiary premium equals the bid adjusted for enrollee risk factors. We note that, in contrast to the language for regional plans at section 1853(a)(1)(G)(ii) of the Act, the formula for local plans does not include a reference to the intra-area variation described in proposed § 422.308(d)(1). We believe this is an unintended omission for local plans, since section 1853(a)(1)(F) of the Act mandates this adjustment for both regional and local plans serving more than one county.

This adjustment must be applied after risk adjusting the payment for the individual MA enrollee's health status and after taking into account adjustments for intra-area variation in local payment rates under § 422.304(d).

Adjustment of payment to reflect the number of enrollees. Proposed § 422.308(f) would implement section 1853(a)(2)(A) of the Act, which is unchanged by MMA. We therefore are proposing to retain the existing implementing regulatory language currently found in Subpart F. This provision requires us to make retroactive payment adjustments to account for any difference between the actual enrollees and the enrollees upon which we based advanced monthly payment.

Adjustment for national coverage determination (NCD) services and legislative changes in benefits. Section 1853(c)(7) of the Act requires that when a national coverage determination (NCD) or legislative change in benefits is established and we project this will result in a significant increase in costs, we must appropriately adjust payments to reflect these new significant costs. In the final rule titled "Modifications to Managed Care Rules," published August 22, 2003 at 68 FR 50840, we amended the MA regulations to refine the definition of "significant" cost and interpret appropriate adjustment of payments to include a new "NCD adjustment factor" effective for CY 2004 that was to be added to the county rates in those counties receiving a 2 percent minimum update rate.

Since all capitation rates under the MMA now automatically build in the annual national MA growth percentage, there is no longer a need to implement the NCD adjustment factor. Therefore, we are proposing to reverse the regulatory change established by the August 22, 2003 final rule, to eliminate this adjustment factor. Proposed § 422.308(g) reflects this change. See the preamble discussion for § 422.109 for additional information on this issue.

Section 1858(c) of the Act provides for temporary risk corridors for adjusting payments to regional plans, and proposed § 422.308(h) specifies data submission requirements to implement risk corridor payments. At the end of contract year 2006 and/or 2007, and before a date we specify, MA organizations offering regional plans must submit sufficient information for us to calculate risk corridor amounts (see the discussion of regional plan risk corridors in proposed § 422.458 below).

This information includes actual allowable costs for the relevant contract year and the portion of allowable costs that are attributable to administrative expenses incurred in providing these

benefits. In addition, the MA organization would be required to provide the total cost for providing rebatable integrated benefits, as well as the portion of rebatable integrated benefits costs that are attributable to administrative expenses.

5. Risk Adjustment Data (§ 422.310)

Proposed § 422.310 reflects changes we made in the methodology for risk adjusting MA payments, under which we moved from the collection of extensive encounter data to collecting targeted risk-adjustment data. The risk-adjustment data that are referenced in this section are data that are used in the application of the current risk-adjustment model. Originally enacted in the BBA, section 1853(a)(3)(B) of the Act provides us with the authority to collect traditional Medicare data in a standard format, but allows MA organizations to submit data in alternative formats. This data collection authority is retained in the MMA. In addition, under this same authority, we believe that we may also collect data regarding other enrollee characteristics such as functional limitations if the data are used in the risk adjustment model.

The language in § 422.310 is similar to that used in subpart F of the current MA regulations at § 422.257. The following summarizes the highlights of those provisions. Under our data collection authority, § 422.310 specifies that each MA organization must submit to us all data necessary (as stipulated under this section) to characterize the context and purpose of each service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. The BBA gave us the authority to collect data regarding inpatient hospital services and other services as we deemed necessary. The BIPA affirmed the collection of ambulatory data. Under section 1853(a)(1)(C) of the Act, beginning for payments in calendar year 2006, we will use these data to determine the risk adjustment factors to be applied to the basic A/B bid and the benchmark amounts upon which the payments and monthly savings for an organization are based. We may also use the data for other purposes, such as quality improvement studies and program integrity functions.

We have implemented a streamlined process for MA organizations to submit risk-adjustment data. MA organizations may submit risk-adjustment data that conform to the requirements for equivalent fee-for-service data. Alternatively, organizations may submit data according to an abbreviated format as specified by us. The purpose of the abbreviated format is to reduce the data submission burden on MA organizations.

In addition, our current practice is to collect a data, a sample of medical records, for conducting validation studies of the risk adjustment data CMS receives. MA organizations will still be required to submit a sample of medical records in a manner specified by CMS to support the validation studies. We do not use medical records data for any other purpose.

The risk adjustment data must be submitted according to the timeframes specified by CMS. A reconciliation process will be allowed to account for late data submissions. Data that we receive after the final deadline for a payment year will not be accepted for purposes of the reconciliation.

6. Announcement of Annual Capitation Rates, Regional Benchmarks, and Methodology Changes (§ 422.312)

Proposed § 422.312 would implement section 1853(b) of the Act, which was revised by MMA to change the date for CMS' announcement of annual capitation rates to no later than the first Monday in April of each year. In addition, we must announce before the beginning of each annual, coordinated election period the non-drug benchmark amounts for each MA region and MA regional plan for which a bid is submitted. We must announce regional benchmarks after the plan bids are submitted in June, since per the new section 1858(f)(5) of the Act, the regional benchmark calculation includes a plan bid component based on regional plans that bid in June and also participated in the MA program in the previous year.

The deadline for our release of the Advance Notice of Methodological Changes was similarly changed by MMA to no later than 45 days before the first Monday in April.

7. Special Rules for Beneficiaries Enrolled in MA MSA Plans (§ 422.314)

Proposed § 422.314 would implement section 1853(e)(2) and (3) of the Act, which sets forth special rules for how we should make payments to enrollees' medical savings accounts. The MMA did not amend the payment provisions in section 1853(e) of the Act, so these provisions are similar to the provisions at § 422.262 in subpart F of the current MA regulations.

In general, we deposit into the individual's MA MSA account at the beginning of a calendar year a lump sum equal to the annual difference between the monthly MSA premium (analogous to a plan bid) and the monthly benchmark amount. The premium filed by the organization offering the MA MSA plan is uniform for all enrollees enrolled in the MA MSA plan. This results in a uniform amount being deposited in enrollees' MSAs in a given service area, since the uniform premium amount will be subtracted from the uniform benchmark amount for every enrollee in the plan service area.

While monthly premiums are uniform within a plan, the advance monthly payments we make to an MA organization for each enrollee in the plan are risk adjusted under § 422.308(c), as discussed in connection with proposed § 422.304(c)(2) on special rules for payments for MSA enrollees. As noted above, we invite comments on improved methods for making payments to MSA plans.

8. Special Payment Rule for Federally Qualified Health Centers (§ 422.316)

MMA added a new section 1853(a)(4) of the Act, which provides for a new payment methodology for FQHCs that contract with MA organizations. Under this methodology, the FQHCs will receive a "wrap-around payment" from us representing the difference (if any) between what they are paid by an MA organization, including beneficiary cost sharing, and 100 percent of their "reasonable costs" of providing care to patients served at the centers who are enrolled in an MA plan.

Section 1857(e)(3) of the Act, also added by MMA, requires that MA organizations that contract with FQHCs pay the FQHCs an amount that is not less than the level and amount of payment they would make for the services if furnished by an entity providing similar services that was not an FQHC. This is designed to avoid an agreement between an MA organization and an FQHC to pay and agree to an artificially low rate, with the knowledge that the FQHC would receive supplemental payments from us resulting in a total of 100 percent cost reimbursement.

9. Special Rules for Coverage That Begins or Ends During an Inpatient Hospital Stay (§ 422.318)

The MMA amended section 1853(g) of the Act, which puts forth special payment rules for situations where a beneficiary's coverage by an MA plan begins or ends while the beneficiary is a hospital inpatient. The MMA amendment expands the list of hospital facilities covered under this provision to include those that have come under a Medicare prospective payment system since the Balanced Budget Act. In addition to "subsection (d)" hospitals,

three other types of facilities are now included: rehabilitation hospitals, distinct part rehabilitation units, and long-term care hospitals. These changes are reflected in proposed § 422.318, which otherwise retains existing language from subpart F applicable only to subsection (d) hospitals.

10. Special Rules for Hospice Care (§ 422.320)

Proposed § 422.320 revises the existing MA special rules for hospice care to reflect the new bidding and payment methodology in sections 1853 and 1854 of the Act, and the creation of a prescription drug benefit under Part D. Previously, no payment was made to an MA organization on behalf of a Medicare enrollee who had elected hospice care under § 418.24 except for the portion of the payment applicable to the additional benefits. Now the MA organization will be paid the portion of the payment attributable to the beneficiary rebate for the MA plan plus the amount of the subsidies related to basic prescription drug coverage for plans that offer prescription drug coverage.

Note that for PACE organizations, PACE enrollees must elect either their PACE plan or the hospice benefit as their provider of Medicare services. An enrollee who elects to enroll in hospice is thereby disenrolled from the PACE benefit. However, PACE plans do provide a service similar to hospice known as "end-of-life-care."

11. Source of Payment and Effect of MA Plan Election on Payment (§ 422.322)

With the exception of a new provision addressing payments for Part D benefits, proposed § 422.322 is identical to § 422.268 in subpart F of the current MA regulations at § 422.268. Section 422.322(a)(2) has been added to reflect the creation of subsidized prescription drug coverage under Part D. As required by section 1853(f) of the Act, subsidy payments to MA–PD organizations for basic drug coverage under this title are included in the payments described in § 422.322(a)(2) (which are made from the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund).

12. Payments to MA Organizations for Graduate Medical Education Costs (§ 422.324)

These provisions are identical to the current MA provisions in subpart F at § 422.270, and require us to make payments to MA organizations for Direct Graduate Medical Education costs that MA organizations incur in dealings with non-hospital provider settings, under specified conditions.

Subpart I—Organization Compliance With State Law and Preemption by Federal Law

(If you choose to comment on issues in this section, please include the caption "Subpart I—Organization Compliance with State Law and Preemption by Federal Law" at the beginning of your comments.)

The MMA amended section 1856(b)(3) of the Act relating to Federal preemption of State law. Before this amendment, section 1856(b)(3) of the Act provided for two types of preemption, general and specific. Section 1856(b)(3)(A) of the Act provided that State laws that were inconsistent with M+C rules were preempted. Section 1856(b)(3)(B) of the Act provided that, even if a State law did not conflict with an M+C standard, it was preempted if it addressed one of four specified areas (benefit requirements, including cost-sharing rules; requirements relating to the inclusion or treatment of providers; requirements concerning coverage determinations and related appeals and grievance processes; and requirements relating to marketing materials and summaries and schedules of benefits concerning M+C plans).

Thus, the presumption was that a State law was *not* preempted if it did not conflict with an M+C requirement, and did not fall into one of the four specified categories. MMA reversed this presumption, providing that State laws are presumed to be preempted unless they fall into two specified categories. Specifically, section 1856(b)(3) of the Act now states that "the standards established under this section shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency)." The reason for such broad preemption authority is that the Congress intended that the MA program, as a Federal program, operate under Federal rules. There has been some confusion in recent court cases with respect to the preemption of State laws. Therefore, this broad preemption would apply prospectively, that is, it would not affect previous and ongoing litigation related to preemption of State laws. Furthermore, we believe the Congress broadened this authority to facilitate the operation of regional PPOs, which may have service areas that cross State lines.

We note that the Conference Report makes it clear that the Congress intended to broaden the scope of preemption through this change. Thus, we believe that the exception for State laws that relate to "State licensing" must be limited to State requirements for becoming State licensed, and would not extend to any requirement that the State might impose on licensed health plans that—absent Federal preemption—must be met as a condition for keeping a State license.

If a State requirement could be considered to relate to State licensing simply because the State could revoke a health plan's license for a failure to meet the requirement, this would mean that States could impose virtually any requirement they wished to impose without the requirement being preempted. This would extend even to State laws that were specifically preempted under the pre-MMA version of section 1856(b)(3) of the Act, such as benefit requirements, rules regarding the inclusion and treatment of providers, and rules regarding coverage decisions and related grievances and appeals. Because we believe that it is clear that the Congress intended to broaden the scope of Federal preemption, not to narrow it, we also believe that the exception for laws relating to State licensing must be limited to requirements for becoming State licensed (such as filing articles of incorporation with the appropriate State agency, or satisfying State governance requirements), and not extended to rules that apply to State licensed health plans.

Upon review of this regulation, we do not believe that the language in existing paragraph (c) of § 422.402 is necessary. Section 422.402(c) currently states that nothing in this section may be construed to affect or modify "any other law or regulation that imposes or preempts a specific State authority." We do not believe that this paragraph has any real effect, since the real issue would be whether the preemption in section 1856(b)(3) of the Act is controlling on the matter. This analysis would be unaffected by language in a regulation implementing section 1856(b)(3) of the Act. We therefore are proposing to remove the current § 422.402(c).

We therefore propose to revise § 422.402 to clearly state that the MA standards supersede State law and regulation with the exception of licensing laws and laws relating to plan solvency. Accordingly, with the exceptions of State licensing laws or State laws related to plan solvency, State laws do not apply to MA plans offered by MA organizations.

MMA also amended section 1854(g) of the Act, which prohibits States from imposing taxes on premiums paid to MA Organizations by us. Section 232 of

the MMA amended section 1854(g) of the Act to provide that States are also expressly prohibited from imposing a premium tax, or similar type of tax, on premiums paid by beneficiaries or third parties on behalf of beneficiaries to MA organizations. We have incorporated this clarification at § 422.404(a).

Subpart J—Special Rules for MA Regional Plans

(If you choose to comment on issues in this section, please include the caption "Subpart J—Special Rules for MA Regional Plans" at the beginning of your comments.)

We are proposing a new Subpart J which would implement the provisions in the new section 1858 of the Act. Section 1858 of the Act sets forth the special rules that apply to new regional MA plans. We note that the regional MA plans would have many similarities with local MA plans. For example, both regional and local MA plans would be subject to the same process of bidding against a "benchmark" amount. In the case of regional plans, however, the benchmark amount would be region-wide, based on a weighted average of the benchmark amounts for the payment areas in the region in question, and (unlike local plans) including plan bids as a determinant of the benchmark. This methodology is set forth in sections 1853 and 1854 of the Act, and would be implemented in subparts F and G of part 422, as discussed in the discussions of those two subparts above.

The Congress has also provided for a number of unique financial and administrative incentives designed to support the introduction of regional PPO plans. These incentives would assist plans as they enter this new line of business and learn the market dynamics of serving beneficiaries across larger geographic areas. We have placed many of the special regional PPO requirements and incentives in subpart J.

However, there are certain provisions relevant to regional MA plans that are not located in subpart J that we also note below to assist the reader in identifying the unique features of MA regional plans, which are required to be structured as preferred provider organizations (PPOs).

To encourage the formation of regional plans, a two-year moratorium is established on new local preferred provider plans from January 1, 2006 until December 31, 2007. PPOs that exist prior to this date (including demonstration PPOs) can continue and expand enrollment in their existing service area (*See* § 422.451). Regional MA PPO plans also would have certain mandatory features to encourage beneficiary enrollment. For example, MA regional plans, to the extent they use deductibles, would have a single deductible for all original Medicare fee-for-service benefits (Part A and Part B) received through providers in the plan's provider network ("preferred providers").

In addition, beneficiaries in regional plans would have an annual catastrophic cap on their out-of-pocket spending for both in-network and out-of-network costs of Part A and B benefits. (*See* section 1858(b) of the Act which is implemented in § 422.112 of subpart C of this proposed rule.) Note that both the single deductible and the annual cap on out-of-pocket spending would be part of a cost sharing structure in which the aggregate actuarial value of the cost sharing across the enrolled population of the plan is equivalent to the aggregate level of Medicare FFS cost sharing. That is, on average enrollees in MA regional plans are paying the same level of cost sharing as they would if the plan's cost sharing structure were the same as Medicare's, but individual enrollees with higher than average health care costs may be paying less in actual cost sharing than they would under Medicare's cost sharing structure because of the catastrophic cap.

A network adequacy fund would also be implemented that would assist regional plans in forming adequate networks, particularly in rural areas. This fund would provide enhanced payments for certain essential hospitals that accept enrollees in regional PPOs. (*See* section 1858(h) of the Act, which is implemented in § 422.112 of subpart C of this proposed rule.)

As discussed in more detail below, the new subpart J would contain regulations that address: (1) The provision in section 1858(a) of the Act for the establishment of MA regions, including the principal factors we must balance in selecting these regions; (2) the availability of a temporary waiver of the State licensure requirement; (3) the MA regional plan risk corridors; and (4) the availability of a stabilization fund for MA regional PPO plans.

1. Establishment of the MA regions (§ 422.455)

In this proposed section we would implement section 1858(a) of the Act, which requires us to establish the regions that would constitute the service areas for the regional MA plans. Under the statutory requirements of section 1858(a) of the Act, MA regional plans would be required to serve an entire region. We would announce the MA regions by January 1, 2005. The regional plan would become operational on January 1, 2006. The statute also specifies that the MA regions should maximize the availability of regional plans for Medicare beneficiaries, particularly those residing in rural areas, regardless of their health status. The statute also requires that we establish between 10 and 50 regions within the 50 States and the District of Columbia. To assist us in developing the MA regions, we must conduct a market survey and analysis, including an examination of current insurance markets. We may periodically review MA regions and, based on the review, revise the regions. An MA regional plan may be offered in more than one region, including all regions.

In the MMA Conference Agreement, the Congress has also provided some general suggestions for us in establishing the MA regions. To the extent possible, the conferees suggest that each region include at least one State, that the regions not divide States across regions, and include multi-State Metropolitan Statistical Areas in a single region.

At this point, we would propose also to consider the following factors in selecting the MA regions:

- The number of eligible Medicare beneficiaries residing in each region.
- The regional payment rates would be reasonably similar.
- To the extent possible each region would contain a balance between rural and urban areas.
- Consideration would also be given to the inclusion of health care market areas within regions.
- To the extent possible, PPO regions should be the same as drug regions.

Due to the requirement to conduct a market analysis, we are not proposing specific regions at this time. We are interested in receiving comments regarding how we can best address the considerations discussed above in selecting the regions in order to meet our goal of maximizing beneficiary access to MA regional PPO plans. We are also interested in comments related to other factors we should consider in defining regions. Our objective is to obtain broad public comment on the supporting information and analysis that will be used by us to inform our selection of the regions. We held a public meeting in Chicago, Illinois on July 21, 2004 to discuss options for PPO and PDP regions. The meeting materials containing preliminary regional PPO and PDP options may be found at *http://www.cms.hhs.gov/medicarereform/mmaregions.*

2. Risk Sharing (§ 422.458)

Section 1858(c) of the Act provides that Medicare will share risk with MA regional plans for contract years 2006 and 2007 if plan costs are above or below a specific risk corridor. Risk sharing is intended to encourage plans to enter the regional market and to provide assistance to these plans during the start-up phase of their business.

Section 1858(c) of the Act defines which plan costs ("allowable costs") and plan revenues ("target amount") we may consider to determine risk-sharing payments to regional MA plans. Under section 1858(c)(1)(D) of the Act, a subset of supplemental benefits called "rebatable integrated benefits" must be included on both the cost and revenue sides of risk corridor calculations. Proposed § 422.258(a) defines rebatable integrated benefits as those non-drug supplemental benefits that are funded through beneficiary rebates (described at § 422.266(b)(1)) and that we determine are: (1) Additional health benefits not covered under the original Medicare program option; and (2) benefits that require expenditures by the plan. We discuss in more detail below what supplemental benefits may be considered rebatable integrated benefits.

Proposed § 422.258(a) would implement section 1858(c)(1)(C) of the Act by defining allowable costs for an MA regional plan as the total amount of costs incurred in a year in providing benefits covered under the original Medicare fee-for-service program option for all enrollees and in providing rebatable integrated benefits as defined in this paragraph), reduced by the portion of those costs attributable to administrative expenses incurred in providing these benefits.

Proposed § 422.258(a) would implement section 1858(c)(2)(D) of the Act by defining the target amount for an MA regional plan as the total amount of payments made to the organization for enrollees in the plan for the year (which means payments attributable to the bid for benefits under the original Medicare fee-for-service program option as defined in § 422.100(c)(1), the total of the MA monthly basic beneficiary premium collectable for those enrollees for the year, plus the total amount of rebatable integrated benefits), reduced by the amount of administrative expenses assumed in the portion of the bid attributable to benefits under original Medicare fee-for-service program option and rebatable integrated benefits.

Proposed § 422.258(b)(2) implements section 1858(c)(1)(B) of the Act by requiring that MA regional plans notify us, before that date in the succeeding year as we specify, of each plan's total allowable costs. As mentioned above, rebatable integrated benefits are the only supplemental benefits that can be included in a plan's allowable costs. We would have discretion to evaluate whether certain rebatable benefits should be included in allowable costs for risk corridor calculations. (Note that rebatable integrated benefits must be offered as mandatory supplemental benefits because, as discussed in subpart F, rebate dollars cannot be used to fund optional supplemental benefits.)

Rebatable integrated benefits. Premium reductions funded by rebates (that is, reductions in the Part B, Part D, and/or supplemental premiums) would not be considered rebatable integrated benefits because premium reductions do not involve expenditures by the plan; they represent foregone revenue. However, any rebate-funded additional health benefits not covered by original Medicare would be considered rebatable integrated benefits.

We invite comment on the issue of whether reductions in cost sharing funded by rebate dollars should be considered rebatable integrated benefits. One approach is to consider cost sharing reductions as an expense to the plan and thus not foregone revenue, that is, if the enrollee pays a smaller share of provider costs, the plan pays a larger share. The second approach is to define a supplemental benefit as a rebatable integrated benefit only if it would not have an impact on the utilization of basic benefits. This approach is parallel with the Part D prescription drug benefit, where CMS does not share risk beyond the basic benefit. Under this second approach, then, we would not share risk on non-Medicare benefits with utilization effects on Parts A, B, and D benefits. That is, cost sharing reductions would not be rebatable integrated benefits.

If we take the first approach, an issue arises. For mandatory supplemental benefits that are non-Medicare benefits and require expenditures by the plan yet are only partly funded by rebate dollars, we would consider whether and how to include only the rebate-funded portion of the costs and revenues in the risk corridor calculation, as a rebatable integrated benefit. We invite comment on this issue, including any concerns about the burden of identifying the relevant portions of costs and payments.

If we take the second approach, a different issue arises. Since the pricing of supplemental benefits includes the utilization effect of cost-sharing reductions on benefits under the original Medicare fee-for-service program, the target amount would not reflect these costs. However, unless an adjustment is made, allowable costs would include the utilization effect of the supplemental benefits. Therefore, we would require that allowable costs be reduced by an estimate of the utilization effect of supplemental benefits. We would assume that any such adjustment would be consistent with the assumptions used in originally pricing the supplemental benefits.

We invite comment on approaches for determining what supplemental benefits are considered to be rebatable integrated benefits.

Payment Adjustments

Proposed § 422.358(c) would implement section 1858(c)(2) of the Act relating to payment adjustments. There would be no payment adjustment if the allowable costs for the plan are at least 97 percent, but do not exceed 103 percent, of the target amount for the plan.

If allowable costs for the plan are more than 103 percent but not greater than 108 percent of the target amount for the plan for the year, we would increase the total monthly payments made to the organization by 50 percent of the difference between allowable costs and 103 percent of the target amount. If allowable costs for the plan are greater than 108 percent of the target amount, we would increase the total monthly payments to the plan by an amount equal to the sum of: (1) 2.5 percent of the target amount; and (2) 80 percent of the difference between allowable costs and 108 percent of the target.

Conversely, if the allowable costs for the plan are less than 97 percent, but greater than or equal to 92 percent of the target amount, we would reduce the total monthly payment to the plan by 50 percent of the difference between 97 percent of the target amount and the allowable cost.

If the allowable costs for the plan are below 92 percent of the target, we would reduce the total monthly payments to the organization by the sum of: (1) 2.5 percent of the target amount; and (2) 80 percent of the difference between 92 percent of the target and the allowable costs.

Disclosure of Information

Proposed § 422.358(d) would implement section 1858(c)(3) of the Act relating to disclosure of information. Each contracting MA plan must provide the information that we deem necessary to carry out this section. While we have the right to inspect and audit all books and records pertaining to information

provided under this section, the information disclosed or obtained for purposes of this section may only be used to carry out this section.

3. State Licensing Waiver

Proposed § 422.458(e) would implement section 1858(d), of the Act' setting forth organizational and financial requirements, including the provision for a temporary waiver of the MA State licensing requirement. In order to facilitate the offering of MA plans in regions encompassing multiple States, we may temporarily waive State license requirements.

MA organizations ordinarily must be State licensed to bear risk in each State within a region. However, if an MA organization offering an MA regional plan is organized and licensed under State law in at least one State in the region but has not met the licensing requirements in other States in the region, under section 1858(d) of the Act, we may temporarily waive the State licensing requirement in the other States. We would waive the State licensing requirement to allow sufficient time for the processing of the application by the State or States where an application is pending.

This waiver can only be granted if the organization demonstrates to us that it has filed the necessary application to meet the other State's requirements. If an organization is granted a waiver, the organization would select the licensing rules of one State in the region and apply those rules to the States in which the organization did not have State licensure until the organization is licensed in all the States. In the event that the waivered MA organization's State licensure application is denied, we would extend the waiver until the end of the year or a shorter period as we determine is appropriate to provide for a transition for the enrollees in the plan or plans offered by the organization.

4. Stabilization Fund

Proposed § 422.438(f) would implement the provisions in section 1858(e) of the Act providing for the creation of a Regional Stabilization Fund. During the past several years, a number of organizations have withdrawn from the Medicare+Choice program due to changing market conditions and an inflexible statutory payment formula. Plans' costs were rising at a faster rate than Medicare payment rates. We had no discretion under the law to respond quickly to these market changes, resulting in plan withdrawals that have affected millions of beneficiaries.

The Congress has authorized an MA Regional Plan Stabilization Fund in order to promote greater stability in the regional program and provide us with a tool to respond to market fluctuations. The Fund can be used to provide incentives for plan entry in each region and plan retention in MA regions with below average MA penetration. Initially, $10 billion would be available for expenditures from the Fund beginning on January 1, 2007, and these start-up funds would only be available until December 31, 2013.

Funds would be drawn from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in a proportion that reflects the relative weight that the benefits under Parts A and B represent of the actuarial value of the total benefit. Additional funds would be available in an amount equal to 12.5 percent of average per capita monthly savings from regional plans that bid below the benchmark. The additional funds would be deposited on a monthly basis into a special account in the Treasury. The Fund is designed to allow us to respond to market conditions on a temporary basis. If the Fund is used for either plan entry or retention for 2 consecutive years, we would report to the Congress on the underlying market conditions in the regions. These reports would give the Congress time to respond to the market conditions through changes to the regions or the underlying payment system.

The funds would be available in advance of appropriations to MA regional plans in accordance with specified funding limitations. The total amount projected to be expended from the Fund in any year may not exceed the amount available in the Fund as of the first day of that year. If the use of the stabilization fund results in increased expenditures under Title XVIII, the increased expenditures would be counted as expenditures from the Fund. We would only obligate funds if the Chief Actuary of CMS, and the appropriate budget officer, certify that there are sufficient funds at the beginning of the year to cover all the obligations for that year. We would take steps to ensure that sufficient funds are available to make the payments for the entire year, which may include computing lower payment amounts or limitations on enrollment in MA regional plans receiving the payments. Expenditures from the Fund would first be made from amounts made available from the initial funding.

5. Plan Entry Funding

Plan entry incentives are available for either a one-year national bonus payment or multi-year adjustments in regional payments; however, in no case can there be a regional payment adjustment if there is a national bonus for that year. In order to encourage the offering of plans in all regions, the national bonus payment would be available to an MA organization that elects to offer a regional plan in each MA region in a year, but only if a national plan is not offered in the previous year.

Funding is only available for a single year, but more than one organization can receive the incentive in the same year. The national bonus payment would: (1) Be available to an organization only if it offers plans in every MA region; (2) be available to all MA regional plans of the organization regardless of whether any other MA regional plan is offered in any region; and (3) be equal to 3 percent of the benchmark amount otherwise applicable for each MA regional plan offered by the organization, subject to funding limitations. If a national bonus payment is not made, a regional payment adjustment can be made. The regional payment adjustment is an increased payment for an MA regional plan offered in an MA region that did not have any MA regional plans offered in the previous year.

We would determine the adjusted payment amount based solely on plans' bids in the region, and the adjusted payment amount would be available to all plans offered in the region. The amount can be based on the mean, mode, median or other measure of the bids and may vary from region to region, but the payment amount would not be determined through a method that limits the number of plans or bids in the region. We expect that such an adjustment would represent a fixed percentage of the relevant measure of plan bids in the region. Such a payment adjustment would be treated as a change to the benchmark amount in that region for purposes of calculating individual plan payments and beneficiary rebates.

6. Regional Payment Adjustment

Subject to funding limitations, we would determine the period of time that funds are available for regional payment changes to encourage plan entry. If funding would be provided for a second consecutive year under this provision, we would submit a report to the Congress describing the underlying market dynamics in the region and recommending changes to the payment

methodology. Multi-year funding may be made available to all MA plans offered in a region. If this multi-year increased amount is made available to MA plans in a region, funding would not be available for plan retention in the region in the following year. Regional payment adjustments would not be taken into account when computing the underlying benchmark for the subsequent year.

7. Plan Retention Funding

In addition to using the Fund to encourage plans to enter regions that might otherwise go unserved, we may also use the fund to encourage plans to remain in regions if market conditions are causing plan withdrawals. Incentives for plan retention could take the form of an increased payment to plans in regions that meet specific requirements. The requirements are: (1) One or more plans inform us that they are going to discontinue service in the region in the succeeding year; (2) we determine that if those plans were not offered, fewer than two MA organizations will be offering MA regional plans in the region in the year; (3) for the previous year, we determine that the proportion of beneficiaries enrolled in MA regional plans in the region is less than the national average of MA regional plan enrollment; (4) funds have not already been awarded for 2 consecutive years.

Any additional payment amount would be treated as if it were an addition to the benchmark amount otherwise applicable, but would not be taken into account in the computation of the benchmark for any subsequent year.

If plans receive funding under this part for a second year, we would submit a report to the Congress that describes the underlying market dynamics in the region and includes recommendations concerning changes in the payment methodology otherwise provided for MA regional plans.

The incentive for plan retention payment would be an amount determined by the Secretary that does not exceed the greater of: (1) 3 percent of the benchmark amount applicable in the region; or (2) an amount that, when added to the benchmark, results in a ratio such that the additional amount plus the benchmark for the region divided by the adjusted average per capita cost (AAPCC) equals the weighted average of benchmarks for all regions divided by the AAPCC.

Subpart K—Application Procedures and Contracts for Medicare Advantage Organizations

(If you choose to comment on issues in this section, please include the caption "Subpart K—Application Procedures and Contracts for Medicare Advantage Organizations" at the beginning of your comments.)

Proposed changes to the existing MA provisions concerning applications and contracts are discussed below. We realize, however, that the programmatic changes contained in this proposed rule may require additional changes to existing MA contracting provisions that could reduce the administrative burden and increase the effectiveness of these provisions. We are studying this issue, requesting comments and will implement the appropriate changes in the final rule.

We are proposing that the application requirements and evaluation and determination procedures from subpart A (§ 422.6 and § 422.8) be incorporated into subpart K. As a result, the subpart K title would be changed to "Application Procedures and Contracts for Medicare Advantage Organizations." The application requirements from subpart A would be added as § 422.501 and the evaluation and determination procedures would be included as § 422.502, with mostly nomenclature changes. The one exception is a change to the compliance program requirements at § 422.502(b)(3)(iv)(G). We believe that mandatory reporting of potential fraud by government contractors is critical, especially in light of the corporate fraud scandals that occurred over the past several years. It is also in keeping with the Sarbanes-Oxley Act of 2002, under which the Securities and Exchange Commission adopted new regulations designed to make corporate compliance and disclosure requirements stronger and more effective. In short, we believe that the self-reporting requirements included in this rule are keeping with the change in the legal, regulatory, and business climates since the compliance program requirements were first implemented. We propose adding the following text to § 422.502(b)(3)(iv)(G): If the MA organization discovers from any source evidence of misconduct related to payment or delivery of health benefits under the contract, it must conduct a timely, reasonable inquiry into that misconduct. If, after reasonable inquiry, the MA organization has determined that the misconduct may violate criminal, civil, or administrative law, the MA organization must report the existence of the misconduct to the appropriate Government authority within a reasonable period, but not more than 60 days after the determination that a violation may have occurred. If the potential violation relates to Federal criminal law, the civil False Claims Act, Federal Anti-Kickback provisions, the civil monetary penalties authorities (primarily under section 1128A and 1857 of the Social Security Act), or related statutes enforced by the HHS Office of Inspector General, the report must be made to that Office. The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees, etc.) in response to the potential violation referenced above.

The existing § 422.501 would be redesignated as § 422.503, the existing § 422.502 would be redesignated as § 422.504, and the existing § 422.504 would be redesignated as § 422.505.

We also propose to add a new paragraph (1) To what would now be § 422.503(b), clarifying that the completion of an application as described in § 422.501 is a condition necessary to contract as an MA organization. The current paragraphs (1) through (5) would be re-designated as paragraphs (2) through (6).

We propose technical corrections to what would now be § 422.503(b)(4)(ii) and § 422.503(b)(4)(vi)(F). In § 422.503(b)(4)(ii), we replaced the word "plan" with the word "implement." In § 422.503(b)(4)(vi)(F), we replaced the word "provisions" with the word "procedures." We also propose technical corrections to newly redesignated § 422.503(b)(6) and § 422.503(b)(6)(i). The current language states "The M+C organization's contract must not have been terminated by CMS under § 422.510 within the past 2 years unless * * *." Section 1857(c)(4) of the Act, however, which is implemented in this provision, applies to plans that elect to non-renew their contracts, not plans terminated by us. We accordingly propose to revise the newly redesignated § 422.503(b)(6) introductory text to read "The MA organization's contract must not have been non-renewed under § 422.506 within the past 2 years unless * * *." Although newly redesignated § 422.503(b)(6)(i) already refers to the MA organization initiating the end of the contract, it uses the term "terminated" and we propose to change it to "non-renew," which is the term used in the regulations. We would revise § 422.503(b)(6)(i) accordingly.

We are proposing several technical corrections to § 422.504 (formerly § 422.502). The first corrections would be to proposed § 422.504(e)(4). We

propose to clarify that paragraph (e)(4) introductory text provides that "HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 6 years from the end of the final contract period * * *" The previous language was not clear that this provision applied after CMS and the MA organization severs their relationship. In paragraph (e)(4)(ii) we propose to add "allegation of" to clarify our use of the word fraud. In paragraph (e)(4)(iii) we propose to add "or similar fault" after the word "fraud." We propose to remove § 422.504(f)(2)(vii) since MSAs are no longer demonstrations. Section 422.504(f)(2)(viii) would be redesignated as § 422.504(f)(2)(vii). We propose to revise § 422.504(i)(3)(ii) by removing § 422.504(i)(3)(ii)(A) "The M+C organization oversees and is accountable to CMS for any functions or responsibilities that are described in these standards." It is not necessary for this provision to be included in contracts between MA organizations and providers. The MA organization is already held accountable for adhering to and otherwise fully complying with all terms and conditions of its contract with us through what would now be § 422.504(i)(1), "MA organization relationship with related entities, contractors, and subcontractors." In addition, there is no statutory requirement that this provision appear in contracts between MA organizations and downstream providers.

Based on the bidding process and establishment of benchmarks, we propose to no longer allow an MA organization's contract to be effective at any time other than the first of the contract year.

We are proposing to move the notification date for nonrenewal of contracts in § 422.506(a)(2)(i) and § 422.506(a)(3) to the first Monday in June to match the bid submission date. We are also proposing to move the notification date for nonrenewal of contracts in § 422.506(a)(2)(i) and § 422.506(a)(3) to the first Monday in June to match the bid submission date. We are also proposing a clarifying change to § 422.506(a)(2)(ii) by adding "prior to issuance" after the existing "CMS approval."

We are proposing to revise § 422.510(a)(4) by adding the phrase "There is credible evidence" in front of the existing language about an MA organization that committed or participated in fraudulent or abusive activities. We have also added the word "false" in front of "fraudulent."

We are proposing technical and clarifying changes to § 422.520, "Prompt payment by MA organization." The phrase "from non-contracted providers" would be added to § 422.520(a)(3) to clarify that this provision was intended to refer only to claims from non-contracted providers (versus contracted providers). Claims by contracted providers are addressed in § 422.520(b). We also propose to add a new § 422.520(b)(2), providing that the MA organization is obligated to pay contracted providers according to the terms of the contract between the MA organization and the provider. Finally, we are proposing that a new paragraph (d) be added clarifying that a CMS decision not to conduct a hearing under paragraph (c) of § 422.520 does not disturb any potential remedy under State law for the non-contracted provider, or affect the provider's rights to pursue payment as provided under section 1866(a)(1)(O) of the Act. Section 1866(a)(1)(o) of the Act establishes that Medicare participating providers who do not have a contract establishing payment amounts agree to accept, as payment in full for covered services provided to MA beneficiaries, an amount equal to the amount the provider would have collected under fee-for-service Medicare if the beneficiary was not enrolled in an MA plan.

Finally, we are proposing a new § 422.527, addressing payments to Federally Qualified Health Centers (FQHC). MMA added a new section 1857(e)(3)(A) of the Act, which applies only to FQHCs and requires that the contract between CMS and MA organizations include a provision that any written arrangements between an MA organization and an FQHC include a level of payment that would be equal to what the MA organization would pay other providers for similar services. Under such a contract, the FQHC must accept this payment as payment in full, except for cost sharing allowed by the contract, and the supplemental Federal payment now provided for in section 1833(a)(3)(B) of the Act, which was added by MMA. We believe that the statute did not intend to require MA organizations to contract with FQHCs. The intent of the statute was to establish payment terms between MA organizations and FQHCs. If an MA organization chooses to contract with an FQHC, the payment terms would be as described in § 422.527.

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

(If you choose to comment on issues in this section, please include the caption "Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract" at the beginning of your comments.)

We are studying the modification of existing change of ownership provisions in order to reduce the administrative burden of these requirements and to increase the effectiveness of these provisions. We request comments regarding how these provisions can be modified to accomplish these objectives. In particular, we seek comments regarding: the situations which constitute a change of ownership, how these provisions should be applied to large companies with multiple business units, the notification requirements related to a change of ownership, the novation agreement provisions, and the provision related to the leasing of facilities.

Subpart M—Grievances, Organization Determinations, and Appeals

(If you choose to comment on issues in this section, please include the caption "Subpart M—Grievances, Organization Determinations, and Appeals" at the beginning of your comments.)

1. Introduction

The MMA did not make any revisions to the statutory requirements in sections 1852(f) and (g) of the Act regarding MA grievances and appeals. Thus, this proposed rule generally proposes to maintain the existing regulatory requirements in subpart M of part 422, which implement these statutory requirements. However, in addition to making the minor changes needed to conform these subpart regulations to MMA terminology and other provisions, we also have undertaken a review of the existing MA grievance and appeal requirements to identify needed refinements. Also, as discussed at the end of this section of the preamble, we are proposing changes to the part 417 regulations, which apply only to section 1876 cost contractors and section 1833 health care pre-payment plans (HCPPs), that would establish uniform grievance and appeal procedures for all Medicare managed care plans.

2. Background

Section 1852(f) of the Act provides that an MA organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any other entity or individual through which the organization provides health care services) and enrollees in its MA plans.

Section 1852(g) of the Act addresses the procedural requirements concerning coverage ("organization")

determinations and reconsiderations and other appeals for MA organizations. As discussed in detail below, only disputes concerning "organization determinations" are subject to the reconsideration and other appeal requirements under section 1852(g) of the Act. In general, organization determinations involve whether an enrollee is entitled to receive a health service or the amount the enrollee is expected to pay for that service. All other disputes are subject to the grievance requirements under section 1852(f) of the Act. For purposes of this regulation, a reconsideration consists of a review of an adverse organization determination (a decision that is unfavorable to the MA enrollee, in whole or in part) by either the MA organization itself or an independent review entity. We use the term "appeal" to denote any of the procedures that deal with the review of organization determinations, including reconsiderations, hearings before administrative law judges (ALJs), reviews by the Medicare Appeals Council (MAC) and judicial review. For the grievance, organization determination, and appeal requirements, an MA organization must establish procedures that satisfy these requirements with respect to each MA plan that it offers. These requirements generally are the same for each type of plan—including coordinated care plans such as HMOs and PPOs, non-network MSA plans, and PFFS plans.

Sections 1833(a)(1)(A) and 1876(a)(5)(B) of the Act reference reasonable cost reimbursement contracts for HCPPs and HMO/CMPs. Section 1876(c)(5) of the Act sets forth the procedures HMO/CMP organizations must follow with regard to grievances, organization determinations, and appeals. Section 417.840 of our regulations requires HCPPs to apply the administrative review procedures set forth for HMO/CMPs. Section 1869 of the Act provides the right to a hearing and to judicial review for any individual dissatisfied with a determination regarding his or her Medicare benefits.

3. General Provisions, Grievances, and Organization Determinations (§ 422.560 through § 422.576)

MMA amended section 1852(g)(5) of the Act to incorporate the provisions of section 1869(b)(1)(E)(iii) of the Act, which was added by MMA. This new clause provides for inflation adjustments to the "amount in controversy" required to pursue a hearing and judicial review. It makes these provisions applicable in determining the amount in controversy under section 1852(g)(5) of the Act "in the same manner as they apply to the dollar amounts specified in section 1869(b)(1)(E)(i)." Although other provisions in section 1869 of the Act do not apply to MA appeals, the existing MA regulations incorporate regulations implementing section 1869 of the Act in implementing the appeals provisions in section 1852(g) of the Act. Specifically, the existing MA regulations incorporate 42 CFR part 405, subparts G and H, and 20 CFR part 404, subparts J and R. Since we will be implementing revisions to section 1869 of the Act in a separate rulemaking creating a new subpart I of part 405, we propose to revise the cross-references for MA appeals at § 422.560(a)(3), § 422.561, and § 422.562 accordingly. We note that when revisions are made to the section 1869 regulations implementing the MMA changes in the way the amount in controversy is determined, these revised provisions will apply to MA appeals.

As noted above, section 1852(g) of the Act requires an MA organization to establish procedures for hearing and resolving disputes between the organization and its Medicare enrollees concerning organization determinations.

In accordance with section 1852(g)(1) of the Act, § 422.566 begins by specifying that an MA organization must have a procedure for making timely organization determinations regarding the benefits an enrollee is entitled to receive and the amount, if any, that an enrollee must pay for a health service. Section 422.566(b) lists actions that are organization determinations; and we are proposing to explicitly specify in that section that a reduction of services constitutes an organization determination that an enrollee may appeal. We fully recognize that reductions of care are a natural outcome of medical services, particularly when an enrollee is progressing along an expected care continuum. When this issue was raised in past rulemaking vehicles, commenters stated that routine notifications in reduction of care situations would confuse enrollees, perhaps causing them to believe that something was wrong in common situations where the discontinuation of services was fully planned and appropriate. We agreed to consider this issue in future rulemaking. The approach proposed here basically clarifies existing policy, under which reductions in service were always appealable issues. Notice requirements would apply whenever an enrollee disputes the reduction. Under those circumstances, MA organizations would consider the disputed discontinuation of service a new request for an organization determination under § 422.566. A request for a new organization determination allows the enrollee to receive notice, appeal rights, and access to the MA appeals system under § 422.570 and § 422.584.

Standard timeframes and notice requirements for organization determinations (§ 422.568)

The only substantive change we are proposing in § 422.568 is the elimination of the practitioner's notice requirement currently set forth in § 422.568(c). This section requires that at each patient encounter with an MA enrollee, a practitioner must notify the enrollee of his or her right to receive, upon request, a detailed written notice from the MA organization regarding any decision to deny services to an enrollee. This provision has proven problematic to implement and impossible to monitor. Instead of requiring practitioners to provide notices to enrollees at each patient encounter, we would propose instead to require MA organizations to provide specific information in the plan's Evidence of Coverage about enrollees' rights when they are denied services in physician office settings.

We are also proposing to modify § 422.570(d)(2)(ii) and § 422.572(b) to require that an MA organization must inform an enrollee of the right to file an "expedited" grievance if the enrollee disagrees with the MA organization's decision not to expedite a request for an expedited organization determination. This is a right that already was established under the grievance provision at § 422.564(d)(2); thus, we are merely making a conforming change.

Timeframe and notice requirements for expedited organization determinations.

Section 422.572(c) now requires that if an MA organization first notifies an enrollee of its expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification. The regulations concerning determinations made within standard timeframes do not require a written follow-up for favorable determinations. We propose in this regulation to revise this provision to eliminate the requirement that oral notice be followed up with written confirmation in cases of fully favorable determinations. Notice would be required only for decisions that are fully or partly adverse to the enrollee.

4. Requests for Reconsiderations (§ 422.582)

The only substantive change we are proposing regarding standard reconsiderations pertains to the manner in which a party to an organization determination would request an appeal. Proposed § 422.582(a)(1) would allow a party to request a standard reconsideration orally or in writing. We have received several requests to modify our policy on the basis that the appeals process would be more convenient and accessible for enrollees, and enable MA organizations to provide better customer service.

Currently, § 422.584(e) specifies that when an MA organization grants a request for an expedited reconsideration, it must give notice in accordance with § 422.590(d). Proposed § 422.584(e) would require an MA organization to give notice in accordance with the broader provision of § 422.590 since there are notice requirements other than those contained in § 422.590(d).

As we proposed above for expedited organization determinations under § 422.570(d)(2)(ii), proposed § 422.590(a) and § 422.590(d)(2) would require an MA organization to inform an enrollee of the right to file an "expedited" grievance if the enrollee disagrees with the MA organization's decision not to expedite a request for an expedited reconsideration. This is a right that already was established under the grievance provision at § 422.564(d)(2); thus, we are merely making a conforming change.

5. Administrative Law Judge (ALJ) Hearings, Appeals to the Medicare Appeals Council, and Judicial Review (§ 422.600 through § 422.612)

If the independent reviewer's reconsidered determination is not fully favorable to the enrollee, any of the parties listed in § 422.574 have a right to request a hearing before an ALJ, assuming that the required minimum amount in controversy is met. (Note that the MA organization does not have a right to request a hearing before the ALJ.) If the ALJ hearing does not result in a favorable determination, any party (including the MA organization) may request that the Appeals Council review the ALJ decision. Following the administrative review process, any party (including the MA organization) is entitled to judicial review of the final determination if the amount remaining in controversy meets the required threshold. As mentioned above generally, the MMA made revisions to provisions in section 1869 of the Act that address the amount in controversy required for ALJ and judicial review. Specifically, these changes provide for an inflation adjustment to these amounts, based on changes to the Consumer Price Index. MMA also amended section 1852(g)(5) of the Act to provide that these revised provisions of section 1869 also apply for purposes of MA appeals. These changes will be set forth in an upcoming final rule in new subpart I of part 405. We propose to revise § 422.600 to cross-reference these revised regulations, and make revisions to § 422.612 to reflect the fact that the amount in controversy is now subject to change.

The regulatory provisions at 42 CFR part 405, subparts G and H, and 20 CFR part 404, subpart J, concerning reopenings of appeals and Departmental Appeals Board review also historically have been cross-referenced in the managed care and M+C appeals regulations. Like other provisions of section 1869 of the Act that will be implemented in an upcoming final rule in a new subpart I of part 405, we propose to modify the cross-references for MA appeals at § 422.608 and § 422.616(a).

6. Noncoverage of Inpatient Hospital Care—Notice and QIO Review (§ 422.620 and § 422.622)

Under § 422.620(a), when an MA organization has authorized coverage of the inpatient admission of an enrollee, either directly or by delegation (or the admission constitutes emergency or urgently needed care), the MA organization (or hospital that has been delegated the authority to make the discharge decision) must provide a written notice of noncoverage when the beneficiary disagrees with the discharge decision, or the MA organization (or the hospital that has been delegated the authority to make the discharge decision) is not discharging the individual but no longer intends to continue coverage of the inpatient stay.

Section 422.620(b) now specifies that an MA organization (or, by delegation, the hospital) must obtain the concurrence of the physician responsible for the enrollee's in-patient care before issuing a notice of noncoverage to an enrollee. However, since publication of our April 4, 2003 final rule that eliminated routine discharge notices in hospitals, an enrollee's right to receive a notice of noncoverage is linked to physician concurrence only to the extent that the physician must concur with the MA organization's decision to discharge the enrollee or change the enrollee's level of care. Under § 422.620(a), an MA organization must issue a notice of noncoverage when an enrollee disagrees with an MA organization's decision to discharge the enrollee or discontinue coverage of the inpatient stay. Under § 422.620(b) of that final rule, we inadvertently failed to include a corresponding change that physician concurrence is necessary for discharging the enrollee rather than for issuing the notice. Therefore, we propose to revise the regulations to clarify that an MA organization's obligation to provide a notice of noncoverage when an enrollee objects to being discharged is not contingent upon physician concurrence.

We also are proposing to revise § 422.620(c) to require that if an MA organization lowers the enrollee's level of care in an inpatient hospital setting, for example, from acute to skilled, but the enrollee is not discharged from the facility, the MA organization must specify the enrollee's new level of care in the notice. This change is consistent with § 422.620(a)(1)(ii), which requires the MA organization to provide a notice to the enrollee when it is not discharging the enrollee, but no longer intends to continue coverage of the in-patient stay.

7. Advance Beneficiary Notices in the MA Program

As Medicare choices have expanded, the relationships among providers, enrollees, and managed care organizations have evolved and become more complicated, often allowing for greater flexibility and choice in making decisions about care. Open access managed care arrangements, where enrollees seek services outside their provider network, or vary their provider choices through tiered cost-sharing arrangements, challenge the constraints of more traditional "gatekeeper oriented" coordinated care models. Increasingly, MA organizations, providers, and enrollees have asked for clarification of Medicare appeal rules when disputes arise about care provided outside the traditional coordinated care model. We recognize that this is a complex issue, touching upon many other regulations that come into play during an appeal process. Those regulations might include, but are not limited to, prompt pay provisions, claims procedures, and post-stabilization requirements. Frequently, an appeal dispute involves whether the enrollee understood that the services in question might not be authorized by the MA plan or covered by Medicare.

In other cases, enrollees may wish to access services from a particular network provider, regardless of whether the plan would cover the care, leaving

the provider in an uncertain situation should the plan eventually deny approval for the care.

Nevertheless, to address these types of issues, we are soliciting comments on whether to permit or require network and non-network providers to furnish a type of advance beneficiary notice (ABN) for use when managed care enrollees access non-Medicare covered services.

We are also requesting public comments about whether managed care providers should be permitted or required to furnish an ABN-like document to alert MA enrollees to their possible liability for out of network services that would otherwise be payable by the MA plan if proper referral was obtained. Alternatively, we could require unaffiliated non-network providers to seek organization determinations from the enrollee's MA organization before providing Medicare covered services. Note that this would not include Medicare excluded services, but would include services that would be otherwise offered through the enrollee's managed care plan.

We believe that ABN-like notices could serve a role in these situations, by clarifying potential liability issues. On the other hand, we are cognizant of the possible burden and potential confusion associated with such notices. Therefore, rather than propose to require any ABNs or other related notices at this time, we believe it is preferable to first assess whether commenters believe such an approach is warranted. Thus, we welcome comments on these issues, as well as alternative recommendations.

8. Appeal Procedures for Cost HMO/CMPs and HCPPs

As discussed in detail above, the MMA specifies that, with respect to appeal and grievance procedures, the same statutory provisions that currently apply to the MA program will continue to apply to MA organizations in the future. These provisions, which have been in effect since 1998, were in turn largely based on the grievance and appeal requirements that had applied to managed care organizations that contract with us under section 1876 of the Act (as well as to health care prepayment plans that are paid under section 1833(a)(1)(A) of the Act). For example, the requirements under section 1852(g)(3) of the Act, concerning expedited organization determinations and reconsiderations essentially incorporated the expedited procedures that were issued in our April 30, 1997 final rule with comment (62 FR 23368). (That final rule established expedited processes for organization and reconsidered determinations, and clarified that the definition of an organization determination included discontinuations of service.)

However, because the BBA provided for the temporary continuation of these so-called "cost plans," we chose not to eliminate or revise the part 417 appeals regulations that applied to these plans. Instead, we opted to leave these regulations, found in subpart Q of part 417, in place until the availability of cost-based contractors expired in 2002, as provided by the BBA. Since that time though, the BBRA subsequently extended the sunset of the cost plans through 2004, and the policy of parallel regulations has been the source of continuing confusion during the past 6 years, particularly in the complicated and evolving world of appeal policy.

The regulations implementing the BBA provisions creating the M+C program, which were set forth in 1998 under new part 422, would now apply, as amended, to MA organizations under this proposed rule. Under the MMA, however, the conferees provided in section 234 for a potentially indefinite extension of reasonable cost contracts, thus eliminating any certainty regarding the previously scheduled sunset of these contractors. (Cost HMO and CMPs will be allowed to operate until 2008, and could operate indefinitely after that date if there are not two MA plans of the same type, that is, two local or two regional non-PFFS plans operating in the cost contract's service area.) Therefore, we believe it is appropriate to revisit the issue of whether these nonrisk plans should be required to comply with the part 422 grievance and appeal requirements.

Note that on October 25, 2002, we solicited comments on whether HCPPs and the remaining cost HMOs/CMPs should follow the MA appeals and grievance procedures under subpart M of part 422. This proposal took into account that the MA appeals processes provide enhanced enrollee protections, such as shorter timeframes for appeals decision making and streamlined notice procedures. We received comments both supporting and opposing applying the part 422 regulations to cost HMO/CMP organizations. Since that time, based both on the comments we received and further study of the issue, we have concluded that it would be appropriate for organizations offering cost plans to follow the same procedures that would apply to MA organizations, as set forth in subpart M of this proposed rule. Again, this decision is also informed by the MMA's reliance on the existing statute's appeals procedures as the basis for the MA program, as well as the indefinite extended existence of these plans.

Therefore, we are proposing under § 417.600(b) that the same rights, procedures, and requirements relating to beneficiary appeals and grievances set forth in subpart M of part 422 of this chapter also apply to organizations offering Medicare cost plans. In proposing this change, we have taken into account that a key difference between cost plans and M+C plans is that virtually all organizations offering cost plans employ a billing option available under § 417.532(c)(1) that reduces a cost plan's financial liability for certain Medicare-covered services. Under this billing methodology, hospitals and skilled nursing facilities (SNFs) that furnish services to cost plan members can obtain direct reimbursement from Medicare fiscal intermediaries for these services. For services paid for under this methodology, the claims appeal procedures available under original Medicare regulations (subpart I, part 405) would be the appropriate recourse when a Medicare fiscal intermediary denies a claim. However, for other services, including any service or payment denial resulting from an organizational determination under a cost plan, as defined in § 417.606, enrollees would appeal through the cost plan's appeal process. The plan appeal procedures would also apply in the rare situation when a fiscal intermediary approved a claim for hospital or SNF services, but the cost plan refused to pay the covered portion of enrollee cost sharing associated with the services. As discussed above, this process would follow the same rules that apply to other MA organizations, as set forth in subpart M of part 422.

Although the appeals procedures set forth in part 417 and part 422 are largely similar, it is important to note that there have been some recent changes to the part 422 regulations that would apply to cost plans for the first time under this proposal. These changes primarily involve § 422.620, § 422.624, and § 422.626 of subpart M and were set forth in the April 4, 2003 final rule, "Improvements to the Medicare+Choice Appeals and Grievance Procedures," also known as the Grijalva regulation. (See 68 FR 16652.) The changes set forth in that final rule established new notice and fast-track appeal procedures for enrollees when an MA organization decides to terminate coverage of its provider services. We are expecting to publish a final rule establishing parallel notice and appeal provisions for original Medicare beneficiaries.

The effect of this proposed rule would be to ensure that all Medicare beneficiaries enjoy the same notice and appeal rights in cases of terminations of Medicare services furnished by hospitals, SNFs, home health agencies, and comprehensive outpatient rehabilitation facilities. Absent these proposed changes, the new notice and fast-track review procedures would apply for all MA enrollees, and for all original Medicare beneficiaries, but would not apply to members of cost plans. This scenario would be confusing and unfair not only for beneficiaries, but also for the providers who are responsible for distributing the service termination notices. Thus, we believe that establishing a level playing field for all Medicare beneficiaries and providers is the only appropriate policy.

9. Federal Preemption of Grievances and Appeals

Under preemption provisions in the BBA that applied to the M+C program, State laws or standards that were stricter than Federal M+C standards generally were not preempted unless they conflicted with, or otherwise precluded compliance with, Federal M+C requirements. However, as noted above in the discussion of subpart I, the BBA also provided for specific preemption of State standards in three specified areas: benefit requirements (rules regarding cost-sharing and rules regarding marketing materials describing benefits were later added to this category), rules regarding the inclusion or treatment of providers (for example, "any willing provider laws"), and rules regarding coverage, along with related appeals and grievance mechanisms. In the M+C regulations, we interpreted the last category to preempt only appeals and grievance mechanisms that addressed the issue of whether services were covered. Thus, general "grievance" mechanisms addressing issues other than coverage were only preempted to the extent they were inconsistent with, and prevented compliance with, M+C requirements.

As noted in our discussion of subpart I above, section 232(a) of the MMA changes the presumption from one in which State laws are not preempted unless they conflict with Federal laws or fall into specified categories to one in which State standards are presumed preempted unless they are licensing or solvency laws. In light of the comprehensive nature of the appeals process already established, we do not believe that the new preemption standard would have any effect on coverage appeals provisions. Because our regulations provide for doing so, we would continue to defer to State law on the issue of authorized representatives of enrollees in the appeals process. We do not believe that the Congress intended for the Secretary to regulate matters such as this that he is not equipped to address (for example, spousal rights, powers of attorney, or legal guardianship). Often, authorized representative matters are non-Federal issues.

We are concerned, however, that with State grievance requirements now preempted, we may need to reexamine our Federal grievance requirements. Since 1997, we have engaged in a significant rulemaking activity concerning the extent to which the Secretary should regulate health plans' grievance procedures. (Issues not related to whether services are covered, or how much an enrollee has to pay for services.) We solicited comments on this issue in the M+C interim final rule on June 26, 1998 (63 FR 35030), as well as the M+C final rule on June 29, 2000 (65 FR 40169). The preamble to the interim final rule alerted the public that we would establish a grievance procedure through proposed rulemaking, and sought comments on ways to make it meaningful. Until publication of that proposed rule, M+C organizations by default were subject only to the general Federal requirement that M+C organizations have grievance mechanisms in place, and any State requirements that applied to complaints unrelated to coverage determinations.

On January 24, 2001, we developed a proposed rule that recommended establishing more specific grievance provisions (66 FR 7593). In the proposed rule, we proposed that M+C organizations would notify enrollees of their decisions as expeditiously as the case required, but no later than 30 calendar days after receiving a complaint. In conjunction with the time frame, we also proposed that the M+C organization be permitted to extend the time frame by up to 14 calendar days if the enrollee requested the extension, or if the organization justified a need for additional information and the delay was in the interest of the enrollee. We also proposed that grievances made orally would be responded to orally or in writing, unless the enrollee specifically requested a written response. If grievances were made in writing, then the response would need to be in writing. In addition, we proposed that M+C organizations would be required to describe the enrollee's right to seek a review by a Quality Improvement Organization (QIO) if the grievance involved a quality of care issue. For any complaint involving the QIO, the organization would be required to cooperate with the QIO in resolving the complaint. We further proposed a 72-hour expedited grievance process for complaints about certain procedural matters in the appeals process. The proposed grievance procedures concluded with the requirement that organizations would have a system to track and maintain records on all grievances.

Taking into account the various comments that we received, we published a final rule on April 4, 2003 that only required an expedited grievance process for complaints involving appeals, and recordkeeping (68 FR 16652). We agreed with several commenters that the regulations did not need to be too prescriptive because "many States have processes to address complaints that involve issues other than coverage, and State grievance procedures, unlike appeal procedures, are not specifically preempted by Federal rules" (68 FR 16652 and 16661). We further reasoned that we should "allow M+C organizations the flexibility needed to maintain current procedures that comply with State requirements." *See id.*

In light of section 232(a) of the MMA, which provides that the standards established under the MA program supersede State law or regulation with respect to MA plans, we once again solicit comments on whether we should adopt the above provisions proposed in January 2001 that did not make it into the April 2003 final rule. Such provisions would include the method for filing and the notification and time frames associated with grievances. We also solicit comments on whether we should impose, as a Federal MA requirement, that MA organizations meet State grievance requirements. Such a requirement would have the effect of restoring the status quo before the enactment of the MMA.

We also have considered how the changes made by section 232(a) of the MMA apply, if at all, to State tort or contract law that could affect MA organizations. Our previous position under the M+C program was that State tort or contract remedies may be available to enrollees whose coverage determination disputes go through the Medicare appeals process. We continue to believe that generally applicable State tort, contract, or consumer protection law would not be preempted under section 232(a). First, we believe that section 232(a) was intended to preempt State standards governing health plans, not generally applicable State laws, such as labor laws, employment law, tax laws, etc. that incidentally could have

applicability to MA organizations. We believe that contract laws and tort laws fall in this category, as they do not apply to the organization based on its status as a health plan, but instead apply generally. Even specific types of tort laws, such as malpractice law, apply generally to all medical practitioners, not to health plans specifically.

We also note that tort law, and often contract law, generally are developed based on case law precedents established by courts, rather than statutes enacted by legislators or regulations promulgated by State officials. We believe that the Congress intended to preempt only the latter type of State standards.

Under principles of Federalism, and Executive Order 13132 on Federalism, which generally requires us to construe preemption narrowly, we believe that an enrollee should still have State remedies available in cases in which the legal issue before the court is independent of an issue related to the organization's status as a health plan or MA organization.

10. Employer Sponsored Benefits and Appeals

When an employer, by contracting with an MA plan, provides health care benefits in addition to those covered under Part C of Title XVIII of the Social Security Act to their retirees, such employer may have established a group health plan governed by both title I of the Employee Retirement Income Security Act of 1974 (ERISA), as amended, and State law (to the extent such State law is not preempted by ERISA). In addition, when MA plans offer benefits covered under Part C, they also would fall under the requirements of part 422 of our proposed regulations, with respect to Part C benefits.

In drafting these rules, we consulted with the Department of Labor (DOL), employer groups, and the health plan industry in trying to eliminate unnecessary Federal regulation of claims and appeals issues that impact matters within the jurisdiction of both DOL and DHHS. Based on our experience, we have reason to believe that some Medicare eligible individuals may receive integrated health care benefits, that is, Part C benefits through an MA plan and supplemental benefits through an ERISA-covered plan. For example, an employer-sponsored plan may pay the cost-sharing amount for a covered item or treatment offered by an MA plan. Clearly, if the enrollee had a dispute about Part C coverage, he or she could file an appeal with the MA plan. If the enrollee's dispute involved only the amount of cost sharing paid by the employer-sponsored plan, he or she would file an appeal in accordance with the procedures of the ERISA covered plan. In some cases, however, the dispute might involve independent coverage decisions under both Part C and the ERISA plan, possibly necessitating parallel appeal procedures on the same case. In this regard, we are soliciting comments on whether, and to what extent, the application of parallel procedures in this context might be a problem for plans, employers, and/or eligible individuals. We also are soliciting suggestions for addressing problems, if any, resulting from the application of parallel procedures.

Subpart O—Intermediate Sanctions

(If you choose to comment on issues in this section, please include the caption "Subpart O—Intermediate Sanctions" at the beginning of your comments.)

We are proposing a technical correction to § 422.752(a)(8). "Entity" was inadvertently left out of the regulation text. We are proposing that paragraph (a)(8) introductory text would read "Employs or contracts with an individual or entity who is excluded from participation in Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with such an individual or entity) for the provision of any of the following."

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether OMB should approve an information collection, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The collection requirements referenced in sections one and two below are currently approved under OMB approval number 0938–0753 (CMS–R–0267, Medicare Plus Choice Program Requirements Referenced in 42 CFR 422.000 through 422.700), with a current expiration date of October 31, 2005.

Section one below outlines the collection requirements referenced in this regulation that have not been modified by the proposed regulatory changes. Section number two references requirements in this regulation that have been technically revised, but do not affect the currently approved burden estimates. Table three below references new collection requirements.

It should be noted that all of the collection requirements summarized and discussed below are open for public comment and will be submitted to OMB for approval.

Section 1—Currently Approved Collection Requirements Not Affected by Proposed Regulation

Section 422.54 Continuation of Enrollment for MA Local Plans

(b) The intent by an enrollee to no longer reside in an area and permanently live in another area must be verified by the plan through documentation that establishes residency, such as a driver's license, voter registration.

(c)(2) The enrollee must make the choice of continuing enrollment in a manner specified by CMS. If no choice is made, the enrollee must be disenrolled from the plan.

Section 422.60 Election process

(b)(1) MA organizations may submit information on enrollment capacity of plans.

(c)(1) The plan election must be completed by the MA eligible individual (or the individual who will soon become eligible to elect an MA plan) and include authorization for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services and its designees and the MA organization. Persons who assist beneficiaries in completing forms must sign the form, or through other approved mechanisms, indicate their relationship to the beneficiary.

(e)(3) The MA organization must give the beneficiary prompt notice of acceptance or denial in a format specified by CMS.

(e)(4) If the MA plan is enrolled to capacity, it must explain the procedures that will be followed when vacancies occur to the potential enrollee.

(e)(5) Upon receipt of the election, or for an individual who was accepted for future enrollment from the date a vacancy occurs, the MA organization

transmits, within the timeframes specified by CMS, the information necessary for CMS to add the beneficiary to its records as an enrollee of the MA organization.

(f)(3) Upon receipt of the election from the employer, the MA organization must submit the enrollment within timeframes specified by CMS.

Section 422.66 Coordination of Enrollment and Disenrollment Through MA Organizations

(f)(2) Upon receipt of the election from the employer, the MA organization must submit a disenrollment notice to CMS within timeframes specified by CMS.

Section 422.506 Nonrenewal of Contract

(a)(2)(ii) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice must include a written description of alternatives available for obtaining Medicare services within the service area, including alternative MA plans, Medigap options, and original Medicare and must receive CMS approval prior to issuance.

Section 422.568 Standard Timeframes and Notice Requirements for Organization Determinations

(a) When a party has made a request for a service, the MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination.

(c) If an MA organization decides to deny service or payment in whole or in part, or if an enrollee disagrees with an MA organization's decision to discontinue or reduce the level of care for an ongoing course of treatment, the organization must give the enrollee written notice of the determination.

Section 422.590 Timeframes and Responsibility for Reconsiderations

(d)(2) When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

Section 422.600 Right to a Hearing

(a) If the amount remaining in controversy after reconsideration meets the threshold requirement established annually by the Secretary, any party to the reconsideration (except the MA organization) who is dissatisfied with the reconsidered determination has a right to a hearing before an ALJ.

Section 422.608 Medicare Appeals Council (MAC) Review

Any party to the hearing, including the MA organization, who is dissatisfied with the ALJ hearing decision, may request that the MAC review the ALJ's decision or dismissal.

Section 422.612 Judicial Review

(b) Any party, including the MA organization, may request judicial review (upon notifying the other parties) of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) In order to request judicial review, a party must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. See part 405, subpart I of this chapter for a description of the procedures to follow in requesting judicial review.

Section 2—Currently Approved Collection Requirements Technically Modified by Proposed Regulation: Not Affecting Burden

Section 422.50 Eligibility To Elect an MA Plan

(a)(5) Completes and signs an election form or another CMS approved election method and gives information required for enrollment.

Section 422.66 Coordination of Enrollment and Disenrollment Through MA Organizations

(b)(1)(i) Elect a different MA plan by filing the appropriate election with the MA organization.

(b)(1)(ii) Submit a request for disenrollment to the MA organization in the form and manner prescribed by CMS or file the appropriate disenrollment request through other mechanisms as determined by CMS.

(b)(3)(ii) Provide enrollee with notice of disenrollment in a format specified by CMS.

(b)(3)(iii) In the case of a plan where lock-in applies, include in the notice a statement.

(d)(5) The individual who is converting must complete an election as described in § 422.60(c)(1).

Section 422.74 Disenrollment by the Medicare Advantage Organization

(c)(1) A notice must be provided to the individual before submission of the disenrollment transaction to CMS.

(d)(1)(i) The MA organization can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount.

(d)(1)(ii) The MA organization provides the enrollee with notice of disenrollment that meets the requirements set forth in paragraph (c) of this section.

(d)(2)(ii) The beneficiary has a right to submit any information or explanation that he or she may wish to submit to the MA organization.

(d)(3)(iii) The MA organization must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraphs (d)(2)(i) through (d)(2)(ii) of this section and any extenuating circumstances.

Section 422.111 Disclosure Requirements

(d)(2) For changes that take effect on January 1, the plan must notify all enrollees 15 days before the beginning of the Annual Coordinated Election Period defined in section 1851(e)(3)(B) of the Act.

(e) The MA organization must make a good faith effort to provide notice of a termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified.

Section 422.112 Access to Services

(a)(1)(i) Maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. These providers are typically used in the network as primary care providers (PCPs), specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics, and other providers.

(a)(1)(ii) MA regional plans, upon CMS pre-approval, can use methods other than written agreements to establish that access requirements are met.

Section 422.152 Quality Improvement Program

(b)(3)(i) Plans must measure performance using the measurement tools required by CMS, and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.

(b)(3)(ii) Make available to CMS information on quality and outcomes measures that will enable beneficiaries to compare health coverage options and select among them, as provided in § 422.64(c)(10).

(d)(5) The organization must report the status and results of each project to CMS as requested.

(e)(2)(i) MA organizations offering an MA regional plan or local PPO plan as defined in this section must measure performance under the plan using standard measures required by CMS and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.

(f)(i) and (iii) For all types of plans that it offers, an organization must maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality improvement program and make all collected information available to CMS.

Section 422.570 Expediting Certain Organization Determinations

(d)(2)(ii) The plan must inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision not to expedite.

Section 422.572 Timeframes and Notice Requirements for Expedited Organization Determinations

(c) If the MA organization first notifies an enrollee of an adverse expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

Section 422.582 Request for a Standard Reconsideration

(a) A party to an organization determination must ask for a reconsideration of the determination by making an oral or written request to the MA organization that made the organization determination or to an SSA office.

(c)(2) If the 60-day period in which to file a request for reconsideration has expired, a party to the organization determination may file a request for reconsideration with the MA organization or the SSA.

Section 422.620 How Enrollees of MA Organizations Must Be Notified of Noncovered Inpatient Hospital Care

(c) A written notice of non-coverage must be issued no later than the day before hospital coverage ends. The written notice must include the elements set forth in this section.

As noted above, while the requirements in this section have been modified, the associated burden has not changed.

Section 3—New/Revised Collection Requirements Proposed in This Regulation: Affecting Burden

Section 422.80 Approval of Marketing Materials and Election Forms

(a)(3) The MA plan meets the performance requirements established by CMS to allow the plan to file designated marketing materials with CMS 5 days before their distribution.

The burden associated with this requirement is the time and effort necessary for the plan to submit the designated marketing materials to CMS five days prior to distribution.

We estimate it will take 350 plans approximately 12 hours to provide the materials to CMS on an annual basis.

Section 422.101 Requirements Relating to Basic Benefits

(d)(4) MA regional plans are required to track the deductible (if any) and catastrophic limits in paragraphs (d)(1) through (d)(3) of this section based on incurred out-of-pocket beneficiary costs for original Medicare covered services, and are also required to notify members when the deductible (if any) or a limit has been reached.

The burden associated with this requirement is the time and effort necessary for the plan to notify members when the deductible (if any) or a limit has been reached. While this requirement is subject to the PRA, we believe this requirement meets the requirements of 5 CFR 1320.3(b)(2), and as such, the burden associated with this requirement is exempt from the PRA.

Section 422.106 Coordination of Benefits With Employer Group Health Plans and Medicaid

(d)(1) To facilitate the offering of MA plans by employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof), of the labor organizations, those MA plans may request, in writing, from CMS, a waiver or modification of those requirements in this part that hinder the design of, the offering of, or the enrollment in, those plans by those individuals.

The burden associated with this requirement is the time and effort necessary for the plan to submit a waiver to CMS. We estimate that on an annual basis it will take plans 2 hours to submit the waiver to CMS. However, we do not anticipate more then nine waiver requests on an annual basis. As such, this requirement is not subject to the PRA as stipulated under 5 CFR 1320.3(c).

Section 422.111 Disclosure Requirements

(f)(10) The names, addresses, and phone numbers of providers from whom the enrollee may obtain in-network coverage in other areas.

The burden associated with this requirement is the time and effort necessary for the plan to notify member of the names, addresses, and phone numbers of providers from whom the enrollee may obtain in-network coverage in other areas. While this requirement is subject to the PRA, we believe this requirement meets the requirements of 5 CFR 1320.3(b)(2), and as such, the burden associated with this requirement is exempt from the PRA.

Section 422.112 Access to Services

(c) An MA regional plan may seek, upon application to CMS, to designate a hospital as an essential hospital as defined in section 1858(h) of the Act that meets the conditions set forth in this section.

The burden associated with this requirement is the time and effort necessary for the plan to submit the required materials to CMS. We estimate that on an annual basis it will take 100 plans 8 hours to submit the materials to CMS.

Section 422.254 Submission of Bids

(a)(1) No later than the first Monday in June, each MA organization must submit to CMS an aggregate monthly bid amount for each MA plan (other than an MSA plan) the organization intends to offer in the upcoming year in the service area (or segment of such an area if permitted under § 422.262(c)(2)) that meets the requirements in paragraph (b) of this section. With each bid submitted, the MA organization must provide the information required in paragraph (c) of this section.

The burden associated with this requirement is the time and effort necessary for the plan to submit the required bid materials to CMS. 350 MA

organizations offering 400 plans 100 hours per plan bid submission to CMS for a total annual burden of 40,000 hours.

(b) For MSA plans, MA organizations must submit the following information: the monthly MSA premium, the plan deductible amount, and the beneficiary supplemental premium, if any. Since CMS does not review or approach MSA plan submissions, we estimate that the submission burden is half that for other MA plans. Under the M+C program, no MSA plans were offered. We estimate that under the MA program 5 organizations will offer an MSA plan and require 50 hours for submission of the above information, for a total annual burden of 250 hours.

Section 422.270 Incorrect Collections of Premiums and Cost-Sharing

(b) An MA organization must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and to pay any other amounts due the enrollees or others on their behalf.

The burden associated with this requirement is the time and effort necessary for the MA organization to provide written assurance to CMS that they will refund all amounts incorrectly collected from its Medicare enrollees or representatives. We estimate that on an annual basis it will take 350 MA organizations 30 minutes to submit a written agreement to CMS.

Section 422.304 Monthly Payments

(e)(2) A State's chief executive may request, no later than February 1 of any year, a geographic adjustment of the State's payment areas, as outlined in this section, for MA local plans for the following calendar year.

The burden associated with this requirement is the time and effort necessary for a State to provide a written request for geographic adjustment to CMS. Under the M+C program, we received inquiries from 2 states and requests from none. Thus, we estimate that on an annual basis we may receive 2 State submissions. As such, this requirement is not subject to the PRA as stipulated under 5 CFR 1320.3(c).

Section 422.310 Risk Adjustment Data

(b) Each MA organization must submit to CMS (in accordance with CMS instructions) all data necessary to characterize the context and purposes of each service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. CMS may also collect data necessary to characterize the functional limitations of enrollees of each MA organization.

The burden associated with this requirement is the time and effort necessary for a plan to submit the required risk adjustment data to CMS. We estimate that on an annual basis it will take 350 MA organizations 121 hours each to submit the required data to CMS.

(d)(1) MA organizations must electronically submit data that conform to the requirements for equivalent data for Medicare fee-for-service when appropriate, and to all relevant national standards. Alternatively, MA organizations may submit data according to an abbreviated format, as specified by CMS.

The burden associated with this requirement is the time and effort necessary for a plan to submit the required risk adjustment data to CMS. The estimate for submission of the abbreviated format data is included in the above estimate.

(e) MA organizations and their providers and practitioners will be required to submit medical records for the validation of risk adjustment data, as required by CMS.

The burden associated with this requirement is the time and effort necessary for a plan to submit the required validation data to CMS. We estimate that on average 350 MA organizations will each submit 29 medical records to CMS, requiring 1 hour per record, for a total annual burden of 9800 hours.

Section 422.314 Special Rules for Beneficiaries Enrolled in MA MSA Plans

(b) An entity that acts as a trustee for an MA MSA must Register with CMS, certify that it is a licensed bank, insurance company, or other entity qualified, under sections 408(a)(2) or 408(h) of the IRS Code, agree to comply with the MA MSA provisions of section 138 of the IRS Code of 1986; and provide any other information that CMS may require.

The burden associated with this requirement is the time and effort necessary for an entity to certify and submit the required materials to CMS as outlined in this section. We estimate 5 MA organizations will submit the required information on an annual basis. As such, this requirement is not subject to the PRA as stipulated under 5 CFR 1320.3(c).

Section 422.320 Special Rules for Hospice Care

(a) An MA organization that has a contract under subpart K of this part must inform each Medicare enrollee eligible to select hospice care under § 418.24 about the availability of hospice care if a Medicare hospice program is located within the plan's service area, or it is common practice to refer patients to hospice programs outside that area.

The burden associated with this requirement is the time and effort necessary for a plan to disclose to each Medicare enrollee about the availability of hospice care. We estimate that on an annual basis it will take 350 plans 1.14 hours to distribute the required materials to enrollees. While this estimate may appear low, we believe that this disclosure requirement will be standardized and incorporated into the plans marketing material routinely disseminated to enrollees.

Section 422.458 Risk Sharing With Regional MA Organizations for 2006 and 2007

(d)(1) Each MA organization offering an MA regional plan must provide CMS with information as CMS determines is necessary to implement this section.

The burden associated with this requirement is the time and effort necessary for a plan to submit the required information to CMS. We estimate that on an annual basis it will take 30 to 100 plans, 40 hours to submit the required information to CMS.

(d)(2) Pursuant to the existing § 422.502(d)(1)(iii) (section 1857(d)(2)(B) of the Act), CMS has the right to inspect and audit any books and records of the organization that pertain to the information regarding costs provided to CMS under paragraph (b)(2) of this section.

This requirement is exempt from the PRA as stipulated under 5 CFR 1320.4.

Section 422.501 Application Requirements

(b)(1) In order to obtain a determination on whether it meets the requirements to become an MA organization and is qualified to provide a particular type of MA plan, an entity, or an individual authorized to act for the entity (the applicant) must complete and submit a certified application, in the form and manner required by CMS, that meets the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for a plan to submit the required application to CMS. We estimate that on an annual basis it will take 350 plans 40 hours to submit the required application to CMS.

If you comment on these information collection and recordkeeping

requirements, please mail copies directly to the following:

Centers for Medicare and Medicaid Services Office of Strategic Operations and Regulatory Affairs, Attn: John Burke (CMS–4069–P), Room C5–13–28, 7500 Security Boulevard, Baltimore, MD 21244–1850;
and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Christopher Martin, CMS Desk Officer, [CMS–4069–P], *Christopher_Martin@omb.eop.gov*. Fax (202) 395–6974.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule under Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) and Executive Order 13132 on Federalism.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impact and equity). A regulatory impact analysis (RIA) must be prepared for any proposed rule with an effect on the economy of $100 million or more in any one year. While we do not believe that this proposed rule will have independent effects of this magnitude, the Medicare Advantage program taken as a whole will have effects that far exceed this threshold. Since this rule, once issued in final form, will be the most significant step in implementing the MA program, we are classifying it as an economically "significant" rule for purposes of E.O. 12866 and as a "major" rule for purposes of the Congressional Review Act (5 U.S.C., section 804(2)). Accordingly, we have prepared this RIA, combined with an Initial Regulatory Flexibility Analysis ((IRFA), pursuant to the Regulatory Flexibility Act), in which we analyze the overall effects of the Medicare Advantage program, including effects not addressed in this rulemaking (for example, rate increases that went into effect in March, 2004). Although the MMA is a highly detailed statute that delineates most important provisions of the MA program, there are alternatives available to us in implementing several important provisions of the statute. We analyze in detail those areas for which regulatory alternatives are available.

Although we have included or summarized most of the required analysis in this section of the preamble, the explanation of the basis for the proposed rule and analysis of some regulatory options are presented elsewhere in the preamble. We note that the preamble to the companion rulemaking concerning the Part D drug benefit also contains an RIA and IRFA, and some effects of the legislation (for example, on Medigap plans) are analyzed in more detail in that preamble.

The Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provides for increasing the role of private plans in providing Medicare benefits to beneficiaries. The statute made changes to the payment system that increase Medicare payment rates to private plans as of 2004, and for subsequent years. A new private plan option is introduced, the regional Medicare Advantage plan, structured as a preferred provider organization (PPO), which will be required to offer services over a wide geographic area. To encourage the formation of such plans, the MMA provides financial incentives above and beyond the payment rate increases applicable to all plans. There are other financial incentives discussed in what follows and elsewhere in the preamble. In addition to increased payments to plans, the MMA will provide benefits to beneficiaries and to entities (such as employers and States) that would otherwise be financially responsible for the cost of beneficiaries' medical care. The benefits to beneficiaries and plans are the result of transfer payments from the Federal Government which we project will total $24.8 billion in the period 2004 to 2009 (as a result solely of the Title II provisions of the MMA), as described in more detail in what follows.

The main purpose of this proposed rule is to implement the statutory provisions of Title II of the MMA, which deal with the Medicare Advantage program. Insofar as the proposed rule implements provisions of the law, we are providing a general discussion of the impact of the law and our basis for projections of the impact. These impact projections reflect the statutory scheme in its entirety, not just the relatively minor effects attributable to discretionary provisions in our proposed regulations. Although the statute prescribes Medicare Advantage rules and procedures in considerable detail, it specifically affords CMS discretion to make decisions on a number of issues regarding how the law will be implemented. The preamble and this impact analysis—particularly the section dealing with alternatives considered—discuss these types of issues in greater detail. The proposed rule also introduces changes to Medicare private health plan requirements which, in most cases, are intended to streamline the administration of the program and make contracting less burdensome for health plans while not impinging on the rights of enrollees. (Note that this analysis does not extend beyond the year 2009; that is, the Comparative Cost Adjustment (CCA) demonstration program of subtitle E of the MMA is not discussed. The CCA regulations will be proposed at a later date.)

1. Objectives of the Proposed Rule

The primary goal of the MMA is to expand the health plan choices available to Medicare beneficiaries. There is also the expectation that private plan enrollment will increase. The expansion of health plan choice is envisioned as occurring at many levels: areas of the country that previously did not have private plans available should see new plans enter the market; areas where there are plans should see an increase in the number of competing plans; and beneficiary choice should be enhanced by the introduction of new types of plans, including specialized plans, and, most importantly, regional plans that are structured as preferred provider organizations. In keeping with the overall objectives of the law, the rule seeks to implement the law in ways that will promote plan participation (and, as a consequence, lead to increased enrollment in private plans). The introduction of regional plans and the choice of the PPO model for such plans are designed to lead to greater plan participation.

Regional Plans. The introduction of regional plans, and the payment policies that apply to such plans, attempt to address both the payment issues affecting plan participation and the structural issues that have prevented greater access to plans. There were two

primary motivating factors in the decision to use a regional PPO approach as one of the means of achieving the MMA goals of increased plan participation and increased beneficiary enrollment in private plans. One factor is that the regional approach requires plans to serve extensive geographic areas specified by CMS. This is a departure from the practice of allowing private plans to pick and choose the counties in which to offer Medicare plans, which will continue to be the policy for local MA plans. The regional service area approach seeks to ensure that areas not heretofore served by private plans in Medicare—particularly, rural counties—will have private, coordinated care plan options available (*see* the MMA conference report discussion of section 201 at pp. 90–91).

The PPO Model. The other motivating factor in choosing the regional approach relates to the choice of the PPO model as the structure for regional plans. The choice of this model is partly a consequence of the decision to require coverage of large geographic areas. Other types of health plans, such as plans that rely exclusively on networks of employed or contracted providers (for example, the more traditional health maintenance organization models) have had difficulty forming viable networks in rural areas. The cost of the infrastructure required in the operation of such a model has also acted as a barrier to serving areas in which enrollment levels would be too low to warrant the necessary level of investment. Another factor in choosing the PPO model reflects consumer preference as seen in the commercial sector, where the PPO model is the model of choice in the employment-based health care market. PPOs are preferred over HMOs by consumers because of their less restrictive provider access, and PPOs are preferred over indemnity FFS plans because they do employ managed care techniques and differential cost sharing to control costs, and there is quality assurance.

Promoting Competition. One of the purposes of the MMA is to promote plan competition, which in turn is expected to lead to greater efficiency among plans and more benefits for enrollees. Certain features of the MMA that promote plan participation are of limited duration in the expectation that plan entry will occur: for example, though plan payments increased effective March of 2004, the provision by which the Government receives 25 percent of the savings that plans can achieve does not take effect until 2006. Similarly, many of the incentives provided to regional plans (such as risk sharing, and the entry and retention bonuses) are time-limited. In highly competitive markets where multiple plans are available to beneficiaries, there is strong evidence that competition among plans leads to improved benefits for enrollees and promotes greater plan efficiency. In an analysis of Medicare health plan benefit premiums and offerings, Pizer and Frakt found that "the effects of competition are comparable in importance to the effects of payment rates. The finding that more intense competition increases benefits and reduces premiums, although predictable from a theoretical standpoint, empirically confirms that it is possible for the Medicare Program to increase benefits without increasing spending or shifting additional costs to beneficiaries. Conversely, reduced competition would have the reverse effect. We acknowledge that competition and spending are related by the fact that lower payments can be expected to induce plan exit, thereby undermining competition. Nevertheless, this research shows that the Federal Government has a strong institutional interest in safeguarding and promoting interplan competition in the M+C Program, independent of its policy on payment rates." (Steven D. Pizer, and Austin B. Frakt, "Payment Policy and Competition in the Medicare+Choice Program," Health Care Financing Review, fall 2002, volume 24, number 1.)

General Impact. In general, the law and regulations will have a positive impact on beneficiaries. Transfer payments from the Federal Government will go towards the provision of additional benefits to enrollees of health plans and reduced out-of-pocket costs, including reduced Part B and Part D premiums for these enrollees. The law will result in increased revenue for participating private plans for the provision of the basic Medicare benefit and the provision of additional benefits. This will help improve the availability of health plan choices for beneficiaries. We also anticipate a positive impact for employers and unions as sponsors of retiree coverage, as discussed in more detail below.

There are revenue effects on States arising directly from the law (the prohibition on premium taxes) and arising indirectly as a result of beneficiary movement towards private plans and away from traditional fee-for-service Medicare with Medigap coverage. The latter effect is relevant to Medigap insurers. The effects on States and insurers are discussed more fully in what follows.

2. Provisions of the Law

The MMA introduces major changes in the payment rules for private plans. These changes are discussed in detail in the preamble text for subparts F and G of these proposed regulations. For local plans, the MMA increased Medicare Advantage payment rates beginning in 2004, by using county fee-for-service rates (minus direct medical education payments) as a minimum payment level and rebasing the rates periodically, by removing a budget neutrality limitation on payment at a national/local blended rate, and by providing for higher yearly payment rate increases (while maintaining minimum payment rate increases).

Payment to plans are risk adjusted for health status (in addition to risk adjustment for demographic factors such as age), with 30 percent of payment being subject to health status risk adjustment in 2004, 50 percent in 2005, 75 percent in 2006, and 100 percent in 2007 and thereafter. Note that CMS is currently implementing health status risk adjustment in a "budget-neutral" manner and will continue to do so in 2005. The difference in payment between the total health status-adjusted payment rates and the rates adjusted only by demographic factors continues to be paid to the health plan "sector," but the funds are distributed among plans based on the relative health status of each plan's enrollees.

Through 2005, there is no change to the payment rules related to how plans must use any excess funds (Medicare payments greater than the amount a health plan requires to provide the Medicare benefit). Currently such funds must be returned to enrollees in the form of reduced cost sharing, or the provision of extra (non-Medicare) benefits. Plans also have the option of using the excess funds to reduce all or a portion of an enrollee's Part B premium, but in that case, the Government retains 20 percent of the reduction in plan payments while reducing the Part B premium that is usually collected through a beneficiary's Social Security payment. Another option for the disposition of excess funds is to make deposits to a "stabilization fund" to be used in a subsequent contract year for reductions in cost sharing or for financing of extra benefits—an option that the MMA eliminates as of the end of the 2005 contract year.

Currently and through 2005, the determination of whether there are excess funds is done through the "adjusted community rate" approval process (a CMS review of proposed

benefits and premiums and the revenue required to provide the benefit package). The MMA does away with the ACR review process and instead institutes a bidding process. As of 2006, plans will present bids that are to be compared against benchmarks to determine whether enrollees will receive rebates or be required to pay a premium to the health plan. For local plans, the benchmark is based on what today are county payment rates. For regional plans, the benchmark represents a weighting of these same county rates and the actual plan bids. CMS will evaluate the bids for reasonableness and actuarial soundness, and can negotiate over the bid amounts and proposed supplemental benefits. In 2006 and thereafter, to the extent that the bid is less than the benchmark, that difference (comparable to the current "excess funds") determines plan rebates. The Government retains 25 percent of this difference, and the remaining 75 percent is to be used for beneficiary "rebates," which can take the form of extra benefits, reduced cost sharing, reduced health plan premiums for supplemental benefits, or reduced Part B and/or Part D premiums. To the extent that the plan bid is greater than the benchmark, that difference becomes the premium the plan must charge enrollees for "basic" benefits.

The limitation on cost sharing for Medicare services that previously existed is modified in the MMA. Prior to the MMA, for coordinated care plans, the combination of the actuarial value of cost sharing for Medicare-covered services, plus any premium or portion of a premium representing a charge in lieu of Medicare cost sharing, could not exceed the average level of cost sharing that beneficiaries face in fee-for-service Medicare. As of 2006, premium amounts that are in lieu of cost sharing are not counted in determining whether the limit is exceeded (which is the rule as it is currently applied to private fee-for-service plans). In addition, the comparison is made to local values of cost-sharing in fee-for-service Medicare rather than to the current use of national values.

The MMA also makes structural changes in the Medicare private plan contracting program. The most important of these statutory changes is the introduction of regional MA plans that will be structured as PPOs, and which would first become available in 2006. While local plans may choose the counties in which they wish to operate as Medicare Advantage plans, regional plans must cover an entire region. Regions will be designated by CMS after a market analysis (as discussed later and in the preamble text for subpart J). To facilitate the ability of regional plans to operate in multiple States, plans can meet Federal solvency and licensure requirements for a period of time pending an organization's meeting such requirements for each State (*see* the preamble text for subpart J). In the first two years of formation of regional plans, there is a moratorium imposed on the formation or expansion of local plans that operate as PPOs.

Regional plans have various incentives to participate, including:

- Sharing risk with the Government in 2006 and 2007,
- Access, beginning in 2007 through the end of 2013, to a "stabilization fund" of $10 billion (plus half of the 25 percent of regional plan rebate dollars that would otherwise go to the Government). The stabilization will be used to encourage plan entry (including a bonus for plans operating in the entire Nation) or to prevent plans from discontinuing contracts;
- Inclusion of plan bids in determining benchmark amounts (as opposed to the benchmarks for local plans, which are comprised only of the local MA payment rates); and
- Access to additional funding payable to "essential" hospitals (as described in the subpart G preamble text).

Other structural changes affecting Medicare health plans include provisions for plans that can exclusively serve special needs individuals, special treatment of enrollees with end-stage renal disease (paid outside of the bidding system—*see* subpart G), authority for direct contracting between CMS and employers or unions for coverage of retirees—*see* § 422.106), and removal of certain limitations that had been imposed on medical savings account plans. There are also provisions calling for the termination of cost-reimbursed contracts with health plans if certain conditions are met (subpart J).

In the following section we list those areas in which CMS will exercise discretion through this rulemaking, either because the law entails a choice of options or because we have elected to exercise regulatory discretion.

3. Regulation Required in the Law

Designation of Regions. The most important feature of the MA program that the statute leaves to the discretion of CMS is to determine the boundaries for the regions in which regional MA plans will operate. Following a market analysis, CMS will designate between 10 and 50 regions, using certain guidelines stated in the MMA (as discussed in the preamble text for subpart J). Some of the issues relating to the configuration of regions are discussed later in the section on alternatives considered. The impact of the configuration of regions cannot be fully evaluated until the regions are designated. The estimates contained in this analysis (shown in Table 2, for example) are for illustrative purposes and are based on the assumption that there would be 15 regions.

Statewide Versus Plan-Specific Risk Adjustment. CMS is given the authority to use a statewide, area-wide, or a plan-specific, risk adjustment methodology for determining rebates. The effects of each and the factors to consider in choosing one or the other approach are discussed in the alternatives considered section below.

4. CMS Regulatory Discretion

The statute spells out in detail most major and many minor parameters of Medicare reform. However, in certain matters, the statute describes a structure or uses terminology that is open to interpretation but which is a necessary component of the statutory scheme. There are also other areas where we believe further interpretation is needed, or where there appear to be internal inconsistencies in the statute that need to be resolved. The following issues are of this nature, and each is noted here briefly, with some of the issues discussed in further detail in the section on alternatives considered.

Actuarial Value of Medicare Cost Sharing. When plans present bids for Medicare-covered services the bid may include only Medicare-covered services and must reflect cost sharing at Medicare levels or with "actuarially equivalent" cost sharing. The options for defining "actuarially equivalent" in this context are discussed in detail in the preamble text of subsection F (where the uniform, plan-specific, and proportional amount methods of determining actuarial equivalence are discussed).

Treatment of Induced Demand as a Supplemental Cost. To the extent that CMS decides to use the "plan-specific" approach to determining cost sharing that is actuarially equivalent to that of traditional Medicare, an additional issue arises. If a plan proposes, through a supplemental benefit, to lower cost sharing included in the base package (the portion of the bid which is used to determine whether rebates or a basic premium apply), we propose that the additional expenditures arising from the induced demand caused by the cost sharing reduction be included in the cost of the supplemental benefits rather than in the cost of the base package.

That is, because cost sharing reduces utilization of services, and plan bids for the basic package are determined using the cost sharing structure of fee-for-service Medicare, if cost sharing is reduced below Medicare levels, the result is higher utilization of services, and higher expenditures. We believe these expenditures should not be included as part of the bid for the basic Medicare package. The additional expenditures would not have arisen if the cost sharing were at Medicare levels or at an actuarially equivalent level. In other words, the additional expenditures do not comprise a part of the bid for the basic benefit package as it is defined in the statute. We propose that the portion of utilization expenditures that result from the reduced cost sharing would be "paid for" entirely as a supplemental benefit. This requirement, consistent with a parallel requirement for Part D drug coverage, assures that the determination of whether rebates or a premium is applicable is based on an "apples-to-apples" comparison of a specific set of benefits reflecting a specific cost sharing structure.

Prohibiting Use of Rebate Dollars for the Purchase of Optional Supplemental Benefits. As stated in the preamble text for subpart F, a bidding system in which there is the possibility of rebate funds that must be spread over the entire enrolled population of a plan is difficult to implement if the rebates can be used to finance optional supplemental benefits that enrollees may decline. Because each enrollee should receive the same level of rebate value as any other enrollee of the same plan, enrollees would have to be offered a menu of options to fashion a combination of rebate possibilities to arrive at the dollar amount of rebate that the enrollee is entitled to. (This issue is discussed more fully in the preamble and the "alternatives considered" section of this impact analysis.)

Intra-Area Geographic Adjustment to Payments. The statute specifies that "if applicable" (1853(a)(1)(B)(i)), CMS "shall adjust" payments "in a manner to take into account variations in MA local payment rates" (1853(a)(1)(F) for regional plans and for local plans operating in more than one local payment area. CMS is requesting comment on the ways in which such adjustments can be made. (This issue is also discussed in the "alternatives considered" section.)

5. Provisions of the Proposed Rules Not Based on Specific MMA Changes

As discussed throughout the preamble, we have made a concerted effort to improve, and wherever possible simplify and reduce the burden of, existing regulations. In general, as previously noted, these provisions reduce the burden on health plans while enhancing beneficiary protections or not adversely affecting the rights of enrollees. Among the changes that are being made that are not a result of the MMA statutory provisions are (a) New beneficiary protections related to coverage of services when network providers can see patients on a "point-of-service" basis (§ 422.105); (b) revisions to the rules limiting beneficiary cost sharing related to emergency episodes (§ 422.113); (c) the elimination of requirements on MA plans that are duplicative of activities already conducted by CMS regarding information about beneficiary health care coverage options (elimination of § 422.111(f)(4) and (f)(6), and portions of (f)(7)); (d) the elimination of certain access to care provisions (changes made at § 422.112); (e) use of alternative election mechanisms other than forms (§ 422.50(a)(5)), and alternative notice options (§ 422.60(e)); (f) allowing MA organizations to submit requests to restrict enrollment for capacity reasons at any time during the year (§ 422.60(b)); (g) providing more flexibility in the procedures for disenrolling beneficiaries for failure to pay premiums (§ 422.74(d)(1)) and rules related to disenrollment due to disruptive behavior (§ 422.74(d)(2)); (h) formal adoption of a "file and use" approach to approval of marketing materials (§ 422.80) for contractors that have demonstrated a record of compliance with marketing rules; (i) changes in requirements regarding information plans provide to enrollees about participating providers (§ 422.111(b)(3), for example); and, in § 422.133 , extending the right under section 1852(l) of the Act for admission to a "home skilled nursing facility" in the event that a health plan admits an enrollee to a skilled nursing facility without a prior qualifying hospital stay. In addition, various changes are made in subpart D that are consistent with a "quality improvement" approach to quality standards.

B. Basis for Estimating Impacts

The extent of the impact of the MMA will depend on whether the goals of the law are realized. We believe that the payment changes and structural changes of the MMA will lead to higher levels of plan participation, and, as a consequence, enrollment in private plans will increase over the next several years. We expect the absolute level of private plan enrollment to increase because of the greater availability of plans, and we expect the rate of enrollment in private plans ("penetration") to increase because plans will be able to offer plan designs that will meet the needs of Medicare beneficiaries, and MA organizations will be able to offer generous benefit packages that Medicare beneficiaries will find attractive. However, there is a great deal of uncertainty involved in making projections of plan participation and beneficiary enrollment levels. The factors contributing to uncertainty include uncertainty about market decisions made by health plans might make, how changes in health care markets and costs will affect plan participation and beneficiary enrollment, whether MA plan offerings will satisfy the enrollment preferences of Medicare beneficiaries, how MA plans will fare in competition with the new PDP plans, and other factors. For the MMA, the designation of MA regions and how the marketplace will react to the regional designations is also a factor contributing to uncertainty.

The uncertainty inherent in attempting to make projections of what might transpire in the health care marketplace is illustrated by the projections that were made for earlier legislation that brought about a major reform of Medicare health plan contracting, the Balanced Budget Act of 1997 (BBA). The BBA sought to expand the availability of private plans throughout the United States (particularly to rural areas), with the expectation that the generous benefit packages that Medicare plans had been offering would continue to be offered and would be available to more beneficiaries. It was also assumed that the new types of plans introduced in the BBA—such as provider-sponsored health plans—would proliferate. For example, in the impact analysis for the regulations implementing the Medicare+Choice program enacted in the BBA (**Federal Register**, vol. 63, no. 123, June 26, 1998), it was noted the Congressional Budget Office had projected that by 2002 there would be 125 provider-sponsored organizations enrolling one million Medicare beneficiaries, and that in particular "a significant portion of the enrollment [would] be in rural areas." The actual outcome was that only a handful of PSOs were formed, and, with regard to projections of increased enrollment because of the BBA, what actually occurred was a decline in enrollment due in part to payment changes made by the BBA and also due to changes in the

overfall health care marketplace that affected Medicare health plans.

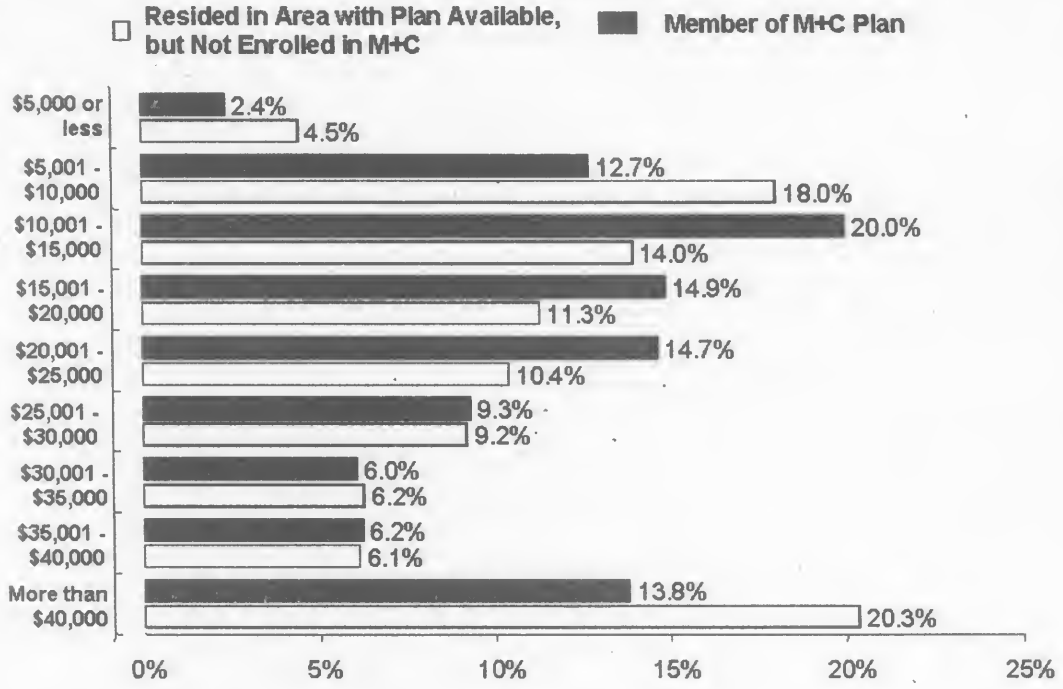
Recent Plan Participation and Enrollment Trends. As of June 2004 about 11 percent of beneficiaries are enrollees of Medicare risk-bearing private plans. This figure compares to a historical high of about 16 percent "penetration" (percent enrolled) achieved in 1999. The reduced penetration is partly a function of reduced access to plans. As of January 2004, about 61 percent of Medicare beneficiaries had access to a private coordinated care plan (and 75 percent had access to a private plan if private fee-for-service plans are included among the types of available plans). In 1998 (the year in which the highest access level was attained), 74 percent of beneficiaries had access to at least one Medicare+Choice plan (there were no private fee-for-service plans in 1998).

Although the national access figure is 61 percent in 2004, 75 percent of Medicare beneficiaries residing in metropolitan counties have access to at least one MA coordinated care plan, but only 14 percent of the residents of non-metropolitan counties—where about 23 percent of all Medicare beneficiaries reside—have access to a coordinated care plan. In terms of plan participation, at the end of 1998, there were 346 Medicare risk contracts, a number that has declined to 145 coordinated care plan contracts as of March 2004 (though some of the decline is attributable to consolidations within a State). Because in 1999 seventy-two percent of beneficiaries resided in a county in which there was at least one M+C coordinated care plan, the penetration rate in areas in which plans were available was an effective rate of 22 percent (with the "effective" penetration being the penetration only among those beneficiaries residing in areas in which there were operating plans). As of 2004, the effective penetration rate is 17 percent, with 4.6 million enrollees and a 61 percent level of availability of plans. This decline in "effective penetration" is partly the result of a decline in generosity of plan benefit offerings as statutorily set payments did not keep pace with plan costs. For example, while in 1999, 61 percent of the Medicare population (85 percent of those with access) lived in a county in which there was a Medicare+Choice plan with no plan premium, by 2003 the figure declined to 29 percent of beneficiaries living in a county with a zero premium plan (50 percent of those with access). (On the decline in benefits and rise in cost sharing in private plans, see, for example, Marsha Gold and Lori Achman, "Average Out-of-Pocket Health Care Costs for Medicare+Choice Enrollees Increase 10 Percent in 2003," Commonwealth Fund Issue Brief number 667, August 2003, available at *http://www.cmwf.org,* as well earlier studies of a similar nature cited therein).

Issues in Predicting Beneficiary Behavior. At the individual beneficiary level, there are a number of reasons why Medicare beneficiaries choose to enroll in private plans. Generally MA plans have significantly lower cost sharing compared to traditional fee-for-service Medicare, and private plans have been able to offer additional benefits not covered by Medicare (in particular, outpatient drugs). Hence, private plans have proven to be very attractive to certain lower-income and minority individuals (*see,* for example, Maggie Murgolo, "Comparison of Medicare Risk HMO and FFS Enrollees," Health Care Financing Review, fall 2002, volume 24, number 1; and Kenneth E. Thorpe and Adam Atherly, "Medicare+Choice: Current Role And Near-Term Prospects," Health Affairs web exclusive, July 17, 2002). The cost of Medigap policies in a particular area also appear to influence Medicare+Choice enrollment (Catherine G. McLaughlin, Michael Chernew, Erin Fries Taylor, "Medigap Premiums and Medicare HMO Enrollment," Health Services Research, December, 2002). The relationship between beneficiary income levels and the tendency to enroll in MA plans is shown in Figure 1, which illustrates how lower-income individuals are more likely to enroll in MA plans. (The lowest income groups include beneficiaries eligible for Medicaid, who face certain difficulties in enrolling in MA plans (*see* Edith G. Walsh and William D. Clark, "Managed Care and Dually Eligible Beneficiaries: Challenges in Coordination," Health Care Financing Review, fall 2002, volume 24, number 1), and who would not have the same incentives to join MA plans as beneficiaries with no Medicaid coverage.) Thus, to the extent that the MMA increases beneficiary choices by making MA plans available in geographic areas where there are currently no plans, we would expect to see lower-income beneficiaries in such areas elect to enroll in plans that would offer benefit packages that reduce their out-of-pocket expenses substantially and provide them with extra benefits that they would otherwise not receive or would have to pay for out-of-pocket. On average, prior to the MA reforms, beneficiaries enrolled in M+C plans had yearly out-of-pocket medical expenses in 2003 that were $667 lower than expenses for beneficiaries in fee-for-service Medicare (with no coverage supplementing Medicare, such as subsidized retiree coverage or Medigap coverage). (*See* Gold and Achman, previously cited, figure 5, page 6). The MA reforms are expected to increase the opportunities for lower cost-sharing and improved benefits for such beneficiaries. Beneficiaries in poorer health, in particular, would find MA plans to be an attractive option: in May 2004, such beneficiaries enrolled in MA plans had annual out-of-pocket costs that were estimated to be $1900 less than beneficiaries in poor health covered by fee-for-service Medicare with no supplemental coverage (based on unpublished CMS data on out-of-pocket costs).

BILLING CODE 4120–01–P

Figure 1: Enrollment Patterns of Medicare Beneficiaries by Yearly Income, Medicare+Choice Enrollment and Traditional Fee-for-Service (In Areas Where M+C Plans Are Available)



Source: Unpublished CMS Medicare Current Beneficiary Survey Data, 2002.

BILLING CODE 4120–01–C

One population group that has disproportionately lower rates of enrollment in Medicare private plans are disabled Medicare beneficiaries. Table 1 illustrates that while the disabled, a growing segment of the Medicare population, comprised 14 percent of the Medicare population in areas with Medicare+Choice plans in 2002, only seven percent of M+C plan enrollees were disabled (based on Medicare Current Beneficiary Survey Data for 2002). However, the M+C private fee-for-service plan option attracts a higher proportion of the disabled, with 17 percent of private fee-for-service (PFFS) plan enrollees being under 65 as of March 2004. This relatively high rate of enrollment of the disabled in PFFS likely reflects a demand for supplemental coverage in the face of less availability of Medigap coverage for Medicare beneficiaries under age 65. According to a September 2002 study, only 14 percent of disabled Medicare beneficiaries reside in States in which there is Medigap open enrollment for the disabled (Becky Briesacher, Bruce Stuart, Jalpa Doshi, and Sachin Kamal-Bahl, Medicare's Disabled Beneficiaries: The Forgotten Population In The Debate Over Drug Benefits, Commonwealth Fund and Henry J. Kaiser Family Foundation, publication #573, September 2002). The enrollment level of the disabled in PFFS plans would also appear to indicate that the disabled are willing to enroll in private plans when there are not restrictions on the providers they can use, even without the inducement of extra benefits or reduced premiums (which are generally not a feature of private fee-for-service plans). If a preference for broader networks is the reason for the willingness to enroll in PFFS plans, then the regional PPOs that the MMA seeks to promote may be an attractive option for disabled Medicare beneficiaries in that enrollees will have out-of-plan coverage and, in addition, are likely to have extra benefits available. The MMA authority for specialized plans for special needs individuals may also facilitate the enrollment of a higher proportion of the disabled in private plans. (On the disabled and their experience with access to care in Medicare HMOs, see Marsha Gold, Lyle Nelson, Randall Brown, Anne Ciemnecki, Anna Aizer, and Elizabeth Docteur "Disabled Medicare Beneficiaries In HMOs," Health Affairs, September/October 1997, particularly pages 155–157).

With regard to minorities and their enrollment in private plans, in 2002 Hispanics were more likely to choose Medicare+Choice enrollment (as compared to non-Hispanic African-Americans and non-Hispanic whites, as illustrated in Table 1). Any changes to the program that would increase the rate of private plan enrollment among the disabled would be likely also to result in higher minority enrollment levels in MA plans. This is because minorities make up a far greater percent of the disabled as compared to their distribution among the aged, as shown in Table 1. Thus, the overall high M+C enrollment rates in 2002 for Hispanics reflects the very high enrollment rates among aged Hispanics. The situation is reversed for the disabled: among Medicare beneficiaries under 65 (entitled to Medicare because of

disability), for the three different racial or ethnic groups (white, black, Hispanic), Hispanics were the least likely to be enrollees of M+C coordinated care plans. Similarly, for blacks, while over one in five aged black enrollees was enrolled in an M+C plan, fewer than one in ten disabled African-American beneficiaries were enrollees of M+C plans.

TABLE 1.—COMPOSITION OF MEDICARE ENROLLMENT BY AGE, RACE AND ETHNICITY IN AREAS WITH MEDICARE+CHOICE PLANS, YEAR 2002

	Composition within total population in areas with plans	Percent of group enrolled in M+C ("penetration")	Composition within FFS in area	Composition in M+C
Aged/Disabled Distribution:				
Aged (Age 65 or Over)	86.4%	21.3%	84.9%	92.9%
Entitled to Medicare Because of Disability (Under Age 65)	13.6%	10.5%	15.1%	7.1%
Racial/Ethnic Distribution:				
Black Non-Hispanic	10.5%	18.9%	10.7%	10.0%
Hispanic	10.3%	23.8%	9.8%	12.3%
White Non-Hispanic	79.2%	19.5%	79.6%	77.7%
	Composition within total aged population in areas with plans	Percent of racial/ethnic group in area enrolled in M+C	Composition of aged within FFS in area	Composition of aged within M+C
Aged by Race/Ethnicity:				
Black Non-Hispanic Aged	9.0%	22.1%	8.9%	9.3%
Hispanic Aged	9.4%	27.7%	8.7%	12.2%
White Non-Hispanic Aged	81.6%	20.5%	82.4%	78.4%
	Composition within total disabled population in areas with plans	Percent of racial/ethnic group in area enrolled in M+C	Composition of aged within FFX in area	Composition of aged within M+C
Disabled by Race/Ethnicity:				
Black Non-Hispanic Disabled	20.3%	9.6%	20.5%	18.7%
Hispanic Disabled	15.7%	8.8%	16.0%	13.1%
White Non-Hispanic Disabled	64.0%	11.2%	63.5%	68.2%

Source: Unpublished CMS Data from the Medicare Current Beneficiary Survey, 2002. Note: Excludes racial/ethnic category "other."

Another factor that influences beneficiary decisions to enroll in M+C is the use of M+C plans as the means of providing retiree health benefits. A substantial number of enrollees (about 18 percent of enrollment) are enrolled as retirees or dependents of retirees of firms that offer retiree coverage through M+C plans. These types of enrollees receive more generous benefits than individual Medicare enrollees of such plans (*see* Geoffrey R. Hileman, Kerry E. Moroz, C. William Wrightson, and Suhn K. Kim, "Medicare+Choice Individual and Group Enrollment: 2001 and 2002," Health Care Financing Review, fall 2002, volume 24, number 1).

A current feature of private Medicare plans that makes them attractive to beneficiaries is the coverage of outpatient drugs. Private drug-only plans will be available to beneficiaries in traditional fee-for-service Medicare as of 2006. There is no direct evidence that we can rely on to assume that beneficiaries will be less likely to enroll in MA plans if drug coverage is available in traditional fee-for-service Medicare (other than pointing out that 18 percent of current enrollees in non-employer-sponsored MA plans are enrolled in plans with no drug coverage, and therefore there is a segment of the population that chooses MA coverage even without drug coverage.) However, for a variety of reasons, we believe the availability of drugs under Part D will only have a marginal impact on private MA plan enrollment. We believe that beneficiaries will view the private MA plans' benefit package integrating drugs and other services as attractive; MA plans will be able to offer drug benefits for a lower premium than PDP plans at a lower cost; and they will continue to be able to offer other extra benefits, including additional drug coverage. Such extra benefits were important in attracting enrollees to private plans in the period of greatest enrollment growth. Another advantageous feature that will continue to be unique to private MA plans is that, unlike PDP plans, they will have the ability to reduce Part B and Part D premiums through the rebates available from Medicare for plans with bids below the applicable benchmark. (Although there are only preliminary results from the experience of Medicare+Choice plans that have offered Part B premium rebates, plans and beneficiaries have had mixed experiences with this relatively new option (*see* "Sub-Zero Premium" (BIPA 606) M+C Plan Evaluation, final report submitted by Bearing Point to CMS, September 30, 2003, contract number 500–95–0057, task order 6, available at *http://www.cms.hhs.gov/researchers/demos/subzeroevaluation.asp*). However, we believe that in combination with other advantages of MA enrollment, and as beneficiaries and plans become more familiar with the premium rebate option, premium reductions will be a significant inducement for beneficiaries to enroll in MA plans. There is also the issue of whether the number of plan withdrawals in recent years and the publicity surrounding the withdrawals may deter beneficiaries from enrolling in MA plans. Again, we believe that the generous benefit packages and financial advantages of MA membership will outweigh such considerations.)

Issues in Predicting Plan Behavior. With respect to plan behavior, whether plans have been available in a particular community (and whether Medicare beneficiaries have chosen to enroll in such plans) is often a function of local market factors. Brown and Gold found that "the capitation rate strongly influences whether and how quickly Medicare managed care develops and grows in an area, but other factors often outweigh the significance of the payment level" (Randy Brown and Marsha Gold, "What Drives Medicare Managed Care's Growth?" Health Affairs (Nov/Dec 1999). Among other factors that they cite as influencing increased Medicare private plan enrollment were factors such as the regulatory environment, whether or not employers and unions are offering supplemental coverage other than through Medicare health plans, and perhaps most importantly whether beneficiaries have greater familiarity with managed care in areas where plans have had a long-standing presence and acceptance in the commercial marketplace and among providers—as in the case of Portland, Oregon, which had, and continues to have, among the highest rates of Medicare private plan penetration even though the benefits available in Oregon have usually been less generous than in other areas with lower penetration levels.

In the case of Oregon, where penetration is near the 50 percent level in urban counties, one factor is that Medicare private plan enrollment includes a much higher percentage of employer-sponsored enrollees (about one-third) than the national average (18 percent) (based on unpublished 2002 CMS data). By way of contrast, in another high-penetration area—Miami-Dade County, Florida—employer-sponsored enrollment is under 5 percent, but the extremely generous benefit packages have attracted about 50 percent of the county's Medicare beneficiaries, who have been able to obtain such benefits as unlimited generic and brand drug coverage, and currently can obtain a full rebate of their Part B premium.

The Medicare regional plans present a market opportunity for insurers to participate in Medicare at less risk, with potentially higher payment levels than local plans in certain areas. With the financial incentives for PPO formation in the MMA, we believe that health plans will view the Medicare regional plan option as a good market opportunity to cover an insured population whose numbers will rise over the coming years, and we believe that many organizations that are already licensed as health insurers in multiple States (and in many cases, licensed in all States) will participate as both local and regional plans.

A major goal in introducing regional plans is to extend health plan access to rural areas through regional MA organizations that will cover relatively large geographic areas (at least the size of a State). There is an extensive literature on the subject of the limited participation of Medicare health plans in rural areas even after the BBA raised payments significantly in rural areas. For example, in testimony to the Congress, the chairman of the Medicare Payment Advisory Commission summed up the reasons for limited availability of Medicare HMOs in rural areas and suggested what remedy there might be: "Even though the floor under payments has been increased substantially (to $475 monthly), coordinated care Medicare+Choice plans offering generous benefit packages at little or no cost have not entered rural areas. We see three reasons for this. First, coordinated care plans rely on provider networks, which are difficult to establish in rural areas. This difficulty arises because rural providers who face little competition have no incentive to accept reduced payments and because there are fewer so-called intermediate entities, such as independent practice associations, willing to accept financial risk. Second, the small populations in many rural areas provide too small an enrollment base over which to spread fixed costs. Third, because relatively few rural areas consume large amounts of health care, there is less scope to achieve efficiency gains * * * What should policymakers do? The efficiency gains and provider discounts that Medicare HMOs in urban areas use to fund additional benefits are unlikely to be achievable in rural areas. Although other alternatives to the current system should be explored—such as risk sharing through partial capitation or split capitation—rural beneficiaries are unlikely to see more generous benefits without an explicit or implicit subsidy." ("Report to the Congress: Medicare in Rural America," Statement of Glenn M. Hackbarth, J.D., chairman, Medicare Payment Advisory Commission, before the Subcommittee on Health Committee on Ways and Means, U.S. House of Representatives, June 12, 2001.)

As previously noted, the use of the PPO model for regional plans, which are to cover wide areas, is intended to address the structural issues that have prevented Medicare plans from operating in rural areas. The payment issues are addressed through the incentives for the formation and continued participation of regional plans. However, the historical reluctance of Medicare plans to participate in rural areas is also a matter of uncertainty in projecting the extent of plan participation. The designation of regions would also be a factor affecting which rural areas may have plans participating.

There is one further area of uncertainty, and that is related to the issue of medical savings account (MSA) plans. The MMA changed the MSA provisions of the BBA with a view towards facilitating the offering of such plans. However, we are unable to determine whether the MMA provisions will result in such plans being introduced and the extent to which beneficiaries might enroll in such plans.

Projections Provided in the Impact Analysis. The methodology used to project the impact of the law and regulations is partially explained in the section on effects on beneficiaries. The projections are based on the assumption, for illustrative purposes, that there would be 15 regions with at least three regional plans in each region. However, we do not know at this time how many regions will be designated, and there is no limit on the number of regional plans. With regard to the number of MA local plans, the projections of enrollment did not involve assumptions about any specific number of local plans. Instead a certain level of enrollment was assumed for local plans based on the benefits they are expected to offer; and it was assumed that there would be sufficient capacity among local plans to enroll all beneficiaries that are expected to join regional plans. The estimates of plan bids are based on the proprietary information submitted to CMS by current Medicare Advantage plans (coordinated care plans as well as demonstration PPO plans). Beneficiary behavior is modeled with utility functions that predict the choices they will make among available health plan options. As previously mentioned, we recognize the high degree of uncertainty entailed in such projections. The projections represent our best estimate of the impact given the assumptions stated.

C. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies identify any Federal mandates resulting from proposed rules that may result in the expenditure by State, local, and tribal governments of $100 million or more (adjusted for inflation and currently

about $110 million). If this threshold is met, a detailed analysis is required. This proposed rule does not contain any "mandate" as such, and other direct effects on State, local, and tribal governments will be minimal. There will, however, be an indirect effect on State premium tax revenues due to the increased enrollment in MA plans and reduced enrollment in certain Medigap policies. These indirect effects, however, are not the result of these proposed rules, but of increased plan payments and prohibitions on sale of those Medigap policies implemented independently of these regulations.

Title II of the MMA contains several provisions that have a direct impact on States. Section 232(a) of the MMA amends section 1856(b)(3) to preempt all State standards other than licensure and solvency as they apply to MA plans. Section 232(b) of MMA amends section 1854(g) to expand a prohibition on State taxes for MA plans to apply to both CMS' payments to MA plans and to enrollee premium payments to MA plans. In addition, section 221(c) of MMA allows for temporary waiver of State licensure in States covered by regional MA plans where those plans cover a multi-State area.

Medicare law prohibiting State taxes on section 1853 payments to M+C organizations, that is, payments made by CMS to health plans contracting with Medicare, was established by the Balanced Budget Act 1997. That prohibition did not apply to enrollee premium payments made to M+C plans.

Section 232(b) of the MMA has expanded the prohibition on State taxes for MA plans, addressed in statute at section 1854(g), to apply to both section 1853 payments to MA plans and to section 1854 enrollee premium payments to MA plans. This provision was effective on the date of enactment of the MMA and is, therefore, not subject to the Regulatory Accountability provisions of the UMRA, which apply only to effects resulting from promulgation of rules. Section 422.404(a) is revised to reflect this change. We do not anticipate that the added prohibition on taxation of enrollee premiums to have a significant cost impact on States. Enrollee premiums to Medicare health plans are a small proportion of total payments to health insurers. Thus, State loss of tax revenue from Medicare enrollee premiums would also be small. Therefore, even if it were subject to UMRA, the prohibition of taxation by States of Medicare enrollee premiums would not approach the UMRA threshold.

We also recognize, however, that there is an indirect effect of the MMA law because of the expected enrollment shift from taxable Medigap insurance, and employer-sponsored private supplemental coverage, to non-taxable MA plans. This indirect effect would vary by State and would be dependent on a variety of factors, including the State's tax rate on health insurance premiums, the extent of Medigap enrollment in a State, the extent that Medigap enrollees choose to shift to MA plans in that State, as well as other resulting factors such as changes in Medigap premiums that could result from enrollment shifts. Due to these factors, estimates of the indirect effect of enrollment shifts away from taxable Medigap and employer-sponsored supplemental plans combined with the prohibition on State taxation of Medicare enrollee premiums would involve great uncertainty and would necessarily be speculative.

D. Federalism

MMA provisions may have qualitative impacts on how States regulate and interrelate with health insurers serving Medicare enrollees due to the expanded preemption of State laws and possible temporary waiver of State licensure for multi-State MA regional plans. Law relating to Federal preemption of State standards for Medicare-contracting health plans has undergone several revisions in recent years. While Federal preemption of State standards was initially established into Medicare law by the Balanced Budget Act of 1997, a general preemption authority existed under Executive Order prior to that time. Federal preemption of State standards for Medicare-contracting health plans was expanded by Congress in 2000 and expanded again by Congress in 2003.

Prior to 1997, Federal law did not contain specific preemption requirements for Medicare-contracting health plans. However, section 1876 Federal requirements could preempt a State law or standard if State provisions were inconsistent with Federal standards based on general constitutional Federal preemption principles, consistent with the provisions of Executive Order 12612 on Federalism, since superseded by Executive Order 13132. Section 1876 requirements did not preempt a State law or standard unless the State law or standard was in direct conflict with Federal law. *See* the June 26, 1998, **Federal Register** notice at page 35012 for further discussion on the history of general Federal preemption of State law prior to the Balanced Budget Act of 1997.

The Balanced Budget Act of 1997 established for the Medicare+Choice program at section 1856(b)(3) a general preemption authority in which State laws or standards would be preempted when they were inconsistent with M+C standards in the same manner that the previous Executive Order applied, and this law also established a specific preemption of State laws and standards in three areas: benefit requirements, requirements relating to inclusion or treatment of providers, and coverage determinations (including related appeals and grievance procedures). This meant that a general preemption applied if State laws, regulations, or other standards were inconsistent with Federal standards and, furthermore, in the specifically preempted areas, meant that State standards were preempted regardless of whether or not those standards were inconsistent with Federal standards.

In 2000, section 614 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) maintained the general preemption authority and expanded specific preemption requirements by amending benefit requirements to include cost-sharing requirements and by adding a fourth specific preemption for requirements relating to marketing materials and summaries and schedule of benefits regarding a M+C plan. Thus, the list of areas of specific preemption effective since 2001 were: benefit requirements (including cost-sharing requirements), requirements relating to inclusion or treatment of providers, coverage determinations (including related appeals and grievance procedures), and requirements relating to marketing materials and summaries and schedule of benefits.

In 2003, section 232(a) of the MMA amended section 1856 for Medicare Advantage plans by eliminating the general and specific preemption distinctions from section 1856 and broadened Federal preemption of State standards to broadly apply preemption to all State law or regulation (other than State licensing laws or State laws relating to plan solvency). § 422.402 of regulation is thus revised. Note that State laws on secondary payer are also preempted by Federal law and a change is made in regulation at § 422.108(f) to reflect that States are prohibited from limiting the amount that MA organizations can recover from liable third parties under Medicare Secondary Payer provisions. Congress indicated its intention to fully preempt State laws in the Conference Report for the MMA

emphasizing that Medicare is a Federal program and that State laws should not apply. Section 232(a) of MMA was effective on enactment.

We do not perceive that there will be a significant cost impact on States from section 232(a) of MMA to broaden Federal preemption authority to preempt all State law and regulation (other than State licensing laws or State laws relating to plan solvency). The specific preemptions already in effect were broad areas where States were most likely to have enacted laws or developed other regulations or standards for health insurance. Apart from those specific preemptions, general preemption already applied where State provisions were inconsistent with Federal standards such that other State standards in conflict with Federal standards were also already preempted.

Areas of State law that will newly be preempted by full preemption of State laws (other than licensing and solvency) do exist, however, and will affect State residents who are Medicare beneficiaries. State governments will be affected in that State governments will no longer be responsible for enforcing preempted laws, which will likely reduce costs to States. A discussion of the diverse types of State laws that previously fell under general preemption is addressed in some detail in the response to public comments in the preamble to a June 29, 2000, final rule implementing the Balanced Budget Act of 1997's preemption law. (*See* pages 35012–35014 of the June 29, 2000, **Federal Register** for a further discussion of the types of State laws that may be affected, which includes grievances and quality complaint reviews conducted by State governments.)

In reality, determinations of which State laws have been subject to general preemption often has not been made unless specific questions or disputes have arisen that resulted in a court review of applicability of law to specific cases. The MMA revision relieves uncertainty of which State laws are preempted by "preempting the field" of State laws other than State laws on licensing and solvency.

As required by Executive Order 13132, because of the implications for the States of the Federal preemption of State laws enacted in the MMA, we will consult with the States regarding the effect of the preemption provision on the role the States will play with respect to the regulation of Medicare plans, and the effect the preemption will have on State agencies and on beneficiaries enrolled in Medicare health plans. We will discuss the results of this consultation when this rule is published as a final rule.

We also request public comment on the effect of the preemption provisions included in this proposed rule.

E. Effect on Beneficiaries

The MMA increases the value of benefits that enrollees of MA plans have and will increase the availability of such benefits. When MA plans can bid at levels below the relevant benchmark, they can offer Medicare enrollees coverage of benefits beyond what Medicare covers (such as eyeglasses and hearing aids, as well as additional drug coverage), reduction in out-of-pocket expenditures for covered services (either as reduced cost sharing, on average, compared to fee-for-service Medicare, or reduced premium expenditures compared to Medigap, for example), and reductions in expenditures for the Medicare Part B and Part D premiums. As a result of the MMA provisions, we project that in the period 2004 through 2009, Medicare beneficiaries enrolling in MA plans will see benefits beyond basic Medicare A and B coverage valued at $1.4 billion. For 2005, the expected dollar value of benefits for beneficiaries will include approximately $256 million in remaining contributions to plan stabilization funds that plans must use by the end of 2005. (Effective for years after 2005, the MMA eliminated the "stabilization fund" option that was used by some plans to deposit Medicare payments for use in a later contract year to finance the cost of additional benefits or premium reductions. These funds will have to be used in the 2005 contract year. There is also a potential spillover effect of increased provision of benefits that competing plans in the same area would have to offer to remain competitive with plans using the stabilization fund dollars.) The estimate of benefits for beneficiaries is shown in Table 2.

The data in Table 2 (and in Table 4) reflect projections we have made about the number of plans participating, their bids and (consequently) their level of benefits, and the level of expected beneficiary enrollment. These projections are based on (a) What we know about the expected benchmarks in each area; (b) the current premium and benefit packages of MA plans and PPO demonstration plans, and their costs for the packages as submitted to CMS; and (c) the current patterns of enrollment in health plans in Medicare and the commercial sector. As previously noted, we assume that there will be at least three regional plans in each region (in our illustrative case that assumes that there are 15 regions), and that there will be a sufficient number of local plans to meet beneficiary demand for enrollment in local plans. In general, in terms of the proportion of funds used to provide extra benefits to enrollees, we expect local MA plans to be able to have significantly more revenue available than regional PPO plans for the provision of extra benefits and reduced out-of-pocket expenditures. However, we would also expect that in many areas, there will only be regional plans available, and no local MA coordinated care plans. As noted elsewhere, areas where there are only regional plan options and no coordinated care MA plans are likely to have higher benchmarks that are a vestige of the "floor" payment status of such counties. Although PPO plans may face higher costs in operating in such areas, the higher benchmarks will enable them to offer enriched benefit packages (compared to traditional fee-for-service Medicare). The projections of Tables 2 and 4 show the distribution of dollars among all plans. The distribution is subject to regional variation (as is currently the case), so that in some areas, for example, beneficiaries will have more offerings and better benefit packages available to them as a result of plans using more funds to provide extra benefits, reduced cost sharing, and lower premiums. Some plans may offer very few extra benefits but would still be attractive to enrollees, as noted elsewhere, and would be viewed by beneficiaries as more advantageous than FFS Medicare with Medigap coverage, for example.

The dollar figures shown in Tables 2 and 4 reflect the projected additional Medicare Part A and B expenditures incurred solely as a result of the MMA provisions. That is, the expenditures are the incremental program expenditures that are incurred because of the MMA provisions, including any difference in expenditures that result when beneficiaries enroll in a private plan rather than receiving care in fee-for-service Medicare.

TABLE 2.—PROJECTED BENEFITS TO MA ENROLLEES RESULTING FROM TITLE II PROVISIONS OF THE MMA, YEARS 2004 TO 2009, IN MILLIONS (AMOUNTS ABOVE AMOUNTS IN ABSENCE OF MMA TITLE II PROVISIONS); PROJECTED TOTAL PLAN ENROLLMENT, 2004 TO 2009, IN MILLIONS

	Year 2004	Year 2005	Year 2006	Year 2007	Year 2008	Year 2009	Total, Years 2004–2009
Enrollment Projection, Local Plans	4.662	5.088	6.449	6.547	6.685	6.825	.....
Enrollment Projection, Regional Plans	.....	.....	3.064	4.665	5.534	6.815	.....
Total Value of Transfer Payments Used for Extra Benefits and/or Premium and Cost Sharing Reductions, Local Plans	134	201	220	177	148	121	1001
Total Value of Transfer Payments Used for Extra Benefits and/or Premium and Cost Sharing Reductions, Regional Plans	.....	.....	48	118	117	117	400
Total Value of Transfer Payments Used for Extra Benefits and/or Premium and Cost Sharing Reductions, Both Types of Plans	134	201	268	295	265	238	1,401

Because of the MMA payment increases effective March 2004, beneficiaries enrolled in private plans have already seen reduced expenditures and increased benefits.

The March payment increases varied by geographic area. For example, because of the MMA provision that made fee-for-service payment rates one of the "prongs" of payment, New Jersey counties had an average 24.3 percent payment rate increase on an enrollment-weighted basis (all counties in New Jersey had 86 or more enrollees and have MA plans available). As a result, in New Jersey, the average monthly M+C coordinated care plan premium across all counties declined from $56 to $15. In all 21 of New Jersey's counties coordinated care plans have added a drug benefit. Previously, a drug benefit was available from an M+C coordinated care plan in only one county for 2004 before the MMA changes (though the two PPO demonstration projects operating in New Jersey did offer drug coverage). As of December 2003, only seven percent of New Jersey Medicare beneficiaries were enrolled in M+C plans or PPO demonstration plans. In July 1999, sixteen percent of New Jersey beneficiaries were enrolled in M+C plans. We would expect enrollment in New Jersey to rise because of the availability of better benefits. (In addition, a Medicare contracting plan in New Jersey recently announced that it would expand its Medicare service to include eight more counties.)

There are notable geographic differences in the benefit offerings of MA plans. In addition to the access differences between rural and urban counties that have already been discussed, the generosity of benefits has been lower in rural areas than urban areas. In 1999, for example, while the enrollment weighted premium for all enrollees of M+C plans was $5 per month, for the three percent of enrollees residing in rural counties and enrolled in M+C plans, the enrollment-weighted premium was $14 per month. In 1999, when 84 percent of the universe of M+C enrollees had drug coverage in a basic plan (zero premium or mandatory premium), 57 percent of rural enrollees had this level of drug coverage. For the March 2004 benefit offerings, this difference between rural and urban areas persists. Zero premium plans are available to 68 percent of urban beneficiaries in counties where there are plans, but only 30 percent of the beneficiaries who live in a non-MSA county in which there is an operating MA coordinated care plan or demonstration PPO have access to a zero premium plan. In rural areas, 72 percent of those with access to a plan can obtain drug coverage through a private plan, while in urban counties with plans available, 95 percent of beneficiaries have access to a drug coverage plan.

This difference between urban and rural areas may persist among MA local plans, which can vary benefits by county. With MA regional plans, there is a requirement that benefits must be uniform throughout the entire region. Hence, regional plans cannot offer different benefits in rural and urban counties, which will eliminate the disparity between such counties in the regional plan arena. However, there may be differences between regions in the generosity of benefits regional MA plans offer, and the degree of disparity would depend in part on the make-up of the regions, which CMS will determine at a later date.

Table 3 illustrates the variation that exists in current coordinated care plan offerings across States. The table lists the types of MA benefit packages available in the counties of each State in which plans are available (coordinated care plans and PPO demonstration plans). The counties are categorized by the most generous benefit package being offered by at least one plan in each county. The table indicates whether the State has any counties in which there are (a) zero premium plans with drug coverage included in the zero premium plan, (b) plans with zero premium but no drug coverage, (c) plans that include drug coverage in a benefit offering for which there is a premium, and (d) counties in which plans charge a premium but no drug coverage plan is offered. This kind of benefit variation at the State level will not occur with regional plans because of the uniform benefit requirement, as noted above, and because Medicare will now include a drug benefit.

BILLING CODE 4120–01–P

BILLING CODE 4120-01-C

Table 3: Distribution of Counties in States by Highest Level of MA Benefit Packages Available in County, March 2004

State	0 Premium Access With Drugs Included	0 Premium Access But No Drugs	Premium Charged, Drug Coverage Available	Premium Charged And No Drug Coverage	State	0 Premium Access And Drugs	0 Premium Access But No Drugs	Premium Charged, Drug Coverage Available	Premium Charged And No Drug Coverage
ALABAMA	X				MONTANA	*No M+C CCP Plans or PPO Demo Plans*			
ALASKA	*No M+C CCP Plans or PPO Demo Plans*				NEBRASKA	X			
ARIZONA	X				NEVADA	X			
ARKANSAS	*No M+C CCP Plans or PPO Demo Plans*				NEW HAMPSHIRE			X	
CALIFORNIA	X		X		NEW JERSEY	X			
COLORADO			X		NEW MEXICO	X			
CONNECTICUT	X	X	X		NEW YORK	X	X	X	
DELAWARE	*No M+C CCP Plans or PPO Demo Plans*				N. CAROLINA	X		X	
DIST. OF COL.	*No M+C CCP Plans or PPO Demo Plans*				N. DAKOTA	*No M+C CCP Plans or PPO Demo Plans*			
FLORIDA	X		X		OHIO	X	X	X	X
GEORGIA				X	OKLAHOMA	X		X	
HAWAII				X	OREGON			X	X
IDAHO				X	PENNSYLVANIA		X	X	X
ILLINOIS	X		X	X	PUERTO RICO	X			
INDIANA	*No M+C CCP Plans or PPO Demo Plans*				RHODE ISLAND	X			
IOWA	X				S. CAROLINA	*No M+C CCP Plans or PPO Demo Plans*			
KANSAS		X	X		S. DAKOTA	*No M+C CCP Plans or PPO Demo Plans*			
KENTUCKY		X	X		TENNESSEE	X		X	X
LOUISIANA	X				TEXAS	X			
MAINE	*No M+C CCP Plans or PPO Demo Plans*				UTAH	*No M+C CCP Plans or PPO Demo Plans*			
MARYLAND	X				VERMONT	*No M+C CCP Plans or PPO Demo Plans*			
MASSACHUSETTS			X		VIRGINIA			X	
MICHIGAN			X	X	WASHINGTON			X	
MINNESOTA			X	X	W. VIRGINIA			X	
MISSISSIPPI	*No M+C CCP Plans or PPO Demo Plans*				WISCONSIN	X			X
MISSOURI	X	X	X		WYOMING	*No M+C CCP Plans or PPO Demo Plans*			

High penetration in MA plans may affect the Medigap market. To the extent that Medicare beneficiaries will be leaving Medigap plans to join MA plans,

or will join MA plans on becoming eligible for Medicare rather than choosing fee-for-service Medicare with Medigap coverage, there is a potential effect on the cost of Medigap premiums in some markets. If fewer new enrollees enroll in Medigap plans, and if MA continues to enroll disproportionately younger beneficiaries, premiums will rise as Medigap subscribers age and use more services. As premiums rise, the premium rate may cause some subscribers to discontinue Medigap coverage (in favor of MA enrollment, or fee-for-service coverage without a supplement), causing a further increase in Medigap premiums as only the subscribers with the greatest perceived health care expenditures maintain their Medigap coverage. If MA plans continue to attract younger or healthier beneficiaries, and relatively older or sicker beneficiaries remain in fee-for-service Medicare, there is a further potential Medigap effect leading to rising premiums. The Medigap effects can potentially have a greater impact on rural areas in a State (where Medigap is a more common form of supplemental coverage than in non-rural areas). Because most Medigap plans are rated on a statewide basis, if the movement away from Medigap to MA plans is the result of the ability of urban local plans to offer extremely generous benefits that regional plans are unable to match, the market changes in the urban area(s) could cause Medigap premium rates to rise for all the State's beneficiaries, even for those beneficiaries that may not have the range of choices available to urban areas. With regard to any Medigap effect, however, it should be noted that the most recent trends in the data from the Medicare Current Beneficiary Survey for 2001 show a significant rise in the number of beneficiaries with Medigap coverage, possibly due to the decline in the availability of employer-sponsored retiree coverage.

F. Effect on Health Plans and Insurers

Health plans will see significant benefits as a result of the MMA through the transfer payments from the Federal Government to participating plans. Plan payments will increase significantly, allowing plan revenues and profits to rise as enrollment increases with the offering of better benefits. Organizations that currently contract with Medicare will have new market opportunities as regional plans and opportunities to expand their participation as local plans (other than as PPOs at a local level, which are prohibited from being newly formed for an interim transition period, 2006 to 2007). Organizations that are not currently participating in Medicare will have a more favorable market environment for participating as local or regional plans.

The Federal Government transfer payments to health plans over and above what would have been paid in the absence of the law, as a result of the Title II provisions of the MMA, are expected to total $23.4 billion. Of this amount, plan administrative costs (which include profits and retained earnings) are expected to total $1.2 billion (over and above amounts that otherwise would have been paid). The remaining amounts will finance the provision of health care benefits (together with other revenue the plan has, such as member premiums). The benefits to health plans will vary geographically, depending on benchmarks and the cost of doing business for the plans. The administrative cost figure cited here for the plans includes projected start-up costs for new organizations becoming Medicare contractors. The estimates of benefits related to MA plans for 2004 through 2009 are shown in Table 4. (The basis for these projections is discussed in the section on effects on beneficiaries, in the discussion of Table 2.)

TABLE 4.—PROJECTED BENEFITS TO MA PLANS RESULTING FROM TITLE II PROVISIONS OF THE MMA, YEARS 2004 TO 2009, IN MILLIONS (AMOUNTS ABOVE AMOUNTS IN ABSENCE OF MMA TITLE II PROVISIONS); PROJECTED TOTAL PLAN ENROLLMENT, 2004 TO 2009, IN MILLIONS

	Year 2004	Year 2005	Year 2006	Year 2007	Year 2008	Year 2009	Total, years 2004–2009
Enrollment Projection, Local Plans	4.662	5.088	6.449	6.547	6.685	6.825	.....
Enrollment Projection, Regional Plans	.....	.....	3.064	4.665	5.534	6.815	.....
Total Value of Transfer Payments Used for the Provision of Medicare A and B Benefits, Local Plans	1,430	2,155	2,356	1,894	1,590	1,299	10,724
Total Value of Transfer Payments Used for the Provision of Medicare A and B Benefits, Regional Plans	.....	.....	1,225	2,990	2,978	2,966	10,159
Total Value of Transfer Payments—Plan Administrative Costs (Including Profit), Local Plans	174	262	286	230	193	158	1,303
Total Value of Transfer Payments—Plan Administrative Costs (Including Profit) Regional Plans	.....	.....	142	345	344	343	1,174
Total Value of Transfer Payments to Plans, Both Types of Plans	1,604	2,417	4,009	5,459	5,105	4,766	23,360

As between regional and local plans, and the choice that an organization can make, regional plans, as described elsewhere, have a number of financial incentives. Local plans have the advantage of being able to selectively market to Medicare beneficiaries in that they can make decisions on a county basis. Local MA plans can choose whether or not to serve a particular county, and they can also vary benefits and premiums by county under one contract by segmenting larger service areas to as small a unit as a single county. The uniform benefit requirement applies to local plans at the service area or segment level, while regional MA plans, as previously noted, must have a uniform benefit in the entire region (for each of the plans that an MA regional organization offers in a region, each of which must be offered on a region-wide basis). One organization may offer both local and regional plans. The possible consequences of these differences in service area configurations are discussed further in the section on alternatives considered.

Although we have emphasized the additional benefits that we expect plans to be able to offer, by having eliminated the adjusted community rate process and its requirement that permissible plan profit levels must be the same as for a plan's commercial product, and having eliminated the limit on premiums related to cost sharing for Medicare-covered benefits, plans can potentially increase their profit levels, as their competitive situation permits.

Plans with bids exceeding the benchmark can also be assured of having adequate revenue to operate as Medicare plans. These provisions may lend stability to the program in allowing plans to make adjustments to revenue needs from one year to the next without facing statutorily imposed limits on their ability to generate needed revenue.

There are a number of statutory and regulatory provisions which reduce burden on Medicare plans, including the statutory changes that eliminated the reporting requirements relating to physician incentive plans, and the major changes in the quality assurance standards for plans. As discussed elsewhere, this proposed rule also has several administrative changes that will reduce plan burden, including the file-and-use approach to marketing material review, elimination of plan disclosure requirements that are redundant, and provisions that streamline the appeals procedure as regards notices to beneficiaries.

In terms of estimating the impact of these changes, the physician incentive plan (PIP) burden reduction was previously codified in regulation CMS–4041–F on August 22, 2003 and effective September 22, 2003. In the regulatory impact statement of that rule (pages 50,853 and 50,854 of the **Federal Register**) we said: "We find that overall the economic impact of this final rule is positive, due to * * * the reductions in regulatory burden due to * * * the reduction of the physician incentive reporting requirements * * * The data available do not allow us to determine the distributional effects * * * We have not considered alternatives to lessen the economic impact or regulatory burden of this final rule because the regulatory burden is reduced * * * " We have no new data at this time that would alter the analysis and conclusions drawn in the prior rule.

With regard to the "file and use" policy, we are codifying in regulation a previously existing program tolerance. The "burden reduction" actually associated with "File and Use" is minimal for two reasons. The first is that it represents a "tolerance" already in use; so additional burden reduction is non-existent. Second, File and Use is simply permission to publish (or use) certain marketing materials prior to CMS review and approval. To the extent that MA plans "earn" (or qualify for) File and Use status, the only advantage gained and the only burden reduction available to them is that MA plans qualifying for File and Use will not need to wait for CMS approval prior to using specific marketing materials. Finally, CMS does not currently collect data nor does it have information on the distributional impact of the currently existing Use and File program, so it is impossible to project the precise impact that File and Use will have on organizations qualifying for it.

We remove certain plan disclosure requirements from § 422.111(f). These disclosure requirements all are information that MA organizations must provide "upon request." We have no data that would help us quantify the actual level of burden reduction. We note that CMS initiated this burden reduction. To the extent that MA organizations did not bring the burden associated with these disclosure requirements to our attention as part of the regulatory reform initiative, they probably also have not actually been called upon to so disclose through actual requests for such information. Therefore, the level of administrative burden mitigation is likely negligible.

As stated in the preamble, we request suggestions for other burden-reducing reforms or innovations that will improve the ability of plans to participate in the program without compromising quality or services. We are particularly interested in comments on whether, within the statutory construct, there are structural or administrative requirements in the MA program that would act either as a barrier to plan entry into the MA market or would adversely impact plan participation, and consequently, beneficiary choice.

Other Effects. Although most Medicare health plans and organizations that can participate as MA plans stand to benefit from the MA provisions, as previously noted Medigap insurers may face price pressures and see declining enrollment if MA enrollment increases to the level that CMS projects, and if fewer individuals in fee-for-service Medicare buy Medigap, though there is the mitigating factor previously . discussed regarding the trend of an increase in the number of Medicare beneficiaries with Medigap policies. It should be noted that many of the insurers that offer Medigap coverage are companies that also operate health plans and are already, or can become, local or regional MA plans.

Medicare Advantage private fee-for-service plans are another class of insurer that may see changes in the competitive environment. To date, such plans have operated primarily in "floor" counties (counties in which, because of the BBA and BIPA payment rules, health plan payment rates are higher than estimated fee-for-service Medicare costs). Private fee-for-service plans generally have not competed directly against coordinated care plans. Private fee-for-service plans offer less generous benefit packages than MA coordinated care plans, but they do offer some level of supplemental coverage for individuals (including, in the case of two organization, drug coverage), and they offer an advantage that some beneficiaries prefer, which is that there is not a limited network of providers that must be used to obtain covered care. As a consequence of the MMA, where there are regional MA plans, regional plans would have a competitive advantage over Medicare private fee-for-service plans that had usually targeted areas in which there were no MA local plans. MA regional plans can offer coverage for out-of-network care, and they are likely to be able to offer a significant level of extra benefits because of the financial incentives in the MMA. (As stated elsewhere in the preamble, regional MA plans may not be private fee-for-service plans; regional plans must operate as a PPO model. All but one of the current private fee-for-service plans is sponsored by an organization that is part of a firm that has local MA plan contracts—though the one exception is the largest PFFS plan.)

G. Effects on States

States may see benefits from Title II of the MMA if more Medicaid beneficiaries who are also entitled to Medicare A and B coverage (the dual eligible population) enroll in private Medicare plans. Because MA enrollees are likely to receive non-Medicare-covered benefits (such as vision care), dual eligible enrollees would receive benefits that the States would otherwise have had to pay for. States may benefit from reduction of the Part B premium which the State would otherwise pay for dual eligibles. It should be noted that to date, the enrollment level of dual eligibles in Medicare plans is not as high as it could be (*see* Edith G. Walsh and William D. Clark, "Managed Care and Dually Eligible Beneficiaries: Challenges in Coordination," Health Care Financing Review, fall 2002, volume 24, number 1). A number of factors could contribute to greater enrollment of dual eligibles in MA plans: the extension of plan availability across an entire State (as part of a regional plan), the likelihood of Part B premium rebates (which the State would be entitled to), and the designation in the law of dual eligibles as a category for purposes of determining whether an MA plan is a specialized plan. As also noted previously, dual eligible individuals do not have the same incentives to enroll in MA plans as other low-income

Medicare beneficiaries. In certain circumstances, a State may require the enrollment of dual eligibles in MA plans (if, for example, the plan is also a Medicaid health plan and the State has a waiver permitting mandatory health plan enrollment for Medicaid beneficiaries).

The direct effect on the States of the expansion of the premium tax prohibition is discussed in the section on unfunded mandates. The MMA changed the law to exempt from State premium taxes the premiums paid by beneficiaries, as well as Federal payments to plans (which the law already exempted). This provision by itself has a relatively minor effect on State revenues, given the prevalence of zero-premium MA plans and given the expected trend in MA benefit packages towards more zero-premium products. However, an indirect effect of the premium tax prohibition is that, to the extent that there are reductions in the number of beneficiaries who hold Medigap policies, States may lose premium tax revenue that would have been derived from Medigap policies (the entire premium of which is generally taxed). As previously discussed, it is unclear what the impact will be if there is such an effect, given the trend of greater numbers of beneficiaries with Medigap coverage.

H. Effect on Employers and Unions as Sponsors of Retiree Coverage

Historically, Medicare-contracting health plans that contracted with employer or union groups to provide benefits had to comply with the same Medicare regulatory requirements that apply to all Medicare-contacting health plans. In 2000, section 617 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) added a new authority at section 1857(i), effective 2001, that provided CMS broad authority to waive or modify requirements that hinder the design of, the offering of, or the enrollment in M+C plans under contracts between M+C organizations and employers, labor organizations, or the trustees of a fund established to furnish benefits to an employer's current or former employees or to a labor organization's current or former members.

Three types of waivers have been approved under the BIPA authority which are discussed in a August 22, 2003, **Federal Register** notice on p. 50845. The three types of waivers are: (1) M+C organizations are allowed to offer employer-only plans that are not open to individuals and plan marketing materials do not have to be submitted for CMS review and approval; (2) M+C organizations are allowed to "swap" benefits not covered by Medicare of approximately equal value when an employer asks for a benefit package different from what is offered on the individual market; and (3) M+C organizations are allowed to raise the co-payments for certain benefits but to provide a higher benefit level or a modification to the premium charged as long as projected beneficiary liability is actuarially equivalent. These waiver authorities also will continue for MA organizations.

Section 222(j) of the MMA adds another authority for employer or union sponsored plans, effective 2006, at section 1857(i)(2) of the Act for CMS to waive or modify requirements that hinder the design of, the offering of, or the enrollment in an MA plan offered directly by an employer, a labor organization, or the trustees of a fund established by employers or labor organizations to furnish benefits to current or former employees or to current or former members of labor organizations. This authority is added in the proposed rule at § 422.106(d). We do not know to what extent employers or labor organizations may be interested in pursuing waivers under this new authority. For an employer or union to contract in this manner may require that the employer or union obtain State licensure as a risk-bearing entity and meet any licensure and solvency standards imposed by the State for health plans. To the extent that such licensure would be required, there may, however, be a few entities that already offer health insurance for their own employees or offer insurance on the market that may be interested.

However, we do believe that there is likely to be a significant increase in the number of retirees whose employer or union provides retiree coverage through an MA plan because of the additional payments MA plans will receive (so that benefits that otherwise would have been financed by the employer or union can be financed by Medicare payments), and because regional plans will be available that can cover wider geographic areas and meet the needs of employers with retirees residing throughout a large geographic area, or dispersed across many geographic areas.

As of January 2002, about 18 percent of enrollees in Medicare+Choice plans were employer- or union-sponsored retirees (see Hileman *et al.*, previously cited). There are 1.1 million beneficiaries residing in counties in which only employer-sponsored retirees or dependents may enroll in MA plans operating in those counties. This particular market segment is attractive to MA plans for a number of reasons, including the ease of marketing to a large group, their status as previously insured individuals, and the ability to offer seamless continuation of coverage between active worker status as a plan enrollee and retiree status. The regional PPO model may also facilitate the ability of plans to serve this population to the extent that retirees no longer reside near their place of work.

According to a 2003 Hewitt-Kaiser Family Foundation survey of large employers, 21 percent of employers with 1000 or more employees require new Medicare-eligible retirees to pay 100 percent of the plan premium. The survey also found that, with regard to future trends, "Serious consideration is also being given to only providing access to health benefits and asking retirees to pay 100 percent of costs; 26 percent of firms said that they are very or somewhat likely to make such a change." (Frank B. McArdle, *et al.*, "Large Firms" Retiree Health Benefits Before Medicare Reform: 2003 Survey Results." Health Affairs, web exclusive, January 14, 2004.) MA plans are a likely vehicle for employers to offer health plans under these circumstances.

I. Effect on the Federal Government

The benefits to beneficiaries and private health plans are the result of transfer payments from the Federal Government to plans, or, in the case of reductions in the Part B and Part D premiums, transfer payments directly to beneficiaries. For the period 2004 through 2009, the total amount of such transferred funds is projected to be $23.4 billion above what would otherwise have been incurred in the absence of the Title II provisions of the law. The total expenditure figure assumes that $5.2 billion of the stabilization fund dollars for regional MA plans are used in the period 2004 through 2009. The preceding figure assumes a private plan penetration rate, for illustrative purposes, of 33 percent by 2009. We have not separately projected an administrative cost to the Government for the administration of Title II of the MMA separate from administration of all portions of the MMA taken together.

The section on alternatives considered examines the impact on expenditures in choosing between statewide and plan-specific risk adjustment to determine rebate amounts. Another issue that has an effect on expenditures is the payment adjustment relating to risk adjustment for bids that exceed the benchmark. Proposed § 422.308(e), discussed in

subpart G of the preamble, would implement section 1853(a)(1)(G) of the Act, which requires CMS to make certain plan payment adjustments to take into account the health status of a plan's enrollees. For plans bidding above the benchmark, this provision would ensure that the total revenue a plan receives for its actual enrollees matches the plan's required revenue. The 1853(a)(1)(G) provision requires CMS to adjust plan payments in recognition of the amount that a health plan receives as a basic premium from its enrollees. The basic member premium that plans actually will charge is the premium for a "1.0" beneficiary—that is, it is determined based on the revenue needs for a person with average health status. For a plan with a risk score above 1.0 (that is, the plan has enrollees that are sicker than average and utilize more services), there would be an additional payment from Medicare to provide the plan with revenue that covers the shortfall between the basic premium determined for a 1.0 enrollee, and the actual revenue necessary from member premiums. (Under the current system, and through 2005, in such a case enrollees would be charged a higher plan premium to cover the needed revenue that matches their enrollees' actual utilization patterns.)

A similar adjustment would be made for plans with risk scores below 1.0. A plan with a risk score below 1.0 would have determined its basic premium for a 1.0 person, and enrollees will be charged that level of premium. This provides the plan with more revenue than it needs. Consequently, the section 1853(a)(1)(G) provision would call for a reduction in Medicare's payment to the plan in recognition of the additional revenue that comes from member premiums that are determined for a 1.0 beneficiary.

The budgetary impact of this provision depends on the number of plans that would have bids above the benchmark, and the health status of enrollees in such plans. One would assume that the majority of organizations deciding to enter the Medicare market would like to be able to offer extra benefits at no cost, or at little cost, to prospective enrollees. Therefore there may be few plans that bid above the benchmark, and those that do so would try to limit the basic premium to an amount that would attract a sufficient number of beneficiaries. However, bids above the benchmark may arise (a) in certain areas—for example, in areas where there may be only one or two plans, or (b) in certain competitive situations—for example, when the reason for a bid above the benchmark is that the plan offers coverage that is expensive but has features that appeal to beneficiaries (such as a wide network of providers, particular "marquee" providers in the network, or generous out-of-network coverage).

With respect to the risk profile of plans that may be bidding above the benchmark, currently private plan enrollees are healthier on average than Medicare beneficiaries in traditional fee-for-service. If plans bidding above the benchmark have healthier-than-average enrollees, the budgetary impact of the 1853(a)(1)(G) provision would actually be net program savings as beneficiaries bear some extra cost in their plan premium. If today's patterns of enrollment continue, there may be such program savings: looking at the subset of plans that currently charge a premium for Medicare-covered services compared to plans that have no premium charge for Medicare-covered services (a rough type of proxy for determining whether a bid will be above the benchmark), the risk status of enrollees of plans in which there is no premium is below 1.0 but closer to 1.0 than among plans charging a premium. The latter group of plans have risk scores that are also below 1.0, but the risk scores are about 10 percent lower—that is, risk scores show that enrollees are healthier—than the risk scores of plans that have no premium charge for Medicare-covered services.

In summary, the 1853(a)(1)(G) risk adjustment provision, which may have limited applicability if few plans bid above the benchmark, may result in program savings. There is also an impact on beneficiaries, who will have higher premiums in plans with bids over the benchmark with healthier-than-average enrollees, and lower premiums in such plans with sicker-than-average enrollees, as compared to a system in which the plan premium is risk adjusted.

J. Administrative Costs

The administrative cost estimates for MA plans included in the section on effects on health plans and insurers are based on the administrative costs currently incurred by Medicare Advantage plans. The administrative cost figures shown in Table 4—at 10 percent of revenue—include both costs to administer the program and the profit or retained earnings of health plans. Administrative costs for local plans and regional plans are considered to be roughly the same based on the reported administrative costs of current MA plans that are PPOs and HMOs (weighted by enrollment).

K. Analysis of Effects on Small Entities

The Regulatory Flexibility Act (RFA) requires us to determine whether a proposed rule will have a "significant economic impact on a substantial number of small entities." If so, the RFA requires that an Initial Regulatory Flexibility Analysis (IRFA) be prepared. Under the RFA, a "small entity" is defined as either a small business (as defined by the size standards of the Small Business Administration, or SBA), a non-profit entity of any size that is not dominant in its field, or a small governmental jurisdiction. The SBA size standard for "small entity" health insurance plans is annual revenue of $6 million or less.

The direct effects of Medicare Advantage fall primarily on insurance firms and on individual enrollees. The competitive market created by Medicare Advantage is likely to have long run indirect effects on health care providers, such as hospitals, physicians, and pharmacies, depending on the extent to which MA plans attract enrollees. However, those effects will result from the workings of market choices made by enrollees, plans, and providers, not from specific provisions of these proposed rules. (There is an MMA provision for paying certain "essential hospitals" higher rates for participation in the MA program; which we analyze below.) Therefore, we primarily analyze effects on the insurance industry (including HMOs as insurers) in this IRFA. We welcome comments on this approach and on whether we have missed some important category of effect or impact.

We do not believe that these proposed rules will create a significant economic impact on a substantial number of small entities.

However, we have prepared a voluntary IRFA. Under longstanding HHS policy we prepare an IRFA if significant impacts of a proposed rule on small entities are positive rather than negative. We also prepare an IRFA if we cannot be certain of a conclusion of no "significant impact" on less than a "substantial number." In this case, the statutory reform is so major and the number of regulatory changes so large that we cannot be certain of our conclusion. Finally, we generally prepare an IRFA if there is likely to be substantial interest on the part of small entities. Essentially all of the insurance firms affected by the statute and our proposed rules exceed size standards for "small entities" within the meaning of the RFA and implementing SBA guidelines, which state that an insurance firm is "small" only if its revenues are below $6 million annually.

We note that under prior law (continued unchanged for Medicare Advantage), no health insurance plan is normally eligible to participate in Medicare Advantage unless it already serves at least 5,000 enrollees, or 1,500 enrollees if it primarily serves rural areas. At the 5,000-enrollee level, no plan would fall below the SBA revenue cutoff assuming, very conservatively, a $2,000 per enrollee cost. While a very small rural plan could fall below the threshold, we do not believe that there are more than a handful of such plans. In the InterStudy Competitive Edge HMO Directory for 2000, discussed below, we found only one rural HMO with a continuing enrollment level below 1,500. Therefore, the statutory limits generally prevent any insurance firm defined as "small" pursuant to the RFA's size standards from participating in the program. However, a substantial fraction of the insurance firms affected by these proposed rules are "small entities" by virtue of their non-profit status. The analysis in this section, taken together with the other regulatory impact sections, and the preamble as a whole, constitute our IRFA for the Medicare Advantage provisions of Title II of the MMA. We note that there is a related IRFA in the companion proposed rule on the Part D-Drug Program of Title I of the MMA.

1. The Health Insurance Industry

The 1997 Economic Census: Finance and Insurance (the latest available edition) states that there were 944 firms classified as "Health and Medical Insurance Carriers" under the North American Industry Classification System. Of these, 851 firms operated the entire year. Using Census data, these firms had total revenue of $203 billion, operated through about 3,200 establishments, and had about 328,000 employees. Of the 851 firms that operated the entire year, 342 had revenues of less than $5 million. Taking into account subsequent inflation, this corresponds closely to the $6 million threshold established by the SBA as the current cutoff for small businesses in this insurance category. Thus, approximately 40 percent of the industry as counted by the Census is "small" using the SBA definition. These small firms had total revenue of about $440 million, rather less than one half of one percent of total health insurance revenue. As discussed below, we do not believe that any of these small firms underwrite comprehensive health insurance policies, or are actual or potential competitors in the Medicare Advantage market.

In contrast, the Census found that the largest 50 firms, or 6 percent, accounted for 75 percent of all health insurance revenue. While these data cannot be reconciled directly with other statistics on numbers and size of health insurance companies, they clearly indicate that the market for comprehensive health insurance policies, covering the lives of about 200 million Americans, is dominated by several hundred companies, few of which, and most likely none of which, are "small" by SBA revenue standards.

Another source of industry data, much richer in detail, is found in the InterStudy Competitive Edge. This annual report covers only HMOs. The discussion that follows uses the 2000 edition as reflecting most of the changes of the 1990s, but still close enough in time to the Census information to be roughly comparable. In 2000, there were 560 HMOs. While these were all separately incorporated, many were subsidiaries of larger corporations. For example, the report lists 40 United HealthCare plans, 22 Aetna and 32 Prudential plans (all owned by Aetna), 31 Cigna plans, 10 Humana plans, and 9 Kaiser plans. Ninety-seven of these HMOs enrolled 200,000 or more people (enrollment is a standard industry measure of size). The InterStudy data, using an enrollment cutoff of 3,000 to correspond roughly to the SBA $6 million threshold, shows that only 5 HMOs were continually operating entities (not entering or exiting the industry) with revenues below the SBA small entity threshold.

Of the approximately 200 contracts under the current M+C program (this figure excludes demonstration contracts), only a handful have enrollment of fewer than one thousand or annual Medicare revenue of under $6 million assuming, conservatively, revenues of $6,000 per enrollee (Medicare enrollees cost, and are reimbursed, more than double working age persons). Of course, these plans have other revenues from non-Medicare clients, and we are unaware of any current M+C organizations with revenues below the SBA threshold. (Note that the number of M+C contracts includes separate Medicare contracts held by a single firm in different parts of the country'as in the case of PacifiCare, for example, which has ten contracts in eight States.)

These data show that few, if any, health insurance firms with revenues of $6 million or less underwrite comprehensive insurance in the national insurance market. Furthermore, discussions with Bureau of the Census staff indicate many and probably most of the smallfirms classified as insurers do not underwrite health care costs (that is, provide comprehensive health insurance), but are firms offering dental or medical discounts through small provider networks or offering indemnity-type policies paying, for example, a few hundred dollars a day for each day spent in a hospital. They would not even be licensed by States to offer comprehensive or group insurance policies. Therefore, we have no reason to believe that the creation of the Medicare Advantage program will have any positive or negative effect on "small" insurance firms, with the possible exception of Medigap insurers.

Some of these small firms may be Medigap insurers. For this limited group, the MMA has major consequences. Specifically, existing categories of Medigap policy that cover prescription drugs will become illegal to sell to new enrollees, and several new Medigap categories will be created. (These changes, however, are specified in the statute and are not subject to regulatory discretion). Furthermore, Medigap insurance is a unique type of product that does not involve accepting insurance risk for the full cost of health benefits, since Medicare itself remains the primary insurer. Therefore, it is unlikely that any consequential number of firms operating solely in the Medigap market would expect to operate in the Medicare Advantage market. Effects of the MMA on Medigap are discussed in more detail the economic effects analysis in the companion Title I proposed rule.

Despite these conclusions, it is possible that there is some potentially burdensome effect on insurance firms we have failed to anticipate. We request comments on whether any provisions of these rules may inadvertently create problems or burdens for any "small" firms in the health insurance industry with annual revenues below $6 million.

The definition of small entities under the RFA also encompasses not-for-profit organizations that are not "dominant" in their field. (HHS interprets "dominant" to mean national dominance). There are many large HMO companies that are non-profit. As of 2000, about 37 percent of HMO enrollment was in non-profit firms, and 152 of 558 HMOs, or 27 percent, were non-profit (InterStudy Competitive Edge HMO Industry Report for 2000). None of these firms is nationally "dominant" in the health insurance industry although many firms achieve large market share in particular health care markets.

About half of these firms already compete in the Medicare M+C market, and most are potential entrants or

reentrants as local Medicare Advantage plans. According to the InterStudy data, about one third of HMOs currently participating in M+C are non-profit. Some HMOs, profit or non-profit, may be potential entrants in the new regional MA markets. This may depend, in part, on how we later define regional boundaries. It will certainly depend on how rapidly the non-profit firms grow by merger or make other market adaptations, such as adding PPO networks. However, relatively few HMO plans (in contrast to parent company or linked HMOs), operating through local HMO networks, are likely to be able to compete in a region encompassing large areas or several States and multiple health care markets.

2. The Local Medicare Advantage Market and Small Entities

Under Medicare Advantage, there are two distinct (though overlapping) markets: local and regional. All existing M+C HMO plans participate on a local area basis, typically covering the several counties encompassed in a metropolitan area. Because HMOs are most common in metropolitan areas, and especially in the largest metropolitan areas, existing plan availability and enrollment is concentrated in these. As discussed previously in this analysis, only about one fifth of U.S. counties, though over 60 percent of the eligible population, have an M+C HMO plan available. The MMA makes one major change for local plans by significantly improving payment rates. This statutory change is already in effect and is not addressed in these proposed rules. These rules will have beneficial effects on local plans, by reducing some administrative burdens, but the changes we propose, singly and collectively, do not rise to the level of "significant economic impact" on local HMOs.

The other major changes of Medicare Advantage include the creation of a new regional plan structure to become operational in 2006, designed for and limited to PPO plans. The regional structure is intended to ensure that the entire beneficiary population, not just those residing in major urban centers, has access to alternative plans. As discussed elsewhere in this analysis, we assume that as a result of these changes private plans may attract as much as one-third of all Medicare enrollment by 2009.

Starting in 2006, local HMOs will face two new sources of competition. First, they will find themselves seeking to attract enrollees from a pool of eligible applicants who will now have Part D drug benefits as enrollees in FFS Medicare. Second, they will be competing against regional MA plans serving their areas. Regional plans will have some advantages specified in the statute, including access to the stabilization fund and, temporarily, to risk sharing with the government. It is possible that some existing local plans will lose some enrollment. The local HMOs will, however, have important assets including integrated benefit packages (as compared to free-standing PDPs), quite likely drug benefits at premiums lower than PDP premiums, and extra benefits (including rebates of the Parts B and D premiums) not available in FFS and possibly more generous than those available in regional MA plans. The local plans will have an existing customer base and pre-existing networks in the areas where most beneficiaries live. Most compete in major metropolitan areas where Medicare payment rates are higher than in other areas that a region would encompass. Finally, many and perhaps most local plans are subsidiaries of large insurance firms that offer multiple product lines. These firms retain the ability to "mix and match" their product offerings to best advantage. Regardless, whether and how much any given plan loses or gains will primarily depend on its overall attractiveness (benefits, services, provider panels, out of network benefits, and premiums) compared to its competitors. Nothing in these proposed rules, as such, either favors or disfavors local plans when competing against regional plans.

While it is impossible to predict the precise situations that these HMOs will face, or their responses, there are some lessons available from the FEHB Program experience. In that program, about 200 local HMOs co-exist in competition with about a dozen national PPO plans. Most HMOs compete in big city markets against 15 or 20 plans, both PPO and HMO. While HMO enrollment in the program has declined slightly in recent years, and almost half of all HMOs have left the program since their peak participation in the early 1990s (reflecting mainly industry consolidations), HMOs currently enroll about 35 percent of all Federal employees, and 9 percent of retirees, down only slightly from the peak levels of 39 percent and 10 percent, respectively, a decade ago.

3. The Regional Medicare Advantage Market and Small Entities

Starting in 2006, health insurance firms both profit and non-profit (and hence "small entities" under the RFA) will be able to compete as regional plans. As discussed elsewhere in this Preamble, we cannot yet predict how many regions there will be, or how their boundaries will be drawn. That decision is not a subject of these proposed rules, but will be announced administratively at a later time.

A firm may compete in as many regions as it chooses, up to and including the entire nation. The chief constraint is that a plan must demonstrate that it has a region-wide network of providers. Elsewhere in this Preamble we ask for comments on some aspects of defining networks and network adequacy, but the alternatives under consideration would all allow normally operated PPOs reasonably feasible methods of building their networks.

We know of one group of potential regional competitors who may be affected by regional boundary decisions. In recent years many Blue Cross/Blue Shield plans have merged within and across State lines. However, there still remain several dozen of these plans that operate on a state-delineated basis. While no decision we make on regional boundaries are not likely to adversely affect current plan operations or revenues, if these plans were not able to compete effectively in multi-State regions they might forego an important business opportunity. We request comments on whether these or any other types of plans face potential disadvantage and, if so, what steps could be taken by us to reduce such problems. However, we note that there are many ways by which health plans can compete on a regional or national basis, and that the Blue Cross plans themselves have a history of national cooperation in the FEHB program. Therefore, we are interested in suggestions not only for steps we might take, but that plans might take, to ameliorate any problems created by the regional structure. Additionally, a local plan may encompass all or most of a State, and/or operate in more than one State if it so chooses. Of course, regional plans have some advantages, but local plans have others. In other words, it is not clear whether, and, if so, the extent to which, regional boundary decisions potentially constrain plan participation in Medicare Advantage in any important way, and we request comments on this. We will also provide additional opportunities at a later time to comment on possible regional boundaries, as discussed previously in this Preamble.

Another potential problem facing regional plans is the requirement, in the statute, that they apply for licensure in each State in which they operate. Since the statute preempts State standards for benefits, coverage, and provider networks, leaving effectively only

solvency standards as State-imposed requirements, we anticipate no important problems for plans. However, we request comments on any problem that the statute may create. In this regard, we note that at present some insurance carriers operate in multiple States, either directly or through subsidiaries, under the far more burdensome legal requirement of meeting every standard in each of those States.

There is another problem that could be important to a plan far larger than the SBA size standard but nonetheless smaller than the plans serving hundreds of thousands or millions of enrollees. Organizing the full resources needed to compete effectively in the Medicare context will require substantial investments in acquiring and maintaining actuarial expertise, legal expertise, effective marketing, network building, benefit design, cost-control, disease management, formulary design, claims processing, financing, *etc.* There are economies of scale in health insurance (like many other businesses), and these presumably favor larger firms, all other things equal, up to some point. We are not aware of any industry studies that seek to measure the minimum size necessary for health insurance firms to compete effectively in local, regional, or national markets and request information on this question. However, to the best of our understanding any such barriers to entry or cost competitiveness are likely to fall well within the size of most firms competing today in such large systems as M+C, the FEHB Program, or the private employer market. However, if there are any statutory or regulatory requirements that impose unnecessary burdens on smaller firms otherwise able to compete effectively, we request comments and suggestions on these.

In summary, the Medicare Advantage program, by having both a regional and local model, provides opportunity for health insurance entities of all types and most sizes (but probably not below the "small" insurance entity cutoff level defined by the SBA, which is lower than appears viable for a comprehensive, risk-bearing insurance plan), and offering many different kinds of plans, to participate. That participation is more likely to take the form of local plans in the case of smaller and non-profit entities. However, the overriding objective of the regional plan model is to give beneficiaries access to and choice among integrated private plans that can offer comprehensive health insurance encompassing Medicare parts A, B, and D. This model is dictated in almost all its important details in the statute. We do have discretion on regional boundaries. If we later decide to design regions that make it harder for some non-profit entities to compete regionally, this will reflect a decision that the objectives of beneficiary access and choice take precedence. However, it is not clear that there is any real conflict, because an organization seemingly disadvantaged as a regional plan may be advantaged as a local plan. In fact, the local plan model provides significant flexibility in terms of letting plans define their own market and service areas, without having to meet the network adequacy and other requirements of the MA regional market area.

Throughout this preamble we have identified regulatory alternatives that may lessen burden on entities of any size. We are particularly interested in comments on those that may differentially affect smaller insurance firms, and on identification of ways to alleviate unnecessary burden, consistent with the underlying purposes of the Medicare Advantage program.

4. Hospitals

An additional program under Medicare Advantage directly affects hospitals. HHS has long taken the approach of treating all hospitals as presumptive "small entities" within the meaning of the RFA, mainly because of the dominance of the non-profit model in the hospital industry (about 80 percent) and also because most of the rest have revenues under the $29 million SBA size threshold for hospitals.

The MMA facilitates the inclusion of hospitals in regional networks in cases in which a plan and a hospital cannot reach an agreement on payment levels. As described in more detail under the Subpart C preamble section, if we find the hospital's participation "essential" to meeting a plan's network adequacy requirement, and the hospital can demonstrate to us that its costs are higher than the normal Part A payment it receives, then the MA plan can pay the normal amount and the network adequacy fund will pay the difference. The total amount available nationally for this purpose is $25 million in 2006 (rising annually at the hospital market basket rate).

This provision will most likely to occur in small towns and rural areas, particularly if such areas are served by only one hospital. It is impossible at this time to predict the frequency with which this situation will arise, since that depends on future bargaining among plans and hospitals, and on hospitals' ability to demonstrate excess costs. Since the hospitals benefiting would otherwise serve Medicare enrollees at Medicare rates, the financial effects of this program on hospitals are positive. Likewise, by allowing regional plans to meet their network requirements at a reasonable cost the effects on them are positive. We note that over 700 rural hospitals are already paid at rates somewhat higher than would otherwise be applicable under Medicare's hospital payment rules. Some of these would be candidates for "essential" hospital payments (although the eligibility criteria are different). However, despite the large number involved (about one in seven hospitals participate), these are small hospitals in sparsely inhabited rural areas and account for only about one percent of Medicare hospital payments. The pattern under the essential hospital program is likely to be similar.

We are not aware of any consequential burden on hospitals in our regulatory proposals for this program, but welcome comments.

5. Medical Savings Accounts

These regulations also change the rules for Medical Savings Accounts (MSAs), which are high deductible plans. This provides new opportunities for insurance firms to participate in Medicare Advantage. High deductible plans are increasingly being offered in the under age 65 market by large insurance firms. As discussed previously in this Preamble, we are implementing the statutorily defined changes (at section 233 of the MMA), which are intended to make MSAs a viable option for beneficiaries. We are also proposing to amend the existing rules in several places to remove requirements that would be inappropriate if applied to MSAs. Nothing we propose adds burden; we welcome comments on any remaining barriers to the sponsorship of MSA plans.

6. Employer Sponsored Plans

The MMA adds new authority for employers and unions to sponsor plans for their employees and former employees, or members. Previously they could sponsor plans through an M+C plan; the statute gives them the flexibility to sponsor plans directly. The statute and the proposed regulation provide for waivers of any Medicare Advantage requirement that would unduly impede employer or union-sponsored plans. We request comments on any potential barriers affecting employers of any size that we should address more directly.

7. Other Requirements in the Regulatory Flexibility Act

The RFA lists five general requirements for an IRFA and four categories of burden reducing alternative to be considered. It also defines as a small entity a "small governmental jurisdiction" whose area has a population of less than fifty thousand. We anticipate no consequential effects of these regulations on small governmental jurisdictions. We know of no relevant Federal rules that duplicate, overlap, or conflict with the proposed rule (which in any event amends an existing rule that is not duplicated or overlapped by other rules). The analysis above, taken together with the rest of this preamble, addresses all these general requirements.

We have not, however, addressed the various categories of burden reducing alternatives listed in the RFA as appropriate in IRFAs. These alternatives, such as an exemption from coverage of the rule for small entities, establishment of less onerous requirements for small entities, or use of performance rather than design standards, simply do not apply to a situation in which a program beneficial to entities both large and small is being created, and in which the regulations do not create economically "significant" burdens. Furthermore, the consumer choice-driven Medicare Advantage program is overwhelmingly a "performance" system rewarding plans that operate at lower costs, provide better service, or provide better benefits as evaluated by enrollees and potential enrollees. CMS operates in a stewardship role, not as the promulgator of detailed design standards (except in a few areas, such as procedural protections for enrollees). However, throughout this Preamble we identify issues and options for attention by affected entities, including a number of proposed changes that would lessen the burden of the existing M+C rule. We welcome comments on these and suggestions for additional steps we can take, consistent with the underlying statute, to minimize any unnecessary burdens on current or potential Medicare Advantage plans or other affected entities.

L. Alternatives Considered

In this section we discuss a decision that CMS has made that prohibits plans from applying rebate dollars to optional supplemental packages. The remaining issues discussed in this section address the major areas in which CMS is seeking comment to determine which option to choose among the options offered in the preamble. As part of the impact analysis, we are providing supplemental information that will help readers of this proposed rule understand some of the issues that need to be considered in evaluating the options, or in suggesting alternatives that CMS should consider as options.

1. Designation of Regions

A number of considerations need to be balanced in designating the regions for the regional Medicare Advantage plans. The statute and the conference report for the MMA provide some guidance about what the Congress considers important factors in delineating regions, as has been discussed in the preamble. The designation of regions will be made after the market study required by the MMA. The law provides for a minimum of ten, and a maximum of 50, regions. There are provisions in the law that favor the development of multi-State regions (for example, the use of Federal licensure and solvency standards pending State licensure), or that favor the development of a national plan (the bonus for a national plan). As noted previously, one of the primary reasons for using the regional plan approach is to provide access to health plans for areas in which "local" plans are less likely to be offered.

The major goal is to maximize access to a choice of private health plans in as many areas as possible. Therefore, an important question is what type of regional configuration, or method of configuring regions, has the greatest likelihood of extending private plan options to areas with no plans or to underserved areas. In terms of public comment, perhaps the greatest benefit for CMS would be to hear from plans and potential plans regarding the factors they would consider important in promoting plan participation. Similarly, other interested parties (beneficiaries, beneficiary advocates, providers), would also have opinions on how the regions should be delineated. We recognize that there are a number of factors that would affect any decision on the designation of regions, including State licensure issues for insurers and size and capital requirements for plans, as well as other potential barriers to initial or subsequent market entry; issues relating to the ability to form provider networks over a wide area; the nature of existing health care market areas for commercial and Medicare plans; the number of competitors that operate in an area or are likely to operate in an area; and the goal of initiating and sustaining competition.

One obvious question is whether the regions should be comprised of the largest possible number (the 50 States, or a close approximation), or a configuration consisting of much larger geographic areas. Designating a relatively small number of large regions may be viewed as providing an undue advantage to larger companies (for example, the several insurance companies already licensed in virtually every State). A larger number of regions may promote the use of local or regional firms that may be better able to form networks because of their current operations in a given State, while an insurer that is new to the market may have more difficulty in network formation. On the other hand, to the extent that participation as a regional plan can involve a relatively high level of risk as a business venture, larger companies may be more willing, and better able, to take such risk. Economies of scale may only be possible if the regions are relatively large and are designed in such a way that a relatively high level of enrollment can be expected. A regional configuration that emphasizes large regions and results in a smaller number of large plans may permit participating plans to have greater leverage in securing provider contracts as compared to a situation in which there are many competitors in an area. Another factor that we are uncertain about is whether it is feasible to assume that, if there are multi-State regions, individual insurance companies would be willing to form consortiums with insurers from other States in order to cover a wider area.

One possibility for the designation of regions is to have the 50 regions consist essentially of the 50 States. Such a configuration may not be the best way to ensure that the designation of regions contributes to the overall goal of maximizing the availability of health plan choices. New Jersey, for example, currently has plans available in every county in the State, including at least one MA coordinated care plan and one demonstration PPO plan in each county. There are nine counties in which only one organization is offering plans, but in all 21 New Jersey counties, there is a zero premium plan available with drug coverage. Making New Jersey a region, if a regional plan were to participate, would bring more competition to the State. However, including New Jersey as one State within a multi-State region might allow Medicare to capitalize on the presumed ability of the highly competitive New Jersey plans to extend their reach beyond New Jersey, and, as discussed previously, help to achieve

the objective of expanding access to private plan choices.

Using Florida as a different kind of example, if Florida by itself were designated as a region, and Florida had only regional plans, all beneficiaries in each Florida county would have the same kinds of benefit offerings. Looking at the current offerings of Florida MA plans as shown in Table 3, there is a range of benefit offerings in the State from county to county, but in all counties in which there are MA plans, drug coverage is available. Some Florida residents must pay a premium to obtain the drug coverage. With a regional plan, there would be a uniform benefit across the State, and the 19 percent of the population (560,000 beneficiaries) that currently does not have access to a private plan could enroll in a plan.

The preamble discusses the kinds of State characteristics that we are looking to balance in the formation of regions. The statute emphasizes extending plans to rural areas. As shown in Table 5, the States with the smallest Medicare populations tend to have the highest proportion of rural beneficiaries as a percent of their Medicare population and also are more likely to be contiguous with each other. Could such States stand alone as individual regions? Would there be a sufficient market to support regional plans in each of these States, or do such small populations require multi-State regions? If it is assumed that multi-State regions must be comprised of States that are contiguous, is there a possible configuration of these smaller States that would create a region in which participation as a regional plan is a viable option for a health insurer? (Note that these States generally are among those with the lowest per capita expenditures. Although this might indicate that there may not be much opportunity for health plans to achieve savings in health care utilization or discounts from providers, it is also true these States are generally the areas in which the fee-for-service component of the benchmarks will be based on floor payments rather than Medicare fee-for-service payments, thereby resulting in potentially higher plan payments and possible higher rebates for enrollees.)

BILLING CODE 4120–01–P

Table 5: Characteristics of the States with the Lowest Medicare Populations, 1999

State	Contiguous with another State on this list?	Part of an MSA with another State on this list?	Among the 15 States with the highest proportion of rural beneficiaries?	Part of an MSA with one of 15 most populous States?	Medicare private plan penetration, 1999	Per capita FFS expenditures, 1999	Rank in per capita FFS expenditures (1 is lowest per capita)	Rank in private plan penetration (1 is highest penetration)	Percent of Medicare Population That is Rural, 1999	Resident Medicare beneficiaries: urban, 1999	Resident Medicare beneficiaries: rural, 1999	Resident Medicare beneficiaries: total, 1999
South Dakota	x		x		0.2%	$4,116	7	51	73%	31,980	85,800	117,780
North Dakota	x		x		0.8%	$4,035	4	49	67%	34,080	67,740	101,820
Maine	x				0.6%	$4,434	16	48	47%	114,520	99,860	214,380
Alaska	no contiguous States		x		0.5%	$5,611	38	47	61%	15,780	24,500	40,280
Vermont	x		x		2.0%	$4,353	14	45	74%	22,780	65,260	88,040
Wyoming	x		x		2.9%	$4,342	13	44	68%	20,080	43,580	63,660
Montana	x		x		2.2%	$3,896	2	43	68%	43,600	91,880	135,480
Utah	x	x (Idaho)			3.6%	$3,974	3	42	28%	146,400	57,720	204,120
Delaware				Philadelphia-Camden-Wilmington	3.7%	$5,200	34	37	28%	80,840	30,980	111,820
Idaho	x	x (Utah)	x		9.2%	$4,038	5	26	67%	54,620	108,780	163,400
New Hampshire	x			Boston-Cambridge-Quincy	10%	$4,312	12	25	34%	108,220	56,800	165,020
New Mexico					19%	$4,310	11	13	46%	123,100	106,680	229,780
Hawaii	no contiguous States				38%	$3,648	1	7	28%	118,620	45,000	163,620
Nevada	x				35%	$5,147	32	6	14%	200,620	34,020	234,640
Rhode Island				Providence-New Bedford-Fall River	30%	$5,876	40	5	0%	168,380	-	168,380
								Total for Above States	42%	1,283,620	918,600	2,202,220

Source: CMS analysis of penetration reports and MSA designation files (available at http://www.cms.hhs.gov/healthplans/reportfilesdata/), and expenditure information from the Statistical Supplement of the Health Care Financing Review.

At the other end of the scale are the most populous States, shown in Table 6. Potentially, each of these States could be designated a region (notwithstanding

the preceding discussion of the case of New Jersey). Although the rural issue is generally thought of in the context of States such as the Mountain States that are sparsely populated, if access were extended throughout each of these 15 primarily urban States, access will have been extended to 50 percent of all rural Medicare beneficiaries (defining "rural" as Medicare beneficiaries who reside in counties that are not within an MSA). This would triple the percent of rural beneficiaries with access to coordinated care plans (which stands at about 15 percent currently).

BILLING CODE 4120–01–P

Table 6: Characteristics of the States with the Highest Medicare Population, 1999

State	Contiguous with a State from list of least populous States?	Medicare private plan penetration, 1999	Per capita FFS expenditures, 1999	Rank in per capita FFS expenditures (1 is lowest)	Rank in private plan penetra-tion (1 is highest)	Percent of Medicare Population that is Rural, 1999	Resident Medicare beneficiaries: urban, 1999	Resident Medicare beneficiaries: rural, 1999	Resident Medicare beneficiaries: total, 1999
California	x (Nevada)	41%	$ 6,148	45	1	5%	3,672,520	188,560	3,861,080
Florida		28%	$ 6,072	44	8	8%	2,573,640	219,600	2,793,240
Pennsylvania		28%	$ 5,902	42	9	16%	1,740,140	341,860	2,082,000
Massachusetts	x (Rhode Island)	25%	$ 6,361	46	11	2%	937,020	15,260	952,280
New York	x (Vermont)	19%	$ 6,424	48	15	9%	2,436,860	236,940	2,673,800
Ohio		18%	$ 5,124	31	16	19%	1,367,600	329,320	1,696,920
Texas	x (New Mexico)	17%	$ 6,014	43	17	23%	1,712,360	513,760	2,226,120
New Jersey		17%	$ 6,552	49	18	0%	1,200,700	0	1,200,700
Missouri		15%	$ 5,029	28	19	37%	534,060	318,080	852,140
Illinois		12%	$ 5,419	37	22	21%	1,279,840	341,680	1,621,520
Georgia		6%	$ 5,164	33	30	39%	550,680	358,940	909,620
Virginia		6%	$ 4,591	18	32	32%	597,540	280,380	877,920
Michigan		5%	$ 5,613	39	35	21%	1,088,740	296,240	1,384,980
Tennessee		5%	$ 5,087	29	36	37%	510,180	304,580	814,760
North Carolina		4%	$ 4,776	24	39	39%	675,480	436,480	1,111,960
Indiana		4%	$ 4,649	21	40	31%	579,740	258,520	838,260
					Total for Above States	17%	21,457,100	4,440,200	25,897,300

Source: CMS analysis of penetration reports and MSA designation files (available at http://www.cms.hhs.gov/healthplans/reportfilesdata/), and expenditure information from the Statistical Supplement of the Health Care Financing Review.

The conference report for the MMA contains two suggestions relating to the designation of regions that are difficult to reconcile: "The Secretary could not divide states so that portions of the state were in different regions" and "[t]o the extent possible, the Secretary would include multi-state metropolitan statistical areas (MSAs) in a single region, except that he or she could divide an MSA where necessary to establish a region of such size and geography to maximize the participation of PPOs." There are 44 multi-State MSAs, with 37 States having at least one multi-State MSA. Looking at the location of these MSAs across the country, it would be necessary in many cases to divide MSAs between regions or to create very large regions. To divide MSAs, CMS would look to the analysis of health care markets and how they are configured, but we would also invite comment on other factors that we should consider when it appears necessary to divide an MSA so that a part, or parts of, the MSA fall within different regional boundaries.

As discussed in the preamble, we will be conducting a market survey and providing additional opportunity for public input during the course of that work. We welcome comments in response to this proposed rule regarding the many considerations related to the designation of the regions for the MA program as well as for the PDPs and the potential for establishing the same or at least similar regional configurations.

2. Statewide or Region-Wide Versus Plan-Specific Risk Adjustment To Determine Savings

The issue of statewide or region-wide versus plan-specific risk adjustment is discussed in the section dealing with "Calculation of Savings" (§ 422.264) in the text and preamble of the proposed rule. The statute and the proposed rule state that, for local plans, CMS may use either a statewide average risk adjuster, a risk adjuster for a geographic area different from a State (for example, a metropolitan statistical area), or a plan-specific risk adjuster, to determine the average per capita savings that exist when there are bids below the benchmark. Similarly, for regional plans, CMS may use a region-wide adjuster, an adjuster for a different geographic area, or a plan-specific risk adjuster in determining average per capita savings.

There are two reasons for applying risk adjustment to determine savings (which in turn determine the dollar value of available enrollee rebates). One is that if the savings computation were not subject to risk adjustment, plan enrollees overall would receive higher rebates than are appropriate because current enrollees in Medicare Advantage plans are on the whole healthier than beneficiaries with fee-for-service Medicare coverage (and, in the future if the situation is reversed, or if in a given area enrollees of health plans are sicker than those in fee-for-service Medicare, rebates would be lower than they should be). In other words, risk adjustment ensures that plans are paid appropriately for their enrolled population. The other reason for applying risk adjustment to the savings computation is that a comparison of the ability of health plans to achieve savings should be based on a comparison that takes into account the relative health status of each plan's enrollees in evaluating whether one plan is more "efficient" than another. To do otherwise would make two plans that are equally efficient look as though one plan (a plan with healthier enrollees) was more efficient than another plan (a plan with sicker enrollees) merely because on a per capita basis the enrollees of the latter plan are more costly than enrollees of the plan with healthier enrollees. If each of the plans is equally efficient, a risk adjustment system would reveal each plan's per capita costs to be the same (assuming beneficiary characteristics other than health status are equal between the two plans). If, under a standard of relative efficiency, two plans are equally efficient, in principle their cost to an enrollee should be the same. If one plan is more efficient than another, beneficiaries would be rewarded for choosing the more efficient plan.

The process called for in the statute for determining a statewide risk adjustment to compute savings for local plans is to compare a risk-adjusted benchmark against risk-adjusted bids. The benchmark, and all plan bids, would be adjusted by the average risk factor for enrollees in all local MA plans in a given State (an enrollment-weighted average that is projected and announced at the time CMS publishes MA rates for a forthcoming year). That is, there is an "apples-to-apples" comparison of bids to the benchmark, and an "apples-to-apples" comparison to other plans. The two numbers that are being adjusted, the benchmark and a plan bid, are numbers for an "average" beneficiary—a beneficiary with demographic and health status characteristics that represent an average across the entire Medicare population in the United States. That is, the benchmark and plan bids that are being adjusted, for purposes of determining the appropriate level of savings, are risk-neutral. (The plan bid that represents a bid for an average, or "1.0" beneficiary, is referred to in the statute as the "unadjusted MA statutory non-drug monthly bid amount.")

In terms of the total dollars that will be available as rebate dollars, there is no difference, among equally efficient plans, between a statewide approach versus any other geographic area approach, or a plan-specific approach, to determining an appropriately risk-adjusted savings. In terms of how one plan compares to another in "efficiency," a statewide risk adjustment system for rebates treats all equally efficient plans the same with respect to the dollar amount of rebates that are available for enrollees, regardless of the health status of the enrollees. Under a statewide system of determining savings, the adjustment is applied at an area-wide level when the savings computation is subject to risk adjustment. That is, the benchmark, and all bids for the State, are adjusted by the average risk factor across all plans. If, for example, the enrollment-weighted average risk factor across all plans is 1.1 (110 percent of the risk factor for an average beneficiary), both the benchmark and all plan bids are adjusted by this factor to determine the dollar difference between the benchmark and each bid. In essence, this removes relative differences in risk among plans as a factor in determining how one plan's bid compares to another. The only difference that remains among plans is any difference in bids that reflects the relative efficiency of one plan versus another. If all plans are equally efficient—that is, if, for example, all plans are able to provide the Medicare benefit at 80 percent of the benchmark level—all plans will have the same rebate dollar amount available per enrollee (representing 20 percent of the statewide or region-wide benchmark, adjusted by the statewide or region-wide average risk factor). A plan-specific approach would incorporate into the savings computation a risk adjustment factor that can vary from plan to plan, yielding different dollar savings per person at the plan level but resulting in the same total dollar rebates when all plans are equally efficient because the statewide or region-wide method uses a weighted average risk factor across all plans. Assuming that all rebate dollars are used by all plans to reduce the Part B premium, and assuming the risk-adjusted average per capita savings had been computed as $25 per person per month, if an individual joins Plan X, with sicker

beneficiaries, the person receives a $25 reduction in his or her Part B premium, which is the same amount he or she would receive on joining Plan Y, with healthier beneficiaries. This $25 rebate would represent the same value to each beneficiary enrolled in either of the two plans because all beneficiaries across the Nation are faced with the same cost of paying the Part B premium, regardless of their health status or the State or county in which they live. However, if rebate dollars are used for other purposes, the value of the rebate in terms of its "buying power," would vary from plan to plan based on the risk profile of the individual plan. Any plan feature that is more expensive if there is higher utilization—for example, the buy-out of cost sharing, or reductions in premiums for supplemental benefits offered by a plan—would have a different value in a plan with a healthier enrollment mix as compared to a plan with sicker enrollees. That is, it costs a plan more to "buy down" cost sharing for a sicker population than for a healthier population. Enrollees will see that difference as a difference in their out-of-pocket costs, which will be higher in a "sicker" plan. (For example, if plans have as their starting point an intent to have a $200 copayment for each hospital inpatient admission, and a plan wishes to reduce the copayment to $100 per admission by paying the provider an additional $100 per admission, the total revenue needed to finance this copayment reduction would be higher for a plan with higher rates of hospital admissions than a plan with lower admission rates. If plans have the same level of rebate dollars per capita, the "healthier" plan can afford enrollees a greater reduction in the hospital copayment (to $50, for example) because the average number of people to whom the copayment applies is lower than in a "sicker" plan.)

The relatively higher cost of obtaining benefits through a "sicker" plan can be mitigated by having a plan-specific risk adjustment for the determination of savings. Plans with less healthy enrollees would have rebate amounts higher than other plans that are equally efficient but have healthier enrollees. In terms of what the benefits look like from an enrollee's point of view, a plan-specific adjustment can help achieve parity between "sicker" and "healthier" plans. However, as just discussed, a plan-specific approach, if used for a dollar reduction in the Part B premium that makes the "sicker" plan appear cheaper than the "healthier" plan defeats the purpose of a rebate, the value of which should only be based on relative efficiency. (As previously discussed, it should also be noted that plan features other than the premium are likely to show a "sicker" plan as a higher cost plan in terms of cost sharing that enrollees must pay or in terms of the level of extra benefits the plan is able to offer in comparison to a "healthier" plan. Because of this, the plan-specific approach may be the more desirable approach if the goal is to achieve some type of parity between equally efficient plans.)

As a possible basis for preferring the statewide approach, there is the argument that it is a normal insurance principle that one would expect enrollees of an insurance plan with a relatively sicker covered group to have to pay more than enrollees in a plan with a relatively healthier covered group. As for the plan-specific approach, it is also true that the differences in risk status among plans may even out over time if a plan-specific adjustment is used. More enrollees will be drawn to the less expensive plan (the plan with the higher rebate, which may be less expensive for healthier enrollees, if, for example, extra benefits are the same as in other plans but cost sharing is higher). If beneficiaries make such enrollment choices, the risk profile of the "sicker" plan will change towards being closer to an average risk profile. Similarly, if a plan that has an apparent advantage in rebates because of selection (enrolling healthier enrollees) rather than because of efficiency, the plan's relative inefficiency will be revealed in subsequent years to the extent that sicker beneficiaries choose to enroll in a plan offering better benefits or lower cost-sharing and premiums.

The preceding discussion deals with plans that are equally efficient and the effects of plan-specific versus statewide risk adjustment in determining rebates. Additional issues arise if there is variation in efficiency among plans and variation in plan risk "profiles" (the makeup of the plan enrollment by health status). Using a statewide risk adjuster to determine rebates will result in higher program payments if efficient plans have relatively healthier enrollees. Using a plan-specific risk adjustment system will result in higher program payments if efficient plans have relatively sicker enrollees. In general, the lowest program expenditures will occur when the plans with the greatest savings are subject to the lowest possible risk adjustment of those savings—whether it is the plan-specific approach or a statewide or other regional approach. The different effects are illustrated in the hypothetical examples shown in Tables 7, 8, and 9. Tables 10 and 11 show a feature of the law that also affects the outcome, which is that plans in which there are no savings are also taken into consideration in determining the risk adjustment when a statewide or other region-wide method is used.

Table 7 shows that when plans are equally efficient (that is, the savings for a 1.0 beneficiary is the same among plans), either risk adjustment method results in the same level of program payments, regardless of the relative risk profiles of each plan's enrollees. Table 8 shows that if the more efficient of the two plans (in this case, a far more efficient plan) has sicker enrollees, the plan-specific method yields higher rebates and greater program spending. Table 9 shows the situation in which the only difference, compared to the Table 8 scenario, is a reversal of the plan risk scores, with the more efficient plan having healthier enrollees. In such a case, the statewide approach yields higher rebates for plan enrollees and higher program spending. Tables 8 and 9 illustrate that even though it is only the hypothetical Plan ABC that is efficient and has any appreciable savings, how these savings are translated into rebates is very much dependent on the characteristics of competing plans when the statewide or region-wide risk adjustment method is used. Similarly, Tables 10 and 11 illustrate the same circumstances with regard to the effect of plans with no savings. Wide swings in the level of rebate dollars are possible under either method, but we cannot quantify the effect at this time without knowing the risk distribution of enrollees for 2006 and the respective bids of the health plans.

TABLE 7.—SAVINGS AND REBATES FOR EQUALLY EFFICIENT PLANS

	Plan ABC	Plan XYZ	Totals
Benchmark	$700	$700	
Bid (for "1.0," average risk individual)—Both plans equally efficient	$600	$600	
Enrollees	1000	1000	2,000

TABLE 7.—SAVINGS AND REBATES FOR EQUALLY EFFICIENT PLANS—Continued

	Plan ABC	Plan XYZ	Totals
Risk At Plan Level in Relation to 1.0—ABC Plan has sicker enrollees	1.4	0.8	
Enrollment-Weighted Statewide Average Risk Computation	0.70	0.40	1.10
Savings With Statewide Method: Adjust Bid and Benchmark by Statewide Average Risk Factor			
Adjust Benchmark	$770	$770	
Adjust Bid	$660	$660	
Per Capita Savings with Statewide Method	$110	$110	
Total Savings	$110,000	$110,000	$220,000
Savings With Plan-Specific Method: Adjust Bid and Benchmark by Plan-Specific Risk Factor			
Adjust Benchmark	$980	$560	
Adjust Bid	$840	$480	
Per Capita Savings with Plan-Specific Method	$140	$80	
Total Savings	$140,000	$80,000	$220,000
Computation of Total Medicare Payment to Plans and on Behalf of Enrollees			
Statewide—			
Plan's Risk-Adjusted Bid × Enrollment	$840,000	$480,000	$1,320,000
Statewide Rebate × Enrollment × .75	$82,500	$82,500	$165,000
Total Payment to Plans	$922,500	$562,500	$1,485,000
Per Enrollee Rebate	$82.50	$82.50	
Plan-Specific—			
Plan's Risk-Adjusted Bid × Enrollment	$840,000	$480,000	$1,320,000
Plan-Specific Rebate × Enrollment × .75	$105,000	$60,000	$165,000
Total Payment to Plans	$945,000	$540,000	$1,485,000
Per Enrollee Rebate	$105	$60	
Net Effect: Each Method Results in the Same Level of Program Payments			

TABLE 8.—SAVINGS AND REBATES WHEN EFFICIENT PLAN HAS SICKER ENROLLEES

	Plan ABC	Plan XYZ	Totals
Benchmark	$700	$700	
Bid (for "1.0," average risk individual)—ABC Plan far more efficient	$600	$699	
Enrollees	1000	1000	2,000
Risk At Plan Level in Relation to 1.0—ABC Plan has sicker enrollees	1.4	0.8	
Enrollment-Weighted Statewide Average Risk Computation	0.70	0.40	1.10
Savings With Statewide Method: Adjust Bid and Benchmark by Statewide Average Risk Factor			
Adjust Benchmark	$770	$770	
Adjust Bid	$660	$769.99	
Per Capita Savings with Statewide Method	$110	$0.01	
Total $$ of Savings	$ 110,000	$11	$110,011
Savings With Plan-Specific Method: Adjust Bid and Benchmark by Plan-Specific Risk Factor			
Adjust Benchmark	$980	$560	
Adjust Bid	$840	$559.99	
Savings with Plan-Specific Method	$140	$0.01	
Total Savings	$140,000	$8	$140,008
Computation of Total Medicare Payment to Plans and on Behalf of Enrollees			
Statewide—			
Plan's Risk-Adjusted Bid × Enrollment	$840,000	$559,992	$1,399,992
Statewide Rebate × Enrollment × .75	$82,500	$8.25	$82,508.25
Total Payment to Plans	$922,500	$560,000.25	$1,482,500
Per Enrollee Rebate:	$82.50	$0.01	
Plan-Specific—			
Plan's Risk-Adjusted Bid × Enrollment	$ 840,000	$559,992	$1,399,992

TABLE 8.—SAVINGS AND REBATES WHEN EFFICIENT PLAN HAS SICKER ENROLLEES—Continued

	Plan ABC	Plan XYZ	Totals
Plan-Specific Rebate × Enrollment × .75	$105,000	$6	$105,006
Total Payment to Plans	$945,000	$559,998	$1,504,998
Per Enrollee Rebate:	$105	$0.01	
Net Effect: Plan-Specific Method Yields Higher Program Payments Totaling: $22,498			

TABLE 9.—SAVINGS AND REBATES WHEN EFFICIENT PLAN HAS HEALTHIER ENROLLEES

	Plan ABC	Plan XYZ	Totals
Benchmark	$700	$700	
Bid (for "1.0," average risk individual)—ABC Plan far more efficient	$600	$699	
Enrollees	1000	1000	2,000
Risk At Plan Level in Relation to 1.0—XYZ Plan has sicker enrollees	.8	1.4	
Enrollment-Weighted Statewide Average Risk Computation	0.40	0.70	1.10
Savings With Statewide Method: Adjust Bid and Benchmark by Statewide Average Risk Factor			
Adjust Benchmark	$770	$770	
Adjust Bid	$660	$769.99	
Per Capita Savings with Statewide Method	$110	$0.01	
Total $$ of Savings	$110,000	$11	$110,011
Savings With Plan-Specific Method: Adjust Bid And Benchmark by Plan-Specific Risk Factor			
Adjust Benchmark	$560	$980	
Adjust Bid	$480	$979.99	
Savings with Plan-Specific Method	$80	$0.01	
Total Savings	$80,000	$14	$80,014
Computation of Total Medicare Payment to Plans and on Behalf of Enrollees			
Statewide			
Plan's Risk-Adjusted Bid × Enrollment	$480,000	$979,986	$1,459,986
Statewide Rebate × Enrollment × .75	$82,500	$8.25	$82,508.25
Total Payment to Plans	$562,500	$979,994.25	$1,542,494
Per Enrollee Rebate	$82.50	$0.01	
Plan-Specific			
Plan's Risk-Adjusted Bid × Enrollment	$480,000	$979,986	$1,459,986
Plan-Specific Rebate × Enrollment × .75	$60,000	$10.50	$60,010.50
Total Payment to Plans	$540,000	$979,996.50	$1,519,997
Per Enrollee Rebate	$60	$0.01	
Net Effect: Statewide Method Yields Higher Program Payments Totaling: $22,498			

BILLING CODE 4120–01–P

Table 10: The Effect of Plans Bidding Above Benchmark; Efficient Plans Have Healthier Enrollees

	Plan ABC	Plan XYZ	Plan Over1	Plan Over2
Benchmark	$700	$700	$700	$700
Bid (For 1.0)—Plans with Savings Equally Efficient	$600	$600	$750	$780
Enrollees (Total Enrollment 4,000)	1000	1000	1000	1000
Risk At Plan Level—Plans with Savings Have Healthier Enrollees	0.9	0.9	2	2
Enrollment-Weighted Statewide Average Risk Computation (Sum of All for Each Plan = 1.45)	0.225	0.225	0.50	0.50
Savings Using Statewide: Adjust Bid & Benchmark By Statewide Average Risk Factor				
Adjust Benchmark	$ 1,015	$ 1,015		
Adjust Bid	$870	$870		
Per Capita Savings With Statewide Method	$145	$145		
Savings Using Plan-Specific: Adjust Bid & Benchmark By Plan-Specific Risk				
Adjust Benchmark	$630	$630		
Adjust Bid	$540	$540		
Per Capita Savings With Plan-Specific Method	$90	$90		
Computation of Total Medicare Payment to Plans And on Behalf of Enrollees: Statewide			**TOTALS**	
Plan Risk-Adjusted Bid x Enrollment	$ 540,000	$ 540,000	$1,080,000	
Statewide Rebate x Enrollment x .75	$ 108,750	$108,750	$217,500	
TOTAL PAYMENT TO PLANS	$ 648,750	$648,750	$1,297,500	
Per Enrollee Rebate:	**$108.75**	**$108.75**		

CMS-4069-P

Computation of Total Medicare Payment to Plans And on Behalf of Enrollees: Plan-Specific			
Plan Risk-Adjusted Bid x Enrollment	$ 540,000	$ 540,000	$1,080,000
Plan-Specific Rebate x Enrollment x .75	$ 67,500	$ 67,500	$135,000
TOTAL PAYMENT TO PLANS	$ 607,500	$ 607,500	$1,215,000
Per Enrollee Rebate:	$ 67.50	$ 67.50	
NET EFFECT: Statewide Method Yields Higher Program Payments Totaling $ 82,500			

Table 11: The Effect of Plans Bidding Above Benchmark; Efficient Plans Have Sicker Enrollees

	Plan ABC	Plan XYZ	Plan Over1	Plan Over2
Benchmark	**$700**	**$700**	**$700**	**$700**
Bid (For 1.0)—Plans with Savings Equally Efficient	**$600**	**$600**	**$750**	**$780**
Enrollees (Total Enrollment 4,000)	**1000**	**1000**	**1000**	**1000**
Risk At Plan Level—Plans with Savings Have Healthier Enrollees	**1.4**	**1.2**	**0.8**	**0.7**
Enrollment-Weighted Statewide Average Risk Computation (Sum of All for Each Plan = 1.025)	**0.35**	**0.30**	**0.20**	**0.175**
Savings Using Statewide: Adjust Bid & Benchmark By Statewide Average Risk Factor				
Adjust Benchmark	$717.50	$ 717.50		
Adjust Bid	$615	$ 615		
Per Capita Savings With Statewide Method	$102.50	$ 102.50		
Savings Using Plan-Specific: Adjust Bid & Benchmark By Plan-Specific Risk				
Adjust Benchmark	$980	$840		
Adjust Bid	$840	$720		
Per Capita Savings With Plan-Specific Method	$140	$ 120		
Computation of Total Medicare Payment to Plans And on Behalf of Enrollees: Statewide			**TOTALS**	
Plan Risk-Adjusted Bid x Enrollment	$840,000	$720,000	$ 1,560,000.00	
Statewide Rebate x Enrollment x .75	$76,875	$76,875	$ 153,750.00	
TOTAL PAYMENT TO PLANS	$916,875	$796,875	$ 1,713,750	
Per Enrollee Rebate:	$76.87	$76.87		

CMS-4069-P

Computation of Total Medicare Payment to Plans And on Behalf of Enrollees: Plan-Specific				
Plan Risk-Adjusted Bid x Enrollment	$840,000	$720,000	$ 1,560,000.00	
Plan-Specific Rebate x Enrollment x .75	$105,000	$90,000	$ 195,000.00	
TOTAL PAYMENT TO PLANS	$945,000	$ 810,000	$1,755,000	
Per Enrollee Rebate:	$ 105	$ 90		
NET EFFECT: Plan-Specific Method Yields Higher Program Payments Totaling $ 41,250				

There is another issue, which is that within a State, local plans may not be competing directly against each other. That is, in a large State, health plans in

one section of the State may not be competing against health plans in another section of the State, or the State could be served by individual plans in individual counties (to use an extreme example), each of which operates in non-overlapping service areas where there is only one plan option available to beneficiaries. In the latter case of single non-competing plans, using a statewide risk adjuster would seem to be unfair to plans and enrollees. In such a situation, it would seem that the fairest approach is to employ a plan-specific risk adjuster. Similarly, if there are discrete market areas smaller than a State in which health plans compete, then—as implied in the statutory language—the appropriate course might be to use a Metropolitan Statistical Area as the geographic area in which a multi-plan risk adjustment system will be used to determine the rebate computation (if CMS decides against the general application of the plan-specific option). In that way, savings that health plans in a particular MSA can achieve would be used for enrollees in that MSA rather than being applicable to a wider geographic area.

The statewide approach to determining rebates differs from the current method of determining savings, which is essentially done on a plan-specific basis (and therefore using the statewide method may result in a different competitive dynamic among plans). The current system for computing extra benefits that enrollees may be entitled to—which will continue through 2005—uses the "adjusted community rate proposal" process. Under this process for determining whether there is excess revenue, there are actual and implicit adjustments at the plan-specific level to account for the risk profile of a plan's enrollees. The excess revenue determination (that is, the savings computation) is based on a comparison of a plan's stated "average payment rate" from CMS (a projection of what CMS will pay the plan—which is a risk-adjusted payment) compared to the plan's "adjusted community rate" (a Medicare term) for its projected Medicare enrollment. This "community rate" is implicitly adjusted for the risk status of projected Medicare enrollees because the "adjusted" aspect of the Medicare "adjusted community rate" is the adjustment that a plan makes to reflect the relatively higher utilization of Medicare enrollees as compared to other enrollees to whom a community rate applies. That is, under a strict community rating system, each group seeking to buy health care coverage from a community-rated plan will receive the same quoted community rate as any other group that is buying coverage (for the same benefit package) from the health plan, regardless of the expected costs and health status of the particular group seeking coverage. For Medicare, plans are allowed to adjust the rate to reflect the utilization and higher expenditures associated with Medicare enrollees. The adjustment is made on the basis of the plan's own history with respect to the relative costs of its Medicare enrollees. Hence, there is an implicit risk adjustment of the "community rate" as it would apply to this segment of a health plan's enrollment. The amount that, under the current system, a Medicare plan must return to beneficiaries as extra benefits when there is excess revenue is the difference between the "adjusted community rate"—implicitly adjusted for risk, as just described—and Medicare's average payment rate, which is explicitly risk adjusted, using CMS risk adjustment factors, at the plan level. The analogue of the current practice would be the plan-specific approach to determining the calculation of savings (rather than what is essentially a type of pooling of savings across multiple plans if the statewide method were to be used).

As noted in the preamble, we welcome comments on the issues related to statewide versus plan-specific (or other geographic area) risk adjustment for the purpose of determining the distribution of rebates among plan enrollees.

3. Prohibiting Use of Rebate Dollars for the Purchase of Optional Supplemental Benefits

The MMA retains a provision from pre-existing law that allows health plans to have optional supplemental benefits that Medicare enrollees can choose to purchase for an additional premium (section 1852(a)(3)(B)). Such optional supplemental packages are financed entirely by enrollee premiums (as is also currently true of mandatory supplemental packages that all beneficiaries are required to purchase from an MA plan, if the mandatory supplement is approved by CMS). Once the bidding system begins in 2006, the concept of an optional supplemental offering seems inconsistent with the new design of the MA program in two ways: with regard to the question of whether an optional supplemental package can have its price reduced by a rebate (which, as explained below, appears not be administratively feasible); and also with regard to the question of how to deal with an optional supplemental package that, because of its features, would have an effect on a plan's bid for coverage of Part A and B services (for example, an optional supplement that buys down cost sharing for A and B services). As noted in the preamble we are prohibiting plans from applying rebate dollars to optional supplemental premiums, and we are asking for comment on the issue of whether optional supplemental plans may include benefits that affect the utilization of A and B services. (The latter issue is discussed in the preamble.)

Under the current adjusted community rate process (the process by which plans submit premium and benefit proposals to CMS for approval), what in 2006 will become rebate dollars are termed "excess revenue." Excess revenue amounts have to be "returned" to beneficiaries in the form of extra benefits, reduced cost sharing, or reduced premiums for basic or mandatory supplemental benefits—that is, a benefit spread over the entire enrolled population. Excess revenue cannot be used to reduce an optional supplemental premium that beneficiaries can decline to pay. Although the statute governing the use of savings beginning in 2006 states that each enrollee is entitled to a rebate of 75 percent of savings (1854(b)(1)(C)), which can be applied as a credit "toward an MA monthly supplemental beneficiary premium (if any)," the statute is silent on the question of whether in 2006 rebates may be applied to optional supplemental packages. One could infer that such a use of rebate dollars is permitted because there is no specific statutory prohibition.

As explained in the preamble, we do not believe that applying a rebate to an optional supplemental benefit is consistent with the requirement that each beneficiary enrolled in a plan is entitled to the same dollar value of the rebate ("the MA plan shall provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings" (1854(b)(1)(C)). (There could be an administratively cumbersome way of permitting the use of rebate dollars to optional supplemental premiums. Because enrollees can decline an optional package, enrollees would have to have an alternative option, or a menu of options to choose from, to fully allocate the individual rebate. For example, if the rebate amount was $50 per month, and an optional supplement was offered at $25, enrollees choosing the supplement would have to dispose of $25 (for example, by a reduction in the Part B premium), and those who decline would have to dispose of $50 (for example, by a $50 reduction in the

Part B premium). We believe, however, that this would present overly burdensome administrative problems for health plans as well as for CMS and the Social Security Administration if there were variable Part B premium rates at the sub-plan level. Rather than relying on the plan identifier to determine the appropriate premium reduction amount, each person's record would have to carry the premium reduction information.)

4. Intra-Area Geographic Adjustment to Payments

In addition to the discussion in the preamble of the adjustment for intra-area variation, which the statute says "shall" be applied to bids and benchmarks, we would note that the statute and the conference report refer only to adjustments to reflect "variations in MA local payment rates," for both local and regional plans. A literal interpretation of the language would entail using only the MA payment rates as the basis for making adjustments to bids and benchmarks. Clearly, although for local plans it may be appropriate to use a benchmark adjustment based on variation in local MA payment rates, for a regional plan such an adjustment to the benchmark is problematic because the benchmarks for regional plans include plan bids as a component of the benchmark. Hence, we believe a strictly literal interpretation is not consistent with the Medicare Advantage bidding and payment process.

The initial bid for a multi-county local plan or for a regional plan assumes a certain mix of enrollees from different parts of the geographic area. The plan presents a single average bid that covers its revenue needs for the population that it assumes will enroll in the plan. If the plan's enrollment mix is from a different geographic area with substantially different costs, the plan's initial bid will either be higher or lower than its actual revenue needs. The plan's costs may not bear a direct relation to Medicare payment rates in a county—particularly if the county rate is historically a "floor" rate (and even when the county rate is based on Medicare fee-for-service rates the payment rate may not represent plan costs, as is clear from the present pattern of extra benefits available to enrollees in MA plans).

The preamble mentions possible ways to ensure that there is an appropriate intra-area adjustment, and seeks public comment on the different options. The suggested approaches seek to establish a relative relationship among the counties in the areas in question, though each is an imprecise measure for purposes of adjusting the bid. For example, in the same way that local Medicare fee-for-service expenditures may not reflect plan revenue needs in a given county, using the relationship between a county's Medicare fee-for-service expenditures and national expenditures, as the preamble suggests, may also not accurately reflect the variation that health plans see in their costs. Using only input prices, as is also suggested, of course ignores utilization differences (practice patterns, beneficiary preferences, the mix of services) that may appropriately be a component of the costs that plans face in a given county.

Another option that we had considered is to have plans themselves provide CMS with the plan's statement of the relationship among counties (or broader geographic area) with regard to the relative revenue needs for each area. CMS would then use the plan's statement of relative costs to make intra-area adjustments. This approach may also be somewhat imprecise in that a plan's revenue needs in a given county may vary with the size of enrollment (for example, a large enrollment base in a county may enable a plan to secure more favorable contracting arrangements from providers, thereby lowering plan costs).

M. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 12 we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of Title II of the MMA that are the subject of this regulation. All expenditures are classified as transfers to either beneficiaries or health plans. The table provides our best estimate of the dollar amount of these transfers, expressed in 2001 dollars, at three percent and seven percent discount rates.

TABLE 12.—ACCOUNTING STATEMENT: CLASSIFICATION OF EXPENDITURES, 2004 THROUGH 2009

[Dollars in millions, discounted to 2001 present value]

Transfers	
Three Percent Annual Discount Rate.	
Annualized Monetized Transfers: "On Budget".	19,083.
From Whom To Whom?.	Federal Government To Private Plans.
Annualized Monetized Transfers: "On Budget".	1,659.
From Whom To Whom?.	Federal Government To Medicare Beneficiaries.
Seven Percent Annual Discount Rate.	
Annualized Monetized Transfers: "On Budget".	15,232.
From Whom To Whom?.	Federal Government To Private Plans
Annualized Monetized Transfers: "On Budget".	1,325.
From Whom To Whom?.	Federal Government To Medicare Beneficiaries.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

1. The authority citation for part 417 continues to read as follows:

Authority: Sec. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

Subpart J—Qualifying Conditions for Medicare Contracts

2. Amend § 417.402 by—

A. Revising paragraph (b).

B. Adding paragraph (c).

The revision and addition read as follows:

§ 417.402 Effective date of initial regulations.

* * * * *

(b) No new cost contracts are accepted by CMS. CMS will, however, accept and approve applications to modify cost contracts in order to expand service areas, provided they are submitted on or before September 1, 2006, and CMS determines that the organization continues to meet regulatory requirements and the requirements in its cost contract. Section 1876 cost contracts will not be extended or renewed beyond December 31, 2007, where conditions in paragraph (c) of this section are present.

(c) *Mandatory HMO or CMP service area reduction and contract non-renewal.* CMS will non-renew all or a portion of an HMO's or CMP's service area using procedures in § 417.492(b) for any period beginning on or after January 1, 2008, where—

(1) There were two or more coordinated care plan-model MA regional plans in the same service area or portion of a service area for the entire previous year meeting one of the conditions in paragraph (c)(3) of this section; or

(2) There were two or more coordinated care plan-model MA local plans in the same service area or portion of a service area for the entire previous year meeting one of the conditions in paragraph (c)(3) of this section.

(3) *Minimum enrollment requirements.* (i) With respect to any service area or portion of a service area that is within a Metropolitan Statistical Area with a population of more than 250,000 and counties contiguous to the Metropolitan Statistical Area, 5,000 enrolled individuals.

(ii) With respect to any service area or portion of a service area that is not within a Metropolitan Statistical Area described in paragraph (c)(3)(i) of this section, 1,500 individuals.

Subpart Q—Beneficiary Appeals

3. Section 417.600 is revised to read as follows:

§ 417.600 Basis and scope.

(a) *Statutory basis.* (1) Section 1869 of the Act provides the right to a redetermination, reconsideration, hearing, and judicial review for individuals dissatisfied with a determination regarding their Medicare benefits.

(2) Section 1876 of the Act provides for Medicare payments to HMOs and CMPs that contract with CMS to enroll Medicare beneficiaries and furnish Medicare-covered health care services to them.

(3) Section 234 of the MMA requires section 1876 contractors to operate under the same provisions as MA plans where two plans of the same type enter the cost contract's service area.

(b) *Applicability.* (1) The rights, procedures, and requirements relating to beneficiary appeals and grievances set forth in subpart M of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(2) In applying those provisions, references to section 1852 of the Act must be read as references to section 1876 of the Act, and references to MA organizations as references to HMOs and CMPs.

§ 417.602 through § 417.638 [Removed]

4. Sections 417.602 through 417.638 are removed.

Subpart U—Health Care Prepayment Plans

5. Section 417.840 is revised to read as follows:

§ 417.840 Administrative review procedures.

The HCPP must apply § 422.568 through § 422.619 of this chapter to organization determinations that affect its Medicare enrollees, and to reconsiderations, hearings, Medicare Appeals Council review, and judicial review of those organization determinations.

PART 422—MEDICARE ADVANTAGE PROGRAM

6. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

7. Revise the heading of Part 422 to read as set forth above.

Subpart A—General Provisions

8. Amend § 422.1(a) by adding the following statutory basis in numerical order:

§ 422.1 Basis and scope.

(a) * * *

1858—Special rules for MA Regional Plans.

* * * * *

9. Amend § 422.2 by—

A. Removing the definitions of "ACR," "Additional benefits," "Adjusted community rate," and "M+C."

B. Revising the definitions of "Basic benefits," "Benefits," "Mandatory supplemental benefits," and "Service area."

C. Adding the definitions of "Institutionalized," "MA," "MA local area," "MA local plan," "MA-Prescription Drug Plan," "MA regional plan," "Prescription drug plan (PDP)," "Prescription drug plan (PDP) sponsor," "Special needs individual," and "Specialized MA plans."

D. Nomenclature change: In the definitions of "M+C eligible individual," "M+C organization," "M+C plan," and "M+C plan enrollee," every occurrence of "M+C" is removed and "MA" is added in its place.

The revisions and additions read as follows:

§ 422.2 Definitions.

* * * * *

Basic benefits means all Medicare-covered benefits (except hospice services).

Benefits means health care services that are intended to maintain or improve the health status of enrollees, for which the MA organization incurs a cost or liability under an MA plan (not solely an administrative processing cost). Benefits are submitted and approved through the annual bidding process.

* * * * *

Institutionalized means for the purpose of defining a special needs individual, an MA eligible individual who continuously resides in a long-term care facility for 90 days or longer, as determined by the presence of a 90-day assessment in the Minimum Data Set (MDS).

* * * * * *

MA stands for Medicare Advantage.

MA local area is defined in § 422.252.

MA local plan means an MA plan that is not an MA regional plan.

MA-Prescription Drug (PD) Plan means an MA plan that provides qualified prescription drug coverage under Part D of the Social Security Act.

MA regional plan means a coordinated care plan structured as a preferred provider organization (PPO) that serves one or more entire regions. An MA regional plan must have a network of contracting providers that have agreed to a specific reimbursement for the plan's covered services and must pay for all covered services whether provided in or out of the network.

* * * * *

Mandatory supplemental benefits means health care services not covered by Medicare that an MA enrollee must purchase as part of an MA plan. The benefits may include reductions in cost-sharing for benefits under the original Medicare fee-for-service program and are paid for in the form of premiums and cost-sharing, or by an application of the beneficiary rebate rule in section 1854(b)(1)(C)(ii)(I) of the Act, or both.

* * * * *

Prescription drug plan (PDP) means approved prescription drug coverage that is offered under a policy, contract, or plan that has been approved as meeting the requirements specified in part 423 of this chapter and that is offered by a MA organization that has a contract with CMS that meets the contract requirements under part 423 of this chapter and does not include a fallback plan unless specifically identified as a prescription drug plan.

Prescription drug plan (PDP) sponsor means a nongovernmental entity that is certified under part 423 of this chapter as meeting the requirements and standards of that part for that sponsor.

* * * * *

Service area means a geographic area that for local MA plans is a county or multiple counties, and for MA regional plans is a region approved by CMS within which an MA-eligible individual may enroll in a particular MA plan offered by an MA organization. Each MA plan must be available to all MA-eligible individuals within the plan's service area. In deciding whether to approve an MA plan's proposed service area, CMS considers the following criteria:

(1) For local MA plans:

(i) Whether the area meets the "county integrity rule" that a service area generally consists of a full county or counties. However, CMS may approve a service area that includes only a portion of a county if it determines that the "partial county" area is necessary, nondiscriminatory, and in the best interests of the beneficiaries.

(ii) The extent to which the proposed services area mirrors service areas of existing commercial health care plans or MA plans offered by the organization.

(iii) For MA coordinated care plans and network MA MSA plans, whether the contracting provider network meets the access and availability standards set forth in § 422.112. Although not all contracting providers must be located within the plan's service area, CMS must determine that all services covered under the plan are accessible from the service area.

(iv) For non-network MA MSA plans, CMS may approve single county non-network MA MSA plans even if the MA organization's commercial plans have multiple county service areas.

(2) For MA regional plans, whether the service area consists of the entire region.

Special needs individual means an MA eligible individual who is institutionalized, as defined above, is entitled for Medicaid under title XIX, or has severe or disabling chronic condition(s) and would benefit from enrollment in a specialized MA based on criteria established by CMS.

Specialized MA Plans means any type of MA coordinated care plan that exclusively enrolls special needs individuals.

10. Amend § 422.4 by—

A. Revising the section heading.

B. Revising paragraph (a)(1)(iii).

C. Redesignating paragraph (a)(1)(iv) as paragraph (a)(1)(v).

D. Adding a new paragraph (a)(1)(iv).

E. Revising newly redesignated paragraph (a)(1)(v).

F. Removing paragraph (a)(2)(ii).

G. Redesignating paragraph (a)(2)(iii) as paragraph (a)(2)(ii).

The revisions and additions read as follows:

§ 422.4 Types of MA plans.

(a) *General rule.* * * *

(1) *A coordinated care plan.* * * *

(iii) Coordinated care plans include plans offered by health maintenance organizations (HMOs), provider-sponsored organizations (PSOs), regional or local preferred provider organizations (PPOs) as specified in paragraph (a)(1)(v) of this section, RFBs, and other network plans (except network MSA and PFFS plans).

(iv) A specialized MA plan includes any type of coordinated care plan that exclusively enrolls special needs individuals as defined in § 422.2.

(v) A PPO plan is a plan that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and, only for purposes of quality assurance requirements in § 422.152(e), is offered by an organization that is not licensed or organized under State law as an HMO.

* * * * *

§ 422.6 [Removed]

11. Remove § 422.6.

§ 422.8 [Removed]

12. Remove § 422.8.

§ 422.10 [Redesignated and Amended]

13. Redesignate § 422.10 as § 422.6 and amend newly redesignated § 422.6 by—

a. Revising the section heading.

b. Revising paragraph (a).

c. Revising paragraph (b).

d. Revising paragraph (d)(2)(ii).

e. Revising paragraph (e).

f. Revising paragraph (f)(1).

g. Revising paragraph (f)(2)

h. Revising paragraph (f)(3).

The revisions read as set forth below:

§ 422.6 Cost-sharing in enrollment-related costs (MA user fee).

(a) *Basis and scope.* This section implements that portion of section 1857 of the Act that pertains to cost-sharing in enrollment-related costs. It sets forth the procedures that CMS follows to determine the aggregate annual "user fee" to be contributed by MA organizations and PDP sponsors under Medicare Part D and to assess the required user fees for each MA plan offered by MA organizations and PDP sponsors.

(b) *Purpose of assessment.* Section 1857(e)(2) of the Act authorizes CMS to charge and collect from each MA plan offered by an MA organization its pro rata share of fees for administering section 1851 of the Act (relating to dissemination of enrollment information), and section 4360 of the Omnibus Budget Reconciliation Act of 1990 (relating to the health insurance counseling and assistance program) and section 1860D–1(c) of the Act (relating to dissemination of enrollment information for the drug benefit).

* * * * *

(d) *Collection of fees.* * * *

(2) *Amount to be collected.* * * *

(ii) For fiscal year 2006 and each succeeding year, $200 million, the applicable portion (as defined in paragraph (e) of this section) of $200 million.

(e) *Applicable portion.* In this section, the term "applicable portion" with respect to an MA plan means, for a fiscal year, CMS' estimate of Medicare Part C and D expenditures for those MA organizations as a percentage of all expenditures under title XVIII and with respect to PDP sponsors, the applicable portion is CMS' estimate of Medicare Part D prescription drug expenditures for those PDP sponsors as a percentage of all expenditures under title XVIII.

(f) *Assessment methodology.* (1) The amount of the applicable portion of the user fee each MA organization and PDP sponsor must pay is assessed as a percentage of the total Medicare payments to each organization. CMS determines the annual assessment

percentage rate separately for MA organizations and for PDPs using the following formula:

(i) The assessment formula for MA organizations (including MA–PD plans):

C divided by A times B where—

A is the total estimated January payments to all MA organizations subject to the assessment;

B is the 9-month (January through September) assessment period; and

C is the total fiscal year MA organization user fee assessment amount determined in accordance with paragraph (d)(2) of this section.

(ii) The assessment formula for PDPs:

A is the total estimated January payments to all PDP sponsors subject to the assessment;

B is the 9-month (January through September) assessment period; and

C is the total fiscal year PDP sponsor's user fee assessment amount determined in accordance with paragraph (d)(2) of this section.

(2) CMS determines each MA organization's and PDP sponsor's pro rata share of the annual fee on the basis of the organization's calculated monthly payment amount during the 9 consecutive months beginning with January. CMS calculates each organization's monthly pro rata share by multiplying the established percentage rate by the total monthly calculated Medicare payment amount to the organization as recorded in CMS' payment system on the first day of the month.

(3) CMS deducts the organization's fee from the amount of Federal funds otherwise payable to the MA organization or PDP sponsor for that month.

* * * * *

Subpart B—Eligibility, Election, and Enrollment

14. Amend § 422.50 by—

A. Revising the section heading.

B. Adding an introductory text.

C. Revising paragraph (a)(5).

The revisions and addition read as follows:

§ 422.50 Eligibility to elect an MA plan.

For this subpart, all references to an MA plan include MA–PD and both MA local and MA regional plans, as defined in § 422.4 unless specifically noted otherwise.

(a) * * *

(5) Completes and signs an election form or another CMS approved election method and gives information required for enrollment; and

* * * * *

15. Add § 422.52 to read as follows:

§ 422.52 Eligibility to elect an MA plan for special needs individuals.

(a) *General rule.* To elect an MA plan for special needs individuals, an individual must meet eligibility requirements specified in this section.

(b) *Basic eligibility requirements.* To be eligible to elect a special needs MA plan, an individual must meet the eligibility requirements for that plan, as well as MA as described in § 422.50. Further, the individual must—

(1) Be institutionalized in a Medicare or Medicaid certified institution as defined by CMS; or

(2) Be entitled to medical assistance under a State plan under title XIX of the Act; or

(3) Meet other eligibility requirements established by CMS to identify individuals who would benefit from enrollment in such a specialized MA plan.

(c) CMS may waive § 422.50(a)(2) that excludes persons with ESRD.

(d) *Deeming continued eligibility.* If a special needs MA plan determines that the enrollee no longer meets the eligibility criteria, but it is reasonable to expect that, in the absence of continued coverage under the MA plan, the individual would meet the special needs criteria of the plan within a certain period of time, as specified by CMS, the enrollee may be deemed to continue to be eligible for the MA plan.

(e) *Exceptions.* As specified in § 422.4, CMS may designate certain MA plans that disproportionately serve special needs beneficiaries as "specialized" MA plans for special needs individuals. If CMS provides the designation:

(1) Individuals already enrolled in an MA plan that CMS subsequently designates as a special needs MA plan may continue to be enrolled in the plan.

(2) The MA plan may restrict future enrollment to only certain specialized needs individuals, as established under § 422.4.

16. Amend § 422.54 by—

A. Revising the section heading.

B. Revising paragraph (a).

C. Revising paragraph (b).

D. Revising paragraph (c)(1)(ii).

E. Revising paragraph (c)(2).

F. Revising paragraph (d)(3).

The revisions read as follows:

§ 422.54 Continuation of enrollment for MA local plans.

(a) *Definition.* Continuation area means an additional area (outside the service area) within which the MA organization offering a local plan furnishes or arranges to furnish services to its continuation-of-enrollment enrollees. Enrollees must reside in a continuation area on a permanent basis. A continuation area does not expand the service area of any MA local plan.

(b) *Basic rule.* An MA organization may offer a continuation of enrollment option to MA local plan enrollees when they no longer reside in the service area of a plan and permanently move into the geographic area designated by the MA organization as a continuation area. The intent to no longer reside in an area and permanently live in another area is verified through documentation that establishes residency, such as a driver's license or voter registration card.

(c) * * *

(1) * * *

(ii) Describe the option(s) in the member materials it offers and make the option available to all MA local plan enrollees residing in the continuation area.

(2) An enrollee who moves out of the service area and into the geographic area designated as the continuation area has the choice of continuing enrollment or disenrolling from the MA local plan. The enrollee must make the choice of continuing enrollment in a manner specified by CMS. If no choice is made, the enrollee must be disenrolled from the plan.

(d) * * *

(3) *Reasonable cost sharing.* For services furnished in the continuation area, an enrollee's cost-sharing liability is limited to the cost-sharing amounts required in the MA local plan's service area (in which the enrollee no longer resides).

* * * * *

17. Amend § 422.56 by—

A. Revising the section heading.

B. Revising paragraph (a).

C. Revising paragraph (b).

The revisions read as follows:

§ 422.56 Enrollment in an MA MSA plan.

(a) *General.* An individual is not eligible to elect an MA MSA plan unless the individual provides assurances that are satisfactory to CMS that he or she will reside in the United States for at least 183 days during the year for which the election is effective.

(b) *Individuals eligible for or covered under other health benefits program.* Unless otherwise provided by the Secretary, an individual who is enrolled in a Federal Employee Health Benefit plan under 5 U.S.C. chapter 89, or is eligible for health care benefits through the Veteran's Administration under 10 U.S.C. chapter 55 or the Department of Defense under 38 U.S.C. chapter 17, may not enroll in an MA MSA plan.

* * * * *

18. Amend § 422.60 by—

A. Revising paragraph (b)(1).
B. Revising paragraph (b)(3).
C. Revising the heading of paragraph (c).
D. Revising paragraph (c)(1).
E. Revising paragraph (d).
F. Revising paragraph (e).
G. Revising paragraph (f)(1).
H. Revising paragraph (f)(3).
The revisions read as follows:

§ 422.60 Election process.

* * * * *

(b) *Capacity to accept new enrollees.* (1) MA organizations may submit information on enrollment capacity of plans.

* * * * *

(3) CMS considers enrollment limit requests for an MA plan service area, or a portion of the plan service area, only if the health and safety of beneficiaries is at risk, such as if the provider network is not available to serve the enrollees in all or a portion of the service area.

(c) *Election forms and other election mechanisms.* (1) The election must comply with CMS instructions regarding content and format and have been approved by CMS as described in § 422.80. The election must be completed by the MA eligible individual (or the individual who will soon become eligible to elect an MA plan) and include authorization for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services and its designees and the MA organization. Persons who assist beneficiaries in completing forms must sign the form, or through other approved mechanisms, indicate their relationship to the beneficiary.

* * * * *

(d) *When an election is considered to have been made.* An election in an MA plan is considered to have been made on the date the completed election is received by the MA organization.

(e) *Handling of elections.* The MA organization must have an effective system for receiving, controlling, and processing elections. The system must meet the following conditions and requirements:

(1) Each election is dated as of the day it is received in a manner acceptable to CMS.

(2) Elections are processed in chronological order, by date of receipt.

(3) The MA organization gives the beneficiary prompt notice of acceptance or denial in a format specified by CMS.

(4) If the MA plan is enrolled to capacity, it explains the procedures that will be followed when vacancies occur.

(5) Upon receipt of the election, or for an individual who was accepted for future enrollment from the date a vacancy occurs, the MA organization transmits, within the timeframes specified by CMS, the information necessary for CMS to add the beneficiary to its records as an enrollee of the MA organization.

(f) *Exception for employer group health plans.* (1) In cases in which an MA organization has both a Medicare contract and a contract with an employer group health plan, and in which the MA organization arranges for the employer to process elections for Medicare-entitled group members who wish to enroll under the Medicare contract, the effective date of the election may be retroactive. Consistent with § 422.250(b), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

* * * * *

(3) Upon receipt of the election from the employer, the MA organization must submit the enrollment within timeframes specified by CMS.

§ 422.62 [Amended]

19. Amend § 422.62 by—
A. Revising the section heading.
B. Revising paragraph (a).
C. Revising paragraph (b) introductory text.
D. Revising the heading of paragraph (d).
E. Revising paragraph (d)(1).
F. Removing paragraph (d)(2)(i)(A).
G. Redesignating paragraph (d)(2)(i)(B) as paragraph (d)(2)(i)(A).
H. Redesignating paragraph (d)(2)(i)(C) as paragraph (d)(2)(i)(B).
The revisions and addition read as follows:

§ 422.62 Election of coverage under an MA plan.

(a) *General: Coverage election periods—(1) Initial coverage election period for MA.* The initial coverage election period is the period during which a newly MA-eligible individual may make an initial election. This period begins 3 months before the month the individual is first entitled to both Part A and Part B and ends on the later of—

(i) The last day of the month preceding the month of entitlement; or

(ii) If after May 15, 2006, the last day of the individual's Part B initial enrollment period.

(2) *Annual coordinated election period.* (i) Beginning with 2002, the annual coordinated election period for the following calendar year is November 15th through December 31st, except for 2006.

(ii) For 2006, the annual coordinated election period begins on November 15, 2005 and ends on May 15, 2006.

(iii) During the annual coordinated election period, an individual eligible to enroll in an MA plan may change his or her election from an MA plan to original Medicare or to a different MA plan, or from original Medicare to an MA plan. If an individual changes his or her election to original Medicare, he or she may also elect a PDP.

(3) *Open enrollment and disenrollment opportunities through 2005.* Through 2005, the number of elections or changes that an MA eligible individual may make is not limited (except as provided for in paragraph (d) of this section for MA MSA plans). Subject to the MA plan being open to enrollees as provided under § 422.60(a)(2), an individual eligible to elect an MA plan may change his or her election from an MA plan to original Medicare or to a different MA plan, or from original Medicare to an MA plan.

(4) *Open enrollment and disenrollment during 2006.* (i) Except as provided in paragraphs (a)(4)(ii), (a)(4)(iii), and (a)(6) of this section, an individual who is not enrolled in an MA plan, but who is eligible to elect an MA plan in 2006, may elect an MA plan only once during the first 6 months of the year.

(A) An individual who is enrolled in an MA–PD plan may elect another MA–PD plan or original Medicare and coverage under a PDP. Such an individual may not elect an MA plan that does not provide qualified prescription drug coverage.

(B) An individual who is enrolled in an MA plan that does not provide qualified prescription drug coverage may elect another MA plan that does not provide that coverage or original Medicare. Such an individual may not elect an MA–PD plan or coverage under a PDP.

(ii) *Newly eligible MA individual.* An individual who becomes MA eligible during 2006 may elect an MA plan or change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the 6th month of the entitlement, or on December 31, whichever is earlier, subject to the limitations in paragraphs (a)(4)(i)(A) and (a)(4)(i)(B) of this section.

(5) *Open enrollment and disenrollment beginning in 2007.* (i) For 2007 and subsequent years, except as provided in paragraphs (a)(5)(ii), (a)(5)(iii), and (a)(6) of this section, an individual who is not enrolled in an MA plan but is eligible to elect an MA plan

may make an election into an MA plan once during the first 3 months of the year.

(A) An individual who is enrolled in an MA–PD plan may elect another MA–PD plan or original Medicare and coverage under a PDP. Such an individual may not elect an MA plan that does not provide qualified prescription drug coverage.

(B) An individual who is enrolled in an MA plan that does not provide qualified prescription drug coverage may elect another MA plan that does not provide that coverage or original Medicare. Such an individual may not elect an MA–PD plan or coverage under a PDP.

(ii) *Newly eligible MA individual.* An individual who becomes MA eligible during 2007 or later may elect an MA plan or change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the 3rd month of the entitlement, or on December 31, whichever is earlier subject to the limitations in paragraphs (a)(5)(i)(A) and (a)(5)(i)(B) of this section.

(6) *Open enrollment period for institutionalized individuals.* After 2005, an individual who is eligible to elect an MA plan and who is institutionalized, as defined by CMS, is not limited (except as provided for in paragraph (d) of this section for MA MSA plans) in the number of elections or changes he or she may make. Subject to the MA plan being open to enrollees as provided under § 422.60(a)(2), an MA eligible institutionalized individual may at any time elect an MA plan or change his or her election from an MA plan to original Medicare, to a different MA plan, or from original Medicare to an MA plan.

(b) *Special election periods.* An individual may at any time (that is, not limited to the annual election period) discontinue the election of an MA plan offered by an MA organization and change his or her election, in the form and manner specified by CMS, from an MA plan to original Medicare or to a different MA plan under any of the following circumstances:

* * * * *

(d) *Special rules for MA MSA plans—(1) Enrollment.* An individual may enroll in an MA MSA plan only during an initial or annual election period described in paragraphs (a)(1) and (a)(2) of this section.

* * * * *

20. Amend § 422.66 by—

A. Revising the section heading.

B. Revising paragraph (b)(1)(i).

C. Revising paragraph (b)(1)(ii).

D. Revising paragraph (b)(3)(ii).

E. Revising paragraph (b)(3)(iii) introductory text.

F. Revising paragraph (d)(5).

G. Revising paragraph (e).

H. Revising paragraph (f)(2).

The revisions and additions read as follows:

§ 422.66 Coordination of enrollment and disenrollment through MA organizations.

* * * * *

(b) * * *

(1) * * *

(i) Elect a different MA plan by filing the appropriate election with the MA organization.

(ii) Submit a request for disenrollment to the MA organization in the form and manner prescribed by CMS or file the appropriate disenrollment request through other mechanisms as determined by CMS.

* * * * *

(3) * * *

(ii) Provide enrollee with notice of disenrollment in a format specified by CMS; and

(iii) In the case of a plan where lock-in applies, include in the notice a statement explaining that he or she—

* * * * *

(d) * * *

(5) *Election.* The individual who is converting must complete an election as described in § 422.60(c)(1).

* * * * *

(e) *Maintenance of enrollment.* (1) An individual who has made an election under this section is considered to have continued to have made that election until either of the following, which ever occurs first:

(i) The individual changes the election under this section.

(ii) The elected MA plan is discontinued or no longer serves the area in which the individual resides, the organization does not offer, or the individual does not elect, the option of continuing enrollment, as provided under § 422.54(b)(3)(ii).

(2) An individual who has elected an MA plan that does not provide prescription drug coverage will not be deemed to have elected an MA–PD plan.

(3) An individual enrolled in an MA plan that, as of December 31, 2005, offers any prescription drug coverage will be deemed to have elected an MA–PD plan offered by the same organization as of January 1, 2006.

(4) If an individual is enrolled with an MA organization that in 2005 offers more than one MA plan that includes drug coverage; the MA plan in which the individual is enrolled as of December 31, 2005 includes drug coverage; and that MA plan becomes an MA–PD plan on January 1, 2006, the individual will be deemed to have elected to enroll in that MA–PD plan.

(5) An individual enrolled in an MA–PD plan as of December 31 of a year is deemed to have elected to remain enrolled in that plan on January 1 of the following year.

(f) * * *

(2) Upon receipt of the election from the employer, the MA organization must submit a disenrollment notice to CMS within timeframes specified by CMS.

21. Amend § 422.68 by revising paragraph (b) to read as follows:

§ 422.68 Effective dates of coverage and change of coverage.

* * * * *

(b) *Annual election periods.* For an election or change of election made during an annual election period as described in § 422.62(a)(2), coverage is effective as of the first day of the following calendar year except that for the special annual election period described in § 422.62(a)(2)(ii), elections made after December 31, 2005 through May 15, 2006 are effective as of the first day of the first calendar month following the month in which the election is made.

* * * * *

22. Amend § 422.74 by—

A. Revising the section heading.

B. Revising paragraph (b)(1)(ii).

C. Revising paragraph (c)(1).

D. Revising paragraph (d)(1).

E. Revising paragraph (d)(2).

The revisions read as follows:

§ 422.74 Disenrollment by the Medicare Advantage Organization.

* * * * *

(b) * * *

(1) * * *

(ii) The individual has engaged in disruptive or threatening behaviors specified at paragraph (d)(2) of this section.

* * * * *

(c) * * *

(1) Be provided to the individual before submission of the disenrollment transaction to CMS; and

* * * * *

(d) *Process for disenrollment*—(1) *Monthly basic and supplementary premiums are not paid timely.* An MA organization may disenroll an individual from the MA plan for failure to pay basic and supplementary premiums under the following circumstances:

(i) The MA organization can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount.

(ii) The MA organization provides the enrollee with notice of disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) If the enrollee fails to pay the premium for optional supplemental benefits but pays the basic premium and any mandatory supplemental premium, the MA organization has the option to discontinue the optional supplemental benefits and retain the individual as an MA enrollee.

(2) *Disruptive or threatening behavior*—(i) *Basis for disenrollment.* An MA organization may disenroll an individual from the MA plan if the individual's behavior is disruptive, unruly, abusive, uncooperative, or threatening. Disruptive behavior may not be based upon the use of medical services or noncompliance with medical advice. An individual who engages in disruptive or threatening behavior refers to an individual who exhibits any of the following:

(A) An individual whose behavior jeopardizes his or her health or safety, or the safety of others;

(B) An individual whose behavior impairs the MA's ability to furnish services to either the individual or other individuals enrolled in the plan; or

(C) An individual with decision-making capacity who refuses to comply with the terms of the enrollment agreement.

(ii) *Effort to resolve the problem.* The MA organization must make a serious effort to resolve the problems presented by the individual, including the use (or attempted use) of the MA organization's grievance procedures. The beneficiary has a right to submit any information or explanation that he or she may wish to submit to the MA organization.

(iii) *Documentation.* The MA organization must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraphs (d)(2)(i) through (d)(2)(ii) of this section and any extenuating circumstances.

(iv) *CMS review of the proposed disenrollment.* CMS will decide after reviewing the documentation submitted by the MA organization and any information submitted by the beneficiary (which the MA organization must forward to CMS) whether the MA organization has met the criteria for disenrollment for disruptive or threatening behavior. CMS will make the decision within 20 working days after receipt of the documentation and will notify the MA organization within 5 working days after making its decision.

(v) *Effective date of disenrollment.* If CMS permits an MA organization to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the MA organization gives the individual notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(vi) *Reenrollment in the MA organization.* Once an individual is disenrolled from the MA organization for disruptive behavior, the MA organization has the option to decline future enrollment by the individual for a period of time specified by CMS.

(vii) *Expedited process.* In the event that an individual's disruptive or threatening behavior is so extreme as to have caused harm to others or prevented the MA plan from providing services, CMS may consider allowing an expedited disenrollment process.

* * * * *

23. Amend § 422.80 by—

A. Revising paragraph (a)(2).

B. Adding paragraph (a)(3).

C. Revising paragraph (e)(1)(ii).

D. Revising paragraph (e)(1)(iii).

E. Revising paragraph (e)(1)(iv).

F. Revising paragraph (e)(1)(v).

G. Adding paragraph (e)(1)(ix).

The revisions and additions read as follows:

§ 422.80 Approval of marketing materials and election forms.

(a) * * *

(1) * * *

(2) CMS does not disapprove the distribution of new material or form; or

(3) If the MA plan is deemed by CMS to meet certain performance requirements established by CMS, the MA plan may distribute designated marketing materials 5 days following their submission to CMS.

* * * * *

(e) * * *

(1) * * *

(ii) Engage in any discriminatory activity, including targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(iii) Solicit Medicare beneficiaries door-to-door.

(iv) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the MA organization. The MA organization may not claim it is recommended or endorsed by CMS or Medicare or the Department of Health and Human Services or that CMS or Medicare or the Department of Health and Human Services recommends that the beneficiary enroll in the MA plan. It may, however, explain that the organization is approved for participation in Medicare.

(v) Distribute marketing materials for which, before expiration of the 45-day period (or 10 days as provided in paragraph (a)(1) of this section), the MA organization receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the MA organization, its marketing representatives, or CMS.

* * * * *

(ix) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

* * * * *

Subpart C—Benefits and Beneficiary Protections

§ 422.100 [Amended]

24. Amend § 422.100 by—

A. Revising paragraph (b)(2).

B. Revising paragraph (c)(1).

C. Removing paragraph (e).

D. Redesignating paragraph (f) as paragraph (e).

E. Redesignating paragraph (g) as paragraph (f).

F. Redesignating paragraph (h) as paragraph (g).

G. Redesignating paragraph (i) as paragraph (h).

H. Redesignating paragraph (j) as paragraph (i).

I. Revising the heading of newly redesignated paragraph (f).

J. Revising newly redesignated paragraph (f) introductory text.

K. Revising newly redesignated paragraph (f)(2).

The revisions read as follows:

Subpart C—Benefits and Beneficiary Protections

§ 422.100 General requirements.

* * * * *

(b) * * *

(2) An MA plan (and an MA MSA plan, after the annual deductible in § 422.103(d) has been met) offered by an MA organization satisfies paragraph (a) of this section with respect to benefits for services furnished by noncontracting provider if that MA plan provides payment in an amount the provider would have received under original Medicare (including balance billing permitted under Medicare Part A and Part B).

* * * * *

(c) * * *

(1) Basic benefits are all Medicare-covered services, expect hospice services.

* * * * *

(f) *CMS review and approval of MA benefits.* CMS reviews and approves MA

benefits using written policy guidelines and requirements in this part and other CMS instructions to ensure that—

* * * * *

(2) MA organizations are not designing benefits to discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services; and

* * * * *

25. Amend § 422.101 by—

A. Revising paragraph (b)(2).

B. Adding paragraph (b)(4).

C. Adding paragraph (d).

D. Adding paragraph (e).

The revision and additions read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(b) * * *

(2) General coverage guidelines included in original Medicare manuals and instructions unless superseded by regulations in this part or related instructions; and

* * * * *

(4) Instead of applying rules in paragraph (b)(3) of this section, an organization offering an MA regional plan may elect to have any local coverage determination that applies in any part of an MA region apply to all parts of that same MA region. The election is at the discretion of the MA regional plan and is not subject to CMS pre-approval.

* * * * *

(d) *Special cost-sharing rules for MA regional plans.* In addition to the requirements in paragraph (a) through paragraph (c) of this section, MA regional plans must provide for the following:

(1) *Single deductible.* MA regional plans, to the extent they apply a deductible, are permitted to have only a single deductible related to combined Medicare Part A and Part B services. Applicability of the single deductible may be differential for specific in-network services and may also be waived for preventative services or other items and services.

(2) *Catastrophic limit.* MA regional plans are required to provide for a catastrophic limit on beneficiary out-of-pocket expenditures for in-network benefits under the original Medicare fee-for-service program (Part A and Part B benefits).

(3) *Additional catastrophic limit.* MA regional plans are required to provide an additional catastrophic limit on beneficiary out-of-pocket expenditures for in-network and out-of-network benefits under the original Medicare fee-for-service program. This second out-of-pocket catastrophic limit, which would apply to both in-network and out-of-network benefits under original Medicare, may be higher than the in-network catastrophic limit in paragraph (d)(2) of this section, but may not increase the limit described in paragraph (d)(2) of this section.

(4) *Tracking of deductible and catastrophic limits and notification.* MA regional plans are required to track the deductible (if any) and catastrophic limits in paragraphs (d)(1) through (d)(3) of this section based on incurred out-of-pocket beneficiary costs for original Medicare covered services, and are also required to notify members when the deductible (if any) or a limit has been reached.

(e) *Other rules for MA regional plans.* (1) MA regional plans are required to provide reimbursement for all covered benefits, regardless of whether those benefits are provided within or outside of the network of contracted providers.

(2) In applying the actuarially equivalent level of cost-sharing with respect to MA bids related to benefits under the original Medicare program option as set forth at § 422.308, only the catastrophic limit on out-of-pocket expenses for in-network benefits in paragraph (d)(2) of this section will be taken into account.

26. Amend § 422.102 by—

A. Revising paragraph (a)(1).

B. Revising paragraph (a)(3).

C. Adding paragraph (a)(4).

The revisions and addition read as follows:

§ 422.102 Supplemental benefits.

(a) * * *

(1) Subject to CMS approval, an MA organization may require Medicare enrollees of an MA plan (other than an MSA plan) to accept or pay for services in addition to Medicare-covered services described in § 422.101.

* * * * *

(3) CMS approves mandatory supplemental benefits if the benefits are designed in accordance with CMS' guidelines and requirements as stated in this part and other written instructions.

(4) Beginning in 2006, an MA plan may reduce cost sharing below the actuarial value specified in section 1854(e)(4)(B) of the Act as a mandatory supplemental benefit.

* * * * *

27. Amend § 422.103 by—

A. Revising the section heading.

B. Revising paragraph (a).

The revisions read as follows:

§ 422.103 Benefits under an MA MSA plan.

(a) *General rule.* An MA organization offering an MA MSA plan must make available to an enrollee, or provide reimbursement for, at least the services described in § 422.101 after the enrollee incurs countable expenses equal to the amount of the plan's annual deductible.

* * * * *

28. Amend 422.105 by revising paragraph (a) to read as follows:

§ 422.105 Special rules for point of service option.

(a) If an MA organization does not offer a POS benefit to members of a plan, or if it offers a POS benefit as an optional supplemental benefit and the member has not selected that benefit, then when those members receive what is a covered item or service from contracted providers of that plan, the member cannot be financially liable for more than the normal in-plan cost sharing, if the member correctly identified himself or herself as a member of that plan to the contracted provider before receiving the covered item or service. As a general rule, a POS benefit is an option that an MA organization may offer in an MA coordinated care plan to provide enrollees with additional choice in obtaining specified health care services. The organization may offer A POS option—

(1) Before January 1, 2006, under a coordinated care plan as an additional benefit as described in § 422.312;

(2) Under a coordinated care plan as a mandatory supplemental benefit as described in § 422.102(a); or

(3) Under a coordinated care plan as an optional supplemental benefit as described in § 422.102(b).

(4) An MA regional plan is permitted to offer a POS–LIKE benefit as described in paragraphs (a)(2) or (a)(3) of this section as a supplemental benefit. An MA regional plan may offer a POS–LIKE option as a supplemental benefit where cost sharing for out-of-network services is reduced, in a limited manner, for services obtained from out-of-network providers. Offering a POS–LIKE supplemental benefit does not affect the MA regional plan's responsibility to provide reimbursement for all covered benefits, regardless of whether those benefits are provided within the network of contracted providers.

* * * * *

29. Amend § 422.106 by—

A. Revising the paragraph (c) heading.

B. Revising paragraph (c)(2).

C. Adding paragraph (d).

The revisions and addition read as follows:

§ 422.106 Coordination of benefits with employer or union group health plans and Medicaid.

* * * * *

(c) *Waiver or modification of contracts with MA organizations.* * * *

* * * * *

(2) Approved waivers or modifications under this paragraph granted to any MA organization may be used by any other MA organization in developing its bid.

(d) *Employer sponsored MA plans for plan years beginning on or after January 1, 2006.* (1) To facilitate the offering of MA plans by employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof), of the labor organizations, those MA plans may request, in writing, from CMS, a waiver or modification of those requirements in this part that hinder the design of, the offering of, or the enrollment in, those plans by those individuals.

(2) An MA plan described in this paragraph may restrict the enrollment of individuals in that plan to individuals who are beneficiaries and participants in that plan.

(3) Approved waivers or modifications under this paragraph granted to any MA plan may be used by any other similarly situated MA plan in developing its bid.

30. Amend § 422.108 by revising paragraph (f) to read as follows:

§ 422.108 Medicare secondary payer (MSP) procedures.

* * * * *

(f) *MSP rules and State laws.* Consistent with § 422.402 concerning the Federal preemption of State law, the rules established under this section supersede any State laws, regulations, contract requirements, or other standards that would otherwise apply to MA plans. A State cannot take away an MA organization's right under Federal law and the MSP regulations to bill, or to authorize providers and suppliers to bill, for services for which Medicare is not the primary payer. The MA organization will exercise the same rights to recover from a primary plan, entity, or individual that the Secretary exercises under the MSP regulations in subparts B through D of part 411 of this chapter.

30. Amend § 422.109 by—

A. Revising paragraph (a)(2).

B. Revising paragraph (c)(2)(iv).

C. Revising paragraph (c)(3).

The revisions read as follows:

§ 422.109 Effect of national coverage determinations (NCDs) and legislative changes in benefits.

(a) * * *

(2) The estimated cost of Medicare services furnished as a result of a particular NCD or legislative change in benefits represents at least 0.1 percent of the national average per capita costs.

* * * * *

(c) * * *

(2) * * *

(iv) Any services, including the costs of the NCD service or legislative change in benefits, to the extent the MA organization is already obligated to cover it as a supplemental benefit under § 422.102.

(3) Costs for significant cost NCD services or legislative changes in benefits for which CMS fiscal intermediaries and carriers will make payment are those Medicare costs not listed in paragraphs (c)(2)(i) through (c)(2)(iv) of this section.

* * * * *

32. Amend § 422.110 by—

A. Revising paragraph (b).

B. Removing paragraph (c).

The revision reads as follows:

§ 422.110 Discrimination against beneficiaries prohibited.

* * * * *

(b) *Exception.* An MA organization may not enroll an individual who has been medically determined to have end-stage renal disease. However, an enrollee who develops end-stage renal disease while enrolled in a particular MA organization may not be disenrolled for that reason. An individual who is an enrollee of a particular MA organization, and who resides in the MA plan service area at the time he or she first becomes MA eligible, or, an individual enrolled by an MA organization that allows those who reside outside its MA service area to enroll in an MA plan as set forth at § 422.50(a)(3)(ii), then that individual is considered to be "enrolled" in the MA organization for purposes of the preceding sentence.

§ 422.111 [Amended]

33. Amend § 422.111 by—

A. Revising paragraph (b)(3).

B. Revising paragraph (c)(1).

C. Revising paragraph (d)(2).

D. Revising paragraph (e).

E. Removing paragraph (f)(4).

C. Removing paragraph (f)(6).

D. Redesignating paragraph (f)(5) as paragraph (f)(4).

E. Redesignating paragraph (f)(7) as paragraph (f)(5).

F. Redesignating paragraph (f)(8) as paragraph (f)(6).

G. Redesignating paragraph (f)(9) as paragraph (f)(7).

H. Redesignating paragraph (f)(10) as paragraph (f)(8).

I. Redesignating paragraph (f)(11) as paragraph (f)(9).

J. Revising newly redesignated paragraph (f)(5)(iv).

K. Removing newly redesignated paragraph (f)(5)(v).

L. Redesignating paragraph (f)(5)(vi) as paragraph (f)(5)(v).

M. Redesignating paragraph (f)(5)(vii) as paragraph (f)(5)(vi).

N. Redesignating paragraph (f)(5)(viii) as paragraph (f)(5)(vii).

O. Revising newly redesignated paragraph (f)(9).

P. Adding new paragraph (f)(10).

The revisions and addition read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(b) * * *

(3) *Access.* The number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected obtain services; any out-of network coverage; any point-of-service option, including the supplemental premium for that option; and how the MA organization meets the requirements of § 422.112 and § 422.114 for access to services offered under the plan.

* * * * *

(c) * * *

(1) The information required in paragraph (f) of this section.

* * * * *

(d) * * *

(2) For changes that take effect on January 1, notify all enrollees at least 15 days before the beginning of the Annual Coordinated Election Period defined in section 1851(e)(3)(B) of the Act.

* * * * *

(e) *Changes to provider network.* The MA organization must make a good faith effort to provide notice of a termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified.

(f) * * *

(5) * * *

(iv) In the case of an MA MSA plan, the amount of the annual MSA deposit.

* * * * *

(9) *Supplemental benefits.* Whether the plan offers mandatory and optional supplemental benefits, including any reductions in cost sharing offered as a mandatory supplemental benefit as permitted under section 1852(a)(3) of the Act (and implementing regulations at § 422.102) and the terms, conditions, and premiums for those benefits.

(10) The names, addresses, and phone numbers of providers from whom the enrollee may obtain in-network coverage in other areas.

§ 422.112 [Amended]

34. Amend § 422.112 by—

A. Revising paragraph (a)(1).

B. Removing paragraph (a)(4).

C. Removing paragraph (a)(7).

D. Redesignating paragraph (a)(5) as paragraph (a)(4).

E. Redesignating paragraph (a)(6) as paragraph (a)(5).

F. Redesignating paragraphs (a)(8) as paragraph (a)(6).

G. Redesignating paragraph (a)(9) as paragraph (a)(7).

H. Redesignating paragraph (a)(10) as paragraph (a)(8).

I. Removing paragraph (b)(4)(i).

J. Redesignating paragraph (b)(4)(ii) as paragraph (b)(4)(i).

K. Redesignating paragraph (b)(4)(iii) as paragraph (b)(4)(ii).

L. Adding paragraph (c).

The revisions and addition read as follows:

§ 422.112 Access to services.

(a) Rules for coordinated care plans.

* * *

(1) *Provider network.* (i) Maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. These providers are typically used in the network as primary care providers (PCPs), specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics, and other providers.

(ii) *Exception:* MA regional plans, upon CMS pre-approval, can use methods other than written agreements to establish that access requirements are met..

* * * * *

(c) *Essential hospital.* An MA regional plan may seek, upon application to CMS, to designate a hospital as an essential hospital as defined in section 1858(h) of the Act under the following conditions:

(1) The hospital that the MA regional plan seeks to designate as essential is a general acute care hospital as defined in section 1886(d) of the Act.

(2) The MA regional plan provides convincing evidence to CMS that the MA regional plan needs to contract with the hospital as a condition of meeting access requirements under this section.

(3) The MA regional plan must establish that it made a "good faith" effort to contract with the hospital to be designated as an essential hospital.

(4) The hospital that is to be designated as an essential hospital provides convincing evidence to CMS that the amounts normally payable under section 1886 of the Act (and which the MA regional plan has agreed to pay) will be less than the hospital's actual costs of providing care to the MA regional plan's enrollees.

(5) If CMS determines the requirements in paragraphs (c)(1) through (c)(4) of this section have been met, it will make payment to the essential hospital in accordance with section 1858(h)(2) of the Act, as limited by the amounts specified in section 1858(h)(3) of the Act.

35. Amend § 422.113 by—

A. Revising paragraph (b)(2)(v).

B. Revising paragraph (c)(2)(iv).

The revisions read as follows:

§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

* * * * *

(b) * * *

(2) * * *

(v) With a limit on charges to enrollees for emergency department services of $50 or what it would charge the enrollee if he or she obtained the services through the MA organization, whichever is less.

* * * * *

(c) * * *

(2) * * *

(iv) Must limit charges to enrollees for post-stabilization care services to an amount no greater than what the organization would charge the enrollee if he or she had obtained the services through the MA organization. For purposes of cost sharing, post-stabilization care services begin upon admission.

* * * * *

36. Amend § 422.114 by—

A. Revising the section heading to read as set forth below.

B. Adding paragraph (c) to read as follows:

§ 422.114 Access to services under an MA private fee-for-service plan.

* * * * *

(c) Private fee-for-service plans that meet network adequacy requirements for a category of health care professional or provider by meeting the requirements in paragraph (a)(2)(ii) of this section may provide for a higher beneficiary copayment in the case of health care professionals or providers of that same category who do not have contracts or agreements to provide covered services under the terms of the plan.

37. Amend § 422.133 by adding paragraph (b)(4) to read as follows:

§ 422.133 Return to home skilled nursing facility.

* * * * *

(b) * * *

(4) If an MA organization elects to furnish SNF care in the absence of a prior qualifying hospital stay under § 422.101(c), then that SNF care is also subject to the home skilled nursing facility rules in this section. In applying the provisions of this section to coverage under this paragraph, references to a hospitalization, or discharge from a hospital, are deemed to refer to wherever the enrollee resides immediately before admission for extended care services.

* * * * *

Subpart D—Quality Improvement

38. In subpart D, remove "quality assurance" wherever it appears and add in its place "quality improvement."

39. Revise § 422.152 to read as follows:

§ 422.152 Quality improvement program.

(a) *General rule.* Each MA organization (other than MA private-fee-for-service and MSA plans) that offers one or more MA plans must have, for each of those plans, an ongoing quality improvement program that meets the applicable requirements of this section for the services it furnishes to its MA enrollees. As part of its ongoing quality improvement program, a plan must—

(1) Have a chronic care improvement program that meets the requirements of paragraph (c) of this section concerning elements of a chronic care program;

(2) Conduct quality improvement projects that can be expected to have a favorable effect on health outcomes and enrollee satisfaction, and meet the requirements of paragraph (d) of this section; and

(3) Encourage its providers to participate in CMS and HHS quality improvement initiatives.

(b) *Requirements for MA coordinated care plans (except for regional MA plans) and including local PPO plans that are offered by organizations that are licensed or organized under State law as HMOs.* An MA coordinated care plan's (except for regional PPO plans

and local PPO plans as defined in § 422.152(e)) quality improvement program must—

(1) In processing requests for initial or continued authorization of services, follow written policies and procedures that reflect current standards of medical practice.

(2) Have in effect mechanisms to detect both underutilization and overutilization of services.

(3) Measure and report performance. The organization offering the plan must do the following:

(i) Measure performance under the plan, using the measurement tools required by CMS, and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.

(ii) Make available to CMS information on quality and outcome measures that will enable beneficiaries to compare health coverage options and select among them, as provided in § 422.64(c)(10).

(4) Special rule for MA local PPO-type plans that are offered by an organization that is licensed or organized under State law as a health maintenance organization must meet the requirements specified in paragraphs (b)(1) through (b)(3) of this section.

(c) *Chronic care improvement program requirements.* Develop criteria for participating in a chronic care improvement program. These criteria must include—

(1) Methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions that would benefit from participating in a chronic care improvement program; and

(2) Mechanisms for monitoring MA enrollees that are participating in the chronic care improvement program.

(d) *Quality improvement projects.* (1) Quality improvement projects are an organization's initiatives that focus on specified clinical and nonclinical areas and that involve the following:

(i) Measurement of performance.

(ii) System interventions, including the establishment or alteration of practice guidelines.

(iii) Improving performance.

(iv) Systematic and periodic follow-up on the effect of the interventions.

(2) For each project, the organization must assess performance under the plan using quality indicators that are—

(i) Objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research; and

(ii) Capable of measuring outcomes such as changes in health status, functional status and enrollee satisfaction, or valid proxies of those outcomes.

(3) Performance assessment on the selected indicators must be based on systematic ongoing collection and analysis of valid and reliable data.

(4) Interventions must achieve demonstrable improvement.

(5) The organization must report the status and results of each project to CMS as requested.

(e) *Requirements for MA regional plans and MA local plans that are PPO plans as defined in this section—(1) Definition of local preferred provider organization plan.* For purposes of this section, the term local preferred provider organization (PPO) plan means an MA plan that—

(i) Has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

(ii) Provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and

(iii) Is offered by an organization that is not licensed or organized under State law as a health maintenance organization.

(2) MA organizations offering an MA regional plan or local PPO plan as defined in this section must:

(i) Measure performance under the plan using standard measures required by CMS and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.

(ii) Evaluate the continuity and coordination of care furnished to enrollees.

(iii) If the organization uses written protocols for utilization review, the organization must—

(A) Base those protocols on current standards of medical practice; and

(B) Have mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation.

(f) *Requirements for all types of plans—(1) Health information.* For all types of plans that it offers, an organization must—

(i) Maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality improvement program;

(ii) Ensure that the information it receives from providers of services is reliable and complete; and

(iii) Make all collected information available to CMS.

(2) *Program review.* For each plan, there must be in effect a process for formal evaluation, at least annually, of the impact and effectiveness of its quality improvement program.

(3) *Remedial action.* For each plan, the organization must correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms.

§ 422.154 [Removed]

40. Remove § 422.154.

41. Amend § 422.156 by adding paragraph (b)(7) to read as follows:

§ 422.156 Compliance deemed on the basis of accreditation.

* * * * *

(b) * * *

(7) Part D prescription drug benefit programs that are offered by MA programs.

* * * * *

Subpart E—Relationships With Providers

§ 422.208 [Amended]

42. In § 422.208, the following changes are made:

A. Paragraph (c)(2) is revised.

B. Paragraph (h) is removed.

C. Paragraph (i) is redesignated as paragraph (h).

The revision reads as follows:

§ 422.208 Physician incentive plans: Requirements and limitations.

* * * * *

(c) * * *

(2) If the physician incentive plan places a physician or physician group at substantial financial risk (as determined under paragraph (d) of this section) for services that the physician or physician group does not furnish itself, the MA organization must assure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with paragraph (f) of this section and conduct periodic surveys in accordance with paragraph (h) of this section.

* * * * *

45. Section 422.210 is revised to read as follows:

§ 422.210 Assurances to CMS.

Each organization will provide assurance satisfactory to the Secretary that the requirements of § 422.208 are met.

46. In 422.214, the following changes are made:

A. Paragraph (a)(1) is revised.

B. Paragraph (b) is revised.

The revisions read as follows:

§ 422.214 Special rules for services furnished by noncontract providers.

(a) * * *

(1) Any provider (other than a provider of services as defined in section 1861(u) of the Act) that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA coordinated care plan, an MSA plan, or an MA private fee-for-service plan must accept, as payment in full. the amounts that the provider could collect if the beneficiary were enrolled in original Medicare.

* * * * *

(b) *Services furnished by section 1861(u) providers of service.* Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA coordinated care plan, an MSA plan, or an MA private fee-for-service plan must accept, as payment in full, the amounts (less any payments under § 412.105(g) and § 413.86(d) of this chapter) that it could collect if the beneficiary were enrolled in original Medicare. (Section 412.105(g) concerns indirect medical education payment to hospitals for managed care enrollees. Section 413.86(d) concerns calculating payment for direct medical education costs.)

43. Subpart F is removed.

44. New subpart F is added to read as follows:

Subpart F—Submission of Bids, Premiums, and Related Information and Plan Approval

Secs.

Subpart F—Submission of Bids, Premiums, and Related Information and Plan Approval

§ 422.250 Basis and scope.

This subpart is based largely on section 1854 of the Act, but also includes provisions from section 1853 and section 1858 of the Act. It sets forth the requirements for the Medicare Advantage bidding payment methodology, including CMS' calculation of benchmarks, submission of plan bids by Medicare Advantage (MA) organizations, establishment of beneficiary premiums and rebates through comparison of plan bids and benchmarks, and negotiation and approval of bids by CMS.

§ 422.252 Terminology.

Annual MA capitation rate means a county payment rate for an MA local area (county) for a calendar year. The terms "per capita rate" and "capitation rate" are used interchangeably to refer to the annual MA capitation rate.

MA local area means a payment area consisting of county or equivalent area specified by CMS. Payments to MA local plans are based on the payment amount for each MA local area in the local plan's service area.

MA monthly basic beneficiary premium means the premium amount an MA plan (except an MSA plan) charges an enrollee for benefits under the original Medicare fee-for-service program option (if any), and is calculated as described at § 422.262.

MA monthly MSA premium means the amount of the plan premium for coverage of benefits under the original Medicare program through an MSA plan, as set forth at § 422.254(e).

MA monthly prescription drug beneficiary premium is the MA–PD plan base beneficiary premium, defined at section 1860D–13(a)(2) of the Act, as adjusted to reflect the difference between the plan's bid and the national average bid (as described in § 422.256(c)) less the amount of rebate the MA–PD plan elects to apply, as described at § 422.266(b)(2).

MA monthly supplemental beneficiary premium is the portion of the plan bid attributable to mandatory and/or optional supplemental health care benefits described under § 422.102, less the amount of beneficiary rebate the plan elects to apply to a mandatory supplemental benefit, as described at § 422.266(b)(2)(i).

MA–PD plan means an MA local or regional plan that provides prescription drug coverage under Part D of the Social Security Act.

Monthly aggregate bid amount means the total monthly plan bid amount for coverage of an MA eligible beneficiary with a nationally average risk profile for the factors described in § 422.308(c), and this amount is comprised of the following:

(1) The unadjusted MA statutory non-drug monthly bid amount for coverage of original Medicare benefits;

(2) The amount for coverage of basic prescription drug benefits under Part D (if any); and

(3) The amount for provision of supplemental health care benefits (if any).

Plan basic cost sharing means cost sharing that would be charged by a plan for benefits under the original Medicare fee-for-service program option before any reductions resulting from mandatory supplemental benefits.

Unadjusted MA area-specific non-drug monthly benchmark amount means, for local MA plans serving one county, the county capitation rate CMS publishes annually, and for local MA plans serving multiple counties it is the weighted average of county rates in a plan's service area, weighted by the plan's projected enrollment per county.

Unadjusted MA region-specific non-drug monthly benchmark amount means, for MA regional plans, the amount described at § 422.258(b).

Unadjusted MA statutory non-drug monthly bid amount means a plan's estimate of its average monthly required revenue to provide coverage of original Medicare benefits to an MA eligible beneficiary with a nationally average risk profile for the risk factors CMS applies to payment calculations as set forth at § 422.308(c).

§ 422.254 Submission of bids.

(a) *General rules.* (1) No later than the first Monday in June, each MA organization must submit to CMS an aggregate monthly bid amount for each MA plan (other than an MSA plan) the organization intends to offer in the upcoming year in the service area (or segment of such an area if permitted under § 422.262(c)(2)) that meets the requirements in paragraph (b) of this section. With each bid submitted, the MA organization must provide the information required in paragraph (c) of this section.

(2) CMS has the authority to determine whether and when it is appropriate to apply the bidding methodology described in this section to ESRD MA enrollees.

(b) *Bid requirements.* (1) The monthly aggregate bid amount submitted by an MA organization for each plan is the organization's estimate of the revenue required for the following categories for providing coverage to an MA eligible beneficiary with a national average risk profile for the factors described in § 422.308(c):

(i) The statutory non-drug bid amount, which is the MA plan's estimated average monthly required revenue for providing benefits under the original Medicare fee-for-service program option (as defined in § 422.252).

(ii) The amount to provide basic prescription drug coverage, if any (defined at section 1860D–2(a)(3) of the Act).

(iii) The amount to provide supplemental health care benefits, if any.

(2) Each bid is for a uniform benefit package for the service area.

(3) Each bid submission must contain all estimated revenue required by the plan, including administrative costs and return on investment. Plan assumptions about revenue requirements must include adjustments for the effect that providing reductions in Part C and/or Part D cost sharing has on utilization.

(4) The bid amount is for plan payments only but must be based on plan assumptions about the amount of revenue required from enrollee cost-sharing. The estimate of plan basic cost-sharing for plan basic benefits must reflect the requirement that the level of cost sharing MA plans charge to enrollees must be actuarially equivalent to the level of cost sharing (deductible, copayments, or coinsurance) charged to beneficiaries under the original Medicare program option.

(c) *Information required for coordinated care plans and MA private fee-for-service plans.* MA organizations' submission of bids for coordinated care plans, including regional MA plans and specialized MA plans for special needs beneficiaries (described at § 422.4(a)(1)(iv)), and for MA private fee-for-service plans must include the following information:

(1) The plan type for each plan.

(2) The monthly aggregate bid amount for the provision of all items and services under the plan, as defined in § 422.252 and discussed in paragraph (a) of this section.

(3) The proportions of the bid amount attributable to—

(i) The provision of benefits under the original Medicare fee-for-service program option (as defined at § 422.100(c));

(ii) The provision of basic prescription drug coverage (as defined at section 1860D–2(a)(3) of the Act; and

(iii) The provision of supplemental health care benefits (as defined § 422.102).

(4) The projected number of enrollees in each MA local area used in calculation of the bid amount, and the enrollment capacity, if any, for the plan.

(5) The actuarial basis for determining the amount under paragraph (c)(2) of this section and the proportions under paragraph (c)(3) of this section, and additional information as CMS may require to verify actuarial bases and the projected number of enrollees.

(6) A description of deductibles, coinsurance, and copayments applicable under the plan and the actuarial value of the deductibles, coinsurance, and copayments.

(7) For qualified prescription drug coverage, the information required under section 1860D–11(b) of the Act with respect to coverage.

(8) For the purposes of calculation of risk corridors under § 422.458, MA organizations offering regional MA plans in 2006 and/or 2007 must submit the following information developed using the appropriate actuarial bases.

(i) Projected allowable costs (defined in § 422.458(a)).

(ii) The portion of projected allowable costs attributable to administrative expenses incurred in providing these benefits.

(iii) The total projected costs for providing rebatable integrated benefits (as defined in § 422.458(a)) and the portion of costs that is attributable to administrative expenses.

(d) *Beneficiary rebate information.* In the case of a plan required to provide a monthly rebate under § 422.266 for a year, the MA organization offering the plan must inform CMS how the plan will distribute the beneficiary rebate among the options described at § 422.266(b).

(e) *Information required for MSA plans.* MA organizations intending to offer MA MSA plans must submit—

(1) The enrollment capacity (if any) for the plan;

(2) The amount of the MSA monthly premium for basic benefits under the original Medicare fee-for-service program option; and

(3) The amount of the plan deductible;

(4) The amount of the beneficiary supplemental premium, if any.

(f) For plans with Part B only enrollees, MA organizations must submit separate bids for their Part A and Part B enrolled members and their Part B only members.

§ 422.256 Review, negotiation, and approval of bids.

(a) *Authority.* Subject to paragraphs (a)(2), (d), and (e) of this section, CMS has the authority to review the aggregate bid amounts submitted under § 422.252 and conduct negotiations with MA organizations regarding these bids (including the supplemental benefits) and the proportions of the aggregate bid attributable to basic benefits, supplemental benefits, and prescription drug benefits.

(1) When negotiating bid amounts and proportions, CMS has authority similar to that provided the Director of the Office of Personnel Management for negotiating health benefits plans under 5 U.S.C. chapter 89.

(2) *Noninterference.* (i) In carrying out Parts C and D under this title, CMS may not require any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services.

(ii) CMS may not require a particular price structure for payment under such a contract, with the exception of payments to Federally qualified health centers as set forth at § 422.316.

(b) *Standards of review.* Subject to paragraphs (d) and (e) of this section, CMS can only accept bid amounts or proportions described in paragraph (a) of this section if CMS determines the following standards have been met:

(1) The bid amount and proportions are supported by the actuarial bases provided by MA organizations under § 422.254.

(2) The bid amount and proportions should reflect the plan's estimated revenue requirements for providing the benefit package, as the term revenue requirements is used in section 1302(8) of the Public Health Service Act.

(3) *Limitation on enrollee cost sharing.* For coordinated care plans (including regional MA plans and specialized MA plans) and private fee-for-service plans (other than MSA plans):

(i) The actuarial value of plan basic cost sharing, reduced by any supplemental benefits, may not exceed—

(ii) The actuarial value of deductibles, coinsurance, and copayments that would be applicable for the benefits to individuals entitled to benefits under Part A and enrolled under Part B in the plan's service area with a national average risk profile for the factors described in § 422.308(c) if they were not members of an MA organization for the year.

(c) *Negotiation process.* The negotiation process may include the resubmission of information to allow MA organizations to modify their initial bid submissions to account for the outcome of CMS' regional benchmark calculations required under § 422.258(b) and the outcome of CMS' calculation of the national average monthly bid amount required under section 1860D–13(a)(4) of the Act.

(d) *Exception for private fee-for-service plans.* For private fee-for-service plans defined at § 422.4(a)(3), CMS will not review, negotiate, or approve the bid amount, proportions of the bid, or the amounts of the basic beneficiary premium and supplemental premium.

(e) *Exception for MSA plans.* CMS does not review, negotiate, or approve amounts submitted with respect to MA MSA plans, except to determine that the deductible does not exceed the statutory maximum, defined at § 422.103(d).

§ 422.258 Calculation of benchmarks.

(a) The term "MA area-specific non-drug monthly benchmark amount" means, for a month in a year:

(1) *For MA local plans with service areas entirely within a single MA local area,* 1/12th of the annual MA capitation rate (described at § 422.306) for the area, adjusted as appropriate for the purpose of risk adjustment.

(2) *For MA local plans with service areas including more than one MA local area,* an amount equal to the weighted average of annual capitation rates for each local area (county) in the plan's service area, using as weights the projected number of enrollees in each MA local area that the plan used to calculate the bid amount, and adjusted as appropriate for the purpose of risk adjustment.

(b) For MA regional plans, the term *MA region-specific non-drug monthly benchmark amount* is:

(1) The sum of two components: the statutory component (based on a weighted average of local benchmarks in the region, as described in paragraph (b)(3) of this section; and the plan bid component (based on a weighted average of plan bids in the region as described in paragraph (b)(5) of this section).

(2) Announced before November 15 of each year, but after CMS has received the plan bids.

(c) *Calculation of MA regional non-drug benchmark amounts.* CMS calculates the monthly regional non-drug benchmark amounts as follows:

(1) *Reference month.* For all calculations that follow, CMS will determine the number of MA eligible individuals in each local area, in each region, and nationally as of the reference month, which is a month in the previous calendar year CMS identifies.

(2) *Statutory market share.* CMS will determine the statutory national market share percentage as the proportion of the MA eligible individuals nationally who were not enrolled in an MA plan.

(3) *Statutory component of the region-specific benchmark.* (i) CMS calculates the unadjusted region-specific non-drug amount by multiplying the county capitation rate by the county's share of the MA eligible individuals residing in the region (the number of MA eligible individuals in the county divided by the number of MA eligible individuals in the region), and then adding all the enrollment-weighted county rates to a sum for the region.

(ii) CMS then multiplies the unadjusted region-specific non-drug amount from paragraph (c)(3)(i) of this section by the statutory market share to determine the statutory component of the regional benchmark.

(4) *Plan-bid component of the region-specific benchmark.* For each plan offered in a region, CMS will multiply the plan's unadjusted region-specific non-drug bid amount by the plan's share of enrollment (as determined under paragraph (c)(5) of this section) and then sum these products across all plans offered in the region. CMS then multiples this by 1 minus the statutory market share to determine the plan-bid component of the regional benchmark.

(5) *Plan's share of enrollment.* CMS will calculate the plan's share of MA enrollment in the region as follows:

(i) In the first year, any MA regional plan is being offered, and more than one MA plan is being offered: CMS will determine each plan's share of enrollment based on one of two possible approaches. CMS may base this on equal division among plans, so that each plan's share will be 1 divided by the number of plans offered. Alternatively, CMS may base this on each plan's estimate of projected enrollment. In that case, each plan's share will be the plan's projected enrollment divided by the total projected enrollment among all plans being offered in the region. Plan enrollment projections are subject to review and adjustment by CMS to assure reasonableness.

(ii) If two or more regional plans are offered in a region and were offered in the reference month: The plan's share of enrollment will be the number of MA eligible individuals enrolled in the plan divided by the number of MA eligible individuals enrolled in all of the plans in the region, as of the reference month.

(iii) If a single regional plan is being offered in the region: The plan's share of enrollment is equal to 1.

§ 422.262 Beneficiary premiums.

(a) Determination of MA monthly basic beneficiary premium. (1) For an MA plan with an unadjusted statutory non-drug bid amount that is less than the relevant unadjusted non-drug benchmark amount, the basic beneficiary premium is zero.

(2) For an MA plan with an unadjusted statutory non-drug bid amount that is equal to or greater than the relevant unadjusted non-drug benchmark amount, the basic beneficiary premium is the amount by which (if any) the bid amount exceeds the benchmark amount. All approved basic premiums must be charged; they cannot be waived.

(b) *Consolidated monthly premiums.* Except as specified in paragraph (b)(2) of this section, MA organizations must charge enrollees a consolidated monthly MA premium.

(1) The consolidated monthly premium for an MA plan (other than a MSA plan) is the sum of the MA monthly basic beneficiary premium (if any), the MA monthly supplementary beneficiary premium (if any), and the MA monthly prescription drug beneficiary premium (if any).

(2) *Special rule for MSA plans.* For an individual enrolled in an MSA plan offered by an MA organization, the monthly beneficiary premium is the supplemental premium (if any).

(c) *Uniformity of premiums*—(1) *General rule.* Except as permitted under § 422.106(d), for MA contracts with employers and labor organizations, the MA monthly bid amount submitted under § 422.254, the MA monthly basic beneficiary premium, the MA monthly supplemental beneficiary premium, the MA monthly prescription drug premium, and the monthly MSA premium of an MA organization may not vary among individuals enrolled in an MA plan (or segment of the plan as provided for local MA plans under paragraph (b)(2) of this section). In addition, the MA organization cannot vary the level of cost-sharing charged for basic benefits or supplemental benefits (if any) among individuals enrolled in an MA plan (or segment of the plan).

(2) *Segmented service area option.* An MA organization may apply the uniformity requirements in paragraph (b)(1) of this section to segments of an MA local plan service area (rather than to the entire service area) as long as such a segment is composed of one or more MA payment areas. The information specified under § 422.256 is submitted separately for each segment. This provision does not apply to MA regional plans.

(d) *Monetary inducement prohibited.* An MA organization may not provide for cash or other monetary rebates as an inducement for enrollment or for any other reason or purpose.

(e) *Timing of payments.* The MA organization must permit payments of MA monthly basic and supplemental beneficiary premiums and monthly prescription drug beneficiary premiums on a monthly basis and may not terminate coverage for failure to make timely payments except as provided in § 422.74(b)(1).

(f) *Beneficiary payment options.* An MA organization must permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the organization through—

(1) Withholding from the enrollee's Social Security benefit payments, in the

manner that the Part B premium is withheld;

(2) An electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account);

(3) Payment by an employer or under employment-based retiree health coverage on behalf of an employee, former employee (or dependent), or by other third parties such as a State; or

(4) According to additional CMS guidelines.

(5) Regarding the option in paragraph (f)(1) of this section, MA organizations may not impose a charge on beneficiaries for the election of this option.

§ 422.264 Calculation of savings.

(a) *Computation of risk adjusted bids and benchmarks*—(1) The *risk adjusted MA statutory non-drug monthly bid amount* is the unadjusted plan bid amount for coverage of original Medicare benefits (defined at § 422.254), adjusted using the factors described in paragraph (c) of this section for local plans and paragraph (e) for regional plans.

(2) The *risk adjusted MA area-specific non-drug monthly benchmark amount* is the unadjusted benchmark amount for coverage of original Medicare benefits by a local MA plan (defined at § 422.258), adjusted using the factors described in paragraph (c) of this section.

(3) The *risk adjusted MA region-specific non-drug monthly benchmark amount* is the unadjusted benchmark for coverage of original Medicare benefits amount by a regional MA plan (defined at § 422.258) adjusted using the factors described in paragraph (e) of this section.

(b) *Computation of savings for MA local plans.* The average per capita monthly savings for an MA local plan is 100 percent of the difference between the plan's risk-adjusted statutory non-drug monthly bid amount (described in paragraph (a)(1) of this section) and the plan's risk-adjusted area-specific non-drug monthly benchmark amount (described in paragraph (a)(2) of this section). Plans with bids equal to or greater than plan benchmarks will have zero savings.

(c) *Risk adjustment factors for determination of savings for local plans.* CMS will publish the first Monday in April before the upcoming calendar year the risk adjustment factors described in paragraph (c)(1), (c)(2), or (c)(3) of this section determined for the purpose of calculating savings amounts for MA local plans.

(1) *Statewide average risk adjustment factors.* The statewide factor for each State is the average of the risk factors calculated under § 422.308(c), based on all enrollees in MA local plans in that State in the previous year.

(2) In the case of a State in which no local MA plan was offered in the previous year, CMS will estimate an average and may base this average on average risk adjustment factors applied to comparable States or applied on a national basis.

(3) For the purpose of calculating savings for MA local plans CMS has the authority to apply risk adjustment factors determined on a basis other than States, including a plan-specific basis.

(d) *Computation of savings for MA regional plans.* The average per capita monthly savings for an MA local plan and year is 100 percent of the difference between the plan's risk-adjusted statutory non-drug monthly bid amount (described in paragraph (a)(1) of this section) and the plan's risk-adjusted region-specific non-drug monthly benchmark amount (described in paragraph (a)(3) of this section), using the risk adjustment factors described in paragraph (e) of this section. Plans with bids equal to or greater than plan benchmarks will have zero savings.

(e) *Risk adjustment factors for determination of savings for regional plans.* CMS will publish the first Monday in April before the upcoming calendar year the risk adjustment factors described in paragraph (e)(1), (e)(2), or (e)(3) of this section determined for the purpose of calculating savings amounts for MA regional plans.

(1) *Region-wide average risk adjustment factors.* The region-wide factor for each MA region is the average of the risk factors calculated under § 422.308(c), based on all enrollees in MA regional plans in that region in the previous year.

(2) In the case of a region in which no regional plan was offered in the previous year, CMS will estimate an average and may base this average on average risk adjustment factors applied to comparable regions or applied on a national basis.

(3) For the purpose of calculating savings for MA regional plans, CMS has the authority to apply risk adjustment factors determined on a basis other than MA regions, including a plan-specific basis.

§ 422.266 Beneficiary rebates.

(a) *General rule.* An MA organization must provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in § 422.264(b) for MA local plans and § 422.264(d) for MA regional plans.

(b) *Form of rebate.* The rebate required under this paragraph must be provided by crediting the rebate amount to one or more of the following:

(1) *Supplemental health care benefits.* MA organizations may apply all or some portion of the rebate toward supplemental health care benefits for enrollees as described in § 422.102, which may include the reduction of cost sharing and additional health care benefits that are not benefits under original Medicare. MA organizations may also credit some part, or all, of the rebate, toward an MA monthly supplemental beneficiary premium (if any). The rebate, or portion of rebate, applied toward supplemental benefits may only be applied to a mandatory supplemental benefit, and cannot be used to fund an optional supplemental benefit.

(2) *Payment of premium for prescription drug coverage.* MA organizations that offer a prescription drug benefit may credit some or all of the rebate toward reduction of the MA monthly prescription drug beneficiary premium.

(3) *Payment toward Part B premium.* MA organizations that offer a prescription drug benefit may credit some or all of the rebate toward reduction of the Medicare Part B premium (determined without regard to the application of subsections (b), (h), and (i) of section 1839 of the Act).

(c) *Disclosure relating to rebates.* MA organizations must disclose to CMS information on the amount of the rebate provided, as required at § 422.254(d).

§ 422.270 Incorrect collections of premiums and cost-sharing.

(a) *Definitions.* As used in this section—

(1) Amounts incorrectly collected—

(i) Means amounts that—

(A) Exceed the limits approved under § 422.262;

(B) In the case of an MA private fee-for-service plan, exceed the MA monthly basic beneficiary premium or the MA monthly supplemental premium submitted under § 422.262; and

(C) In the case of an MA MSA plan, exceed the MA monthly beneficiary supplemental premium submitted under § 422.262, or exceed permissible cost sharing amounts after the deductible has been met per § 422.103; and

(ii) Includes amounts collected from an enrollee who was believed to be entitled to Medicare benefits but was later found not to be entitled.

(2) *Other amounts due* are amounts due for services that were—

(i) Emergency, urgently needed services, or other services obtained outside the MA plan; or

(ii) Initially denied but, upon appeal, found to be services the enrollee was entitled to have furnished by the MA organization.

(b) *Basic commitments.* An MA organization must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and to pay any other amounts due the enrollees or others on their behalf.

(c) *Refund methods*—(1) *Lump-sum payment.* The MA organization must use lump-sum payments for the following:

(i) Amounts incorrectly collected that were not collected as premiums.

(ii) Other amounts due.

(iii) All amounts due if the MA organization is going out of business or terminating its MA contract for an MA plan(s).

(2) *Premium adjustment or lump-sum payment, or both.* If the amounts incorrectly collected were in the form of premiums, or included premiums as well as other charges, the MA organization may refund by adjustment of future premiums or by a combination of premium adjustment and lump-sum payments.

(3) *Refund when enrollee has died or cannot be located.* If an enrollee has died or cannot be located after reasonable effort, the MA organization must make the refund in accordance with State law.

(d) *Reduction by CMS.* If the MA organization does not make the refund required under this section by the end of the contract period following the contract period during which an amount was determined to be due to an enrollee, CMS will reduce the premium the MA organization is allowed to charge an MA plan enrollee by the amounts incorrectly collected or otherwise due. In addition, the MA organization would be subject to sanction under subpart O of this part for failure to refund amounts incorrectly collected from MA plan enrollees.

47. Subpart G is removed.

48. New subpart G is added to read as follows:

Subpart G—Payments to Medicare Advantage Organizations

Sec.

Subpart G—Payments to Medicare Advantage Organizations

§ 422.300 Basis and scope.

This subpart is based on sections 1853, 1854, and 1858 of the Act. It sets forth the rules for making payments to Medicare Advantage (MA) organizations offering local and regional MA plans, including calculation of MA capitation rates and benchmarks, conditions under which payment is based on plan bids, adjustments to capitation rates (including risk adjustment), and other payment rules.

See § 422.458 in subpart J for rules on risk sharing payments to MA regional organizations.

§ 422.304 Monthly payments.

(a) *General rules.* Except as provided in paragraph (b) of this section, CMS makes advance monthly payments of the amounts determined under paragraphs (a)(1) and (a)(2) of this section for coverage of original fee-for-service benefits for an individual in an MA payment area for a month.

(1) *Payment of bid for plans with bids below benchmark.* For MA plans that have average per capita monthly savings (as described at § 422.264(b) for local plans and § 422.264(d) for regional plans), CMS pays:

(i) The unadjusted MA statutory non-drug monthly bid amount defined in § 422.252, risk-adjusted as described at § 422.308(c) and adjusted (if applicable) for variations in rates within the plan's service area (described at § 422.258(a)(2)) and for the effects of risk adjustment on beneficiary premiums (described at § 422.262); and

(ii) The amount (if any) of the rebate described in paragraph (a)(3) of this section.

(2) *Payment of benchmark for plans with bids at or above benchmark.* For MA plans that do not have average per capita monthly savings (as described at § 422.264(b) for local plans and § 422.264(d) for regional plans), CMS pays the unadjusted MA area-specific non-drug monthly benchmark amount specified at § 422.258, risk-adjusted as described at § 422.308(c) and adjusted (if applicable) for variations in rates within the plan's service area (described at § 422.258(a)(2)) and for the effects of risk adjustment on beneficiary premiums (described at § 422.262).

(3) *Payment of rebate for plans with bids below benchmarks.* The rebate amount under paragraph (a)(1)(ii) of this section is the amount of the monthly rebate computed under § 422.266(a) for that plan, less the amount (if any) applied to reduce the Part B premium, as provided under § 422.266(b)(3)).

(b) *Separate payment for Federal drug subsidies.* In the case of an enrollee in an MA–PD plan, defined at § 422.252, the MA organization offering such a plan also receives—

(1) Direct and reinsurance subsidy payments for qualified prescription drug coverage, described at section 1860D–15(a) and (b) of the Act (other than payments for fallback prescription drug plans described at section 1860D–11(g)(5) of the Act); and

(2) Reimbursement for premium and cost sharing reductions for low-income individuals, described at section 1860D–14 of the Act.

(c) *Special rules*—(1) *Enrollees with end-stage renal disease.* (i) For enrollees determined to have end-stage renal disease (ESRD), CMS establishes special rates that are actuarially equivalent to rates in effect before the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(ii) CMS publishes annual changes in these capitation rates no later than the first Monday in April each year, as provided in § 422.312.

(iii) CMS applies appropriate adjustments when establishing the rates, including risk adjustment factors.

(iv) CMS reduces the payment rate for each renal dialysis treatment by the same amount that CMS is authorized to reduce the amount of each composite rate payment for each treatment as set forth in section 1881(b)(7) of the Act. These funds are to be used to help pay for the ESRD network program in the same manner as similar reductions are used in original Medicare.

(2) *MSA enrollees.* In the case of an MSA plan, CMS pays the unadjusted MA area-specific non-drug monthly benchmark amount for the service area less 1/12 of the annual lump sum amount (if any) CMS deposits to the enrollee's MA MSA, determined in accordance with § 422.314(c), risk adjustment as set forth at § 422.308(c).

(3) *RFB plan enrollees.* For RFB plan enrollees, CMS adjusts the capitation payments otherwise determined under this subpart to ensure that the payment level is appropriate for the actuarial characteristics and experience of these

enrollees. That adjustment can be made on an individual or organization basis.

(d) *Payment areas*—(1) *General rule.* Except as provided in paragraph (e) of this section—

(i) An MA payment area for an MA local plan is an MA local area defined at § 422.252.

(ii) An MA payment area for an MA regional plan is an MA region, defined at § 422.455(b)(1).

(2) *Special rule for ESRD enrollees.* For ESRD enrollees, the MA payment area is a State or other geographic area specified by CMS.

(e) *Geographic adjustment of payment areas for MA local plans*—(1) *Terminology.* "Metropolitan Statistical Area" and "Metropolitan Division" mean any areas so designated by the Office of Management and Budget in the Executive Office of the President.

(2) *State request.* A State's chief executive may request, no later than February 1 of any year, a geographic adjustment of the State's payment areas for MA local plans for the following calendar year. The chief executive may request any of the following adjustments to the payment area specified in paragraph (c)(1)(i) of this section:

(i) A single statewide MA payment area.

(ii) A metropolitan-based system in which all non-metropolitan areas within the State constitute a single payment area and any of the following constitutes a separate MA payment area:

(A) All portions of each single Metropolitan Statistical Area within the State.

(B) All portions of each Metropolitan Statistical Area within each Metropolitan Division within the State.

(iii) A consolidation of noncontiguous counties.

(3) *CMS response.* In response to the request, CMS makes the payment adjustment requested by the chief executive. This adjustment cannot be requested or made for payments to regional MA plans.

(4) *Budget neutrality adjustment for geographically adjusted payment areas.* If CMS adjusts a State's payment areas in accordance with paragraph (d)(2) of this section, CMS at that time, and each year thereafter, adjusts the capitation rates so that the aggregate Medicare payments do not exceed the aggregate Medicare payments that would have been made to all the State's payments areas, absent the geographic adjustment.

§ 422.306 Annual MA capitation rates.

Subject to adjustments at § 422.308(b) and § 422.308(g), the annual capitation rate for each MA local area is determined under paragraph (a) of this section for 2005 and each succeeding year, except for years when CMS announces under § 422.312(b) that the annual capitation rates will be determined under paragraph (b) of this section.

(a) *Minimum percentage increase rate.* The annual capitation rate for each MA local area is equal to the minimum percentage increase rate, which is the greater of—

(1) 102 percent of the annual capitation rate for the preceding year; or

(2) The annual capitation rate for the area for the preceding year increased by the national per capita MA growth percentage (defined at § 422.308(a)) for the year, but not taking into account any adjustment under § 422.308(b) for a year before 2004.

(b) *Greater of the minimum percentage increase rate or local area fee-for-service costs.* The annual capitation rate for each MA local area is the greater of—

(1) The minimum percentage increase rate under paragraph (a) of this section; or

(2) The amount determined, no less frequently than every 3 years, to be the adjusted average per capita cost for the MA local area, as determined under section 1876(a)(4) of the Act, based on 100 percent of fee-for-service costs for individuals who are not enrolled in an MA plan for the year, with the following adjustments:

(i) Adjusted as appropriate for the purpose of risk adjustment;

(ii) Adjusted to exclude costs attributable to payments under section 1886(h) of the Act for the costs of direct graduate medical education; and

(iii) Adjusted to include CMS' estimate of the amount of additional per capita payments that would have been made in the MA local area if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs.

§ 422.308 Adjustments to capitation rates, benchmarks, bids, and payments.

CMS performs the following calculations and adjustments to determine rates and payments:

(a) *National per capita growth percentage.* The national per capita growth percentage for a year, applied under § 422.306, is CMS' estimate of the rate of growth in per capita expenditures under this title for an individual entitled to benefits under Part A and enrolled under Part B. CMS may make separate estimates for aged enrollees, disabled enrollees, and enrollees who have ESRD.

(b) *Adjustment for over or under projection of national per capita growth percentages.* CMS will adjust the minimum percentage increase rate at § 422.306(a)(2) and the adjusted average per capita cost rate at § 422.306(b)(2) for the previous year to reflect any differences between the projected national per capita growth percentages for that year and previous years, and the current estimates of those percentages for those years. CMS will not make this adjustment for years before 2004.

(c) *Risk adjustment*—(1) *General rule.* CMS will adjust the payment amounts under § 422.304(a)(1), (a)(2), and (a)(3) for age, gender, disability status, institutional status, and other factors CMS determines to be appropriate, including health status, in order to ensure actuarial equivalence. CMS may add to, modify, or substitute for risk adjustment factors if those changes will improve the determination of actuarial equivalence.

(2) *Risk adjustment: Health status*—(i) *Data collection.* To adjust for health status, CMS applies a risk factor based on data obtained in accordance with § 422.310.

(ii) *Implementation.* CMS applies a risk factor that incorporates inpatient hospital and ambulatory risk adjustment data. This factor is phased as follows:

(A) 100 percent of payments for ESRD MA enrollees in 2005 and succeeding years.

(B) 75 percent of payments for aged and disabled enrollees in 2006.

(C) 100 percent of payments for aged and disabled enrollees in 2007 and succeeding years.

(3) *Uniform application.* Except as provided for MA RFB plans under § 422.304(b)(3), CMS applies this adjustment factor to all types of plans.

(d) *Adjustment for intra-area variations.* CMS makes the following adjustments to payments.

(1) *Intra-regional variations.* For payments to MA regional plans, CMS will adjust the payment amounts specified at § 422.304(a)(1) and (a)(2) to take into account variations in local payments rates among the different MA local areas included in the region.

(2) *Intra-service area variations.* For payments to MA local plans with service areas covering more than one MA local area (county), CMS will adjust the payment amounts specified in § 422.304(a)(1) and (a)(2) to take into account variations in local payment rates among the different MA local areas included in the plan's service area.

(e) *Adjustment relating to risk adjustment and beneficiary premiums.* CMS will adjust payments to an MA plan as necessary to ensure that the sum of CMS' monthly payment made under § 422.304(a) and the plan's monthly

basic beneficiary premium equals the unadjusted MA statutory non-drug bid amount adjusted for risk and for intra-area or intra-regional payment variation.

(f) *Adjustment of payments to reflect number of Medicare enrollees*—(1) *General rule.* CMS adjusts payments retroactively to take into account any difference between the actual number of Medicare enrollees and the number on which it based an advance monthly payment.

(2) *Special rules for certain enrollees.* (i) Subject to paragraph (f)(2)(ii) of this section, CMS may make adjustments, for a period (not to exceed 90 days) that begins when a beneficiary elects a group health plan (as defined in § 411.1010) offered by an MA organization, and ends when the beneficiary is enrolled in an MA plan offered by the MA organization.

(ii) CMS does not make an adjustment unless the beneficiary certifies that, at the time of enrollment under the MA plan, he or she received from the organization the disclosure statement specified in § 422.111.

(g) *Adjustment for national coverage determination (NCD) services and legislative changes in benefits.* If CMS determines that the cost of furnishing an NCD service or legislative change in benefits is significant, as defined in § 422.109, CMS will adjust capitation rates, or make other payment adjustments, to account for the cost of the service or legislative change in benefits. Until the new capitation rates are in effect, the MA organization will be paid for the significant cost NCD service or legislative change in benefits on a fee-for-service basis as provided under § 422.109(b).

(h) *Adjustments to payments to regional MA plans for purposes of risk corridor payments.* For the purpose of calculation of risk corridors under § 422.458, MA organizations offering regional MA plans in 2006 and/or 2007 must submit, after the end of a contract year and before a date CMS specifies, the following information:

(1) Actual allowable costs (defined in § 422.458(a)) for the previous contract year.

(2) The portion of the costs attributable to administrative expenses incurred in providing these benefits.

(3) The total costs for providing rebatable integrated benefits (as defined in § 422.458(a)) and the portion of the costs that is attributable to administrative expenses in addition to the administrative expenses described in paragraph (h)(2) of this section.

§ 422.310 Risk adjustment data.

(a) *Definition of risk adjustment data.* Risk adjustment data are all data that are used in the application of a risk adjustment payment model.

(b) *Data collection: Basic rule.* Each MA organization must submit to CMS (in accordance with CMS instructions) the data necessary to characterize the context and purposes of each service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. CMS may also collect data necessary to characterize the functional limitations of enrollees of each MA organization.

(c) *Sources and extent of data.* (1) To the extent required by CMS, risk adjustment data must account for the following:

(i) Services covered under the original Medicare program.

(ii) Medicare covered services for which Medicare is not the primary payer.

(iii) Other additional or supplemental benefits that the MA organization may provide.

(2) The data must account separately for each provider, supplier, physician, or other practitioner that would be permitted to bill separately under the original Medicare program, even if they participate jointly in the same service.

(d) *Other data requirements.* (1) MA organizations must submit data that conform to the requirements for equivalent data for Medicare fee-for-service when appropriate, and to all relevant national standards. Alternatively, MA organizations may submit data according to an abbreviated format, as specified by CMS.

(2) The data must be submitted electronically to the appropriate CMS contractor.

(3) MA organizations must obtain the risk adjustment data required by CMS from the provider, supplier, physician, or other practitioner that furnished the services.

(4) MA organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate risk adjustment data as required by CMS. These provisions may include financial penalties for failure to submit complete data.

(e) *Validation of risk adjustment data.* MA organizations and their providers and practitioners will be required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS.

(f) *Use of data.* CMS uses the data obtained under this section to determine the risk adjustment factor used to adjust payments, as required under § 422.304(a)(1), (a)(2), and (a)(3). CMS may also use the data for other purposes except for medical records data.

(g) *Deadlines for submission of risk adjustment data.* Risk adjustment factors for each payment year are based on risk adjustment data submitted for services furnished during the 12-month period before the payment year that is specified by CMS. As determined by CMS, this 12-month period may include a 6-month data lag that may be changed or eliminated as appropriate. (For example, the interim risk adjustment factors for CY 2004 were based on data for services furnished during the period July 1, 2002 through June 30, 2003, and the final risk adjustment factors for CY 2004 were based on data for services furnished during the period January 1, 2003 through December 31, 2003.)

(1) The annual deadline for risk adjustment data submission is the first Friday in September for risk adjustment data reflecting services furnished during the 12-month period ending the prior June 30, and the first Friday in March for data reflecting services furnished during the 12-month period ending the prior December 31. (For example, the deadline for submission of data for the period July 1, 2002 through June 30, 2003 was September 5, 2003, and the deadline for the period January 1, 2003 through December 31, 2003 was March 5, 2004.)

(2) CMS allows a reconciliation process to account for late data submissions. CMS continues to accept risk adjustment data submitted after the September and March deadlines until June 30 and December 31 of the payment year, respectively. (For example, until June 30, 2004 for data from the period July 1, 2002 through June 30, 2003; and, until December 31, 2004 for data from the period January 1, 2003 through December 31, 2003.) After the payment year is completed, CMS recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary. Risk adjustment data that are received after the annual December 31 late data submission deadline will not be accepted for the purposes of the reconciliation.

§ 422.312 Announcement of annual capitation rate, benchmarks, and methodology changes.

(a) *Capitation rates*—(1) *Initial announcement.* Not later than the first Monday in April each year, CMS announces to MA organizations and other interested parties the following information for each MA payment area for the following calendar year:

(i) The annual MA capitation rate.

(ii) The risk and other factors to be used in adjusting those rates under § 422.308 for payments for months in that year.

(2) CMS includes in the announcement an explanation of assumptions used and a description of the risk and other factors.

(3) *Regional benchmark announcement.* Before the beginning of each annual, coordinated election period under § 422.62(a)(2), CMS will announce to MA organizations and other interested parties the MA region-specific non-drug monthly benchmark amount for the year involved for each MA region and each MA regional plan for which a bid was submitted under § 422.256.

(b) *Advance notice of changes in methodology.* (1) No later than 45 days before making the announcement under paragraph (a)(1) of this section, CMS notifies MA organizations of changes it proposes to make in the factors and the methodology it used in the previous determination of capitation rates.

(2) The MA organizations have 15 days to comment on the proposed changes.

§ 422.314 Special rules for beneficiaries enrolled in MA MSA plans.

(a) *Establishment and designation of medical savings account (MSA).* A beneficiary who elects coverage under an MA MSA plan—

(1) Must establish an MA MSA with a trustee that meets the requirements of paragraph (b) of this section; and

(2) If he or she has more than one MA MSA, designate the particular account to which payments under the MA MSA plan are to be made.

(b) *Requirements for MSA trustees.* An entity that acts as a trustee for an MA MSA must—

(1) Register with CMS;

(2) Certify that it is a licensed bank, insurance company, or other entity qualified, under sections 408(a)(2) or 408(h) of the IRS Code, to act as a trustee of individual retirement accounts;

(3) Agree to comply with the MA MSA provisions of section 138 of the IRS Code of 1986; and

(4) Provide any other information that CMS may require.

(c) *Deposit in the MA MSA.* (1) The payment is calculated as follows:

(i) The monthly MA MSA premium is compared with 1/12 of the benchmark amount for the area determined under § 422.306.

(ii) If the monthly MA MSA premium is less than 1/12 of the annual capitation rate, the difference is the amount to be deposited in the MA MSA for each month for which the beneficiary is enrolled in the MSA plan.

(2) CMS deposits the full amount to which a beneficiary is entitled under paragraph (c)(1)(ii) of this section for the calendar year, beginning with the month in which MA MSA coverage begins.

(3) If the beneficiary's coverage under the MA MSA plan ends before the end of the calendar year, CMS recovers the amount that corresponds to the remaining months of that year.

§ 422.316 Special rules for payments to federally qualified health centers.

If an enrollee in an MA plan receives a service from a federally qualified health center (FQHC) that has a written agreement with the MA organization offering the plan concerning the provision of this service (including the agreement required under section 1857(e)(3) of the Act and as codified in § 422.527)—

(a) CMS will pay the amount determined under section 1833(a)(3)(B) of the Act directly to the FQHC at a minimum on a quarterly basis; and

(b) CMS will not reduce the amount of the monthly payments under this section as a result of the application of paragraph (a) of this section.

§ 422.318 Special rules for coverage that begins or ends during an inpatient hospital stay.

(a) *Applicability.* This section applies to inpatient services in a "subsection (d) hospital" as defined in section 1886(d)(1)(B) of the Act, a rehabilitation hospital described in section 1886(d)(1)(B)(ii) of the Act, a distinct part rehabilitation unit described in the matter following clause (v) of section 1886(d)(1)(B) of the Act, or a long-term care hospital (described in section 1886(d)(1)(B)(iv)).

(b) *Coverage that begins during an inpatient stay.* If coverage under an MA plan offered by an MA organization begins while the beneficiary is an inpatient in one of the facilities described in paragraph (a) of this section—

(1) Payment for inpatient services until the date of the beneficiary's discharge is made by the previous MA organization or original Medicare, as appropriate;

(2) The MA organization offering the newly-elected MA plan is not responsible for the inpatient services until the date after the beneficiary's discharge; and

(3) The MA organization offering the newly-elected MA plan is paid the full amount otherwise payable under this subpart.

(c) *Coverage that ends during an inpatient stay.* If coverage under an MA plan offered by an MA organization ends while the beneficiary is an inpatient in one of the facilities described in paragraph (a) of this section—

(1) The MA organization is responsible for the inpatient services until the date of the beneficiary's discharge;

(2) Payment for those services during the remainder of the stay is not made by original Medicare or by any succeeding MA organization offering a newly-elected MA plan; and

(3) The MA organization that no longer provides coverage receives no payment for the beneficiary for the period after coverage ends.

§ 422.320 Special rules for hospice care.

(a) *Information.* An MA organization that has a contract under subpart K of this part must inform each Medicare enrollee eligible to select hospice care under § 418.24 of this chapter about the availability of hospice care (in a manner that objectively presents all available hospice providers, including a statement of any ownership interest in a hospice held by the MA organization or a related entity) if—

(1) A Medicare hospice program is located within the plan's service area; or

(2) It is common practice to refer patients to hospice programs outside that area.

(b) *Enrollment status.* Unless the enrollee disenrolls from the MA plan, a beneficiary electing hospice continues his or her enrollment in the MA plan and is entitled to receive, through the MA plan, any benefits other than those that are the responsibility of the Medicare hospice.

(c) *Payment.* (1) No payment is made to an MA organization on behalf of a Medicare enrollee who has elected hospice care under § 418.24 of this chapter, except for the portion of the payment attributable to the beneficiary rebate for the MA plan, described in § 422.266(b)(1) plus the amount of the monthly prescription drug beneficiary premium (described at § 422.252). This no-payment rule is effective from the first day of the month following the month of election to receive hospice care, until the first day of the month following the month in which the election is terminated.

(2) During the time the hospice election is in effect, CMS' monthly capitation payment to the MA organization is reduced to the sum of—

(i) An amount equal to the beneficiary rebate for the MA plan, as described in § 422.304(a)(3) or to zero for plans with

no beneficiary rebate, described at § 422.304(a)(2); and

(ii) The amount of the monthly prescription drug beneficiary premium (if any).

(3) In addition, CMS pays through the original Medicare program (subject to the usual rules of payment)—

(i) The hospice program for hospice care furnished to the Medicare enrollee; and

(ii) The MA organization, provider, or supplier for other Medicare-covered services to the enrollee.

§ 422.322 Source of payment and effect of MA plan election on payment.

(a) *Source of payments.* (1) Payments under this subpart for original fee-for-service benefits to MA organizations or MA MSAs are made from the Federal Hospital Insurance Trust Fund or the Supplementary Medical Insurance Trust Fund. CMS determines the proportions to reflect the relative weight that benefits under Part A, and benefits under Part B represents of the actuarial value of the total benefits under title XVIII of the Act.

(2) Payments to MA–PD organizations for statutory drug benefits provided under this title are made from the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

(b) *Payments to the MA organization.* Subject to § 412.105(g) and § 413.86(d) of this chapter and § 422.109, § 422.264, and § 422.266, CMS' payments under a contract with an MA organization (described in § 422.304) with respect to an individual electing an MA plan offered by the organization are instead of the amounts which (in the absence of the contract) would otherwise be payable under original Medicare for items and services furnished to the individual.

(c) *Only the MA organization entitled to payment.* Subject to § 422.314, § 422.318, § 422.320, and § 422.520 and sections 1886(d)(11) and 1886(h)(3)(D) of the Act, only the MA organization is entitled to receive payment from CMS under title XVIII of the Act for items and services furnished to the individual.

§ 422.324 Payments to MA organizations for graduate medical education costs.

(a) MA organizations may receive direct graduate medical education payments for the time that residents spend in non-hospital provider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs.

(b) MA organizations may receive direct graduate medical education payments if all of the following conditions are met:

(1) The resident spends his or her time assigned to patient care activities.

(2) The MA organization incurs "all or substantially all" of the costs for the training program in the non-hospital setting as defined in § 413.86(b) of this chapter.

(3) There is a written agreement between the MA organization and the non-hospital site that indicates the MA organization will incur the costs of the resident's salary and fringe benefits and provide reasonable compensation to the non-hospital site for teaching activities.

(c) An MA organization's allowable direct graduate medical education costs, subject to the redistribution and community support principles specified in § 413.85(c) of this chapter, consist of—

(1) Residents' salaries and fringe benefits (including travel and lodging where applicable); and

(2) Reasonable compensation to the non-hospital site for teaching activities related to the training of medical residents.

(d) The direct graduate medical education payment is equal to the product of—

(1) The lower of—

(i) The MA organization's allowable costs per resident as defined in paragraph (c) of this section; or

(ii) The national average per resident amount; and

(2) Medicare's share, which is equal to the ratio of the number of Medicare beneficiaries enrolled to the total number of individuals enrolled in the MA organization.

(e) Direct graduate medical education payments made to MA organizations under this section are made from the Federal Supplementary Medical Insurance Trust Fund.

Subpart I—Organization Compliance With State Law and Preemption by Federal Law

49. Section 422.402 is revised to read as follows:

§ 422.402 Federal preemption of State law.

The standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to the MA plans that are offered by MA organizations.

50. Amend § 422.404 by revising paragraph (a) to read as follows:

§ 422.404 State premium taxes prohibited.

(a) *Basic rule.* No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, or any of their political subdivisions or other governmental authorities with respect to any payment CMS makes on behalf of MA enrollees under subpart G of this part, or with respect to any payment made to MA plans by beneficiaries, or payment to MA plans by a third party on a beneficiary's behalf.

* * * * *

51. A new subpart J is added to read as follows:

Subpart J—Special Rules for MA Plans

Sec.

Subpart J—Special Rules for MA Plans

§ 422.451 Moratorium on new local preferred provider organization plans.

CMS will not approve the offering of a local preferred provider organization plan during 2006 or 2007 in a service area unless the plan was offered before December 31, 2005.

§ 422.455 Special rules for MA plans.

(a) *Coverage of entire MA region.* The service area for an MA regional plan will consist of an entire MA region established under paragraph (b) this section, and an MA region may not be segmented as described in § 422.262(c)(2).

(b) *Establishment of MA regions*—(1) *MA region.* The term "MA region" means a region within the 50 States and the District of Columbia as established by CMS under this section.

(2) *Establishment*—(i) *Initial establishment.* By January 1, 2005, CMS will establish and publish the MA regions.

(ii) *Periodic review and revision of service areas.* CMS may periodically review MA regions and may revise the regions if it determines the revision to be appropriate.

(3) *Requirements for MA regions.* CMS will establish, and may revise, MA regions in a manner consistent with the following:

(i) *Number of regions.* There will be no fewer than 10 regions, and no more than 50 regions.

(ii) *Maximizing availability of plans.* The main purpose of the regions is to maximize the availability of MA regional plans to all MA eligible individuals without regard to health status, or geographic location, especially those residing in rural areas.

(4) *Market survey and analysis.* Before establishing MA regions, CMS will

conduct a market survey and analysis, including an examination of current insurance markets, to assist CMS in determining how the regions should be established.

(c) *National plan.* An MA regional plan can be offered in more than one MA region (including all regions).

§ 422.458 Risk sharing with regional MA organizations for 2006 and 2007.

(a) *Terminology.* For purposes of this section—

Allowable costs means, with respect to an MA regional plan offered by an organization for a year, the total amount of costs that the organization incurred in providing benefits covered under the original Medicare fee-for-service program option for all enrollees under the plan in the region in the year and in providing rebatable integrated benefits, as defined in this paragraph, reduced by the portion of those costs attributable to administrative expenses incurred in providing these benefits.

Rebatable integrated benefits means those non-drug supplemental benefits that are funded through beneficiary rebates (described at § 422.266(b)(1)) and that CMS determines are: additional health benefits not covered under the original Medicare program option; and benefits that require expenditures by the plan. For purposes of the calculation of risk corridors, these are the only supplemental benefits that count towards allowable costs.

Target amount means, with respect to an MA regional plan offered by an organization in a year, the total amount of payments made to the organization for enrollees in the plan for the year (which includes payments attributable to benefits under the original Medicare fee-for-service program option as defined in § 422.100(c)(1), the total of the MA monthly basic beneficiary premium collectable for those enrollees for the year, and the total amount of rebatable integrated benefits), reduced by the amount of administrative expenses assumed in the portion of the bid attributable to benefits under original Medicare fee-for-service program option and rebatable integrated benefits.

(b) *Application of risk corridors for benefits covered under original fee-for-service Medicare*—(1) *General rule.* This section will only apply to MA regional plans offered during 2006 or 2007.

(2) *Notification of allowable costs under the plan.* In the case of an MA organization that offers an MA regional plan in an MA region in 2006 or 2007, the organization must notify CMS, before that date in the succeeding year as CMS specifies, of—

(i) Its total amount of costs that the organization incurred in providing benefits covered under the original Medicare fee-for-service program option for all enrollees under the plan (as described in paragraph (a) of this section).

(ii) Its total amount of costs that the organization incurred in providing rebatable integrated benefits for all enrollees under the plan (as described in paragraph (a) of this section), and, with respect to those benefits, the portion of those costs that is attributable to administrative expenses that is in addition to the administrative expense incurred in provision of benefits under the original Medicare fee-for-service program option.

(c) *Adjustment of payment*—(1) *No adjustment if allowable costs within 3 percent of target amount.* If the allowable costs for the plan for the year are at least 97 percent, but do not exceed 103 percent of the target amount for the plan and year, there will be no payment adjustment under this section for the plan and year.

(2) *Increase in payment if allowable costs above 103 percent of target amount*—(i) *Costs between 103 and 108 percent of target amount.* If the allowable costs for the plan for the year are greater than 103 percent, but not greater than 108 percent of the target amount for the plan and year, CMS will increase the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a) of the Act) by an amount equal to 50 percent of the difference between those allowable costs and 103 percent of that target amount.

(ii) *Costs above 108 percent of target amount.* If the allowable costs for the plan for the year are greater than 108 percent of the target amount for the plan and year, CMS will increase the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) of the Act by an amount equal to the sum of—

(A) 2.5 percent of that target amount; and

(B) 80 percent of the difference between those allowable costs and 108 percent of that target amount.

(3) *Reduction in payment if allowable costs below 97 percent of target amount*—(i) *Costs between 92 and 97 percent of target amount.* If the allowable costs for the plan for the year are less than 97 percent, but greater than or equal to 92 percent, of the target amount for the plan and year, CMS will reduce the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a) of the Act) by an amount (or otherwise recover from the plan an amount) equal to 50 percent of the difference between 97 percent of the target amount and those allowable costs.

(ii) *Costs below 92 percent of target amount.* If the allowable costs for the plan for the year are less than 92 percent of the target amount for the plan and year, CMS will reduce the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a) of the Act) by an amount (or otherwise recover from the plan an amount) equal to the sum of—

(A) 2.5 percent of that target amount; and

(B) 80 percent of the difference between 92 percent of that target amount and those allowable costs.

(d) *Disclosure of information*—(1) *General rule.* Each MA organization offering an MA regional plan must provide CMS with information as CMS determines is necessary to implement this section; and

(2) According to existing § 422.502(d)(1)(iii) (section 1857(d)(2)(B) of the Act), CMS has the right to inspect and audit any books and records of the organization that pertain to the information regarding costs provided to CMS under paragraph (b)(2) of this section.

(3) *Restriction on use of information.* Information disclosed or obtained for the purposes of this section may be used by officers, employees, and contractors of DHHS only for the purposes of, and to the extent necessary, in implementing this section.

(e) *Organizational and financial requirements*—(1) *General rule.* In the case of an MA organization that is offering an MA regional plan in an MA region, the following rules apply:

(i) The MA organization must be licensed to bear risk in at least one State of the region.

(ii) For the other States in a region in which the organization is not licensed to bear risk, if it demonstrates to CMS that it has filed the necessary application to meet those requirements, CMS may temporarily waive the licensing requirement with respect to each State for a period of time as CMS determines appropriate for the timely processing of the application by the State or States.

(iii) If the State licensing application or applications are denied, CMS may extend the licensing waiver through the end of the plan year or as CMS determines appropriate to provide for a transition.

(2) *Selection of appropriate State.* In the case of an MA organization to which CMS grants a waiver and that is licensed in more than one State in a region, the MA organization will select one of the States and CMS will apply its licensing rules in States where the organization is not licensed for the period of the waiver.

(f) *Regional stabilization fund*—(1) *Establishment.* The MA Regional Plan Stabilization Fund (referred to in this paragraph as the "Fund") is available beginning in 2007 for two purposes:

(i) *Plan entry.* To provide incentives to have MA regional plans offered in each MA region under paragraph (f)(4) of this section.

(ii) *Plan retention.* To provide incentives to retain MA regional plans in certain MA regions with below-national-average MA market penetration under paragraph (f)(5) of this section.

(2) *Availability of funding from savings.* Funds made available under section 1853(f) of the Act are transferred into a special account in the Treasury from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in the proportion specified in section 1853(f) of the Act, "payments From Trust Funds," on a monthly basis.

(3) *Funding limitation*—(i) *General rule.* The total amount expended from the Fund as a result of the application of this section through the end of a calendar year may not exceed the amount available to the Fund as of the first day of that year. For purposes of this section, amounts that are expended under this title insofar as those amounts would not have been expended but for the application of this section will be counted as amounts expended as a result of that application.

(ii) *Application of limitation.* CMS will obligate funds from the Fund for a year only if the Chief Actuary of CMS and the appropriate budget officer certify that there are available in the Fund at the beginning of the year sufficient amounts to cover all of those obligations incurred during the year consistent with paragraph (f)(3)(i) of this section. CMS will take those steps, in connection with computing additional payment amounts under paragraphs (f)(4) and (f)(5) of this section and including limitations on enrollment in MA regional plans receiving those payments, to ensure that sufficient funds are available to make those payments for the entire year.

(4) *Plan entry funding*—(i) *General rule.* Funding is available under this paragraph for a year in the following situations:

(A) *National plan.* For a national bonus payment described in paragraph (f)(4)(ii) of this section, when a single MA organization offers an MA regional plan in each MA region in the year, but only if there was not a national plan offered in each region in the previous year. Funding under this paragraph is only available with respect to any individual MA organization for a single year, but may be made available to more than one such organization in the same year.

(B) *Regional plans.* Subject to paragraph (f)(4)(i)(C) of this section, for an increased amount under paragraph (f)(4)(iv) of this section for an MA regional plan offered in an MA region that did not have any MA regional plan offered in the prior year.

(C) *Limitation on regional plan funding in case of national plan.* There will be no payment adjustment under paragraph (f)(4)(iii) of this section for a year for which a national bonus payment is made under paragraph (f)(4)(ii) of this section.

(ii) *National bonus payment.* The national bonus payment under this paragraph will—

(A) Be available to an MA organization only if the organization offers MA regional plans in every MA region;

(B) Be available for all MA regional plans of the organization regardless of whether any other MA regional plan is offered in any region; and

(C) Be subject to amounts available under paragraph (f)(3) of this section for a year and be equal to 3 percent of the benchmark amount otherwise applicable for each MA regional plan offered by the organization.

(iii) *Regional payment adjustment*—(A) *General rule.* The increased amount under this paragraph for an MA regional plan in an MA region for a year must be an amount, determined by CMS, based on the bid submitted for that plan (or plans) and will be available to all MA regional plans offered in that region and year. That amount may be based on the mean, mode, or median or other measure of those bids and may vary from region to region. CMS will not limit the number of plans or bids in a region.

(B) *Multi-year funding.* Subject to amounts available under paragraph (f)(3) of this section, funding will be available for a period determined by CMS.

(C) *Application to all plans in a region.* Funding under this paragraph for an MA region will be made available for all MA regional plans offered in the region.

(D) *Limitation on availability of plan retention funding in next year.* If plans receive plan entry funding in a year, plans in that region are prohibited from receiving plan retention funding in the following year.

(iv) *Application.* Any additional payment under this section provided for an MA regional plan for a year will be treated as if it were an addition to the benchmark amount otherwise applicable to that plan and year, but will not be taken into account in the computation of any benchmark amount for any subsequent year.

(5) *Plan retention funding*—(i) *General rule.* Funding is available under this paragraph for a year with respect to MA regional plans offered in an MA region for the increased amount specified in paragraph (f)(5)(ii) of this section but only if the region meets the requirements of paragraphs (f)(5)(iii)(A), (f)(5)(iii)(B), (f)(5)(iii)(C) and (f)(5)(iii)(E) of this section.

(ii) *Payment increase.* The increased amount under this paragraph for an MA regional plan in an MA region for a year will be an amount, determined by CMS, that does not exceed the greater of—

(A) 3 percent of the benchmark amount applicable in the region; or

(B) The amount as (when added to the benchmark amount applicable to the region) will result in the ratio of—

(*1*) That additional amount plus the benchmark amount computed under section 1854(b)(4)(B)(i) of the Act, "the risk-adjusted benchmark amount" for the region and year, to the adjusted average per capita cost for the region and year, as estimated by CMS under section 1876(a)(4) of the Act and adjusted as appropriate for the purpose of risk adjustment; being equal to—

(*2*) The weighted average of those benchmark amounts for all the regions and that year, to the average per capita cost for the United States and that year, as estimated by CMS under section 1876(a)(4) of the Act and adjusted as appropriate for the purpose of risk adjustment.

(iii) *Regional requirements.* The requirements of this paragraph for an MA region for a year are as follows:

(A) *Notification of plan exit.* CMS has received notice (as specified by CMS) before a new contract year, that one or more MA regional plans that were offered in the region in the previous year will not be offered in the succeeding year.

(B) *Regional plans available from fewer than two MA organizations in the region.* CMS determines that if the plans referred to in paragraph (f)(5)(ii)(A) of this section are not offered in the year, fewer than two MA organizations will

be offering MA regional plans in the region in the year involved.

(C) *Percentage enrollment in MA regional plans below national average.* For the previous year, CMS determines that the average percentage of MA eligible individuals residing in the region who are enrolled in MA regional plans is less than the average percentage of those individuals in the United States enrolled in those plans.

(D) *Application.* Any additional payment under this paragraph provided for an MA regional plan for a year will be treated as if it were an addition to the benchmark amount otherwise applicable to that plan and year, but will not be taken into account in the computation of any benchmark amount for any subsequent year.

(E) *2-consecutive-year limitation.* In no case will plan retention funding be available under this paragraph in an MA region for more than 2 consecutive years.

Subpart K—Contracts With Medicare Advantage Organizations

§ 422.501, § 422.502, and § 422.504 [Redesignated]

52. Redesignate § 422.501, § 422.502, and § 422.504 as § 422.503, § 422.504, and § 422.505 respectively.

53. Add new § 422.501 to read as follows:

§ 422.501 Application requirements.

(a) *Scope.* This section sets forth application requirements for entities that seek a contract as an MA organization offering an MA plan.

(b) *Completion of an application.* (1) In order to obtain a determination on whether it meets the requirements to become an MA organization and is qualified to provide a particular type of MA plan, an entity, or an individual authorized to act for the entity (the applicant) must complete a certified application, in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards applicable to MA plans, and is authorized by the State to accept prepaid capitation for providing, arranging, or paying for the comprehensive health care services to be offered under the MA contract; or

(ii) For regional plans, documentation of application for State licensure in any State in the region that the organization is not already licensed.

(2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, the requirements described in this part.

(c) *Responsibility for making determinations.* CMS is responsible for determining whether an entity qualifies as an MA organization and whether proposed MA plans meet the requirements of this part.

(d) *Resubmittal of application.* An application that has been denied by CMS may not be resubmitted for 4 months after the date of the notice from CMS denying the application.

(e) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exceptions provided in 45 CFR part 5 (the Department's regulations providing exceptions to disclosure), should label the material "privileged" and include an explanation of the applicability of an exception described in 45 CFR part 5.

54. Add new § 422.502 to read as follows:

§ 422.502 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an application for an MA contract on the basis of information contained in the application itself and any additional information that CMS obtains through other means such as on-site visits, public hearings, and any other appropriate procedures.

(2) If the application is incomplete, CMS notifies the contract applicant and allows 30 days from the date of the notice for the contract applicant to furnish the missing information.

(3) After evaluating all relevant information, CMS determines whether the contract applicant's application meets the applicable requirements of § 422.501.

(b) *Use of information from a prior contracting period.* If an MA organization has failed to comply with the terms of a previous contract with CMS under title XVIII of the Act, or has failed to complete a corrective action plan during the term of the contract, CMS may deny an application from a contract applicant based on the contract applicant's failure to comply with that prior contract with CMS even if the contract applicant meets all of the current requirements.

(c) *Notice of determination.* Within timeframes determined by CMS, it notifies each applicant that applies for an MA contract under this part of its determination and the basis for the determination. The determination may be approval, intent to deny, or denial.

(d) *Approval of application.* If CMS approves the application, it gives written notice to the contract applicant, indicating that it meets the requirements for an MA contract.

(e) *Intent to deny.* (1) If CMS finds that the contract applicant does not appear to be able to meet the requirements for an MA organization within 60 days, CMS gives the contract applicant notice of intent to deny the application for an MA contract and a summary of the basis for this preliminary finding.

(2) Within 60 days from the date of the intent to deny notice, the contract applicant may respond in writing to the issues or other matters that were the basis for CMS' preliminary finding and may revise its application to remedy any defects CMS identified.

(f) *Denial of application.* If CMS denies the application, it gives written notice to the contract applicant indicating—

(1) That the contract applicant does not meet the contract requirements under Part C of title XVIII of the Act;

(2) The reasons why the contract applicant does not meet the contract requirements; and

(3) The contract applicant's right to request reconsideration in accordance with the procedures specified in subpart N of this part.

(g) *Oversight of continuing compliance.* (1) CMS oversees an MA organization's continued compliance with the requirements for an MA organization.

(2) If an MA organization no longer meets those requirements, CMS terminates the contract in accordance with § 422.510.

§ 422.503 [Amended]

55. Amend newly redesignated § 422.503 by—

A. Redesignating paragraphs (b)(1) through (b)(5) as paragraphs (b)(2) through (b)(6) respectively.

B. Adding new paragraph (b)(1).

C. Revising newly redesignated paragraph (b)(4)(ii).

D. Revising newly redesignated paragraph (b)(4)(vi)(F).

E. Adding new paragraphs (b)(4)(vi)(G)(*1*), (*2*), and (*3*).

F. Revising newly redesignated paragraph (b)(6) introductory text.

G. Revising newly redesignated paragraph (b)(6)(i).

The revisions read as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *

(1) Complete an application as described in § 422.501.

* * * * *

(4) * * *

(ii) Personnel and systems sufficient for the M+C organization to organize, implement, control, and evaluate financial and marketing activities, the furnishing of services, the quality assurance program, and the administrative and management aspects of the organization.

* * * * *

(vi) * * *

(F) Procedures for internal monitoring and auditing.

(G) * * *

(*1*) If the MA organization discovers from any source evidence of misconduct related to payment or delivery of health benefits under the contract, it must conduct a timely, reasonable inquiry into that misconduct.

(*2*) If, after reasonable inquiry, the MA organization has determined that the misconduct may violate criminal, civil or administrative law, the sponsor must report the existence of the misconduct to the appropriate Government authority within a reasonable period, but not more than 60 days after the determination that a violation may have occurred. If the potential violation relates to Federal criminal law, the civil False Claims Act, Federal Anti-Kickback provisions, the civil monetary penalties authorities (primarily under section 1128A and 1857 of the Social Security Act), or related statutes enforced by the HHS Office of Inspector General, the report must be made to that Office.

(*3*) The PDP sponsor must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees, etc.) in response to the potential violation referenced above.

* * * * *

(6) The MA organization's contract must not have been non-renewed under § 422.506 within the past 2 years unless—

(i) During the 6-month period beginning on the date the organization notified CMS of the intention to non-renew the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing MA payments in the payment area or areas at issue; or

* * * * *

§ 422.504 [Amended]

56. Amend newly redesignated § 422.504 by—

A. Revising paragraph (e)(4) introductory text.

B. Revising paragraph (e)(4)(ii)

C. Revising paragraph (e)(4)(iii).

D. Removing paragraph (f)(2)(vii).

E. Redesignating paragraph (f)(2)(viii) as paragraph (f)(2)(vii).

F. Revising paragraph (i)(3)(ii).

The revisions read as follows:

§ 422.504 Contract provisions.

* * * * *

(e) * * *

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 6 years from the end of the final contract period or completion of audit, whichever is later unless—

* * * * *

(ii) There has been a termination, dispute, or allegation of fraud or similar fault by the MA organization, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, fraud, or similar fault; or

(iii) CMS determines that there is a reasonable possibility of fraud or similar fault, in which case CMS may inspect, evaluate, and audit the MA organization at any time.

* * * * *

(i) * * *

(3) * * *

(ii) Accountability provisions that indicate that the MA organization may only delegate activities or functions to a provider, related entity, contractor, or subcontractor in a manner consistent with the requirements set forth at paragraph (i)(4)of this section.

* * * * *

57. Amend § 422.506 by—

A. Revising paragraph (a)(2)(i).

B. Revising paragraph (a)(2)(ii).

C. Revising paragraph (a)(3) introductory text.

The revisions read as follows:

§ 422.506 Nonrenewal of contract.

(a) * * *

(2) * * *

(i) CMS in writing, by the first Monday in June of the year in which the contract would end;

(ii) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice must include a written description of alternatives available for obtaining Medicare services within the service area, including alternative MA plans, Medigap options, and original Medicare and must receive CMS approval prior to issuance.

* * * * *

(3) CMS may accept a nonrenewal notice submitted after the first Monday in June if—

* * * * *

58. Amend § 422.510 by revising paragraph (a)(4) to read as follows:

§ 422.510 Termination of Contract by CMS.

(a) * * *

(4) There is credible evidence that the PDP sponsor committed or participated in false, fraudulent, or abusive activities affecting the Medicare program, including submission of false or fraudulent data.

* * * * *

§ 422.520 [Amended]

59. Amend § 422.520 by—

A. Revising the section heading.

B. Revising paragraph (a)(3).

C. Redesignating paragraph (b) introductory text as paragraph (b)(1).

D. Adding new paragraph (b)(2).

E. Adding new paragraph (d).

The revisions and additions read as follows:

§ 422.520 Prompt payment by MA organization.

(a) * * *

(3) All other claims from non-contracted providers must be paid or denied within 60 calendar days from the date of the request.

(b) * * *

(2) The MA organization is obligated to pay contracted providers under the terms of the contract between the MA organization and the provider.

* * * * *

(d) A CMS decision to not conduct a hearing under paragraph (c) of this section does not disturb any potential remedy under State law for 1866(a)(1)(O) of the Act.

60. Add new § 422.527 at the end of subpart K to read as follows:

§ 422.527 Agreements with federally qualified health centers.

The contract between the MA organization and CMS must contain the following provisions:

(a) The MA organization must pay a federally qualified health center (FQHC) a similar amount to what it pays other providers for similar services.

(b) Under such a contract, the FQHC must accept this payment as payment in full, except for allowable cost sharing which it may collect.

Subpart M—Grievances, Organization Determinations and Appeals

61. Amend § 422.560 by adding paragraph (a)(3) to read as follows:

§ 422.560 Basis and scope.

(a) * * *

(3) Section 1869 of the Act specifies the amount in controversy needed to pursue a hearing and judicial review and authorizes representatives to act on

behalf of individuals that seek appeals. These provisions are incorporated for MA appeals by section 1852(g)(5) of the Act.

* * * * *

62. Amend § 422.561 by revising the definition of "Authorized representative" to read as follows:

§ 422.561 Definitions.

* * * * *

Authorized representative means an individual authorized by an enrollee, or under State law, to act on his or her behalf in obtaining an organization determination or in dealing with any of the levels of the appeal process, subject to the rules described in part 405, subpart I of this chapter, unless otherwise stated in this subpart.

* * * * *

63. Amend § 422.562 by—

A. Revising paragraph (b)(4)(iv).

B. Revising paragraph (b)(4)(vi).

C. Revising paragraph (c)(1)(ii).

D. Revising paragraph (d).

The revisions read as follows:

§ 422.562 General provisions.

* * * * *

(b) * * *

(4) * * *

(iv) The right to an ALJ hearing if the amount in controversy is met, as provided in § 422.600.

* * * * *

(vi) The right to judicial review of the hearing decision if the amount in controversy is met, as provided in § 422.612.

(c) * * *

(1) * * *

(ii) The QIO review decision is subject only to the appeal procedures set forth in part 478 of this chapter.

* * * * *

(d) *When other regulations apply.* Unless this subpart provides otherwise, the regulations in part 405, subpart I of this chapter (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act), apply under this subpart to the extent they are appropriate.

64. Amend § 422.566 by revising paragraph (b)(4) to read as follows:

§ 422.566 Organization determinations.

* * * * *

(b) * * *

(4) Discontinuation or reduction of a service if the enrollee believes that continuation of the services is medically necessary.

* * * * *

§ 422.568 [Amended]

65. Amend § 422.568 by—

A. Revising paragraph (a).

B. Removing paragraph (c).

C. Redesignating paragraph (d) as paragraph (c).

D. Redesignating paragraph (e) as paragraph (d).

E. Redesignating paragraph (f) as paragraph (e).

F. Revising newly redesignated paragraph (c).

The revisions read as follows:

§ 422.568 Standard timeframes and notice requirements for organization determinations.

(a) *Timeframe for requests for service.* When a party has made a request for a service, the MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. The MA organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension.

* * * * *

(c) *Written notice for MA organization denials.* If an MA organization decides to deny service or payment in whole or in part, or if an enrollee disagrees with an MA organization's decision to discontinue or reduce the level of care for an ongoing course of treatment, the organization must give the enrollee written notice of the determination.

* * * * *

66. Amend § 422.570 by revising paragraph (d)(2)(ii) to read as follows:

§ 422.570 Expediting certain organization determinations.

* * * * *

(d) * * *

(2) * * *

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision not to expedite; and

* * * * *

67. Amend § 422.572 by revising paragraph (c) to read as follows:

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

* * * * *

(c) *Confirmation of oral notice.* If the MA organization first notifies an enrollee of an adverse expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

* * * * *

§ 422.582 [Amended]

68. Amend § 422.582 by—

A. Revising paragraph (a).

B. Revising paragraph (b).

C. Revising paragraph (c)(2).

The revisions read as follows:

§ 422.582 Request for a standard reconsideration.

(a) *Method and place for filing a request.* A party to an organization determination must ask for a reconsideration of the determination by making an oral or written request to—

(1) The MA organization that made the organization determination; or

(2) An SSA office.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a party must file a request for reconsideration within 60 calendar days from the date of the notice of the organization determination. If the SSA receives a request, it forwards the request to the MA organization for its reconsideration. The timeframe within which the organization must conduct its review begins when it receives the request.

(c) * * *

(2) *How to request an extension of timeframe.* If the 60-day period in which to file a request for reconsideration has expired, a party to the organization determination may file a request for reconsideration with the MA organization or the SSA. If the SSA receives a request, it forwards the request to the MA organization for its reconsideration. The request for reconsideration and to extend the timeframe must—

(i) Be in writing; and

(ii) State why the request for reconsideration was not filed on time.

* * * * *

69. Amend § 422.584 by revising paragraph (e) to read as follows:

§ 422.584 Expediting certain reconsiderations.

* * * * *

(e) *Action following acceptance of a request.* If an MA organization grants a request for expedited reconsideration, it must conduct the reconsideration and

give notice in accordance with § 422.590.

* * * * *

70. Amend § 422.590 by revising paragraph (d)(2) to read as follows:

§ 422.590 Timeframes and responsibility for reconsiderations.

* * * * *

(d) * * *

(2) *Extensions.* The MA organization may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

* * * * *

71. Amend § 422.600 by—

A. Revising paragraph (a).

B. Revising paragraph (b).

The revisions read as follows:

§ 422.600 Right to a hearing.

(a) If the amount remaining in controversy after reconsideration meets the threshold requirement established annually by the Secretary, any party to the reconsideration (except the MA organization) who is dissatisfied with the reconsidered determination has a right to a hearing before an ALJ.

(b) The amount remaining in controversy, which can include any combination of Part A and Part B services, is computed in accordance with part 405, subpart I of this chapter.

* * * * *

72. Amend § 422.602 by revising paragraph (d) to read as follows:

§ 422.602 Request for an ALJ hearing.

* * * * *

(d) *Insufficient amount in controversy.* (1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 422.600, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under § 422.600, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.

73. Revise § 422.608 to read as follows:

§ 422.608 Medicare Appeals Council (MAC) review.

Any party to the hearing, including the MA organization, who is dissatisfied with the ALJ hearing decision, may request that the MAC review the ALJ's decision or dismissal. The regulations under part 405, subpart I of this chapter regarding MAC review apply to matters addressed by this subpart.

74. Amend § 422.612 by—

A. Revising paragraph (a)(2).

B. Revising paragraph (b).

C. Revising paragraph (c).

The revisions read as follows:

§ 422.612 Judicial review.

(a) *Review of ALJ's decision.* * * *

(2) The amount in controversy meets the threshold requirement established annually by the Secretary.

(b) *Review of MAC decision.* Any party, including the MA organization, may request judicial review (upon notifying the other parties) of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) *How to request judicial review.* In order to request judicial review, a party must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. See part 405, subpart I of this chapter for a description of the procedures to follow in requesting judicial review.

75. Amend § 422.616 by revising paragraph (a) to read as follows:

§ 422.616 Reopening and revising determinations and decisions.

(a) An organization or reconsidered determination made by an MA organization, a reconsidered determination made by the independent entity described in § 422.592, or the decision of an ALJ or the MAC that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in part 405, subpart I of this chapter.

* * * * *

76. Amend § 422.620 by—

A. Revising the section heading.

B. Revising paragraph (b).

C. Revising paragraph (c).

The revisions read as follows:

§ 422.620 How enrollees of MA organizations must be notified of noncovered inpatient hospital care.

* * * * *

(b) *Physician concurrence required.* Before discharging an individual or changing the level of care in an inpatient hospital setting, the MA organization must obtain the concurrence of the physician who is responsible for the enrollee's inpatient care.

(c) *Notice to the enrollee.* The written notice of non-coverage must be issued no later than the day before hospital coverage ends. The written notice must include the following elements:

(1) The reason why inpatient hospital care is no longer needed or covered;

(2) The effective date and time of the enrollee's liability for continued inpatient care;

(3) The enrollee's appeal rights;

(4) If applicable, the new lower level of care being covered in the hospital setting; and

(5) Any additional information specified by CMS.

77. Amend § 422.622 by revising paragraph (b)(1)(i) to read as follows:

§ 422.622 Requesting immediate QIO review of noncoverage of inpatient hospital care.

* * * * *

(b) * * *

(1) * * *

(i) To the QIO that has an agreement with the hospital under part 475, subpart C of this chapter;

* * * * *

Subpart O—Intermediate Sanctions

78. Amend § 422.752 by revising paragraph (a)(8) introductory text to read as follows:

§ 422.752 Basis for imposing sanctions.

(a) * * *

(8) Employs or contracts with an individual or entity who is excluded from participation in Medicare under section 11128 or 1128A of the Act (or with an entity that employs or contracts with such an individual or entity) for the provision of any of the following:

* * * * *

Nomenclature Changes

79. In part 422, remove "Departmental Appeals Board" wherever it appears and add in its place "Medicare Appeals Council".

80. In part 422, remove "DAB" wherever it appears and add in its place "MAC".

81. In part 422, remove "Medicare+Choice" wherever it appears and add in its place "Medicare Advantage".

82. In part 422, remove "M+C" wherever it appears and add in its place "MA".

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 26, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: June 28, 2004.

Tommy G. Thompson,

Secretary.

[FR Doc. 04–17228 Filed 7–26–04; 12:01 pm]

BILLING CODE 4120–01–P

Reader Aids

Federal Register

Vol. 69, No. 148

Tuesday, August 3, 2004

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6064**
Public Laws Update Service (numbers, dates, etc.)	**741–6043**
TTY for the deaf-and-hard-of-hearing	**741–6086**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **http://www.gpoaccess.gov/nara/index.html**

Federal Register information and research tools, including Public Inspection List, indexes, and links to GPO Access are located at: **http://www.archives.gov/federal_register/**

E-mail

FEDREGTOC-L (Federal Register Table of Contents LISTSERV) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **http://listserv.access.gpo.gov** and select *Online mailing list archives, FEDREGTOC-L, Join or leave the list (orchange settings);* then follow the instructions.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html** and select *Join or leave the list* (or change settings); then follow the instructions.

FEDREGTOC-L and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, AUGUST

46095–46398..... 2
46399–46978..... 3

CFR PARTS AFFECTED DURING AUGUST

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

10 CFR

Administrative Orders:
Presidential Determinations:
No. 2004-40 of July 21, 2004.....46399

10 CFR

Proposed Rules:
50.....46452

14 CFR

Proposed Rules:
39.....46456

26 CFR

1.....46401
14a.....46401

38 CFR

3.....46426

42 CFR

Proposed Rules:
403.....46632
411.....46632
417 (2 documents).....46632, 46866
422.....46866
423.....46632

44 CFR

64.....46435
67 (2 documents).....46436, 46437

47 CFR

0.....46438
1.....46438
2.....46438
73.....46447
90.....46438
95.....46438

Proposed Rules:
2.....46462
73 (2 documents).....46474, 46476
90.....46462

50 CFR

660.....46448
679.....46451

REMINDERS
The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT AUGUST 3, 2004

COMMERCE DEPARTMENT
National Oceanic and Atmospheric Administration
Fishery conservation and management:
West Coast States and Western Pacific fisheries—
Pacific whiting; published 8-3-04

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Airworthiness directives:
Airbus; published 6-29-04
BAE Systems (Operations) Ltd.; published 6-29-04
Boeing; published 6-29-04
Bombardier; published 6-29-04
Empresa Brasileira de Aeronautica, S.A. (EMBRAER); published 6-29-04
Garmin AT; published 6-29-04
Pratt & Whitney Canada; published 7-19-04
Short Brothers; published 6-29-04

TREASURY DEPARTMENT
Internal Revenue Service
Income taxes:
Statutory stock options; published 8-3-04

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT
Agricultural Marketing Service
Cotton classing, testing and standards:
Classification services to growers; 2004 user fees; Open for comments until further notice; published 5-28-04 [FR 04-12138]
Kiwifruit grown in—
California; comments due by 8-12-04; published 7-28-04 [FR 04-17271]

AGRICULTURE DEPARTMENT
Cooperative State Research, Education, and Extension Service
Grants:
Food and Agricultural Sciences National Needs Graduate and Postgraduate Fellowship Program; comments due by 8-11-04; published 7-12-04 [FR 04-15779]

COMMERCE DEPARTMENT
National Oceanic and Atmospheric Administration
Fishery conservation and management:
Alaska; fisheries of Exclusive Economic Zone—
Pacific halibut fisheries; subsistence fishing; comments due by 8-9-04; published 7-9-04 [FR 04-15548]

COURT SERVICES AND OFFENDER SUPERVISION AGENCY FOR THE DISTRICT OF COLUMBIA
Semi-annual agenda; Open for comments until further notice; published 12-22-03 [FR 03-25121]

DEFENSE DEPARTMENT
Acquisition regulations:
Architect-engineer services contracting; comments due by 8-9-04; published 6-8-04 [FR 04-12935]
Commercial items acquisition; comments due by 8-9-04; published 6-8-04 [FR 04-12937]
Reporting contract performance outside United States; comments due by 8-9-04; published 6-8-04 [FR 04-12934]
Technical data conformity; written assurance; comments due by 8-9-04; published 6-8-04 [FR 04-12936]
Personnel, military and civilian:
DoD dependents; early intervention and special education services; comments due by 8-9-04; published 6-10-04 [FR 04-12497]

EDUCATION DEPARTMENT
Elementary and secondary education:
Disadvantaged children; academic achievement improvement; comments due by 8-9-04; published 6-24-04 [FR 04-14358]

ENERGY DEPARTMENT
Federal Energy Regulatory Commission
Electric rate and corporate regulation filings:
Virginia Electric & Power Co. et al.; Open for comments until further notice; published 10-1-03 [FR 03-24818]

ENVIRONMENTAL PROTECTION AGENCY
Air pollution; standards of performance for new stationary sources:
Large municipal waste combustors; emission guidelines; comments due by 8-13-04; published 7-14-04 [FR 04-15942]
Air quality implementation plans; approval and promulgation; various States; air quality planning purposes; designation of areas:
Ohio; comments due by 8-9-04; published 7-8-04 [FR 04-15203]
Air quality implementation plans; approval and promulgation; various States:
Hawaii; comments due by 8-9-04; published 7-9-04 [FR 04-15527]
Environmental statements; availability, etc.:
Coastal nonpoint pollution control program—
Minnesota and Texas; Open for comments until further notice; published 10-16-03 [FR 03-26087]
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Fenpyroximate; comments due by 8-9-04; published 6-10-04 [FR 04-13146]
Solid waste:
Hazardous waste; identification and listing—
Exclusions; comments due by 8-9-04; published 6-25-04 [FR 04-14460]
Water pollution; effluent guidelines for point source categories:
Meat and poultry products processing facilities; Open for comments until further notice; published 12-30-99 [FR 04-12017]
Water programs:
Water quality standards—
Coastal and Great Lakes recreation waters; bacteriological criteria; establishment; comments due by 8-9-04; published 7-9-04 [FR 04-15614]

FEDERAL COMMUNICATIONS COMMISSION
Radio stations; table of assignments:
Alabama; comments due by 8-9-04; published 6-22-04 [FR 04-13994]
Colorado; comments due by 8-9-04; published 6-22-04 [FR 04-13995]
New Mexico; comments due by 8-9-04; published 6-25-04 [FR 04-14484]

FEDERAL DEPOSIT INSURANCE CORPORATION
Deposit insurance coverage:
Assessments; certified statements; comments due by 8-9-04; published 6-8-04 [FR 04-12922]

HEALTH AND HUMAN SERVICES DEPARTMENT
Food and Drug Administration
Animal drugs, feeds, and related products:
Bovine spongiform encephalopathy prevention in U.S. cattle; Federal mitigation measures; comments due by 8-13-04; published 7-14-04 [FR 04-15882]
Foods and cosmetics:
Prohibited cattle materials; use; recordkeeping requirements; comments due by 8-13-04; published 7-14-04 [FR 04-15880]
Reports and guidance documents; availability, etc.:
Evaluating safety of antimicrobial new animal drugs with regard to their microbiological effects on bacteria of human health concern; Open for comments until further notice; published 10-27-03 [FR 03-27113]

HOMELAND SECURITY DEPARTMENT
Coast Guard
Anchorage regulations:
Maryland; Open for comments until further notice; published 1-14-04 [FR 04-00749]
Drawbridge operations:
Connecticut; comments due by 8-9-04; published 6-10-04 [FR 04-13076]

HOUSING AND URBAN DEVELOPMENT DEPARTMENT
Community development block grants:
Small cities and insular areas programs; comments due by 8-9-04; published 6-10-04 [FR 04-12954]

LIBRARY OF CONGRESS
Copyright Office, Library of Congress
Copyright office and procedures:

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "PLUS" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal_register/public_laws/public_laws.html.*

The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html.* Some laws may not yet be available.

H.R. 4916/P.L. 108–280

Surface Transportation Extension Act of 2004, Part IV (July 30, 2004; 118 Stat. 876)

Last List July 26, 2004

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.

Public Laws

108th Congress

Pamphlet prints of public laws, often referred to as slip laws, are the initial publication of Federal laws upon enactment and are printed as soon as possible after approval by the President. Legislative history references appear on each law. Subscription service includes all public laws, issued irregularly upon enactment, for the 108th Congress.

Individual laws also may be purchased from the Superintendent of Documents, U.S. Government Printing Office. Prices vary. See Reader Aids Section of the Federal Register for announcements of newly enacted laws or access the online database at http://www.access.gpo.gov/nara1/nara005.html

---

Superintendent of Documents **Subscriptions** Order Form

Order Processing Code:
*** 6216**

☐ **YES**, enter my subscription(s) as follows:

Charge your order. It's Easy! MasterCard VISA

To fax your orders (202) 512–2250
Phone your orders (202) 512–1800

_____ subscriptions to **PUBLIC LAWS** for the 108th Congress for $285 per subscription.

The total cost of my order is $ _____. **Price includes regular domestic postage and handling** and is subject to change. International customers please add 25%.

Company or personal name (Please type or print)

Additional address/attention line

Street address

City, State, ZIP code

Daytime phone including area code

Purchase order number (optional)

May we make your name/address available to other mailers? YES ☐ NO ☐

Please Choose Method of Payment:

☐ Check Payable to the Superintendent of Documents
☐ GPO Deposit Account ☐☐☐☐☐☐☐ – ☐
☐ VISA ☐ MasterCard Account
☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐
☐☐☐☐ (Credit card expiration date)

Thank you for your order!

Authorizing signature 2/03

Mail To: Superintendent of Documents
P.O. Box 371954, Pittsburgh, PA 15250–7954

Printed on recycled paper