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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 39

**[Docket No. FAA–2013–0575; Directorate Identifier 2013–NE–21–AD; Amendment 39–17718; AD 2013–26–09]**

**RIN 2120–AA64**

## Airworthiness Directives; Turbomeca S.A. Turboshaft Engines

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for all Turbomeca S.A. ASTAZOU XIV B and XIV H engines. This AD was prompted by reports of cracks on the 2nd-stage turbine disk. This AD requires replacement of the 2nd-stage turbine disk. We are issuing this AD to prevent disk cracking, uncontained 2nd-stage turbine blade release, damage to the engine, and damage to the helicopter.

**DATES:** This AD becomes effective February 14, 2014.

**ADDRESSES:** The Docket Operations office is located at Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

### Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2013–0575; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the mandatory continuing airworthiness information (MCAI), the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (phone: 800–647–5527) is provided in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

**FOR FURTHER INFORMATION CONTACT:** Frederick Zink, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7779; fax: 781–238–7199; email: *frederick.zink@faa.gov*.

**SUPPLEMENTARY INFORMATION:**

### Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to the specified products. The NPRM was published in the **Federal Register** on August 6, 2013 (78 FR 47581). The NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

> Some cracks have been reported on the second stage turbine disc of ASTAZOU XIV engines inducted into a Repair Centre. These cracks are located in the serrations of the disc. The results of the technical investigation concluded that the cracks were present on non-shot peened second stage turbine discs (discs on which AB 138 modification was not incorporated), and on second stage turbine discs that were shot peened during their service life (discs on which AB 138 modification was incorporated after initial service use without shot peening). Until now, no crack has been reported on second stage turbine discs shot peened since new, these discs accounting for more than half of all ASTAZOU XIV flight hours. It was not possible to clearly identify what caused the cracks.
>
> This condition, if not corrected, could lead to some events of disc serrations rupture, possibly resulting in uncontained second stage turbine blade release with consequent damage to, and reduced control of, the helicopter.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2013-0575-0002*.

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (78 FR 47581, August 6, 2013). However, we did make an editorial change to the preamble of this AD.

### Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting this AD with the changes described previously. We determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

### Costs of Compliance

We estimate that this AD will affect about 6 engines of U.S. registry. We also estimate that it will take about 5 hours per engine to comply with this AD. The average labor rate is $85 per hour. Required parts will cost about $6,560 per engine. Based on these figures, we estimate the cost of this AD on U.S. operators to be $41,910.

### Authority for This Rulemaking

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

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

### Regulatory Findings

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

For the reasons discussed above, I certify this AD:

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

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and

Procedures (44 FR 11034, February 26, 1979),

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

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

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

### List of Subjects in 14 CFR Part 39

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

### Adoption of the Amendment

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

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

### § 39.13 [Amended]

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

**2013–26–09 Turbomeca S.A.:** Amendment 39–17718; Docket No. FAA–2013–0575; Directorate Identifier 2013–NE–21–AD.

**(a) Effective Date**

This AD becomes effective February 14, 2014.

**(b) Affected ADs**

None.

**(c) Applicability**

This AD applies to all Turbomeca S.A. ASTAZOU XIV B and XIV H engines.

**(d) Reason**

This AD was prompted by reports of cracks on the 2nd-stage turbine disk. We are issuing this AD to prevent disk cracking, uncontained 2nd-stage turbine blade release, damage to the engine, and damage to the helicopter.

**(e) Actions and Compliance**

Unless already done, do the following actions.

(1) For ASTAZOU XIV B engines that have not incorporated AB 138 modification remove the 2nd-stage turbine disk, part number (P/N) 0265260270, as follows:

(i) For engines with 1,800 or more engine cycles since new (CSN) or cycles since last overhaul (CSLO), remove the 2nd-stage turbine disk, P/N 0265260270, within 10 operating hours after the effective date of this AD.

(ii) For engines with less than 1,800 CSN or CSLO, remove the 2nd-stage turbine disk, P/N 0265260270, within 300 operating hours after the effective date of this AD or before 1,800 CSN or CSLO, whichever comes first.

(2) For ASTAZOU XIV B engines that have incorporated AB 138 modification, remove the 2nd-stage turbine disk, P/N 0283270200, with P/N 0265260270 written or scratched onto the disk, within 1,800 CSN or CSLO, or within 10 operating hours after the effective date of this AD, whichever occurs later.

(3) For ASTAZOU XIV H engines, remove the 2nd-stage turbine disk, P/N 0265260270, within 300 operating hours after the effective date of this AD.

**(f) Alternative Methods of Compliance (AMOCs)**

The Manager, Engine Certification Office, FAA, may approve AMOCs to this AD. Use the procedures found in 14 CFR 39.19 to make your request.

**(g) Related Information**

(1) For more information about this AD, contact Frederick Zink, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7779; fax: 781–238–7199; email: *frederick.zink@faa.gov*.

(2) Refer to MCAI European Aviation Safety Agency airworthiness directive 2013–0111R1, dated June 3, 2013, for more information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2013-0575-0002*.

(3) Turbomeca S.A. Alert Mandatory Service Bulletin (MSB) No. A283 72 0809, Version A, dated May 16, 2013, and Turbomeca S.A. Alert MSB No. A283 72 0808, Version A, dated May 16, 2013, which are not incorporated by reference in this AD, can be obtained from Turbomeca S.A. using the contact information in paragraph (g)(4) of this AD.

(4) For service information identified in this AD, contact Turbomeca, S.A., 40220 Tarnos, France; phone: 33 (0)5 59 74 40 00; telex: 570 042; fax: 33 (0)5 59 74 45 15.

(5) You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

**(h) Material Incorporated by Reference**

None.

Issued in Burlington, Massachusetts, on January 6, 2014.

**Colleen M. D'Alessandro,**

*Assistant Directorate Manager, Engine & Propeller Directorate, Aircraft Certification Service.*

[FR Doc. 2014–00166 Filed 1–9–14; 8:45 am]

BILLING CODE 4910–13–P

## SECURITIES AND EXCHANGE COMMISSION

## 17 CFR Part 200

**[Release No. 34–71238]**

## Responsibilities of the General Counsel

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Final rule.

**SUMMARY:** The Securities and Exchange Commission (''Commission'') is amending its rules to reflect that the Commission's General Counsel is responsible for providing advice to Commission attorneys on professional responsibility issues relating to their official duties and investigating allegations of professional misconduct by Commission staff and, where appropriate, making referrals to state professional boards or societies.

**DATES:** *Effective Date:* January 10, 2014.

**FOR FURTHER INFORMATION CONTACT:** Richard M. Humes, Associate General Counsel, at (202) 551–5140, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549; Shira Pavis Minton, Ethics Counsel, at (202) 551–7938, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

**SUPPLEMENTARY INFORMATION:**

### I. Discussion

These amendments conform the Commission's regulations, in part 200 of Title 17 of the Code of Federal Regulations, to the current responsibilities of the General Counsel. They do so by adding language that describes the General Counsel's responsibility for providing advice to Commission attorneys on professional responsibility issues relating to their official duties, investigating allegations of professional misconduct by Commission staff and, where appropriate, making referrals to state professional boards or societies. In addition, the amendments clarify that the Ethics Counsel is not responsible for investigating and potentially referring allegations of professional misconduct by Commission staff. Finally, the amendments include several minor corrections to provisions that relate to the responsibilities of the Ethics Counsel.

### II. Related Matters

#### *A. Administrative Procedure Act and Other Administrative Laws*

The Commission has determined that these amendments to its rules relate

solely to the agency's organization, procedure, or practice. Accordingly, the provisions of the Administrative Procedure Act regarding notice of proposed rulemaking and opportunity for public participation are not applicable.[1] The Regulatory Flexibility Act, therefore, does not apply.[2] Because these rules relate solely to the agency's organization, procedure, or practice and do not substantially affect the rights or obligations of non-agency parties, they are not subject to the Small Business Regulatory Enforcement Fairness Act.[3] Finally, these amendments do not contain any collection of information requirements as defined by the Paperwork Reduction Act of 1995, as amended.[4]

*B. Consideration of Burden on Competition*

Section 23(a)(2) of the Exchange Act requires the Commission, in making rules pursuant to any provision of the Exchange Act, to consider among other matters the impact any such rule would have on competition. The Commission does not believe that the amendments that the Commission is adopting today will have any impact on competition.

**Statutory Authority**

The amendments to the Commission's rules are adopted pursuant to 15 U.S.C. 77o, 77s, 77sss, 78d, 78d–1, 78d–2, 78w, 78ll(d), 78mm, 80a–37, 80b–11, and 7202.

**List of Subjects in 17 CFR Part 200**

Administrative practice and procedure, Authority delegations (Government agencies), Organization and functions (Government agencies).

**Text of Amendments**

In accordance with the preamble, the Commission hereby amends Title 17, Chapter II of the Code of Federal Regulations as follows:

## PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

### Subpart A—Organization and Program Management

■ 1. The authority citation for part 200, Subpart A, continues to read, in part, as follows:

**Authority:** 15 U.S.C. 77o, 77s, 77sss, 78d, 78d–1, 78d–2, 78w, 78*ll*(d), 78mm, 80a–37, 80b–11, 7202, and 7211 et seq., unless otherwise noted.

* * * * *

■ 2. In § 200.21 paragraph (a), after the fourth sentence, that begins with ''In addition, he or she is responsible'', add two new sentences to read as follows:

**§ 200.21 The General counsel.**

(a) * * * The General Counsel is responsible for providing advice to Commission attorneys on professional responsibility issues relating to their official duties. The General Counsel is further responsible for investigating allegations of professional misconduct by Commission staff and, where appropriate, making referrals to state professional boards or societies. * * *

* * * * *

**§ 200.21a [Amended]**

■ 3. In § 200.21a:
■ a. In paragraph (a), remove the phrase ''Office of Administrative and Personnel Management,'' and add in its place, ''Office of Human Resources, the Office of Government Ethics,'';
■ b. In paragraph (b)(1), at the end of the paragraph, add the phrase ''that relate to the Commission's Ethics Program'' before the period;
■ c. In paragraph (b)(2), at the end of the paragraph, add the phrase '', which the Ethics Counsel shall refer to the General Counsel'' before the period;
■ d. Remove paragraph (b)(7);
■ e. Redesignate paragraph (b)(8) as (b)(7).

### Subpart M—Regulation Concerning Conduct of Members and Employees and Former Members and Employees of the Commission

■ 4. The authority citation for Part 200, Subpart M, continues to read as follows:

**Authority:** 15 U.S.C. 77s, 77sss, 78w, 80a–37, 80b–11; E.O. 11222, 3 CFR, 1964–1965 Comp., p. 36; 5 CFR 735.104 and 5 CFR 2634; and 5 CFR 2635, unless otherwise noted.

**§ 200.735–15 [Amended]**

■ 5. In § 200.735–15:
■ a. Remove paragraph (b).
■ b. Redesignate paragraphs (c), (d) (e) and (f) as paragraphs (b), (c), (d) and (e), respectively.
■ c. In the first sentence of newly redesignated paragraph (b), remove the words ''any Deputy Counselor or''.
■ d. In newly redesignated paragraph (c), remove the words ''and Deputy Counselors''. Also in newly redesignated paragraph (c), remove the words ''they receive'' and add in their place ''he or she receives'' wherever they appear.

Dated: January 6, 2014.

By the Commission.

**Elizabeth M. Murphy,**

*Secretary.*

[FR Doc. 2014–00219 Filed 1–9–14; 8:45 am]

BILLING CODE 8011–01–P

[1] 5 U.S.C. 553(b).
[2] 5 U.S.C. 601–612.
[3] 5 U.S.C. 804.
[4] 44 U.S.C. 3501–3520.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 814

**[Docket No. FDA–2009–N–0458]**

**RIN 0910–AG29**

## Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final rule amending the regulations on premarket approval of medical devices to include requirements relating to the submission of information on pediatric subpopulations that suffer from the disease or condition that a device is intended to treat, diagnose, or cure.

**DATES:** This rule is effective April 10, 2014.

**FOR FURTHER INFORMATION CONTACT:** Sheila Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1651, Silver Spring, MD 20993, 301–796–6563.

**SUPPLEMENTARY INFORMATION:**

### I. Background

The Food and Drug Administration Amendments Act of 2007 (FDAAA)[1] (Pub. L. 110–85) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by among other things, adding section 515A of the FD&C Act (21 U.S.C. 360e–1). Section 515A(a) of the FD&C Act requires persons who submit certain medical device applications to include, if readily available, a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. The information submitted under section 515A(a) of the FD&C Act

[1] Title III of FDAAA, which includes new section 515A, is also known as the Pediatric Medical Device Safety and Improvement Act of 2007.

will be essential to completing the annual report that FDA is required to submit to Congress under section 515A(a)(3) of the FD&C Act, including:

- The number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure; and
- The review time for each such device application.

On April 1, 2010, FDA published a proposed rule, along with a companion direct final rule, with a 75-day comment period to request input from interested parties (75 FR 16365, April 1, 2010) as a step towards implementing section 515A(a) of the FD&C Act. A few months later, FDA withdrew the direct final rule because we received significant adverse comment (75 FR 41986, July 20, 2010.)

Due to the changes made since the April 1, 2010, proposed rule, particularly changes to the scope of applications to which this requirement applies (see section II), a supplemental notice of proposed rulemaking was issued on February 19, 2013 (78 FR 11612 at 11616), to allow for public comment on the re-drafted proposed rule. In addition to providing FDA's revised proposal for implementing section 515A(a) of the FD&C Act, that document served to supplement the proposed rule that issued with the companion direct final rule (75 FR 16365, April 1, 2010). FDA received four additional comments on the supplemental notice of proposed rulemaking that were considered when developing this final rule.

## II. How are pediatric patients and pediatric subpopulations defined?

Section 515A(c) of the FD&C Act states that, for the purposes of that section, the term ''pediatric subpopulation'' has the meaning given the term in section 520(m)(6)(E)(ii) of the FD&C Act (21 U.S.C. 360j(m)(6)(E)(ii)). Section 520(m)(6)(E)(ii) of the FD&C Act defines the term ''pediatric subpopulation'' to mean one of the following populations:

- Neonates;
- Infants;
- Children; or
- Adolescents.

Section 515A additionally requires that the descriptions of pediatric subpopulations include the number of affected ''pediatric patients.'' Section 515A does not define the term ''pediatric patients.'' The term ''pediatric patients'', however, is defined for purposes of section 520(m)(6)(E)(i) of the FD&C Act (relating to humanitarian device exemptions for pediatric patients) as patients who are 21 years of age or younger at the time of the diagnosis or treatment. The definition for ''pediatric patients'' in section 520(m)(6)(E)(i) is consistent with the definition of ''pediatric subpopulations'' in section 520(m)(6)(E)(ii).

These definitions of pediatric subpopulation and pediatric patient are reflected in FDA's previously issued 2004 guidance on pediatric medical devices, which recommended the age range for each of the populations included in the term ''pediatric subpopulation.'' Those age ranges span from birth to 21 years of age (that is, from birth through the 21st year of life, up to but not including the 22nd birthday). See ''Premarket Assessment of Pediatric Medical Devices'' (May 14, 2004); *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089740.htm.*

For purposes of the requirements in this final rule, FDA is codifying a definition of the term ''pediatric patients'' as patients who are 21 years of age or younger (that is, from birth through the 21st year of life, up to but not including the 22nd birthday) at the time of the diagnosis or treatment.

## III. What applications are subject to this final rule?

In accordance with the FD&C Act, the requirements to include, if readily available, a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients apply to the following applications when submitted on or after the effective date of this rule:

- Any request for a humanitarian device exemption (HDE) submitted under section 520(m) of the FD&C Act;
- Any premarket approval application (PMA) or supplement to a PMA submitted under section 515 of the FD&C Act; and
- Any product development protocol (PDP) submitted under section 515 of the FD&C Act.

FDA concludes that section 515A applies to all submission types listed in the statute—PMA, HDE, PDP, and all PMA supplements—not just the subset of PMA supplements that propose a new indication for use, as was proposed in the April 1, 2010, proposed rule. The Agency also wants to clarify that it does not interpret 30-day notices submitted under § 814.39(f) (21 CFR 814.39(f)) to be PMA supplements for purposes of this final rule. Section 515(d)(6)(A) of the FD&C Act (21 U.S.C. 360e(d)(6)(A)) distinguishes between modifications to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of a device subject to an approved PMA, which require the submission of a written notice, and other changes that affect safety and effectiveness that require the submission of a ''supplemental application.'' Because of this statutory distinction, 30-day notices are not considered PMA supplements for purposes of this final rule and, therefore, are not required to include readily available pediatric information.

Moreover, an applicant submitting a PMA supplement that previously submitted information satisfying the pediatric subpopulation requirements for the device may include that information by referencing the previous application rather than resubmitting the same information. However, if additional information has become readily available to the applicant since the previous submission, the applicant must submit that information as part of the supplement.

Many premarket approval applications begin with the submission of one or more PMA modules; see ''Premarket Approval Application Modular Review—Guidance for Industry and FDA Staff,'' available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089764.htm.* Applicants who choose to use the modular approach should submit the information required by section 515A(a) of the FD&C Act in the final PMA module (i.e., the module that includes final clinical data, proposed labeling, and the Summary of Safety and Effectiveness Data).

## IV. What does this final rule do?

This final rule implements section 515A(a) of the FD&C Act by amending part 814 (21 CFR part 814), Premarket Approval of Medical Devices, to include requirements relating to the submission of readily available information on pediatric subpopulations that suffer from the disease or condition that a device is intended to treat, diagnose, or cure.

### *A. What information must the applicant provide?*

This final rule requires each applicant who submits an HDE, PMA, supplement to a PMA, or PDP to include, if ''readily available,'' a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. FDA is codifying a definition of ''readily available'' and

will be issuing a guidance document entitled ''Guidance for Industry and Food and Drug Administration Staff: Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act'' to explain the Agency's current thinking on the meaning of ''readily available information'' and how to comply with the requirements set forth in section 515A of the FD&C Act.

*B. What are the consequences of not submitting ''Readily Available'' information?*

If the applicant does not submit the information required by section 515A(a) of the FD&C Act, FDA may not approve the application until the applicant provides the required information. The Agency intends to contact the applicant during the normal course of our review to inform the applicant that the submission lacks the information required by section 515A(a) of the FD&C Act and by this final rule, and to ask the applicant to amend the application to provide the required information. If the application has no other deficiencies and otherwise meets applicable statutory and regulatory requirements for approval, but still lacks information required by section 515A(a), the Agency intends to send the applicant an ''approvable'' letter informing them that FDA will approve the application after the applicant provides the information required by section 515A(a). If the application has other deficiencies or does not meet all applicable statutory and regulatory requirements for approval, the Agency intends to send the applicant a ''not approvable'' letter or a ''major deficiency'' letter describing what information or data the applicant needs to provide before FDA can approve the application; the ''not approvable'' or ''major deficiency'' letter may cite the absence of section 515A(a) information in the section listing minor deficiencies. For additional information concerning ''approvable,'' ''not approvable,'' and ''major deficiency'' letters, see ''FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals,'' available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089733.htm.*

**V. How has FDA addressed comments received on the proposed rule?**

A number of comments recommended using age 18 as the upper boundary for the definition of ''pediatric patients'' instead of age 21 for reasons such as attainment of skeletal maturity by age 18 and how the phrase is understood in certain professional communities. After considering this suggestion, FDA has opted to keep age 21 as the definitional upper boundary ''pediatric patients.'' FDA oversees a wide array of medical devices and combination products including various medical devices that are used in pediatric populations. With this in mind, and as part of initiatives designed to help FDA achieve the intent of several pediatric provisions added to the FD&C Act by the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250, 116 Stat. 1588 (2002)), CDRH established the definition of the pediatric population in the 2004 Guidance ''Premarket Assessment of Pediatric Medical Devices'' (*http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089740.htm*). Beyond setting the upper age limit, the Guidance document further defines the pediatric population as comprising the following subpopulations: Neonate, infant, child, and adolescent. The definition mirrors that used by the American Academy of Pediatrics and takes into consideration the different pediatric subpopulations that make up the pediatric population. This definition ensures that the term ''pediatric'' applies to populations who may be mature skeletally or according to other measures, but who remain developmentally immature in certain anatomical or physiological systems.

This definition reflects the scientific evidence that children are not merely young adults, but that there are unique host characteristics across the various pediatric subpopulations that should be considered before using medical devices in the pediatric population or subpopulation. FDA recognizes that not all 18- to 21-year-olds are identical: Different rates of pubertal development may be encountered; different disease processes may cause delayed maturation, or conversely, accelerated maturation (e.g. precocious puberty). Moreover, Congress also used age 21 as the upper boundary for a pediatric population when it enacted FDAAA (section 303(a)(3)).

One comment stated that FDA should not have removed the proposed requirement on ''potential pediatric uses'' in the supplemental notice of proposed rulemaking because providing readily available information on potential pediatric uses is easily achievable and would pose no serious burden to applicants. FDA declines to accept the recommendation in the comment because section 515A of the FD&C Act does not require sponsors to speculate as to possible pediatric uses and possible subpopulations. However, if such information were readily available and provided in a premarket submission, FDA would find the information useful in support of advancing pediatric device development. Therefore, in the forthcoming guidance document, ''Guidance for Industry and Food and Drug Administration: Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act,'' FDA invites applicants to include pediatric use information for uses of the device outside the approved or proposed indication if such uses are described or acknowledged in acceptable sources of readily available information.

One comment proposed that FDA require applicants to state whether each new PMA supplement relates to a new device and that PMA applicants provide the number of new devices approved under the PMA during the preceding year in the PMA annual report. The comment also requested that, in order to ease the administrative burden on FDA and applicants, PMA supplements filed subsequent to the initial submission of pediatric population information update this information only if there is new information readily available that results in a change in the identification of pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, or the number of affected pediatric patients. FDA appreciates the suggested additions to the rule, but declines to include a requirement that applicants state whether each supplement relates to a new device because each applicant could interpret the types of changes that could be considered a ''new device'' differently. To better ensure consistency for reporting purposes, FDA's internal tracking system will be used for the collection and compilation of data regarding the number of devices approved each year. FDA also declines to require applicants to provide information in their PMA annual report regarding the number of new devices approved under the PMA in the prior year because, while FDA must provide a report to Congress once per year, PMA annual reports can be due at different times throughout the calendar year as the report is due on the anniversary of the initial PMA approval. Since the PMA annual reports would each address different time periods for the prior year, this information would not enable FDA to compile the data needed for the report to Congress.

One comment disputed FDA's estimate of the amount of time it will

take to fulfill the requirements instated by this rule for original HDE and PMA applications. The comment states that reading just a single article in the medical literature to obtain a thorough understanding of a specific situation can take 1 to 2 hours and therefore the estimate that 8 hours are needed for an applicant to fulfill the requirement is unreasonably low. FDA disagrees that 8 hours is insufficient to fulfill the requirements implemented by this final rule because applicants are not expected to make an assessment of whether the information is clinically appropriate or would support a particular indication; rather, when reviewing sources, applicants are only required to identify any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, as well as the number of affected pediatric patients. Please see the forthcoming guidance document, ''Guidance for Industry and Food and Drug Administration: Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act'' for more information on how to comply with this requirement.

Some comments took the position that by implementing the rule, FDA, in effect, would be promoting the off-label use of devices. FDA disagrees with this comment. The rule does not ask applicants to perform any clinical studies or to use or promote the device outside its approved indications for use; rather, the rule requires the submission of information already in existence on any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure.

One comment stated that if FDA were to request an applicant to submit a PMA supplement for a PMA that was approved prior to the effective date of FDAAA solely to provide readily available pediatric information, then this would be retroactive application of law. FDA does not intend to require any applicant to submit a PMA supplement solely to provide readily available pediatric information. However, if an applicant is submitting a PMA supplement for any of the reasons in § 814.39, it must include readily available pediatric information as required by § 814.39(c)(2).

One comment stated that the rule should provide an exemption from the requirement of submitting readily available pediatric information in instances where the device does not and will never have pediatric uses, as well as instances where the device is specifically indicated for use in pediatric patients. FDA declines to incorporate this comment because an exemption for devices that do not and are thought not to ever have pediatric uses undermines the intent of the rule. It is not possible to determine whether a device will have pediatric uses in the future as modifications to the device (e.g., design or size) and advances in medicine could change whether a device could be used in a pediatric population. Furthermore, an exemption for devices intended specifically for use in pediatric subpopulations would undermine the intent of the rule because there could be other pediatric subpopulations not included in the proposed or approved indications for use that suffer from the disease or condition that the device is intended to treat, diagnose, or cure. If there are no pediatric uses of the device at the time of the PMA or PMA supplement submission, FDA merely expects applicants to state such in the application.

## VI. What is the legal authority for this final rule?

Section 302 of FDAAA amended the FD&C Act by adding, among other things, a new section 515A. Section 515A(a) of the FD&C Act requires persons who submit certain medical device applications to include, if readily available, a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. Therefore, FDA is issuing this final rule under section 515A(a), and section 701(a) of the FD&C Act (21 U.S.C. 371(a)) (which provides FDA the authority to issue regulations for the efficient enforcement of the FD&C Act). The Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144, section 620(b)) directs FDA to issue a final rule implementing section 515A(a) of the FD&C Act by December 31, 2013.

## VII. What is the environmental impact of this final rule?

FDA has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## VIII. What is the economic impact of this final rule?

We have examined the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on a substantial number of small entities. Because this regulation only requires some submissions include a small amount of readily available information at about $90 per submission, the Agency certifies that the final rule does not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. We do not expect this rule to result in any 1-year expenditure that would meet or exceed this amount.

We believe that the only costs to industry are those that we account for in our Paperwork Reduction Act analysis, which immediately follows this section. The final rule does not require additional clinical research or other costly efforts, and simply requires the applicant to briefly summarize readily available information that will have been reviewed by the applicant during the course of its development of the device and preparation of its application to FDA. As explained in the Paperwork Reduction Act analysis, we expect to receive annually 40 PMAs and 5 applications for HDE. We also expect to receive 693 supplements that include the pediatric use information required by section 515A(a) of the FD&C Act and this final rule.

Based on our experience with similar requirements regarding readily available information, we estimate it will take 8

hours to gather and submit information for original applications and amendments to those applications. Because supplements can include this information by referencing a previous submission, we estimate it will take only 2 hours to obtain and submit the required information on pediatric populations.

The estimated time burden for all 45 annual applications is 360 hours. For the 693 supplements, the time burden is an estimated 1,386 hours for a total of 1,746 hours. The 2011 median wage for a compliance officer in the medical device manufacturing industry is $31.75.[2] Adjusting the wage by average private sector benefits of 29.6 percent of total compensation, the benefits-adjusted wage is $45.10.[3] At this wage, the estimated cost of submitting an application with pediatric information is $361 or $16,236 for all applications. The estimated cost of submitting pediatric information for a supplement is $90 or $62,508 for all supplements. The estimated cost of this final rule is $78,744.

We expect FDA's additional costs will be inconsequential, as the information required here will be filed and managed as an integral part of each submission, using existing filing, storage, and data management systems and processes.

## IX. How does the Paperwork Reduction Act of 1995 apply to this final rule?

This final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

*Title:* Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended to Treat, Diagnose, or Cure.

*Description:* Section 515A(a) of the Food and Drug Administration Amendments Act of 2007 requires applicants who submit certain medical device applications to include readily available information providing a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. The information submitted will allow FDA to track the number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure and the review time for each such device application.

*Description of Respondents:* These requirements apply to applicants who submit the following applications on or after the effective date of this rule:

- Any request for an HDE submitted under section 520(m) of the FD&C Act;
- Any PMA or supplement to a PMA submitted under section 515 of the FD&C Act;
- Any PDP submitted under section 515 of the FD&C Act.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity/21 CFR section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Pediatric information in an original PMA or PDP—814.20(b)(13) | 30 | 1 | 30 | 8 | 240 |
| Pediatric information in a PMA amendment—814.37(b)(2) | 10 | 1 | 10 | 8 | 80 |
| Pediatric information in a PMA supplement—814.39(c)(2) | 693 | 1 | 693 | 2 | 1,386 |
| Pediatric information in an HDE—814.104(b)(6) | 5 | 1 | 5 | 8 | 40 |
| Total | | | 738 | | 1,746 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA expects to receive approximately 45 original PMA/PDP/HDE applications each year, 5 of which FDA expects to be HDEs. This estimate is based on the actual average of FDA's receipt of new PMA applications in FY 2010–2011. The Agency estimates that 10 of those 40 original PMA submissions will fail to provide the required pediatric use information and their sponsors will therefore be required to submit PMA amendments. The Agency also expects to receive 693 supplements that will include the pediatric use information required by section 515A(a) of the FD&C Act and this final rule.

All that is required is to gather, organize, and submit information that is readily available, using any approach that meets the requirements of section 515A(a) of the FD&C Act and this final rule. We believe that because the final rule requires that the applicant organize and submit only readily available information, no more than 8 hours will be required to comply with section 515A(a) of the FD&C Act and this final rule for original applications and amendments to those applications. Furthermore, because supplements may include readily available information on pediatric populations by referencing a previous submission, FDA estimates the average time to obtain and submit the information required by this final rule in a supplement to be 2 hours. FDA estimates that the total burden created by this final rule is 1,746 hours.

We estimate the ''Average Burden per Response'' based on our experience with similar information collection requirements and on consultations with the Interagency Pediatric Devices Working Group that includes the Agency for Healthcare Research and Quality, FDA, National Institutes of Health, members of the Pediatric Advisory Committee, researchers, health care practitioners, medical device trade associations, and medical device manufacturers.

The information collection provisions in this final rule have been submitted to OMB for review as required by section

[2] U.S. Bureau of Labor Statistics, 2011 National Industry-Specific Occupational Employment and Wage Estimates, SOC 13–1041 (*http://www.bls.gov/oes/current/naics4_339100.htm*).

[3] U.S. Bureau of Labor Statistics, Employer Costs for Employee Compensation, Table 5. Employer costs per hour worked for employee compensation and costs as a percent of total compensation: Private industry workers, by major occupational group and bargaining unit status, June 2012 (*http://www.bls.gov/news.release/ecec.t05.htm*).

3507(d) of the Paperwork Reduction Act of 1995.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. 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.

This final rule also refers to previously approved collections of information found in FDA regulations. The collections of information in part 814, subpart B have been approved under OMB control number 0910–0231 and the collections of information in part 814, subpart H have been approved under OMB control number 0910–0332.

### X. What are the federalism impacts of this final rule?

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

### List of Subjects in 21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 814 is amended as follows:

## PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 1. The authority citation for 21 CFR part 814 continues to read as follows:

**Authority:** 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

■ 2. In § 814.1, revise paragraph (a) to read as follows:

**§ 814.1 Scope.**

(a) This section implements sections 515 and 515A of the act by providing procedures for the premarket approval of medical devices intended for human use.

* * * * *

■ 3. In § 814.3, add paragraphs (s) and (t) to read as follows:

**§ 814.3 Definitions.**

* * * * *

(s) Pediatric patients means patients who are 21 years of age or younger (that is, from birth through the twenty-first year of life, up to but not including the twenty-second birthday) at the time of the diagnosis or treatment.

(t) Readily available means available in the public domain through commonly used public resources for conducting biomedical, regulatory, and medical product research.

■ 4. In § 814.20, redesignate paragraph (b)(13) as paragraph (b)(14) and add new paragraph (b)(13) to read as follows:

**§ 814.20 Application.**

* * * * *

(b) * * *

(13) *Information concerning uses in pediatric patients.* The application must include the following information, if readily available:

(i) A description of any pediatric subpopulations (neonates, infants, children, adolescents) that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and

(ii) The number of affected pediatric patients.

* * * * *

■ 5. In § 814.37, revise the section heading and paragraph (b) to read as follows:

**§ 814.37 PMA amendments and resubmitted PMAs.**

* * * * *

(b)(1) FDA may request the applicant to amend a PMA or PMA supplement with any information regarding the device that is necessary for FDA or the appropriate advisory committee to complete the review of the PMA or PMA supplement.

(2) FDA may request the applicant to amend a PMA or PMA supplement with information concerning pediatric uses as required under §§ 814.20(b)(13) and 814.39(c)(2).

* * * * *

■ 6. In § 814.39, redesignate paragraph (c) as (c)(1) and add paragraph (c)(2) to read as follows:

**§ 814.39 PMA supplements.**

* * * * *

(c) * * *

(2) The supplement must include the following information:

(i) Information concerning pediatric uses as required under § 814.20(b)(13).

(ii) If information concerning the device that is the subject of the supplement was previously submitted under § 814.20(b)(13) or under this section in a previous supplement, that information may be included by referencing a previous application or submission that contains the information. However, if additional information required under § 814.20(b)(13) has become readily available to the applicant since the previous submission, the applicant must submit that information as part of the supplement.

* * * * *

■ 7. In § 814.44, redesignate paragraphs (e)(1)(ii) through (e)(1)(iv) as paragraphs (e)(1)(iii) through (e)(1)(v), respectively, and add new paragraph (e)(1)(ii) to read as follows:

**§ 814.44 Procedures for review of a PMA.**

* * * * *

(e) * * *

(1) * * *

(ii) The submission of additional information concerning pediatric uses required by § 814.20(b)(13);

* * * * *

■ 8. Amend § 814.100 as follows:

■ a. Redesignate paragraphs (b) through (e) as paragraphs (d) through (g), respectively.

■ b. Redesignate paragraph (a) as paragraph (b), and remove the first sentence of redesignated paragraph (b); and

■ c. Add new paragraphs (a) and (c) to read as follows:

**§ 814.100 Purpose and scope.**

(a) This subpart H implements sections 515A and 520(m) of the act.

* * * * *

(c) Section 515A of the act is intended to ensure the submission of readily available information concerning:

(1) Any pediatric subpopulations (neonates, infants, children, adolescents) that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and

(2) The number of affected pediatric patients.

* * * * *

■ 9. Amend § 814.104 as follows:

■ a. Revise the last sentence of paragraph (b)(4)(ii);.

■ b. Revise the last sentence of paragraph (b)(5); and

■ c. Add paragraph (b)(6) to read as follows:

**§ 814.104 Original applications.**

* * * * *

(b) * * *

(4) * * *

(ii) * * * The effectiveness of this device for this use has not been demonstrated;

(5) * * * If the amount charged is $250 or less, the requirement for a report by an independent certified public accountant or an attestation by a responsible individual of the organization is waived; and

(6) Information concerning pediatric uses of the device, as required by § 814.20(b)(13).

* * * * *

■ 10. In 814.116, redesignate paragraphs (c)(2) through (c)(4) as paragraphs (c)(3) through (c)(5), respectively, and add new paragraph (c)(2) to read as follows:

**§ 814.116 Procedures for review of an HDE.**

* * * * *

(c) * * *

(2) The submission of additional information concerning pediatric uses of the device, as required by § 814.20(b)(13);

* * * * *

Dated: January 6, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–00267 Filed 1–9–14; 8:45 am]

BILLING CODE 4160–01–P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 117

**[Docket No. USCG–2013–1039]**

### Drawbridge Operation Regulation; Upper Mississippi River, Sabula, IA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of deviation from drawbridge regulations.

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating schedule that governs the Sabula Railroad Drawbridge across the Upper Mississippi River, mile 535.0, at Sabula, Iowa. The deviation is necessary to allow the bridge owner time to perform repairs and maintenance that is essential to the continued safe operation of the drawbridge. This deviation allows the bridge to remain in the closed-to-navigation position while a damaged gear assembly is replaced and structural steel repairs are completed.

**DATES:** This deviation is effective from 7 a.m., January 6, 2014 to 7 a.m., March 4, 2014.

**ADDRESSES:** The docket for this deviation, USCG–2013–1039 is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH''. Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary deviation, call or email Eric A. Washburn, Bridge Administrator, Western Rivers, Coast Guard; telephone 314–269–2378, email *Eric.Washburn@uscg.mil.* If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

**SUPPLEMENTARY INFORMATION:** The Canadian Pacific Railway requested a temporary deviation for the Sabula Railroad Drawbridge, across the Upper Mississippi River, mile 535.0, at Sabula, Iowa to remain in the closed-to-navigation position while a damaged gear assembly is replaced and structural steel repairs are completed. The closure period will start at 7 a.m., January 6, 2014 to 7 a.m., March 4, 2014. Work is scheduled in the winter and when there is less impact on navigation; instead of scheduling work in the summer, when river traffic increases.

Once the gear assembly is removed and structural steel repairs have commenced, the swing span will not be able to open, even for emergencies, until repairs are complete and gear assembly is installed.

The Sabula Railroad Drawbridge currently operates in accordance with 33 CFR 117.5, which states the general requirement that drawbridges shall open promptly and fully for the passage of vessels when a request to open is given in accordance with the subpart. In order to facilitate the needed bridge work, the drawbridge must be kept in the closed-to-navigation position.

There are no alternate routes for vessels transiting this section of the Upper Mississippi River.

The Sabula Railroad Drawbridge, in the closed-to-navigation position, provides a vertical clearance of 18.1 feet above normal pool. Navigation on the waterway consists primarily of commercial tows and recreational watercraft. This temporary deviation has been coordinated with the waterway users. No objections were received.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: December 18, 2013.

**Eric A. Washburn,**

*Bridge Administrator, Western Rivers.*

[FR Doc. 2014–00284 Filed 1–9–14; 8:45 am]

BILLING CODE 9110–04–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

### 42 CFR Parts 412, 413, 414, 419, 424, 482, 485, and 489

**[CMS–1599–CN4]**

**RIN 0938–AR53**

### Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Payment Policies Related to Patient Status; Corrections

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule; correction.

**SUMMARY:** This document corrects technical errors in the correcting document that appeared in the January 2, 2014 **Federal Register** entitled ''Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Payment Policies Related to Patient Status; Corrections.''

**DATES:** *Effective Date:* This correcting document is effective January 8, 2014.

*Applicability Date:* This correcting document is applicable on January 1, 2014.

**FOR FURTHER INFORMATION CONTACT:** Tzvi Hefter, (410) 786–4487.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In the August 19, 2013 **Federal Register** (78 FR 50495), we published a final rule entitled ''Medicare Program; Hospital Inpatient Prospective Payment

Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Payment Policies Related to Patient Status'' (hereinafter referred to as the FY 2014 IPPS/LTCH PPS final rule). To correct typographical and technical errors in the FY 2014 IPPS/LTCH PPS final rule, we published correcting documents that appeared in the October 3, 2013 **Federal Register** (78 FR 61197) and the January 2, 2014 **Federal Register** (79 FR 61). We left out Code of Federal Regulations (CFR) part numbers from the heading and left out the applicability date from the **DATES** section of the January 2, 2014 correcting document. Therefore, in this correcting document, we add the omitted CFR part numbers and the applicability date.

## II. Summary of Errors

On page 61 of the January 2, 2014 correcting document (79 FR 61), we inadvertently omitted some CFR part numbers from the heading, and inadvertently omitted the applicability date from the **DATES** section.

## III. Waiver of Proposed Rulemaking and Delay of Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive this notice and comment procedure if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the notice.

Section 553(d) of the APA ordinarily requires a 30-day delay in effective date of final rules after the date of their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued.

In our view, this correcting document does not constitute a rulemaking that would be subject to the APA notice and comment or delayed effective date requirements. This correcting document simply adds the CFR part numbers and the applicability date that were inadvertently omitted and does not make substantive changes to the policies or payment methodologies that were adopted in the final rule.

In addition, even if this were a rulemaking to which the notice and comment procedures and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the January 2, 2014 correcting document (which corrected the FY 2014 IPPS/LTCH final rule) or delaying the effective date would be contrary to the public interest, because it is in the public's interest for providers to receive appropriate payments in as timely a manner as possible. Furthermore, such procedures would be unnecessary, as we are not altering the policies that were already subject to comment and finalized in our final rule, but rather, we are simply adding the CFR part numbers and applicability date that were inadvertently omitted. Therefore, we find good cause to waive the notice and comment and effective date requirements.

## IV. Correction of Errors

In FR Doc. 2013–31432 of January 2, 2014 (79 FR 61), make the following corrections:

1. On page 61, in the heading, the CFR citation ''42 CFR Parts 412, 482, 485, and 489'' is corrected to read ''42 CFR Parts 412, 413, 414, 419, 424, 482, 485, and 489''.

2. On page 61, in the **DATES** section, the caption and sentence, ''**DATES:** *Effective Date:* This correcting document is effective on January 2, 2014.'' are corrected to read as follows:

''**DATES:** *Effective Date:* This correcting document is effective January 2, 2014.

*Applicability Date:* This correcting document is applicable on January 1, 2014.''

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 7, 2014.

**Jennifer Cannistra,**

*Executive Secretary to the Department, Department of Health and Human Services.*

[FR Doc. 2014–00273 Filed 1–8–14; 4:15 pm]

BILLING CODE 4120–01–P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Parts 413 and 424**

**[CMS–1446–CN3]**

**RIN 0938–AR65**

# Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2014; Correction

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule; correction.

**SUMMARY:** This document corrects technical errors in the correcting document that appeared in the January 2, 2014 **Federal Register** entitled ''Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2014; Correction.''

**DATES:** *Effective Date:* This correcting document is effective January 8, 2014.

*Applicability Date:* This correcting document is applicable to skilled nursing facility services furnished on or after January 1, 2014.

**FOR FURTHER INFORMATION CONTACT:** John Kane, (410) 786–0557.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In the August 6, 2013 **Federal Register** (78 FR 47936), we published a final rule entitled ''Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2014'' (hereinafter referred to as the FY 2014 SNF PPS final rule). To correct typographical and technical errors in the FY 2014 SNF PPS final rule, we published correcting documents that appeared in the October 3, 2013 **Federal Register** (78 FR 61202) and the January 2, 2014 **Federal Register** (79 FR 63). We left out the applicability date from the **DATES** section of the January 2, 2014 correcting document; therefore, in this correcting document, we add the applicability date.

## II. Summary of Errors

On page 63 of the January 2, 2014 correcting document (79 FR 63), we inadvertently omitted the applicability date from the **DATES** section.

## III. Waiver of Proposed Rulemaking and Delay of Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal**

**Register** to provide a period for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive this notice and comment procedure if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefor in the notice.

Section 553(d) of the APA ordinarily requires a 30-day delay in effective date of final rules after the date of their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued.

In our view, this correcting document does not constitute a rule that would be subject to the APA notice and comment or delayed effective date requirements. This correcting document simply adds the applicability date that was inadvertently omitted and does not make substantive changes to the policies or payment methodologies that were adopted in the final rule.

In addition, even if this correcting document were a rule to which the notice and comment procedures and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the correction in this document into the January 2, 2014 correcting document (which corrected the FY 2014 SNF PPS final rule) or delaying the effective date would be contrary to the public interest, because it is in the public's interest for providers to receive appropriate SNF PPS payments in as timely a manner as possible. Furthermore, such procedures would be unnecessary, as we are not altering our payment methodologies or policies, but rather, are simply adding the applicability date that was inadvertently omitted. Therefore, we find good cause to waive notice and comment procedures, as well as the 30-day delay in effective date.

## IV. Correction of Errors

In FR Doc. 2013–31435 of January 2, 2014 (79 FR 63), make the following corrections:

1. On page 63, in the **DATES** section, the caption and sentence, ''**DATES:** *Effective Date:* This correction is effective January 2, 2014.'' are corrected to read as follows:

**DATES:** *Effective Date:* This correcting document is effective January 2, 2014.

*Applicability Date:* This correcting document is applicable to skilled nursing facility services furnished on or after January 1, 2014.''

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 6, 2014.

**Jennifer Cannistra,**

*Executive Secretary to the Department, Department of Health and Human Services.*

[FR Doc. 2014–00277 Filed 1–8–14; 4:15 pm]

**BILLING CODE 4120–01–P**

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## DEPARTMENT OF TRANSPORTATION

### Federal Railroad Administration

### 49 CFR Part 214

**[Docket No. FRA–2008–0059, Notice No. 8]**

**RIN 2130–AC37**

## Railroad Workplace Safety; Adjacent-Track On-Track Safety for Roadway Workers

**AGENCY:** Federal Railroad Administration (FRA), Department of Transportation (DOT).

**ACTION:** Final rule; response to petitions for reconsideration.

**SUMMARY:** This final rule responds to two petitions for reconsideration of FRA's final rule published November 30, 2011, which would have amended the existing regulations governing the on-track safety protections of roadway workers from the movement of trains or other on-track equipment on an adjacent controlled track, but which has not taken effect. In response to the petitions for reconsideration, FRA delayed the effective date of the November 30, 2011, final rule until July 1, 2013 (subsequently delayed until July 1, 2014), and requested comments on the petitions. This document further responds to the petitions, addresses the comments on the petitions, and amends and clarifies certain sections of the November 30, 2011, final rule.

**DATES:** The amendments in this final rule are effective on July 1, 2014.

**FOR FURTHER INFORMATION CONTACT:** Kenneth Rusk, Staff Director, Track Division, Office of Safety Assurance and Compliance, FRA, 1200 New Jersey Avenue SE., RRS–15, Mail Stop 25, Washington, DC 20590 (202) 493–6236; or Joseph E. Riley, Track Specialist, Track Division, Office of Safety Assurance and Compliance, FRA, 1200 New Jersey Avenue SE., RRS–15, Mail Stop 25, Washington, DC 20590 (202) 493–6357; or Joseph St. Peter, Trial Attorney, Office of Chief Counsel, FRA, 1200 New Jersey Avenue SE., RRS–10, Mail Stop 10, Washington, DC 20590 (202) 493–6052.

**SUPPLEMENTARY INFORMATION:**

## I. Executive Summary

On November 30, 2011, FRA published a final rule (Final Rule) governing the on-track safety protections of roadway workers from train movements on adjacent controlled tracks. 76 FR 74586. The Final Rule requires that railroads adopt specified on-track safety procedures to protect certain roadway work groups from the movement of trains or other on-track equipment on an adjacent controlled track. These on-track safety procedures are required for each adjacent controlled track when a roadway work group with at least one of the roadway workers on the ground is engaged in a common task with on-track, self-propelled equipment or coupled equipment on an occupied track. An adjacent controlled track is a controlled track whose track center is spaced 19 feet or less from the track center of an occupied track.

After publication of the Final Rule, FRA received two petitions for reconsideration (Petitions) of certain of the Final Rule's requirements. The requests made in the Petitions are described in detail below. In response to the Petitions, FRA is modifying the Final Rule (Final Rule Amendments; Amendments) to do the following: (1) Expand the definition of ''minor correction'' to include welding and certain uses of any handheld power tools; (2) increase the maximum authorized speed at which passenger trains may move on an adjacent controlled track to 40 mph while roadway workers continue their on-ground work on the occupied track; (3) delete the requirement that a non-controlled track whose track center is spaced 19 feet or less from the occupied track be treated as an adjacent controlled track; (4) exempt rail-bound vehicles (on-track vehicles not equipped with highway wheels) used for conducting inspections or performing minor correction work (including welding) while applying the same limitations that apply to hi-rail vehicles; (5) and expand the exception pertaining to repairs performed alongside the roadway work machine or equipment to include work within the perimeter of the machine or equipment. FRA previously delayed the effective date of

the Final Rule until July 1, 2014 (78 FR 33754). FRA is denying the request to permit roadway workers to resume work after the leading-end of a train or other on-track equipment traveling over 25 mph (40 mph passenger) has passed a roadway work group on an adjacent controlled track, and has retained the Final Rule's requirement that the entire train must pass the work zone.

The Amendments and the other issues raised by the Petitions are described in further detail below, and the discussions of the items being modified should be read in conjunction with the specific discussion in the Section-by-Section Analysis that identifies the modifications being made to the text of the Final Rule. For a full discussion of those aspects of the rulemaking and the Final Rule that remain unchanged, FRA respectfully refers interested parties to the agency's preamble discussions and Section-by-Section Analysis of the Final Rule and the NPRM. See 76 FR 74586 and 74 FR 61633, respectively.

FRA estimated the costs associated with the additional flexibilities provided by the Amendments being made in response to the Petitions in terms of increased risk and the benefits in terms of cost savings relative to the burdens imposed by the Final Rule. The table below presents the present value of these estimates for the first 20 years of this rule discounted at 3 percent and 7 percent.

| Amendments to the final rule | Potential cost implications | Benefits: Estimated cost savings (PV, 7%) | Benefits: Estimated cost savings (PV, 3%) |
|---|---|---|---|
| Expanding the definition of "minor correction" to include welding and certain uses of any handheld power tools. | Negligible. Very small increase in risk. No quantifiable increases in casualties. | $158.9 Million [1] | $223.2 Million. |
| Increasing the maximum authorized speed at which passenger trains may move on an adjacent controlled track to 40 mph while roadway workers continue their on-ground work on the occupied track. | Negligible | $33.4 Million [2] This estimated benefit only considers cost savings for LIRR and Metro-North. | $46.9 Million. This estimated benefit only considers cost savings for LIRR and Metro-North. |
| Deleting the requirement that a non-controlled track whose track center is spaced 19 feet or less from the occupied track be treated as an adjacent controlled track. | None: FRA has no record of past casualties covered by this provision. | $8,000 [3] | $11,200. |
| Exempting rail-bound vehicles (on-track vehicles not equipped with highway wheels) used for conducting inspections, performing minor correction work (including welding), while applying the same limitations that apply to hi-rail vehicles. | N/A | N/A | N/A. |
| Expanding the exception pertaining to repairs performed alongside the roadway work machine or equipment to include work within the perimeter of the machine or equipment. | Negligible. Minor reduction in the safety benefit of workers extricating themselves from under machinery so as to be safe in the event a collision with the machinery. | $149.2 Million [4] Non-quantified benefits include lowered injury risks due to fewer instances of workers having to extract themselves from a machine each time a train passes. | $208.3 Million. Non-quantified benefits include lowered injury risks due to fewer instances of workers having to extract themselves from a machine each time a train passes. |
| Total | | $341.6 Million | $478.4 Million. |

All values are discounted (PV, 7 and 3%) for a 20-year period.

## II. Background

On January 26, 2005, the Railroad Safety Advisory Committee (RSAC) formed the roadway worker protection (RWP) Working Group to consider specific actions to advance the on-track safety of employees of covered railroads and their contractors who are engaged in maintenance-of-way activities throughout the general system of railroad transportation, including clarification of existing requirements in 49 CFR part 214. The Working Group's assigned task was to review the existing RWP regulation, technical bulletins, and a safety advisory dealing with on-track safety forroadway workers, and, as appropriate, consider enhancements to the existing rule that would further reduce the risk of serious injury or death to roadway workers. The Working Group was directed to report specific actions identified as appropriate, including planned milestones for completion of projects and progress towards completion, to the full RSAC at each scheduled RSAC meeting.

The Working Group was comprised of members from the following organizations:

- American Public Transportation Association (APTA);
- American Short Line and Regional Railroad Association (ASLRRA);
- American Train Dispatchers Association;
- Association of American Railroads (AAR), including members from BNSF Railway Company (BNSF), Canadian National Railway Company (CN), Canadian Pacific Railway, Limited (CP), Consolidated Rail Corporation (Conrail), CSX Transportation, Inc. (CSXT), The Kansas City Southern Railway Company (KCS), Norfolk Southern Corporation railroads (NS), and Union Pacific Railroad Company (UP);
- Belt Railroad of Chicago;
- Brotherhood of Locomotive Engineers and Trainmen;
- Brotherhood of Maintenance of Way Employees Division (BMWED);
- Brotherhood of Railroad Signalmen (BRS);
- FRA;

[1] From FRA staff estimate.

[2] See discussion in section IV.A.2 below. Extrapolated from Long Island Rail Road (LIRR) estimate to include the Metro-North Commuter Railroad Company, in proportion to passenger miles.

[3] From FRA staff estimate.

[4] The cost savings estimate is based on an annual $14 million in costs from AAR's comment on the Petitions. FRA believes that the amendments to the Final Rule will avoid these costs that AAR's comment raised.

- Indiana Harbor Belt Railroad;
- Long Island Rail Road (LIRR);
- Metro-North Commuter Railroad Company (Metro-North);
- Montana Rail Link;
- National Railroad Construction and Maintenance Association;
- National Railroad Passenger Corporation;
- Northeast Illinois Regional Commuter Railroad Corporation;
- RailAmerica, Inc.;
- Southeastern Pennsylvania Transportation Authority;
- United Transportation Union; and
- Western New York and Pennsylvania Railroad.

The Working Group held 12 multi-day meetings and was able to reach consensus on 32 separate items related to how to amend existing part 214's roadway worker protection requirements. On June 26, 2007, the full RSAC voted to accept the recommendations presented by the Working Group.

One of the issues on which the Working Group was able to reach consensus dealt specifically with adjacent-track on-track safety issues. In light of roadway worker fatality trends involving adjacent track protections, and to expedite the lowering of the safety risk associated with roadway workers fouling adjacent tracks, FRA decided to undertake this rulemaking proceeding separately, and in advance of a rulemaking addressing all of the consensus items, to specifically address adjacent-track safety issues contemplated by the Working Group. Accordingly, FRA published an NPRM addressing adjacent-track on-track safety on July 17, 2008 (73 FR 41214), but formally withdrew the NPRM on August 13, 2008 (73 FR 47124). FRA then issued a revised NPRM, which was published on November 25, 2009 (74 FR 61633), and the Final Rule, which was published on November 30, 2011 (76 FR 74586), and which was to become effective on May 1, 2012.[5] The Final Rule, upon its effective date, will replace FRA's existing provision governing adjacent-track on-track safety procedures for roadway workers at 49 CFR 214.335(c). That existing provision only requires that train approach warning be provided on adjacent tracks that are not included within working limits for roadway work groups engaged in large-scale maintenance or construction projects. The Final Rule specifies more comprehensive on-track safety procedures that must be adopted and followed to protect roadway workers from the movement of trains or other on-track equipment on an ''adjacent controlled track''. An ''adjacent controlled track'' is a track whose track center is spaced 19 feet or less from the track center of the occupied track on which a roadway work group is conducting work with at least one of the roadway workers on the ground engaged in a common task with on-track, self-propelled equipment or coupled equipment. The Final Rule requires that a non-controlled track whose track center is spaced 19 feet or less from the track center of the occupied track be treated as an adjacent controlled track for purposes of establishing on-track safety when there is an adjacent controlled track on the opposite side of the occupied track. When train or other on-track equipment movements on an adjacent controlled track are permitted to be made at speeds greater than 25 mph, roadway workers on the occupied track must cease work and occupy a predetermined place of safety. When movements on the adjacent controlled tracks are permitted to be made at speeds of 25 mph or less, the Final Rule permits roadway workers on the occupied track to continue work, provided that the work is performed exclusively between the rails of the occupied track, and provided that no on-ground work is performed within the areas 25 feet in front of and 25 feet behind any on-track, self-propelled equipment or coupled equipment permitted to move on the occupied track. The Final Rule also establishes three categories of exceptions: (1) On-ground work performed on a side of the occupied track meeting specified condition(s); (2) maintenance or repairs performed alongside machines or equipment on the occupied track; and, (3) work activities involving certain equipment and purposes. If the equipment specified in one of the exceptions is being used for inspection or minor correction purposes, and otherwise meet the criteria for the exception, the work group would not be required to establish adjacent-track on-track safety. In the Final Rule, FRA added a definition for the term ''minor correction'' that did not include welding activities or work involving power hand tools other than handheld pneumatic power tools.

In response to the Final Rule, FRA received two petitions for reconsideration that raised substantive issues. AAR and ASLRRA filed a joint Petition (AAR/ASLRRA Joint Petition), and APTA also filed a Petition (APTA's Petition). The AAR/ASLRRA Joint Petition included a request for a delay in the effective date of the Final Rule until July 1, 2013. The Petitions raised issues relating to the cost-benefit analysis of the Final Rule, and also requested relief from several specific provisions of the Final Rule, principally related to the following subjects: The definition of ''minor correction''; the requirement that a roadway work group cease working until the trailing end of a train authorized to travel more than 25 mph has passed the roadway work group; the treatment of an adjacent non-controlled track as a controlled track; an additional exception for maintenance or repairs being performed within the perimeter of a roadway maintenance machine; an additional exception for manual inspections being conducted by rail bound vehicles; the release of working limits when the roadway work group is in the clear; the application of the Final Rule to repair and maintenance of roadway maintenance machines; the effective date of the Final Rule; and the maximum speed at which passenger trains may pass a roadway work group on an adjacent occupied track while the roadway work group continues its on-ground work on the occupied track.

On March 8, 2012, FRA published a final rule delaying the effective date of the Final Rule until July 1, 2013, and establishing a 60-day comment period in order to permit interested parties an opportunity to respond to the Petitions. 77 FR 13978. FRA received five comments on the Petitions from the following parties: AAR; BMWED and BRS (BMWED/BRS joint comment); APTA; LIRR; and Metro-North. Some of the comments raised additional substantive issues or provided further detailed information on the issues already raised in the Petitions. The Petitions and the comments on the Petitions are available for review in the docket for this rulemaking.[6] On August 31, 2012, FRA published a **Federal Register** document which explained that, due to the complex issues raised and extensive estimates provided in the Petitions and public comments received, FRA was continuing to formulate an appropriate response. 77 FR 53164. FRA noted that the response to the Petitions would be published as soon as practicable. On June 5, 2013, FRA published another final rule delaying the effective date of the Final Rule until July 1, 2014, explaining that FRA's response to the Petitions was still being reviewed, and that this effective date would allow railroads appropriate

[5] The Final Rule is now scheduled to take effect July 1, 2014. 78 FR 33754.

[6] See Docket No. FRA–2008–0059; available online at *http://www.regulations.gov/#!docketDetail;D=FRA-2008-0059*.

time to implement the requirements of, and train their employees on, the requirements of the Amended Final Rule prior to its effective date. 78 FR 33754. Below, this document addresses all of the issues raised in the Petitions and also in the public comments received in response to the Petitions.

## III. Issues Raised by the Petitions

### *A. Cost-Benefit Analysis*

Both Petitions raised concern with FRA's cost-benefit analysis of the Final Rule requirements, such as by saying that the Final Rule did not accurately account for the costs of the Final Rule and that the Final Rule overstated its potential benefits (AAR/ASLRRA). AAR, APTA, LIRR, and Metro-North also raised concerns related to the cost of the Final Rule's requirements in their comments on the Petitions. FRA has chosen to grant many of the requests for relief raised in the Petitions. Thus, many of the concerns related to cost have been alleviated, as is explained further below. Further, FRA has calculated the costs and benefits of the Amended Final Rule based on information conveyed in the Petitions and in the comments. The chart below reflects a comparison of (1) the costs and benefits of the Final Rule as originally estimated by FRA, (2) the costs and benefits of the Final Rule as asserted by AAR, and (3) the costs and benefits of the Amended Final Rule as currently estimated by FRA [7]:

| Estimated cost-benefit comparison * | Costs | Benefits |
|---|---|---|
| FRA's Original Estimate of 20-Year Costs and Benefits of the Final Rule | $151 Million | $151 Million. |
| AAR's Asserted 20-Year Costs and Benefits of the Final Rule as Asserted in Comments on Petition for Reconsideration. | $2.1 Billion | $64 Million. |
| FRA's Current Estimate of the 20-Year Costs and Benefits of the Amended Final Rule | $22 Million | $108 Million. |

* PV 7-Percent for all figures listed.

While not required to complete a Regulatory Impact Analysis (RIA) in responding to petitions for reconsideration, FRA has done so here, in section V.A. of the preamble below. The RIA below addresses the five modifications being made to the Final Rule, and the resultant cost-savings impacts and qualitative benefits of those modifications. The RIA for the Final Rule Amendments also takes into account the new value of a statistical life (VSL) to be used for DOT analyses assessing the benefits of rulemakings.[8]

Further, FRA has also completed a sensitivity analysis (Special Sensitivity Analysis) of the Amended Final Rule that will be posted in the public docket for this rulemaking. While also not required to complete such a supplementary analysis in responding to petitions for reconsideration, FRA has done so here in order to fully inform all interested parties of the costs and benefits associated with this rulemaking in its entirety (to include the modifications being made by the Amendments) after considering all of the information provided in the Petitions related to the Final Rule's RIA. The Special Sensitivity Analysis addresses the specific cost-benefit related items raised in the Petitions and in the comments that are not otherwise addressed by the modifications of the Final Rule and the interpretations explained below. (See the Special Sensitivity Analysis, the RIA below, and the discussion in section III.C. of the preamble below for further discussion related to the costs of the ''trailing end'' provision at § 214.336(b)(2) and any resultant train delays.)

#### 1. Training Costs

For purposes of the Special Sensitivity Analysis, FRA has adjusted its estimate for the amount of time that it would take to train roadway workers on the requirements of this rulemaking. FRA had originally estimated that it would take five minutes of additional training for roadway workers in year 1, and two minutes of additional training per year in subsequent years. AAR's comment asserts that four hours of additional training time will be required in year 1, and one hour of additional training time per year thereafter. Based on AAR's assertion, along with FRA staff experience in teaching the subject matter contained in the Final Rule internally, FRA has adjusted its training estimate in the Special Sensitivity Analysis to four hours for year 1, and to one hour for each year thereafter. This adjustment raised the training cost estimate in the Special Sensitivity Analysis from $182,271 (when discounted at 7 percent over 20 years) to $12.17 million (when discounted at 7 percent over 20 years). The details of this calculation may be found in section 2.1 the Special Sensitivity Analysis. These costs are not affected by the Amendments, in which FRA is removing burdens that it had not included in training cost estimates previously.

#### 2. Casualty Estimates and Injury Data

The AAR/ASLRRA Joint Petition stated that ''the record just does not support a finding that there will be benefits in the areas addressed by this petition for reconsideration.'' The AAR/ASLRRA Joint Petition did not allege that the number of injuries that FRA estimated would be prevented by the Final Rule (93.6) over 10 years was too high, but AAR's later comment on the Petitions directly challenged the number of such injuries. Specifically, AAR estimated that only 13 of 90 total injuries that AAR identified in an analysis of non-fatal injuries from 1999–2008 should be included, resulting in AAR's adjustment of FRA's estimate from 9.36 injuries prevented per year to 1.35. AAR claimed that reports of the other 77 injuries specified involvement of maintenance-of-way equipment or

[7] The difference between FRA's estimate on the costs and benefits of the Amended Final rule relative to AAR's estimate as stated in its comment on the Petitions is due to both regulatory changes being made in the Final Rule Amendments and differences in how FRA and AAR formulated the estimates. AAR's estimate in its comment on the Petitions is not broken down by specific provision of the Final Rule, so within a given cost category FRA's analysis may differ for multiple reasons. AAR's estimate does break costs into five categories: Additional watchmen needed to comply with the Final Rule; train delay; lost productivity; training of maintenance of way employees; and job briefings. The largest cost category AAR estimates involves the need for additional watchmen/lookouts, which AAR estimates will cost approximately $1.4 billion over 20 years at a 7 percent discount rate. Under the Amended Final Rule, FRA does not believe new watchmen/lookouts will need to be hired (see below discussion). FRA's conclusion is based on an analysis of the combination of relief granted in the Final Rule Amendments and differences between how FRA and AAR understand that railroads will comply with the Amended Final Rule's requirements.

[8] Since publication of the Final Rule, the value of a statistical life (VSL) to be used for DOT analyses assessing the benefits of preventing fatalities has increased to $9.1 million, allowing for 1.07 percent annual growth in median real wages in future years before discounting to present value. The revised benefit analyses for the Amendments and the Amended Final Rule utilized this updated VSL. *See* ''Guidance on Treatment of the Economic Value of a Statistical Life in U.S. Department of Transportation Analyses''; available online at *http://www.dot.gov/regulations/economic-values-used-in-analysis.*

construction equipment, or no equipment at all, and that the equipment was probably working in the same gangs and probably on the occupied track in most cases.

AAR apparently did not consider an incident in which a roadway worker was struck by maintenance-of-way equipment as relevant to this rule,[9] and that view could account for some of the difference between the FRA and AAR estimates. However, upon further review of the narratives providing more details as to the circumstances and extent of the injuries, FRA has determined that its original estimate was too high. For purposes of the revised economic analysis in the Special Sensitivity Analysis, FRA has used AAR's injury estimate as stated in its comment on the Petitions by adjusting it to 1.35 injuries per year. However, FRA believes the number of injuries per year could likely be increased to 1.62, at a minimum, because 1.62 is the AAR estimate of 1.35 per year, plus 20 percent. The 20-percent increase is based on findings from the original RWP rulemaking in 1996, where FRA found that roughly 20 percent of RWP injuries had been incorrectly assigned to other cause codes. The reduction in estimated number of injuries would reduce the estimated benefit over 20 years by $58,571,993 using a 7-percent discount factor or $42,717,512 using a 3-percent discount factor. This represents a roughly 28-percent decrease in total benefits estimated by FRA.

In addition, the AAR/ASLRRA Joint Petition and the AAR comment challenged the number of fatalities that FRA estimated would have been prevented by the Final Rule. Metro-North, in its comment, offered to partner with FRA to perform a safety analysis of the adjacent-track scenarios for which it requested relief to demonstrate that the Final Rule would not save .6 fatalities annually. (Metro-North's comment did not provide a suggested fatality estimate.) AAR's comment argued that in four of the seven fatalities discussed in Appendix E to the Final Rule's RIA (Appendix E), that a significant level of roadway worker protection was already being provided on the adjacent track and that the incidents could just as well have occurred under the Final Rule. As a result, AAR explained, FRA's estimate of .6 fatalities per year should be reduced by 4/7 to .34. Note, however, that AAR apparently intended to reduce FRA's estimate by 3/6 to .3, as the first incident listed in Appendix E that AAR challenged was not included in FRA's estimate of the benefits because it occurred in 1998, and was outside of the 10-year data period of 1999–2008. Appendix E included all of the relevant adjacent-track fatalities since the original RWP rule went into effect in 1997. Since publication of the Final Rule, a roadway worker fatality occurred on July 5, 2013, in Chicago, Illinois, when a railroad employee was struck by a train passing on an adjacent controlled track. That incident remains under investigation by FRA and the National Transportation Safety Board.

Further, FRA stands by including in the estimate of benefits incidents number 3 and 5 as listed in Appendix E that AAR's comment challenged. Incident number 3 as listed in Appendix E involved a surfacing gang with several roadway workers on the ground working in common with the on-track self-propelled equipment on the occupied track. The fatally injured employee did not have adjacent controlled track protection in place at the time of the incident. He was struck while fouling the adjacent track. The Final Rule would have required, at a minimum, that train approach warning have been provided when the train approached on the adjacent track. If the Final Rule's requirements had been in effect, the roadway worker in charge would have been required to ensure that all roadway workers (including himself) were clear of the adjacent controlled track prior to releasing foul time authority for a train movement on the adjacent track, and then, would also have had to employ train approach warning as the form of on-track safety on the adjacent track. When this incident occurred, the train was traveling at 45 mph at impact. The Final Rule would have required that that the freight train's speed be reduced to 25 mph when passing the roadway work group on the occupied track if their work was to continue while the train passed. Further, the Final Rule would have prohibited any roadway worker from being in the foul of the adjacent track or beyond the plane of the rail of the occupied track closest to the adjacent controlled track once the train was authorized through the working limits or when a warning was provided by a watchman/lookout utilizing train approach warning. Observance of the Final Rule's requirements would have prevented this fatality.

Incident number 5 as listed in Appendix E also involved a roadway work group (surfacing gang) performing work on the ground on an occupied track in common with on-track, self-propelled equipment (tamper and regulator). Under the Final Rule, the adjacent controlled track (13′6″ track centers) would have required the establishment of working limits any time the regulator wing was deployed toward the adjacent controlled track, and, at a minimum, that train approach warning be used as the method of on-track safety for the adjacent track at all other times. Adjacent track protection was not in place at the time of the accident. The Final Rule would require that freight train speeds be reduced to 25 mph for adjacent track movements where work continues on the occupied track. The train in this incident was moving on the adjacent track at 50 mph. The roadway worker in charge was fouling the adjacent controlled track when struck. Under the Final Rule the nearest he or she would have been allowed to be to the occupied track was in the gage of the occupied track without breaking the plane of the rail closest to the adjacent track that the train was moving on, but only then if the freight train's speed had been limited to 25 mph (otherwise he or she would have had to cease work and occupy a place of safety if the train was authorized to pass at its actual speed of 50 mph).

Finally, AAR argued that the fatality in incident number 6 listed in Appendix E would not have been prevented by compliance with the Final Rule's requirements. FRA disagrees. Again, under the Final Rule's requirements, the struck employee would have had to receive train approach warning as the train moved toward the struck employee's location on the adjacent controlled track after foul time (which had been previously been established on the adjacent controlled track) was released. Even though FRA disagrees with AAR regarding this fatality that occurred on a commuter railroad, in the accompanying Special Sensitivity Analysis FRA has not counted this fatality as a benefit of the Amended Final Rule. Instead, FRA has only calculated benefits for five fatalities that occurred during the 1999–2008 analysis period, as FRA focused its analysis on impacts affecting freight operations in light of AAR's submissions after publication of the Final Rule.

AAR's comment argued that some of the requirements of the Final Rule are similar to existing requirements that were not followed in some of the incidents. As mentioned above,

[9] It appears AAR failed to consider a roadway worker's being struck by maintenance-of-way equipment as relevant despite that the Final Rule addresses movements of ''other on-track equipment'' on adjacent controlled tracks and establishes a 25-foot buffer zone between roadway workers and such equipment as a condition for permitting certain work to continue on the occupied track during low-speed movements on the adjacent-controlled track.

however, given the respective speeds of 45 and 50 mph at which the trains were passing the roadway work groups at the time incident numbers 3 and 5 occurred under the requirements of the Amended Final Rule all roadway workers would have had to have previously occupied a predetermined place of safety upon notification that a train was being permitted through the working limits at a speed of greater than 25 mph.[10] As AAR's comment also mentioned, for both incident numbers 3 and 5, it does not appear there was any form of on-track safety was being provided on the adjacent controlled tracks at the time those incidents occurred. Further, the procedures for adjacent-track on-track safety set forth in the Final Rule are more comprehensive and specific (*e.g.,* with regard to where the roadway workers are permitted to be located during the time that a train or other on-track equipment is authorized to pass the roadway workers' location), and FRA's inclusion of these fatalities is supported. In addition, the heightened job briefing requirements of the Final Rule will raise awareness of adjacent-track movements and the required roadway worker protections from such movements.

3. Miscellaneous Costs

This section discusses assorted cost items that are not otherwise explained below and that the AAR/ASLRRA Joint Petition and AAR's comment asserted were missing from the RIA or estimated inaccurately. First, the AAR/ASLRRA Joint Petition and the AAR comment discussed the potential need for railroads to purchase more trucks in which to transport additional roadway workers to work sites. This concern appeared to be particularly related to the Final Rule's definition of ''minor correction'' as that definition excluded welding activities and also inadvertently described hand-operated power tools more narrowly than FRA had intended. In the Amendments FRA has expanded that definition to both include welding and account for additional hand operated power tools as explained below; therefore, AAR's cost concern has been alleviated. Further, FRA's decision to include rail-bound vehicles in the ''hi-rail'' exception per AAR's request further addresses this cost concern.

Second, AAR's comment addressed the number of workdays per year (195) that FRA had assumed in the Final Rule for purposes of estimating costs, stating that it was a somewhat low, but still reasonable, estimate for large productions gangs rather than the smaller gangs that the Final Rule would most affect. AAR instead recommended that FRA estimate costs using the assumption of 250 workdays per year.

The number of workdays per year was calculated at the time that FRA published the first NPRM in this rulemaking. In the first NPRM, the proposed rule text excluded hi-rails without condition. As the ''hi-rail'' exception was later narrowed during this rule's development, FRA's assumption of 195 workdays per year was not adjusted to take into account that roadway work groups work more continuously throughout the year utilizing hi-rail vehicles only. However, as FRA has made the below-described modifications to the Final Rule (*e.g.,* expanding the ''hi-rail'' exception by modifying the definition of ''minor correction'' and including other rail-bound vehicles), FRA believes that AAR's concern regarding the number of shifts being used has been addressed. After reviewing timetables and tonnage data from two of the four largest Class I railroads in light of the different schedules of large production gangs and smaller maintenance gangs, FRA believes that its original estimate (combined with the modifications made to the Final Rule) of 195 workdays per year was actually conservative, and that the number of workdays could be adjusted down to 185 days. However, for purposes of the Special Sensitivity Analysis, in order to be very conservative, FRA has accepted the AAR estimate of 250 workdays per year for section gangs and bridge gangs, but has used 180 days per year for surfacing gangs. Based on FRA experience, these gangs tend to work during a more limited season, and FRA also used actual production gang data from a large Class I railroad to help estimate actual shifts.

Next, the AAR/ASLRRA Joint Petition and AAR's comment both stated that the Final Rule would require the hiring of additional watchmen/lookouts, and that FRA did not account for the costs of hiring those new employees. Metro-North's comments expressed concern that four of the Final Rule's requirements would necessitate hiring additional watchmen/lookouts, and that those costs would outweigh the benefits. FRA has largely alleviated those stated cost concerns with the modifications made in the Amendments. FRA's modifications to the definition of ''minor correction'' and the addition of rail-bound vehicles to the ''hi-rail'' exception specifically address three of Metro-North's four stated concerns.[11] FRA does not believe that railroads will have to hire additional watchmen/lookouts to comply with the Amended Final Rule, as the modifications being made here eliminate the need to hire additional watchmen/lookouts for the welding and section gangs that the AAR/ASLRRA Joint Petition specifically discussed.

Further, the Joint Petition and the AAR comment discussed the need to hire additional watchmen/lookouts for small division surfacing gangs, and generally to hire more roadway workers to make up for lost productivity as a result of the need to stop work and clear the occupied track when trains pass the work zone under the Final Rule. However, as is further discussed below and in the Special Sensitivity Analysis, FRA conducted an analysis of the Amended Final Rule's requirements, and has found that stopping work would be more costly than slowing freight trains for any likely roadway work groups on an adjacent occupied track once the volume of train traffic reaches a certain level, especially since stopping work increases the time of track occupancy required to perform the maintenance, and the track occupancy itself by the roadway work group is the most costly factor involved in the analysis.

With regard to the concern in AAR's comment regarding the need to hire additional watchmen/lookouts for small division surfacing gangs, FRA notes that in such small division surfacing gangs oftentimes an existing member of the roadway work group, such as the roadway worker in charge or another roadway maintenance machine operator, is available to act as a watchman/lookout when necessary. Further, existing § 214.335(c) has long required that train approach warning for movements on adjacent tracks not included within working limits be provided to roadway work groups engaged in large-scale maintenance or construction. In addition, on-track safety on an adjacent track is already required to be provided if roadway workers have the potential to foul that adjacent track. In the instances where watchmen/lookouts are deployed under the Final Rule, those watchmen/lookouts are roadway workers who will already be performing roadway work along the railroad right of way, and FRA is unable to quantify whether there are increased risks while performing duties

[10] Incident number 1 that AAR's comment challenged occurred in 1998 and was not included in the Final Rule RIA's benefit analysis.

[11] Metro-North's fourth concern regarding the need for watchmen/lookouts for roadway workers performing maintenance or repair is addressed further below.

as a watchman/lookout versus performing other roadway work duties as part of the same roadway work group. Last, the concerns regarding train delay and lost productivity that were raised by the AAR/ASLRRA Joint Petition and in several comments are addressed by the modifications being made to the Final Rule that are addressed in the discussions below, and in the Special Sensitivity Analysis.

*B. Definition of ''Minor Correction'' (Section 214.336(a)(3) of the Final Rule)*

One of the exceptions to the Final Rule's requirement for adjacent-track on-track safety permits work of a roadway work group to continue during times that the roadway work group is exclusively performing work activity involving a hi-rail vehicle being used ''for inspection or minor correction purposes.'' The Final Rule defined ''minor correction'' as ''one or more repairs of a minor nature, including, but not limited to, spiking, anchoring, hand tamping, and joint bolt replacement that is accomplished with hand tools or handheld pneumatic tools only. The term does not include welding, machine spiking, machine tamping, or any similarly distracting repair.''

Both the AAR/ASLRRA Joint Petition and AAR's comment argued that the definition of ''minor correction'' should (i) include, not exclude, welding (because the welders typically confine their movements to the track on which they are working), and (ii) should not be limited to handheld pneumatic tools but rather expanded to encompass all hand tools, such as gas- and diesel-powered, hydraulic, electric, pneumatic, and perhaps others. Metro-North raised similar concerns in its comment. AAR's comment asserted that, without these two changes to the Final Rule, the industry would incur a year 1 cost of $93 million and in subsequent years an annual cost of $82 million. The AAR/ASLRRA Joint Petition argued that excluding welding from ''minor correction'' would effectively require an extra watchman for (1) welding gangs (because railroads never know when an emergency will occur where a thermite weld will be necessary) and (2) section gangs using hydraulic tools and other powered (i.e., non-pneumatic) hand tools. Further, AAR indicated that FRA failed to consider the costs for the additional watchmen/lookouts required (namely, wage and fringe benefits, the need to purchase larger trucks to accommodate an additional person, and new-hire training to replace employees who become watchmen/lookouts). Metro-North and APTA raised similar concerns regarding the added cost of additional watchmen/lookouts for welding gangs and section gangs using hand tools (Metro-North), and for small maintenance gangs (APTA). APTA's comment also mentioned the cost of transporting the additional employees to job sites and other associated costs, such as for additional training and equipment.

The BMWED/BRS joint comment did not oppose the recommendation that FRA clarify which handheld power tools are permissible for ''minor correction'' work, and suggested that FRA expand that term's definition to include ''handheld power tools only'' instead of ''handheld pneumatic tools only.'' However, the BMWED/BRS joint comment did oppose an expansion of the definition of ''minor correction'' to include welding, indicating that small and large welding crews very often divide up any necessary watchman/lookout duties amongst themselves and that where circumstances prevent the use of watchmen/lookouts, another form of on-track safety is available for use. The BMWED/BRS joint comment also noted that thermite field welding operations are particularly dangerous due to the intricacy and complexity of the work, noise from the roadway maintenance machines, reduced visibility, and the necessity of thermite welders to position themselves both within the gage and to the outside rail of an occupied track when performing certain steps.

In response to the Petitions, FRA is modifying the definition of ''minor correction'' to include both welding and certain uses of all handheld, hand-supported or hand-guided power tools (such as hydraulic, pneumatic, gas powered, and others). FRA did not intend to limit the exception for handheld power tools so narrowly; therefore, FRA has removed the word ''pneumatic'' from the definition. With respect to welding operations, FRA is classifying welding as a ''minor correction'' activity.

FRA weighed several factors in making the latter decision. First, the RSAC consensus language did not include hi-rail related welding activities, and in the Final Rule FRA did not specifically assess costs for the inclusion of such welding operations. Further, there have been no fatalities related to activities that would have been implicated by the Final Rule's welding-related requirement. Next, welders often need to verify that no trains will be passing on the adjacent controlled track before igniting the charge for the weld because the weld could fail if a train were to pass by it before it has solidified. This verification element that is inherent in the welding process lessens the risk that the roadway workers would be struck by a train on an adjacent track. Welding is also often performed on the occupied track or immediately adjacent to the occupied track with little distraction, and, therefore, is not the type of activity intended to be covered by this rulemaking. Further, existing part 214 already requires that on-track safety be established on an adjacent track (typically by the welder's helper serving as a watchman/lookout) during the portions of the welding task that create a potential to foul the adjacent track. See 49 CFR 214.315, 214.335.

The BMWED/BRS joint comment failed to consider that the Final Rule, if unmodified, would have required that on-track safety be established on the adjacent controlled track for the duration of the welding task (as opposed to the occasional establishment of on-track safety only when the potential to foul the adjacent controlled track exists under the existing RWP regulation). Again, FRA notes that for any welding activities that foul or have the potential to foul an adjacent track, that existing part 214 still requires that on-track safety be established on that adjacent track.

AAR estimated that the additional costs of applying the adjacent-track provisions to welding operations would be $48 million in the first year and $37 million annually in subsequent years. FRA had not anticipated that the Final Rule would have such an impact on welding, and, thus, these costs had not been included in FRA's original economic analysis. AAR stated that railroads would have to buy a number of trucks (i.e., motor vehicles not capable of moving on railroad track, rather than hi-rail vehicles) at $40,000 each to accommodate the additional watchmen/lookouts because existing on-track welding trucks do not usually include sufficient cab space for one or more additional workers. AAR's estimated cost of $40,000 per truck was too low to provide hi-rail vehicles for the additional workers. This fact implies that the additional roadway workers would gain access to the work area by riding in the additional truck and then by walking to the track requiring the weld from the nearest available point at which they can park the truck. This situation presents additional risks and the possibility of additional worker casualties from slipping and tripping hazards, limited visibility conditions, exposure to injury from traversing an other-than-public access way en route to the place on the track requiring welding,

and from other hazards along the right-of-way.

In some cases, the watchmen/lookouts would not walk to the work area, but rather ride in an on-track welding truck would drop some workers near the work area, return to an access point, and pick up the remaining workers. The additional time of track occupancy needed to pick up, transport, and drop off roadway workers in these scenarios would be very costly, because FRA's analysis of the Final Rule provisions shows that the greatest cost of occupying track comes from the occupancy itself, not from slowing trains on an adjacent track. FRA believes that AAR has potentially overstated these cost totals with regard to welding activities because in a high percentage of situations involving welding, the Final Rule's requirements would not have applied. However, FRA does acknowledge that in order to be prepared for situations in which the Final Rule's requirements would have applied to welding, that significant costs would have been incurred by the industry to purchase new hi-rails or trucks to accommodate a third roadway worker in certain situations.

Last, it is not clear from the evidence that FRA currently has that the general inclusion of welding operations as within the scope of the term ''minor correction'' would reduce injuries from operation on adjacent tracks. However, if welding operations were not a ''minor correction,'' the evidence is clear that costs could increase substantially, and it is likely that new risks could be imposed by the fact that additional workers will have to travel to the welding worksites.

FRA's decision to modify the definition of ''minor correction'' to include welding operations and to expand the hand tools allowable under the definition to include ''hand tools or handheld, hand-supported, or hand-guided power tools'' eliminates the concern raised in the AAR/ASLRRA Joint Petition with regard to the cost of the activities excluded from the definition of ''minor correction'' in the Final Rule. This modification also addresses the concerns raised by Metro-North and APTA regarding the added cost of additional watchmen/lookouts for welding gangs and section gangs using hand tools (Metro-North), and for small maintenance gangs (APTA). This modification also eliminates APTA's concern regarding the cost of transporting the additional employees to job sites and regarding other associated costs, such as for additional training and equipment.

*C. Speed Increase for Passenger Trains and Other Passenger On-Track Equipment Passing Roadway Workers on an Adjacent Controlled Track (Paragraphs (b) and (c) of Section 214.336 of the Final Rule)*

Under the Final Rule, each roadway worker in a roadway work group that is affected by the movement of a train or other on-track equipment on an adjacent controlled track at an authorized speed of 25 mph or less is permitted to continue his or her on-ground work performed exclusively between the rails of the occupied track and outside the 25-foot zone to the front or rear of any on-track, self-propelled equipment or coupled equipment permitted to move on the occupied track. However, if the movement on the adjacent controlled track is authorized to exceed 25 mph, then the roadway workers on the occupied track must cease all on-ground work and occupy a predetermined place of safety, and equipment movement on the occupied track must also cease.

APTA's comments on the NPRM, Petition, and comment on the Petitions all requested that FRA raise the Final Rule's 25-mph maximum authorized speed for adjacent-controlled-track passenger train movements during which roadway workers are allowed to continue to work. APTA noted that FRA did not adopt that request in the Final Rule. APTA's comment indicated that, while quantifying the cost impacts of the Final Rule, to include this 25-mph maximum, is difficult, there is an indirect cost related to disruption of scheduled revenue service and loss of passenger business due to lack of service reliability. (*E.g.,* TriRail experienced an almost 10-percent dip in passenger ridership during a construction project in which on-time performance averaged 68 percent.) APTA's comment also speculated regarding the impacts on large-scale passenger operations, such as at New York City's Penn Station.

Similarly, LIRR alleged that implementation of the 25-mph maximum would lead to train delays, cancellations, and missed connections, due to the requirement to reduce to such speed on the adjacent track when work is being performed on the occupied track. LIRR indicated that if a 25-mph maximum speed restriction is put in place in the block between the Nassau and Divide towers during the hours between 10 a.m. and 3 p.m., when work is typically performed, that five eastbound trains and six westbound trains (affecting 5,000 to 10,000 riders) would need to be canceled. Other customers transferring from those trains would also be affected. While no quantified costs have been provided related to the above scenarios, LIRR estimated increased yearly costs of $1.4 million as a result of the Final Rule's requirements, because jobs would take longer to complete and might need to be performed on weekends and nights, when employee wage rates are higher. Also, although not directly alleging that the maximum speed was too low, AAR also noted that FRA failed to account for either passenger-train delay or freight-train delay for situations where the use of watchmen/lookouts is not feasible or desirable, indicating that such situations shut down both the occupied track and the adjacent track on what are usually busy rail lines, and that delays range from ten minutes to an hour or more.

The BMWED/BRS joint comment stated that the 25-mph maximum was a consensus agreement and should not be increased. The joint comment also stated that the 25-mph maximum speed for both passenger and freight trains when passing a roadway work group while work continues on an adjacent controlled track provides for uniformity within the Final Rule, and does not introduce additional hazards associated with conducting/ceasing work on an occupied track based upon different types of trains operating under different speed thresholds on the adjacent controlled track. The comment also noted that roadway workers in charge have the authority to permit the passenger trains through working limits at speeds higher than 25 mph (provided roadway workers on the occupied track would have to cease work and occupy a place of safety) and that it is not at all uncommon for passenger trains to be authorized through at speeds substantially over 40 mph.

After considering the above-listed arguments, FRA is modifying the Final Rule by raising to 40 mph the maximum allowable speed for adjacent-controlled-track movements by passenger rail traffic while roadway workers are permitted to continue their on-ground work on the occupied track. FRA considered the following factors when determining that granting the petition request regarding the 25-mph maximum speed is the appropriate course of action from a safety perspective. First, passenger trains are shorter than freight trains and do not present the dangers of shifted loads and swinging doors that exist for freight trains. Second, unlike much longer freight trains, commuter trains are only typically 6 to 8 cars in length, and whether traveling at 40 mph or 25 mph, pass within a matter of seconds. Because there is less danger of swinging doors and shifted loads, risk

exposure is much more minimal than when compared to a much longer passing freight train. Third, passenger equipment is typically narrower than comparable freight train equipment, meaning it is physically farther from roadway workers who continue work in the gage of the occupied adjacent track while a passenger train passes. Fourth, the type of shelf couplers utilized on passenger equipment is designed to keep equipment upright and in-line in the event of derailment. Fifth, the superior braking capabilities and shorter stopping distances of passenger equipment reduce risks while approaching and passing adjacent track roadway work zones. Sixth, track-caused train derailments are a leading cause of accidents reported to FRA, and if a train were to derail on an adjacent controlled track while passing a roadway work group work on the occupied track, there are obvious casualty risks to the roadway work group. FRA's Track Safety Standards, at 49 CFR part 213, have long differentiated between the speeds passenger trains and freight trains are permitted to travel on the same class of railroad track. For example, § 213.9(a) permits freight trains to travel only 40 mph over Class 3 track, while allowing passenger trains to travel 60 mph. This longstanding distinction permitting increased speeds for passenger trains was justified, with no loss in safety, generally because suspension systems on passenger trains are designed to provide a safer dynamic response than freight trains to the same track conditions.[12] Last, FRA does not have data or analyses to show that the higher speed at which commuter trains currently pass work zones on an adjacent track is unsafe.

Further, if the assertions in LIRR's comment are correct and in some instances several thousand of LIRR's passengers could be affected daily by the Final Rule's 25-mph limitation, FRA believes unintended passenger safety issues could occur if the Final Rule's speed restriction is not increased for passenger trains. Crowding, on both passenger platforms and on passenger trains that results from commuter train cancellations and delays, presents the potential for platform falls and other obvious risks to passenger safety. These cancellations and delays could occur because commuter train ''meet'' times can be critical in passenger operations when a missed meet for one train often compounds and affects later-scheduled trains. Further, a 25-mph limitation for commuter trains could have the unintended impact of encouraging passengers to take other modes of transportation, namely automobiles. Automobile travel is statistically less safe than passenger train travel and is also less fuel efficient. As media coverage of the recent May 2013, Metro-North train accident in Bridgeport, Connecticut, illustrates, passenger train cancellations can raise concerns regarding highway congestion and parking complications for commuters who instead choose to travel by automobile. FRA's statistics indicate that the average commuter train trip is 24 miles long. Last, in granting this request to raise the speed at which passenger trains may pass work zones to 40 mph, FRA also avoids giving railroads perverse incentive to defer track or signal maintenance rather than delay or cancel scheduled passenger trains in complying with the Final Rule's requirements. Of course, such deferred maintenance can potentially lead to track- or signal-caused train derailments and other accidents, thereby endangering railroad operating crews and other railroad employees, rail passengers, and the general public.

Finally, the potential cost implications related to passenger-train delay/cancellation issues resulting from this provision of the Final Rule had not previously been raised with FRA until it was posed by APTA's petition for reconsideration. Thus, in figuring the costs of the Final Rule, FRA did not consider the train-cancellation issue. The train delay implications for commuter operations that LIRR and APTA raise were also not fully considered in the analysis. LIRR was the only entity to put forth an actual cost figure with regard to the 25 mph speed restriction for passenger operations, and FRA does not have information to refute LIRR's assertions. FRA estimates that this response's amendment to the Final Rule will create cost savings for the commuter rail industry to at least the extent estimated by LIRR ($1.4 million annually). As discussed further in the RIA below, FRA cannot simply extrapolate the LIRR case to all other commuter railroads. FRA believes that the only other commuter railroad likely to have had impacts similar to those on the LIRR was Metro-North. Extrapolated to the combination of Metro-North and LIRR based on passenger miles, the total cost for the industry would have been $3,152,297 per year. The total cost savings resulting from this amendment to the Final Rule is $33.4 million (PV, 7) and $46.9 million (PV, 3), when discounted over a twenty-year period.

FRA is, however, retaining the existing maximum of 25 mph for adjacent-controlled-track movements of freight trains and other freight on-track equipment movements. The AAR/ASLRRA Joint Petition did not make a request for the Final Rule's 25 mph speed restriction to be increased with respect to freight operations. As mentioned above, when freight trains pass works zones on an adjacent track, the safety risk of shifted loads is present, as well as the safety risk of swinging doors, loose banding, and dragging equipment, and the hazards associated with debris, dust, stone, and construction/maintenance materials being strewn by freight trains, which tend to be longer and much heavier than passenger trains. The discussion in Section III.D. directly below also contains a more extensive discussion of some of FRA's rationale for retaining the 25-mph speed limit for freight trains with regard to any potential cost concerns.

*D. The Requirement That Roadway Workers May Resume Work Only After the Trailing-End of All Trains or Other On-Track Equipment Movement Authorized To Travel Greater Than 25 MPH Has Passed (Paragraph (b) of Section 214.336 of the Final Rule)*

The Final Rule provided that roadway workers may resume work only after the trailing end of a train or other on-track equipment (authorized to travel past the roadway work gang at a speed greater than 25 mph) has passed the roadway work group (''trailing end'' provision). The original RSAC consensus language did not specify whether the trailing end or the leading end of the movement had to pass before work could resume, but rather only stated that ''on-ground work and equipment movement on the occupied track may resume only after all such movements on adjacent track have passed each component of the Roadway Work Group(s).'' FRA specified that the trailing end of the train must have passed before work resumes because we believed that this consensus language meant, and plain language indicated, that the entire train movement must have passed before the resumption of work. *See* 73 FR 74598. The ''trailing end'' provision was also adopted, in part, due to the concerns raised by BMWED and BRS on this issue, namely that there are hazards presented to roadway workers by abnormal consist conditions (*e.g.,* ''shifted loads/shifted ladings, loose banding, dragging chains/binders, loose

[12] FRA proposed different speed limits for passenger and freight operations in 1972, largely relying on the differences in suspension systems used. 37 FR 18398. The rule was adopted as proposed in 1973. 38 FR 873.

brake piping, loose/swinging boxcar doors, [and] fragmented brake shoes'') and by ''dust, rust, debris, stone, and track construction/maintenance materials[,]'' which may become airborne while trains on an adjacent track pass in close proximity to a roadway work group.

The AAR/ASLRRA Joint Petition requested that the Final Rule be modified to permit roadway workers to resume work after the leading end of a train has passed. They cited the following points as support for their request: (1) There are no fatalities from shifted loads and no widespread problem of employees injured by shifted loads; (2) there are many railroad employees working near passing trains, not just roadway workers; (3) there is a heightened awareness of the roadway workers after the leading end of a train passes; and (4) prohibiting the resumption of work until the entire train or equipment has passed would adversely affect productivity and require the hiring of additional roadway workers. AAR, in its supplemental comments, estimated that this amendment to the Final Rule would save the railroads approximately $56 million annually (based on an estimate for four Class I railroads alone). APTA's comment expressed support for the AAR/ASLRRA Joint Petition's position with regard to the ''trailing end'' provision. The BMWED/BRS joint comment stated that the AAR/ASLRRA Joint Petition ignored the risks associated with shifted loads/shifted ladings and the hazards associated with materials being kicked up by trains operating at track speed.

FRA is denying the request made in the AAR/ASLRRA Joint Petition. FRA notes that when trains pass a roadway work group on an adjacent track that injury risks are present, and that this provision also serves railroad safety where roadway workers are observing the passing of the train for any dragging equipment or any other condition that may compromise the safe movement of a train An additional safety rationale for FRA retaining the requirements of the ''trailing end'' provision relates to increased derailment risks when trains accelerate. As is generally understood in the railroad industry from voluminous research, there are in-line forces (''buff and draft'' forces) that push and pull on the individual railroad cars in a train, resulting in increasing or decreasing slack.[13] Slack is the free movement in each railroad car via its coupling equipment and draft gear. Locomotive tractive effort applied to accelerate a train's speed is one of these forces acting within a train that cause slack action to occur.[14] Excessive slack action forces can result in train separation, cause a rail to turn over, or cause a rail car to climb a rail, leading to derailments. Thus, while roadway workers continue to work on the occupied track while a freight train passes at 25 mph or less (40 mph or less for passenger) on an adjacent-controlled track, FRA believes that to permit the train to accelerate as soon as the head end of the train has passed increases the risk of derailment at the work location, even if the risk is normally well managed.

Further, FRA believes that AAR has overestimated the costs of complying with the ''trailing end'' provision by approximately $55,741,196.[15] FRA's analysis has not found cases above a certain train traffic volume where stopping work while trains pass at greater than 25 mph (or, as amended, greater than 40 mph for passenger trains) would be less costly than slowing trains to 25 mph (or 40 mph for passenger) for any likely roadway worker work groups on an adjacent occupied track. Stopping work increases the time of track occupancy required to perform the maintenance. The track occupancy itself by a roadway work group is the most costly factor involved in the analysis.

To formulate a revised cost-benefit analysis to account for the modifications that FRA is making to the Final Rule, and also to study thoroughly AAR's assertions regarding the costs associated with the Final Rule generally and the ''trailing end'' provision specifically, FRA staff conducted a modeling analysis. FRA calculated the delay associated with implementing the Amended Final Rule, and also the ''trailing end'' provision specifically, by simulating train movements. Simulated train movements were modeled in accordance with DOT's train performance simulator (TPS).[16] The models that FRA developed were detailed and were correlated with actual rail traffic. FRA developed 27 simulation runs in total (or nine simulations each for low, medium, and heavy traffic volumes) over 270 miles of simulated double-track railroad. FRA believes that the simulated track used in this modeling provided a representative sample of terrain, track geometry, and track speed limits, as the infrastructure data was developed from publicly available track charts and included changes in elevation, direction, and curvature.

The results of the modeling showed that congestion-induced costs did not increase when trains slowed to 25 mph to pass a work zone when freight train volumes were at or above threshold. FRA found that rail lines operating above capacity, with more than 20 minutes of delay per train before the trains even reached the roadway work zone, would incur minor additional congestion-related costs as a result of this rulemaking. At most, these additional congestion-related costs would be the result of an additional 1 minute of headway required to traverse the roadway work zone occupying the adjacent track. FRA modeling found that, on average, the level of congestion needed to incur these minor congestion-related costs occurred when freight train volumes exceeded 34 trains per 24-hour period, or approximately 10 trains per 7-hour shift for a roadway work group occupying an adjacent track. FRA believes that its assumption of 10 trains per shift as a threshold for congestion for purposes of calculating the cost-benefit analysis is very conservative. The modeling documents and accompanying results are located in the public docket for this rulemaking and are also discussed more extensively in the Special Sensitivity Analysis.

In order to evaluate more fully the costs of the Amended Final Rule (along with the ''trailing end'' provision, specifically), FRA then applied the results of the modeling analysis to the railroad industry as a whole by utilizing the assumptions described more completely in the Special Sensitivity Analysis (assumptions governing train speed, train length, train weight, work

[13] *See, e.g.,* FRA, Report to the Senate Committee on Commerce, Science and Transportation and the House Committee on Transportation and Infrastructure; Safe Placement of Train Cars (June 2005).

[14] *Id.*

[15] The costs of the ''trailing end'' provision were estimated by subtracting the costs that would exist if trains were permitted to accelerate to maximum authorized speed after only the head end of the train had passed the work zone, from the costs of the Final Rule, as analyzed (where the entire length of a train may only travel 25 mph by a work zone such that work on the occupied track could continue). This is equivalent to the costs of passing a length of track equal to the length of the work zone at 25 mph compared to the costs of passing the work zone at maximum authorized track speed, from actual speed limits on track segments. This may actually overstate costs, because in the absence of the Final Rule, not all trains would accelerate to maximum authorized speed (freight train tonnage, crossovers, and other common factors often inhibit a train's ability to accelerate to maximum authorized speed until a train is well past a work zone). The model assumes that trains decelerate from maximum authorized speed to 25 mph, and after passing the work zone, accelerate back to maximum authorized speed, except where congestion would affect the trains' initial or final speeds.

[16] Train Performance Simulator Version 5c, revised March 1988 by DOT.

stoppage times, etc.). FRA then applied those assumptions to estimated roadway worker production gang efforts for a simulated large Class I railroad.

FRA first had to estimate the number of shifts that the Amended Final Rule would affect for each of the different types of roadway worker groups (section gangs, surfacing gangs, and bridge gangs). For this simulated large railroad, FRA estimated three section gangs per roadmaster, 138 roadmasters per railroad, 250 shifts per year per gang, with 20 percent of those shifts on occupied track with on-track equipment subject to the requirements of the Amended Final Rule. FRA estimated that the simulated railroad had 18 divisions, with 3 surfacing gangs per division and each gang working 180 shifts per year, with 100 percent of those shifts on occupied track with on-track equipment subject to the Amended Final Rule. FRA also estimated 7 bridge gangs per division, 250 shifts per year per gang, with 40 percent of those shifts on occupied track with on-track equipment subject to the Amended Final Rule.

FRA then allocated shifts for section gangs, surfacing gangs, and bridge gangs to each subdivision in proportion to the subdivision's share of total ton-miles. This allocation reflects an assumption that maintenance of rail infrastructure needs to be performed in proportion to wear and tear on rail infrastructure, which occurs as a direct result of train traffic and tonnage. FRA assigned train-delay costs to each gang shift based on the number of trains expected to be affected, multiplied by the cost of affecting a single train. For production gangs and surfacing gangs, FRA assumed that work zones were one mile long, while for bridge and section gangs, operating in smaller groups, the work zones were estimated to be one-quarter mile long.

Delay costs [17] were estimated by subtracting the time it would have taken for the train to pass without slowing to pass a roadway work group from track speed (or 40 mph, whichever was lower) from the total time for a freight train to slow from 40 mph (or track speed, if track speed were lower) and pass a work zone, including waiting for the trailing end to pass, and the time to accelerate back up to 40 mph or track speed. Braking was estimated at ⅙ mph per second, with a total braking time from 40 mph to 25 mph of 90 seconds, based on field experience of FRA staff. The calculation for time and distance during acceleration from 25 mph to 40 mph (168.91 seconds over 8,194 feet) was based on an 8,000-ton train powered by motive power totaling 6,640 horsepower.[18]

For each category of work gang, for each subdivision, FRA estimated the annual cost of the ''trailing end'' provision by multiplying cost per affected train for that gang type by the affected trains per shift by total shifts per year. FRA totaled those costs for each subdivision and then totaled all subdivision costs. The total cost for the large simulated Class I railroad created for purposes of this modeling analysis was $674,801 for one year.

FRA then attempted to estimate similar costs for three other simulated large Class I railroads by allocating affected gang shifts per year to each subdivision based on affected gang shifts per ton-mile per year from the first railroad, and otherwise continuing to use the same assumptions. This led to a much lower estimate of costs per ton-mile at the other railroads. The total annual cost estimate ranged from $90,758 for the next largest Class I by revenue-ton-miles down to $34,114 for the smallest of the four large Class I railroads. These values are lower than for the first railroad as the railroads simulated had less affected trackage where the Amended Final Rule's requirements would apply and were smaller than the largest Class I first simulated, which mirrors the state of actual existing Class I railroad hierarchy. FRA decided to extrapolate to all Class I freight railroads using the proportionate share of revenue-ton-miles. The total annual cost of slowing trains as they pass work zones was estimated at $2,192,720. This total estimated cost represents the entire cost of slowing trains to pass work zones on the occupied track, to include the estimated $258,803 cost of the ''trailing'' end provision.

In the Special Sensitivity Analysis FRA follows an assumption employed in the Final Rule's RIA that 70 percent of affected railroad operations were in compliance with the requirements of this rulemaking, and would continue to be in compliance even in the absence of the rulemaking. Thus, after accounting for pre-existing compliance the real annual costs will be 30 percent of $2,192,720, or $673,840. After accounting for pre-existing compliance, the real annual cost of complying with the ''trailing end'' provision will be $77,641, or 30 percent of $258,803. The costs of the ''trailing end'' provision were estimated by comparing the difference between the costs of the Amended Final Rule and the costs of the Amended Final Rule were trains permitted to accelerate to maximum authorized speed after the head end of the train had passed the work zone.

FRA has no data to estimate costs to Class II or Class III railroads; however, FRA believes that the unit costs for those railroads are likely to be no greater than those for the lower-cost Class I railroads (some smaller railroads have no adjacent controlled tracks that are subject to the requirements of the Amended Final Rule). FRA has chosen the most conservative assumption, extrapolating the costs on a revenue-ton-mile basis from the first Class I railroad analyzed. FRA believes this course of action more than makes up for the absence of any data from Class II or Class III railroads. Had FRA used the methodology that derived lower unit costs, the estimated total cost of the Amended Final Rule would have been 67-percent lower than the estimate presented in the Special Sensitivity Analysis.

In sum, FRA believes that the costs of the ''trailing end'' provision as asserted by AAR were overestimated. FRA's analysis shows that by far the largest cost involved in the analysis is the occupancy of the track itself by a roadway work group. Slowing trains to pass a roadway work group is a less costly alternative than a roadway work group ceasing work to permit a train to pass at a higher speed, as that extends the length of time the track is occupied by the roadway work group and correspondingly slows all subsequent train traffic. FRA believes that the results of the modeling and resultant costs as extrapolated on a revenue-ton mile basis show that the Amended Final Rule, including its ''trailing end'' provision, is cost-beneficial.

[17] Delay costs were estimated at $350 per train hour. A recent study (Schafer, D.H., Effect of Train Length on Railroad Accidents and a Quantitative Analysis of Factors Affecting Broken Rails, M.S. Thesis, University of Illinois at Urbana-Champaign, Urbana, IL (2006)) found train delay cost to be $213 per hour for freight trains; however, FRA has heard that railroads offer higher costs at RSAC meetings, and FRA uses a higher figure for purposes of this analysis in order to be conservative.

[18] FRA assumed that the fuel costs were 20-horsepower per gallon per hour, with fuel cost of $3.50 per gallon. This assumption is based on locomotive performance data (Railroad Facts and Figures, A.A. Krug, available online at *http://www.alkrug.vcn.com/rrfacts/fueluse.htm.*) The fuel costs were attributed only to the 6,640 horsepower. In reality this assumption is conservative, because of the reduction in fuel usage during braking. FRA estimates the cost to slow a train to 25 mph, pass a one-mile-long work zone, including trailing end of the train, and then accelerate to 40 mph, would be $39.74.

*E. Elimination of Requirement That a Non-Controlled Track Be Treated as an Adjacent Controlled Track (Section 214.336(a)(2) of the Final Rule)*

In the Final Rule FRA adopted a requirement that a non-controlled track whose track center is spaced 19 feet or less from the occupied track be treated as an adjacent controlled track if the occupied track has an adjacent controlled track on the other side. This requirement was adopted due to concern that confusion could arise by requiring that roadway work groups make a determination regarding whether adjacent-track on-track safety was necessary on a closely-spaced adjacent track based only on whether that adjacent track was controlled or not. FRA had concern that such confusion could result in incidents involving train movements on adjacent non-controlled tracks. FRA also noted this approach was consistent with its rationale for adopting the language in § 214.336(e)(1)(ii), which imposes conditions on the exception for work performed on a side with one or more adjacent tracks only if the danger posed by the closest adjacent track (controlled or non-controlled) on that side had been essentially eliminated.

The AAR/ASLRRA Joint Petition argued that no accident/incident data supports this provision and that the provision itself could cause confusion as to why the roadway workers have to treat the non-controlled track as an adjacent controlled track. APTA's Petition expressed the separate concern that the provision would disrupt scheduled passenger train operations and, thus, also affect the cost of scheduled train operations in a manner that was not contemplated by FRA in the Final Rule.

The BMWED/BRS comment stated that they shared FRA's concern regarding the risk of additional confusion and also believed that the provision added a level of clarity and uniformity to the Final Rule, applied only in very limited circumstances, and ensured that roadway workers would not clear into or foul the adjacent non-controlled track without protection.

FRA is deleting this provision from the Final Rule, in part because there is no accident data to support it, which was the basis for the original RSAC decision not to adopt this provision in its recommendation to FRA. FRA has also made this decision because the on-track safety job briefing required by the Final Rule is intended to make clear to roadway workers that no on-track safety is being provided on that track, as the job briefing requires a discussion of all adjacent tracks regardless of whether they are controlled or non-controlled. Further, on a non-controlled track, roadway work groups have the authority to establish working limits by making a track inaccessible on their own, and are not reliant on a control operator or dispatcher to do so as they are with controlled tracks. And finally, given the limited circumstances under which this provision would apply, there is little risk to the roadway workers, especially since Note 1 of Table 1 of § 214.336 specifically states that a ''predetermined place of safety'' ''may not be on a track, unless the track has working limits on it and no movements permitted within such working limits by the [roadway worker in charge].'' This same requirement was also expressly proposed in FRA's RWP Miscellaneous Revisions NPRM, which was published last year. 77 FR 50324. For these reasons, FRA has determined that this provision is unnecessary. This decision also makes moot APTA's concern stated in its Petition that this provision would have adversely affected passenger train schedules.

*F. Additional Exception for ''Rail-Bound Vehicles'' Used for Conducting Inspections, Minor Corrections, or Welding (Section 214.336(e)(3)(i) of the Final Rule)*

The Final Rule, at § 214.336(e)(3)(i), exempted inspections and minor correction work involving a hi-rail vehicle from the adjacent-track on-track safety requirements, but did not similarly expressly exempt rail-bound vehicles (not equipped with highway wheels) conducting the same inspection or minor correction work. The AAR/ASLRRA Joint Petition, along with Metro-North in its comment, requested that there be an exception for rail-bound vehicles where manual inspections are being conducted. They requested such because they involve the same activities as those performed during an inspection conducted by a hi-rail vehicle, but differentiate between the two based only on whether the vehicle from which the inspections are being conducted has highway wheels in addition to rail wheels. The Joint Petition also argued that the duties clearly would not produce dust or noise.

The BMWED/BRS joint comment did not oppose extending the exception for hi-rail vehicles to rail-bound equipment being used exclusively for inspection or minor correction purposes, provided that all of the limitations that apply to hi-rail vehicles in § 214.336(e)(3)(i) (i.e., limiting the exception to those hi-rails not coupled to one or more railroad cars and requiring that the on-track safety job briefing include discussion of the nature of the work to determine if on-track safety is necessary where multiple hi-rails are engaged in a common task) would apply to the rail-bound vehicles.

FRA is granting the request to create an additional exception for rail-bound vehicles being used for inspection or minor correction purposes by broadening the ''hi-rail vehicle'' exception to apply to on-track, self-propelled equipment (other than an automated inspection car or catenary maintenance tower vehicle) being used for inspection or minor correction (including welding). FRA already permits visual track inspections to be conducted with such equipment under 49 CFR 213.233(b), and there should be no additional safety risks when the equipment is being used for inspection or minor correction purposes, especially if the same limitations for hi-rails are applied to this exception, as suggested by the BMWED/BRS joint comment. FRA concurs with the labor organizations' suggestion and has adopted the same limitations as are applied to hi-rails.

*G. Expansion of an Exception To Include Roadway Workers Performing Maintenance or Repairs Who Are Positioned Within the Perimeter of a Machine or Coupled Equipment on the Occupied Track (Section 214.336(e)(2) of the Final Rule)*

The Final Rule contained an exception to the requirement that on-track safety be established on an adjacent controlled track when maintenance or repairs are being performed while the worker is positioned on a side of the occupied track as described in paragraph (e)(1)(i), (ii), or (iii) of § 214.336 [19] alongside a roadway maintenance machine or coupled equipment that would prevent a roadway worker from fouling the adjacent track on the other side of the equipment. FRA adopted that provision in response to BMWED's and BRS' concern that work should not be permitted in the foul of the occupied track (even if mostly positioned on the side opposite from the train movement) unless the machine acted as a physical barrier between the roadway worker and the adjacent controlled track on which the movement was occurring. FRA

[19] (I.e., on the side of the occupied track that has no adjacent track; on the side with one or more adjacent tracks, the closest of which has working limits on it and no movements permitted within such working limited by the roadway worker in charge; or on the side with one or more adjacent tracks, provided that it has an inter-track barrier between the occupied track and the closest adjacent track on that side.)

believed that this exception would permit the changing out of a grinding stone on the side of the equipment opposite of that where an adjacent track movement was occurring and, in some cases, depending on the location of the fuel tank, the fueling of a machine. Under the Final Rule such activities would not require that adjacent-controlled- track protections be established.

The AAR/ASLRRA Joint Petition argued that the exception as put forth in the Final Rule was too narrow and that it should also apply to a worker positioned within the perimeter of the equipment on the occupied track, without regard to whether the maintenance or repairs are performed while positioned on a side of the occupied track as described in paragraph (e)(1)(i), (ii), or (iii) of § 214.336. AAR/ASLRRA argued that a repairman who is working beneath a machine should not be forced to extract him or herself each time a train passed on the adjacent track in order to go to the predetermined place of safety. They argue that this requirement could increase the risk of injury to the worker and that a roadway worker working performing repairs under the machine is not at risk of being struck by a train on the adjacent track. The BMWED/BRS joint comment stated that the term ''perimeter'' is too broad and would include those sides of the occupied track that do not provide a barrier as contemplated by this section, and that such an amendment was undesirable from a safety standpoint.

After considering the above arguments, FRA is expanding the exception to include a roadway worker performing maintenance while positioned ''within the perimeter of the machine or equipment'' (meaning, while either on or under the body of the machine or coupled equipment). To ensure that the term is not too broad in its application, the amended rule text explains that any part of the roadway worker's person not wholly positioned within the perimeter must not break the plane of a rail of the occupied track, unless the part of the roadway worker's person is towards one of the above-referenced sides of the occupied track. A boom or other equipment extending beyond the body of the machine toward the adjacent controlled track is not considered to be ''within the perimeter of the machine or coupled equipment.'' FRA decided to expand this exception for the following three reasons: (1) There have been no adjacent-track-related fatalities involving a roadway worker positioned within the perimeter of the machine; (2) there is no danger of a roadway worker's fouling an adjacent controlled track while he or she is positioned between the rails of the occupied track where the equipment would effectively prevent the worker from fouling the adjacent controlled track; and (3) there would be a risk of injury to the worker from having to extract himself or herself from underneath or on top of a machine. FRA had not considered the latter risk when formulating the Final Rule.

*H. Application of the Final Rule To Repair or Maintenance of Roadway Maintenance Machines*

The AAR/ASLRRA Joint Petition and AAR's and Metro-North's comments all questioned whether the Final Rule addressed mechanics performing maintenance and repair work on roadway maintenance machines. Existing § 214.7 defines the term ''roadway worker.'' That term, since its inception with the promulgation of the original RWP regulation in 1996, has always included employees of a railroad or a contractor to a railroad ''whose duties include inspection, construction, maintenance or repair of . . . roadway maintenance machinery on or near track or with the potential of fouling a track . . . .'' Clearly, such maintenance or repair is, and always has been, a roadway worker duty covered by the RWP regulation and the on-track safety requirements of part 214. This adjacent track provision, from its RSAC consensus conception, would have applied to roadway workers on the ground engaged in a common task with on-track, self-propelled equipment or coupled equipment on an occupied track, and the term would have included such employees within such groups performing maintenance or repairs on machinery who foul, or have the potential to foul, track. Thus, the activities of those roadway workers were clearly intended to be subject to the requirements of the RSAC consensus agreement if adopted.

However, even in light of that point, much of the work performed on roadway maintenance machines may be accomplished without the requirements of the Amended Final Rule applying to such work. By utilizing the exceptions in § 214.336(e), particularly the expansion of the exception pertaining to repairs performed alongside the machine or equipment to include work performed within the perimeter of the machine or equipment (on or under such machine or equipment), most maintenance or repair work may be performed without triggering the requirements for adjacent-controlled-track protections. The Amended Final Rule requires adjacent-controlled-track protection when maintenance work is being performed on the side of the equipment nearest that adjacent track or if any part of a roadway worker's body not wholly positioned within the perimeter of the machine breaks the plane of the rail of the occupied track toward the adjacent controlled track, unless the part of the roadway worker's person is towards one of the above-referenced sides of the occupied track. Further, a lone worker mechanic who is not part of a roadway work group, and therefore not subject to the requirements of § 214.336, may also be utilized to perform work on roadway maintenance machines. During the limited circumstances that the maintenance or repair work on a roadway maintenance machine falls within the scope of § 214.336, a mechanic's helper is permitted to serve as a watchman/lookout, or obviously another member of the roadway work gang who is not presently performing other duties may serve as a watchman/lookout. (Note that if machines are stopped in order to be repaired, there may be several members of the roadway work gang available to act as watchmen/lookouts.)

*I. Clarification Regarding Release of Working Limits*

The AAR/ASLRRA Joint Petition stated that the Final Rule was ambiguous with regard to whether a roadway worker in charge is permitted to release working limits on an adjacent controlled track after all members of the roadway work group have acknowledged that they are in the clear. The Joint Petition then also suggested that FRA adopt rule text expressly stating that working limits may be released on an adjacent controlled track to allow for train or on-track equipment movements.

FRA believes that such additional rule text is unnecessary. The Final Rule permits working limits to be released on an adjacent controlled track in accordance with existing § 214.319(c). That provision permits working limits to be released for the operation of trains once all roadway workers have occupied a place of safety or have been afforded on-track safety through train approach warning; the provision applies with regard to releasing working limits on an adjacent controlled track in § 214.336. For example, under § 214.336(b) as promulgated in the Final Rule and the Amended Final Rule, if a roadway worker in charge wishes to release working limits on an adjacent controlled track in order to permit a train movement on that adjacent controlled track, he or she may do so

after notifying all roadway workers in the group and after all workers having occupied a place of safety, or, after notifying the roadway work gang that working limits are being released, that train approach warning will now be the method of on-track safety on the adjacent controlled track. A train may then travel past the roadway work group on the adjacent controlled track, with the train's authorized speed dictating whether work is permitted to continue within the rails of the occupied track (maximum authorized speed of 25 mph or less for trains or on-track equipment, or 40 mph or less for passenger trains), or whether the roadway workers must cease work and occupy a place of safety after having received train approach warning (maximum authorized speed of greater than 25 mph for trains or other on-track equipment or greater than 40 mph for passenger trains).

## IV. Section-By-Section Analysis

*Section 214.336 On-Track Safety Procedures for Certain Roadway Work Groups and Adjacent Tracks*

For the reasons described in Section III above, FRA is making several changes to § 214.336 of the Final Rule. First, FRA is amending the heading of § 214.336(a)(2) to address only a single circumstance arising in territories with at least three tracks to account for situations if the occupied track is between two adjacent controlled tracks. This change is being made because, as discussed above, FRA is removing the requirement that a non-controlled track spaced 19 feet or less from an occupied track be treated as an adjacent controlled track. Accordingly, FRA is also deleting § 214.336(a)(2)(ii), which contained the requirement to treat a non-controlled track as a controlled track in certain circumstances. FRA is also amending § 214.336(a)(2) to reference that FRA has raised the maximum authorized speed at which passenger trains or other passenger on-track equipment may pass a roadway work group while roadway work continues within the gage of the occupied track from 25 mph to 40 mph.

Third, FRA is deleting the second sentence of the definition of ''adjacent controlled track'' in § 214.336(a)(3). This amendment is also to implement FRA's decision to delete the Final Rule's requirement in § 214.336(a)(2) that if an occupied track has an adjacent controlled track on one side and a non-controlled track spaced 19 feet or less from an occupied track on the other side that both tracks must be treated as adjacent controlled tracks.

Fourth, FRA is amending the first sentence of the definition of ''minor correction'' in § 214.336(a)(3) by adding the word ''welding'' and replacing the words ''handheld pneumatic tools only'' with ''handheld, hand-supported, or hand-guided power tools[,]'' because FRA is including both welding and additional types of power tools within this definition. FRA is also amending the second sentence of that definition by deleting the word ''welding[,]'' because the second sentence lists exclusions from the term ''minor correction'' and FRA has decided to include welding explicitly as an example of ''minor correction.''

Fifth, FRA is adding the words ''or at a speed greater than 40 mph for a passenger train or other passenger on-track equipment movement'' to paragraph (b). As explained above, this amendment is to reflect that FRA has decided to raise to 40 mph the maximum speed at which passenger trains may pass a roadway work group without the roadway work group's having to cease work and occupy a place of safety. FRA has also amended the heading of paragraph (b) to implement this decision to raise the maximum allowable speed for passenger trains to 40 mph for purposes of the requirements of this paragraph.

Sixth, FRA is adding the words ''or at a speed of 40 mph or less for a passenger train or other passenger on-track equipment movement'' to paragraph (c). As explained above, this amendment is to reflect that FRA has decided to raise to 40 mph the maximum speed at which passenger trains may pass a roadway work group without the roadway work group's having to cease work and occupy a place of safety, but rather while the group continues on-ground work and equipment movement within the gage of the occupied track. To reflect this change to the text of paragraph (c), FRA has also amended the heading of the paragraph.

Next, FRA is amending the heading of § 214.336(e)(2) to implement the decision to include maintenance or repairs performed within the perimeter of a roadway maintenance machine or coupled equipment on the occupied track within an exception to the adjacent-controlled-track on-track safety requirements. FRA has redesignated what was existing paragraph (e)(2) as (e)(2)(i). This redesignation is to carry out FRA's decision discussed above to add a new provision (§ 214.336(e)(2)(ii)) to this paragraph regarding the additional exception for maintenance or repair performed within the perimeter of a roadway maintenance machine or coupled equipment. This new provision states that a roadway worker performing maintenance or repairs under § 214.336(e)(2)(ii) is not considered to be within the perimeter of the roadway maintenance machine or coupled equipment if any part of his or her person breaks the plane of the rail of the occupied track, except toward one of the sides referenced in § 214.336(e)(1)(i)–(iii). Booms or other equipment extending beyond the body of a roadway maintenance machine or coupled equipment toward an adjacent controlled track are not considered to be with the perimeter of the machine or coupled equipment.

Last, FRA is amending the first and second sentences of § 214.336(e)(3)(i) to reference rail-bound vehicles. This change is to follow through on FRA's decision to add rail-bound vehicles to the ''hi-rail'' exception of this section.

*Table 1 in Section 214.336 of the Final Rule*

FRA is amending the multiple references to the 25-mph maximum authorized speed for adjacent-controlled-track movements above which roadway workers on the occupied track must cease work and occupy a place of safety to add references to the higher maximum authorized speed for passenger trains of 40 mph. These changes are to reflect FRA's decision to raise the maximum authorized speed at which passenger trains may pass the roadway work on an adjacent controlled track to 40 mph such that the roadway work group may continue to work on the occupied track, as is discussed above.

FRA has also amended the second sentence of footnote 2 of the table to reference § 214.336(a)(2) rather than § 214.336(a)(2)(i). Due to the decision to delete § 214.336(a)(2)(ii) from the Final Rule, the former § 214.336(a)(2)(i) now forms paragraph (a)(2) in its entirety. FRA has also amended footnote 3 of the table in order to reflect that another exception has been included in the Amended Final Rule for maintenance or repair work performed within the perimeter of a roadway maintenance machine or coupled equipment on the occupied track.

*Figure 1 in Section 214.336*

FRA is amending Examples 1, 2, 3, 4, and 6 of Figure 1 to reflect that the Amended Final Rule raises the maximum authorized speed at which passenger trains and other passenger on-track equipment may are authorized to pass a roadway work group on an adjacent controlled track to 40 mph such that the roadway work group may

continue to work on the occupied track, as is discussed in detail above.

*Appendix A to Part 214*

FRA is revising appendix A to assure that the existing entries for § 214.315(b)–(e) remain in the table, as they would have been inadvertently deleted because of incorrect **Federal Register** publication signals if the Final Rule had gone into effect.

FRA is also deleting the reference in appendix A to the guideline civil penalty for § 214.336(a)(2)(ii), and is redesignating the reference to § 214.336(a)(2)(i) in the civil penalty to § 214.336(a)(2). This change is necessary because, as discussed above, FRA is deleting § 214.336(a)(2)(ii) from the regulatory text after deciding to eliminate the requirement that a non-controlled track spaced 19 feet or less from an occupied track be treated as an adjacent controlled track. FRA is also amending the guideline civil penalty entries for § 214.336(a) and (c) to implement FRA's decision to raise to 40 mph the speed at which a distinction is made for passenger train movements and other passenger on-track equipment movements on adjacent controlled tracks.

FRA is also amending a reference in footnote 1 to the appendix A, Schedule of Civil Penalties, to account for the inflation adjustment to the aggravated maximum civil penalty for a violation of an FRA safety regulation or order, or of a Federal railroad safety law. In a final rule published April 24, 2012 (77 FR 24415), FRA raised upward the maximum aggravated civil penalty from $100,000 to $105,000. FRA is amending footnote 1 to reflect that final rule's adjustment, which would be reversed if the Final Rule went into effect without this additional amendment. FRA is also amending the second sentence of footnote 1 to refer to the particular regulatory ''provision(s)'' rather than the ''section(s)''.

## V. Regulatory Impact and Notices

### *A. Executive Order 12866, Executive Order 13563, and DOT Regulatory Policies and Procedures*

The Final Rule Amendments have been evaluated in accordance with Executive Orders 12866 and 13563, and in accordance with existing DOT policies and procedures. *See* 44 FR 11034 (Feb. 26, 1979); 76 FR 3821 (Jan. 21, 2011); DOT Order 2100.5 (May 22, 1980). This regulatory action has been determined to be significant under Executive Orders 12866 and DOT policies and procedures. What follows is FRA's Regulatory Impact Analysis (RIA) addressing the economic impacts of the Amendments. The analysis presented here includes quantitative measurements and qualitative discussions of reductions in implementation costs and safety impacts resulting from amendments to the Final Rule made by FRA in response to the Petitions.

The modifications being made in the Amendments all reduce burdens, or potential burdens, of the Final Rule. Thus, the benefits result from reduced regulatory costs. In the same way, the costs associated with each amendment, if any, would result from foregone risk reduction. FRA is granting requests contained in the petitions for reconsideration by:

- Expanding the definition of ''minor correction'' to include welding and certain uses of any handheld power tools;
- Increasing the maximum authorized speed at which passenger trains may move on an adjacent controlled track to 40 mph while roadway workers continue their on-ground work on the occupied track;
- Deleting the requirement that a non-controlled track whose track center is spaced 19 feet or less from the occupied track be treated as an adjacent controlled track;
- Exempting rail-bound vehicles (on-track vehicles not equipped with highway wheels) used for conducting inspections or performing minor correction work (including welding), while applying the same limitations that apply to hi-rail vehicles;
- Expanding the exception pertaining to repairs performed alongside the roadway work machine or equipment to include work within the perimeter of the machine or equipment.

In analyzing the modifications listed above that are being made to the Final Rule, FRA has applied updated DOT guidance on the economic value of a statistical life (VSL) that was issued in March 2013.[20] This updated guidance increased the VSL from $6.2 million to $9.1 million, and revised the guidance used to compute benefits based on injury and fatality avoidance in each year of the analysis based on forecasts from the Congressional Budget Office of a 1.07 percent annual growth rate in median real wages over the next 30 years (2013–2043). FRA also adjusted wage-based labor costs in each year of the analysis accordingly. Real wages represent the purchasing power of nominal wages. Non-wage inputs are not impacted. All monetary references are in 2012 dollars, unless noted otherwise. The Final Rule's prior analyses had used 2009 dollars. However, in order to incorporate this latest guidance, FRA has evaluated the Amendments in 2012 constant dollars. This analysis, with different wage levels and VSL depending on year, uses 2014 as the first year that the requirements of the Amendments will be effective.

The table below summarizes the potential cost savings that will result from FRA's above-listed Amendments in response to the Petitions, as well as potential cost implications resulting from forgone risk reduction. The costs and benefits have been evaluated over a 20-year period using discount rates of 7 percent and 3 percent. For the 20-year period analyzed, the estimated costs that will be imposed on the industry are negligible. For the same 20-year period, the estimated quantified benefits total $643 million, with a PV (7 percent) of approximately $341.6 million and a PV (3 percent) of approximately $478.4 million:

| Amendments to the final rule | Potential cost implications | Benefits: Estimated cost savings (PV, 7%) | Benefits: Estimated cost savings (PV, 3%) |
|---|---|---|---|
| Expanding the definition of ''minor correction'' to include welding and certain uses of any handheld power tools. | Negligible. Very small increase in risk. No quantifiable increases in casualties. | $158.9 Million[21] ..... | $223.2 Million. |

[20] *See* ''Guidance on Treatment of the Economic Value of a Statistical Life in U.S. Department of Transportation Analyses'', available online at *http://www.dot.gov/regulations/economic-values-used-in-analysis.*

| Amendments to the final rule | Potential cost implications | Benefits: Estimated cost savings (PV, 7%) | Benefits: Estimated cost savings (PV, 3%) |
|---|---|---|---|
| Increasing the maximum authorized speed at which passenger trains may move on an adjacent controlled track to 40 mph while roadway workers continue their on-ground work on the occupied track. | Negligible | $33.4 Million [22] This estimated benefit only considers cost savings for LIRR and Metro-North. | $46.9 Million. This estimated benefit only considers cost savings for LIRR and Metro-North. |
| Deleting the requirement that a non-controlled track whose track center is spaced 19 feet or less from the occupied track be treated as an adjacent controlled track. | None: FRA has no record of past casualties covered by this provision. | $8,000 [23] | $11,200. |
| Exempting rail-bound vehicles (on-track vehicles not equipped with highway wheels) used for conducting inspections, performing minor correction work (including welding), while applying the same limitations that apply to hi-rail vehicles. | N/A | N/A | N/A. |
| Expanding the exception pertaining to repairs performed alongside the roadway work machine or equipment to include work within the perimeter of the machine or equipment. | Negligible. Minor reduction in the safety benefit of workers extricating themselves from under machinery so as to be safe in the event a collision with the machinery. | $149.2 Million [24] Non-quantified benefits include lowered injury risks due to less instances of workers having to extract themselves from a machine each time a train passes. | $208.3 Million. Non-quantified benefits include lowered injury risks due to less instances of workers having to extract themselves from a machine each time a train passes. |
| Total | | $341.6 Million | $478.4 Million. |

All values are discounted (PV, 7 and 3%) for a 20-year period.

**Petition Requests Granted and Associated Cost Savings Estimates**

*1. Definition of ''Minor Correction''*

FRA's response expands the definition of ''minor correction'' work to avoid the Final Rule's requirements applying to roadway work gangs using handheld power tools or engaged in welding activities. The Railroad Safety Advisory Committee's (RSAC) Roadway Worker Protection (RWP) Working Group's consensus agreement did not include a definition of ''minor correction'', as the consensus language excluded hi-rail vehicle activities from the adjacent track on-track safety requirements (except if coupled to railroad cars). FRA added the ''minor correction'' definition to the Final Rule to expand the consensus language and include specific hi-rail activities within the final rule's on-track safety requirements. FRA's response expands the definition of ''minor correction'' because in the Final Rule: (a) FRA inadvertently excluded certain handheld power tools from the minor correction work exception; and (b) FRA did not realize that the inclusion of welding activities could impose such substantial potential cost burdens. Thus, the Final Rule did not specifically assess costs for either of these items. However, in its comment on the Petitions, AAR's cost estimate for the additional watchmen/lookouts, new employees, and trucks (for three-person welding crews) related to these two items were $144 million in the first year and $127 million per year in subsequent years. APTA also estimated that the Final Rule generally would cost commuter railroads $22 million per year. AAR stated that it arrived at its estimated costs by drawing on track maintenance costs data from the four largest Class I freight railroads and from a large commuter railroad, but did not break those costs down by individual railroad. Instead, AAR provided overall cost estimates for each item that FRA's Regulatory Impact Analysis (RIA) analyzing the Final Rule addressed, while adding in additional cost estimates that it stated FRA did not consider (costs related to the hiring and training of additional roadway workers, new trucks, and train delays). FRA's modification of the definition will remove these potential costs estimated by AAR that were created by the Final Rule.

FRA inadvertently described the type of hand tool use that would have been exempted from the Final Rule's requirement, which would have had the unintended effect of narrowing the type of work that was excluded from the Final Rule's requirements. FRA's response amending the description of hand tools will clarify the agency's intent and resolve that issue. With regard to the decision to grant AAR's request to also exclude hi-rail related welding activities from the Final Rule's requirements, FRA weighed several factors in making its decision. As stated above, the RSAC consensus language did not include hi-rail related welding activities. Other factors include that there have been no fatalities related to activities that would have been implicated by the Final Rule's welding requirement and also because FRA did not realize certain of the additional welding-related costs that would have to be incurred by railroads (the purchase of new hi-rail trucks, the number of additional situations in which the final rule could apply, etc.).

However, FRA also believes that APTA's and AAR's cost estimates with regard to welding were overstated. No watchmen/lookouts would have been required for any welding activities involving the occupancy of a controlled track in single-track territory. Further, the Final Rule would not have applied to welding operations where no on-track equipment occupied a controlled track, or where no welding operations were being performed in connection with another roadway work group's work. Further, any welding operations taking place where the roadway work group would have the potential to foul an adjacent track for any reason are already required to establish on-track safety on that adjacent track under the existing RWP regulations, even in the absence of the Final Rule's requirements. FRA

[21] From FRA staff estimate.

[22] Extrapolated from LIRR estimate in proportion to passenger miles.

[23] From FRA staff estimate.

[24] The cost savings estimate is based on an annual $14 million in costs from AAR's comment on the Petitions. FRA believes that the Amendments will avoid these costs that AAR's comment raised.

believes that many existing railroad hi-rail trucks could have accommodated (or could have been modified to accommodate) an additional roadway worker for purposes of traveling to a welding worksite. Finally, a significant percentage of welding worksites are accessible via railroad right-of-way, which negates the need for newly purchased or modified hi-rail trucks to accommodate an additional roadway worker. FRA believes that these factors could have eliminated a high percentage of the welding costs claimed by AAR prior to FRA granting this request. FRA does acknowledge, however, that in order to be prepared for situations in which the Final Rule's requirements would have applied to welding operations, that significant costs likely would have been incurred by the industry to purchase larger new hi-rail trucks to accommodate a third roadway worker in certain situations.

The foregone benefits that would have resulted from the previous, narrower, definition of minor corrective work appear to be small. FRA is not aware of any accidental injuries in the ten year statistical period reviewed for the Final Rule in which the expanded definition of minor corrective work would have applied to the work performed, but the previous definition would not have applied to the work. This does not mean that there is no risk from such work. It only means that if reporting is accurate and past experience is a good basis from which to estimate risk, then the risk is small, with an expected value less than the cost of one injury every ten years.

It appears to FRA that expanding the definition of minor corrective work will produce benefits by reducing costs, although it is unlikely that the benefits will be within an order of magnitude of the cost reductions that AAR claims would occur, $93 million in the first year and $82 million in subsequent years. FRA has roughly estimated those costs to be between $15–30 million per year. For purposes of calculating the total cost savings for this amendment, FRA used the low end of the range, i.e., $15 million per year. The total cost savings over 20 years is $300 million. The discounted value of this cost is $158.9 million (PV, 7) and $223.2 million (PV, 3).

On the other hand, it does not appear to FRA, based on reported injuries and fatalities, that the benefits foregone, which are the costs of expanding the definition of minor corrective work, would be within an order of magnitude of the benefits of expanding the definition of minor corrective work. Overall, FRA concludes that the cost burden reduction benefit would exceed the very small increase in risk resulting from this particular amendment.

*2. Speed Limit Increase to 40 MPH for Passenger Trains*

The Final Rule Amendments increase the maximum authorized speed at which passenger trains may move on an adjacent track to 40 mph while roadway workers continue their on-ground work on the occupied adjacent track. This change is being made due to unanticipated costs that the Final Rule's 25-mph limitation could have potentially imposed on the commuter railroads. Further, FRA's information indicates that 40 mph is already largely the speed at which commuter trains pass roadway work zones on adjacent controlled tracks, and FRA has no data or analyses to show that this current 40 mph speed is unsafe.

APTA's petition for reconsideration requested this speed increase to 40 mph. A review of the public record for the RWP Working Group meeting where the 25-mph speed was agreed upon indicates that that no APTA representative was present at that meeting, though APTA apparently did have a representative present at the full RSAC meeting where the consensus language was approved after the conclusion of the RWP Working Group's work. However, APTA's comment on the NPRM, its Petition, and its comment on the Petitions all requested that FRA increase the speed to 40 mph for passenger trains. FRA notes that APTA did not provide data or economic analysis regarding those requests to raise the speed limit for passenger trains. APTA member LIRR also stated in its comment on the Petitions that the imposition of a 25-mph work zone speed limit (versus a 40-mph work zone speed limit that would permit work on an adjacent track to continue) would cost them $1.4 million dollars per year, and would lead to train delays and cancellations potentially impacting thousands of passengers per day when roadway work projects were being performed. APTA's comment on the Petitions raised the general concern of costs related to disruption of scheduled passenger service and loss of passenger train business, specifically citing the example of a dip in ridership during a South Florida Regional Transportation Authority (TriRail) construction project. APTA's comment also speculated regarding the final rule's impacts on large passenger operations, such as at New York City's Penn Station.

From a safety perspective in choosing to grant this request, passenger trains are shorter than freight trains and also do not present the dangers of shifted loads and swinging doors that freight trains do. In addition, the superior braking capabilities and shorter stopping distances of passenger equipment could reduce risk while approaching and passing adjacent track roadway work zones. Next, shelf couplers on passenger equipment are designed to keep equipment upright and in-line in the event of derailment. Passenger equipment is also typically narrower than comparable freight train equipment, meaning it is physically farther from roadway workers who continue work in the gage of the occupied adjacent track while a passenger train passes. Further, unlike much longer freight trains, passenger trains are only typically 6 to 8 cars in length, and whether traveling at 40 mph or 25 mph, pass within a matter of seconds. Because there is less danger of swinging doors and shifted loads, risk exposure is much more minimal than when compared to a much longer passing freight train. As also stated above, FRA does not have data or analyses to show that the 40-mph speed at which commuter trains largely pass work zones on an adjacent track presently is unsafe.

Next, if the assertions in LIRR's comment are correct and in some instances on LIRR several thousand passengers could be affected daily by the Final Rule's 25-mph limitation, FRA believes unintended passenger safety issues could occur if the Final Rule's speed restriction is not increased for passenger trains. Crowding on both passenger platforms and on passenger trains that results from commuter train cancellations and delays present platform fall and other obvious risks to passenger safety. These cancellations and delays could occur because commuter train ''meet'' times, particularly when tracks merge from different subdivisions of a railroad, can be critical in passenger operations when a missed meet for one train compounds and affects later-scheduled trains. Further, a 25-mph limitation for commuter trains could have the unintended impact of driving passengers to other modes of transportation, namely automobiles. Automobile travel is statistically less safe than passenger train travel and is also less fuel efficient, which is undesirable from both a safety and emissions standpoint. Last, in granting this request to raise the speed at which passenger trains may pass work zones to 40 mph, FRA avoids giving railroads perverse incentives to defer track or signal maintenance rather than delay or cancel scheduled passenger trains in

complying with the Amended Final Rule's requirements. Of course, such deferred maintenance can potentially lead to track- or signal-caused train derailments and other accidents, thereby endangering railroad operating crews and other railroad employees, rail passengers, and the general public.

The potential cost implications related to passenger train delay/cancellation issues resulting from this provision of the Final Rule had not previously been raised with FRA until APTA's Petition discussed such. Thus, in estimating the costs of the Final Rule, FRA did not consider the train cancellation issue. The train delay implications for commuter operations that LIRR and APTA raise were also not fully considered in the analysis. LIRR was the only entity to put forth an actual cost figure with regard to the 25-mph speed restriction for passenger operations, and FRA does not have information to verify or refute LIRR's assertions.

LIRR stated that the imposition of a 25-mph work zone speed limit (versus a 40-mph work zone speed limit that would permit work on an adjacent track to continue) would cost them $1.4 million dollars per year. FRA cannot simply extrapolate the LIRR case to all other commuter railroads. The LIRR runs a busy schedule, even on weekends, and unlike many other railroads the LIRR has one main line carrying the bulk of its traffic, which then branches out. Most other large commuter operations branch out relatively close to their downtown terminals. Further, most commuter operations have few, if any, trains operating between rush hours. FRA believes that the only other commuter railroad likely to have had impacts similar to those on the LIRR was Metro-North. Extrapolated to the combination of Metro-North and LIRR based on passenger miles, as reported by APTA in its 2013 yearbook (which contains 2011 data) the total cost for the industry would have been $3,152,297 per year.[25] The total cost savings resulting from this amendment to the Final Rule over 20 years is $63 million. The discounted value of this cost is $33.4 million (PV, 7) and $46.9 million (PV, 3).

There would be additional costs avoided by the displaced riders who would have had to find alternate transportation or forego the benefits of their intended trips. As mentioned above, alternate transportation may expose passengers to additional safety costs, as well.

FRA analyzed whether there might be foregone safety benefits as a result of the amendment. There was one relevant fatality analyzed for the Final Rule on a commuter railroad. The train in that case was traveling at 45 mph, in excess of 40 mph, but FRA does not believe that the reduction in speed to 25 mph by itself would have been sufficient to prevent the fatality. Had the Final Rule or the Amended Final Rule been in effect at the time of that accident, the roadway worker would have benefited from, at a minimum, train approach warning being the method of on-track safety on the adjacent controlled track. The speed of the train was not what would have prevented the accident; rather it would have been the combination of the Final Rule's job briefing requirements and train approach warning. Thus, FRA believes that the potential safety costs of this modification are negligible.

*3. Deletion of Requirement That Non-Controlled Track Be Treated as an Adjacent Controlled Track*

FRA's response deletes the requirement that a non-controlled track whose track center is spaced 19 feet or less from the occupied track be treated as an adjacent controlled track. This requirement in the Final Rule was not an RSAC consensus agreement, but rather was added into the Final Rule by FRA in response to a comment on the NPRM. The AAR/ASLRR Petition noted that the Final Rule's provision requiring that roadway work groups treat a non-controlled track as an adjacent-controlled track could cause confusion. APTA's Petition expressed the separate concern that the provision would disrupt scheduled passenger train operations and, thus, also affect the cost of scheduled train operations in a manner which was not contemplated by FRA in the Final Rule. FRA believes that non-controlled tracks may have accounted for equivalent to 1–2 percent of the total siding track mileage that would have been affected by the Final Rule. Based on this small percentage of total track mileage affected, FRA roughly estimates that removing non-controlled track from the coverage of this rule would reduce the delay costs of slowing trains by a minimum of roughly $750 per year. The total discounted cost savings over a 20-year period is $8,000 (PV, 7) and $11,200 (PV, 3).[26] FRA has no record of injuries or fatalities involving roadway workers on an occupied track that also involved train operations on an adjacent non-controlled track. Given the limited circumstances under which this requirement would have applied, there is little risk to the roadway workers by excluding it. FRA no longer has any reason, quantifiable or otherwise, to believe that the benefits of this Final Rule provision exceed its costs.

*4. Exemption for Rail-Bound Vehicles Used for Conducting Inspections or Performing Minor Correction Work*

The Final Rule Amendments provide an exemption for rail-bound vehicles used for conducting inspections, performing minor correction work or welding while applying the same limitations that apply to hi-rail vehicles. The AAR/ASLRRA Joint Petition requested this exception for rail-bound vehicles where manual inspections or minor correction work are being conducted, because they involve the same activities as those performed during an inspection conducted by a hi-rail vehicle (which are excepted from the Final Rule's requirements). Neither the RSAC consensus agreement nor the Final Rule addressed rail-bound vehicles performing inspection or minor correction work. The BMWED/BRS joint comment submitted in response to the Petitions stated that they did not oppose expanding this exception to rail-bound equipment per the AAR/ASLRRA Joint Petition's suggestion. FRA agrees, and does not believe that excepting rail-bound vehicles from the final rule's requirements will present any additional risk beyond those risks faced by hi-rail vehicles and the roadway workers working near them. In the process of reviewing the AAR/ASLRRA Joint Petition, FRA recognized that there were a substantial number of other rail-bound vehicles used for these functions. Rail bound vehicles often have the capability to perform automated track inspections for geometry, gage restraint or internal flaws. FRA believes that limiting the productivity of such vehicles might reduce their ability to assist in identifying track related hazards and therefore limit their ability to prevent track-caused accidents. It is difficult to estimate the foregone benefit

[25] According to APTA's 2013 fact book, in 2011 LIRR had 2,087,848,900 passenger miles, and Metro-North had 2,613,236,500 passenger miles, for a total of 4,701,085,400 passenger miles. Dividing 4,701,085,400 by 2,087,848,900 yields 2.251640624. Multiplying $1.4 million by 2.251640624 yields $3,152,297.

[26] FRA estimated this cost savings based on the figure of 1–2 percent of all siding track mileage affected and applying 1 percent of the total estimated on-track safety (§ 214.336) costs of this rulemaking. The APTA Petition asserted this provision (if not amended by FRA) would cause passenger train operation disruptions. However, FRA does not have data to be able to quantify APTA's assertion regarding resultant large cost savings as a result of this amendment.

of avoiding those track-caused accidents, but FRA believes the accident costs avoided far exceed any risks induced by modifying the Final Rule.

FRA does not have sufficient information available to reliably estimate how frequently this exception would be applicable. Further, FRA does not have any record of accidents having occurred that would be prevented by subjecting the newly excluded work to the provisions of the Final Rule. Nonetheless, because there is no reason to distinguish minor corrective work being performed from rail bound vehicles from identical work being performed from hi-rail vehicles, FRA is adopting the exception, but does not analyze the exception further.

*5. Expansion of the Exception Pertaining to Repairs Performed on Roadway Maintenance Machines or Equipment*

The Final Rule Amendments expand the exception pertaining to repairs performed alongside roadway maintenance machines or equipment contained in the Final Rule to also include work performed within the perimeter of the machine or equipment. The AAR/ASLRRA Joint Petition noted that the exception as stated in the Final Rule was too narrow and should also apply to a worker positioned within the perimeter of the equipment, without regard to whether the maintenance or repairs are performed while positioned on a side of the occupied track. They also noted that that a repair person who is working beneath a machine should not be forced to extract himself or herself each time a train passed on an adjacent controlled track as this could increase the risk of injury to the worker, and that a roadway worker working performing repairs under the machine is not at risk of being struck by a train on the adjacent track. FRA did not consider these potential risks in its analysis of the Final Rule but agrees with AAR's assertions. Consequently, FRA's response adds an alternate condition that would expand the existing exception to include a roadway worker performing maintenance while positioned within the perimeter of the machine or equipment (either on or under it). This amendment to the Final Rule will reduce the risk of injury to employees extracting themselves from a machine or equipment in these circumstances, and, thus, will eliminate any potential costs associated with those potential injuries. This exception from the requirements of the Final Rule will also alleviate virtually all of the estimated $14 million annual cost that AAR's comment on the Petitions stated would result if the Final Rule applied to repairs performed on roadway maintenance machines standing on an adjacent controlled track.[27] The total cost savings of this amendment over 20 years is $280 million. The discounted value of this cost is $149.2 million (PV, 7) and $208.3 million (PV, 3).

The benefits of this change come both from reduced burden on productivity and from enhanced safety of workers who will not have to extricate themselves from under machinery, with a risk of injury each time they extricate themselves. FRA has no data on which to base an estimate of the reduced burden on productivity. Of course, since this provision had not yet taken effect, FRA had not seen any injuries caused by employees extricating themselves from under machinery in order to comply with the provision. FRA has no data on which to base an estimate of that risk. On the other hand, workers remaining under machinery may face a very small risk from potential train accidents that could injure the workers if the machines they are working on get hit in a collision between the train and roadway maintenance machines. The cost of this change, if any, would be a reduction in the safety benefit of having workers extricate themselves from under the machinery so as to be safe in the event of such a collision. FRA has no data on which to base that estimate, either.

**Special Sensitivity Analysis of the Amended 2011 Final Rule**

As discussed above, in response to the Petitions FRA has also prepared a Special Sensitivity Analysis, which analyzes the Amended Final Rule, comprising the requirements of the 2011 Final Rule as revised by the Final Rule Amendments described above. The Special Sensitivity Analysis addresses the concerns raised in the Petitions regarding the cost-benefit analysis of the 2011 Final Rule. FRA notes that that this Special Sensitivity Analysis is not an evaluation of the 2011 Final Rule, and that it uses updated VSL and wage rate estimates.

[27] The cost of repairing roadway maintenance machines was not specifically figured in the Final Rule's RIA. Instead, the RIA generally assessed the cost of complying, as such repair activity on an occupied track is ''roadway work'' and, thus, it was not contemplated by FRA that such work was not covered by the Final Rule. However, because the Final Rule Amendments further expand the exception that would accommodate such repair work, FRA believes that AAR's estimated cost is overstated and such repair work will, in all but rare circumstances, be able to be performed without these costs being incurred because the Amended Final Rule's requirements will not apply.

**Requests Denied (Alternatives to the Final Rule)**

FRA is denying two of the requests made in joint AAR/ASLRRA Joint Petition. Those requests were to: (1) Clarify that the Final Rule did not address repair and maintenance of roadway maintenance machines, and (2) amend the Final Rule to permit work to resume when the leading end, rather than the trailing end, of a train traveling over 25 mph has passed a roadway work group on an adjacent occupied track (trailing end provision). Since FRA is not making any regulatory modifications based on these requests, FRA is not accounting for any changes in costs or benefits in analyzing the denied requests in this response to the Petitions.

*1. Application of the Final Rule to Roadway Maintenance Machine Repair*

FRA is denying the first request because most of the work performed on roadway maintenance machines may be accomplished without the requirements of the Amended Final Rule applying to such work, particularly in light of FRA's decision to grant the request to expand the exception mentioned above pertaining to work performed within the perimeter of (to include on or under) roadway maintenance machines. Further, FRA does not believe that AAR's assertion that the repair of roadway maintenance machines on an adjacent track was not intended to be covered by the final rule has merit. Since the 1996 promulgation of the RWP regulations at 49 CFR part 214, such repair work to roadway maintenance machines or equipment has always required that on-track safety be established when roadway workers have the potential to foul track.

*2. Trailing End Provision*

FRA is denying the second request regarding the trailing end provision. AAR's comment on the Petitions significantly overestimated the costs of complying with this provision ($56 million annually). Stopping work rather than slowing trains increases the time of track occupancy required to perform the maintenance, and the track occupancy itself by a roadway work group is the most costly factor involved in the analysis. FRA staff conducted a modeling analysis to calculate the delay associated with implementing this provision in the Amended Final Rule, and the results showed that congestion-induced costs were limited when freight train volumes were at or above a ten train per shift (7 hours per shift affected by the Amended Final Rule) threshold.

Moreover, once the leading end of a freight train is slowed to 25 mph (a requirement agreed to by AAR) then the ability of a freight train to increase speed while passing a work gang is extremely limited. Thus, in FRA's view, the overall impact of this requirement is far less than the impact claimed by AAR in its petition. Further, when trains pass a roadway work group on an adjacent controlled track, injury risks are present (risk of shifted loads/shifted ladings, loose banding, dragging chains/binders, loose brake piping, loose/swinging boxcar doors, and fragmented brake shoes).

The 2011 Final Rule provided that roadway workers may resume work only after the trailing end of a train or other on-track equipment (authorized to travel past the roadway work gang at a speed greater than 25 mph) has passed the roadway work group (''trailing end'' provision). The AAR/ASLRRA Joint Petition requested that the Final Rule be modified to permit roadway workers to resume work after the leading end of a train has passed. They cited the following points as support for their request: (1) There are no fatalities from shifted loads and no widespread problem of employees injured by shifted loads; (2) there are many railroad employees working near passing trains, not just roadway workers; (3) there is a heightened awareness of the roadway workers after the leading end of a train passes; and (4) prohibiting the resumption of work until the entire train or equipment has passed would adversely affect productivity and require the hiring of additional roadway workers, costing the railroads approximately $56 million annually (based on an estimate for four Class I railroads alone). APTA's comment expressed support for the AAR/ASLRRA Joint Petition's position with regard to the ''trailing end'' provision. The BMWED/BRS joint comment stated that the AAR/ASLRRA Joint Petition ignored the risks associated with shifted loads/shifted ladings and the hazards associated with materials being kicked up by trains operating at track speed.

FRA's analysis has not found cases above a certain train traffic volume (ten trains per shift) where stopping work while trains pass at greater than 25 mph (or, as amended, greater than 40 mph for passenger trains) would be less costly than slowing trains to 25 mph (or 40 mph for passenger) for any likely roadway worker work groups on an adjacent occupied track. Stopping work increases the time of track occupancy required to perform the maintenance. The track occupancy itself by a roadway work group is the most costly factor involved in the analysis.

FRA performed modeling, described in more detail in the Special Sensitivity Analysis, that analyzes the impacts of the Amended Final Rule and which addresses petitioners' concerns with the previous analysis. The 20-year discounted costs of the trailing end provision of the 2011 Final Rule are estimated to total $841,300, discounted at 7 percent or $1,185,447, discounted at 3 percent. These costs are far below AAR's estimates of $56 million per year. This point is discussed in further detail in the Special Sensitivity Analysis.

Also, in rejecting AAR's petition, FRA is retaining the existing maximum speed of 25 mph for adjacent-controlled-track movements of freight trains and other freight on-track equipment movements which permits roadway work to continue on the occupied adjacent track. As mentioned above, when freight trains pass works zones on an adjacent track, the safety risk of shifted loads is present, as well as the safety risk of swinging doors, loose banding, and dragging equipment, and the hazards associated with debris, dust, stone, and construction/maintenance materials being strewn by freight trains, which tend to be longer and much heavier than passenger trains. FRA's revised analysis of the impact of the combined final rules shows that congestion impacts that slow traffic when a track is occupied also limit the costs of slowing trains to 25 mph when they pass an adjacent occupied track. The costs, while not negligible, are much lower than the safety benefits provided. The 20-year discounted costs of slowing trains to 25 mph for adjacent-controlled-track movements of freight trains and other freight on-track equipment movements, exclusive of trailing end costs, will be $7.3 million, discounted at 7 percent or $10.2 million, discounted at 3 percent.

**Clarification**

In response to AAR's request in its Petition, FRA also clarified how railroads may release working limits. A clarification neither removes nor imposes a requirement and therefore creates neither benefits nor costs.

**Conclusion**

FRA believes the cost-saving benefits of the Final Rule Amendments exceed their costs.

*B. Regulatory Flexibility Act and Executive Order 13272; Final Regulatory Flexibility Assessment*

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) and Executive Order 13272 require a review of proposed and final rules to assess their impacts on small entities. FRA certifies that the Final Rule Amendments will not have a significant economic impact on a substantial number of small entities.

''Small entity'' is defined in 5 U.S.C. 601 (Section 601). Section 601(3) defines a small entity as having the same meaning as ''small business concern'' under Section 3 of the Small Business Act. This includes any small business concern that is independently owned and operated, and is not dominant in its field of operation. Section 601(4) includes within the definition of small entities not-for-profit enterprises that are independently owned and operated, and are not dominant in their fields of operation. Additionally, Section 601(5) defines small entities as governments of cities, counties, towns, townships, villages, school districts, or special districts with populations less than 50,000. The U.S. Small Business Administration (SBA) stipulates in its size standards that the largest a railroad business firm that is for-profit may be, and still be classified as a small entity, is 1,500 employees for ''line haul operating railroads'' and 500 employees for ''switching and terminal establishments.''

Federal agencies may adopt their own size standards for small entities in consultation with SBA and in conjunction with public comment. Pursuant to that authority, FRA has published a final policy that formally establishes small entities as railroads that meet the line haulage revenue requirements of a Class III railroad.[28] The revenue requirements are currently $20 million or less in annual operating revenue. The $20 million limit (which is adjusted by applying the railroad revenue deflator adjustment)[29] is based on the Surface Transportation Board's (STB) threshold for a Class III railroad carrier. FRA is using the STB's threshold in its definition of small entities for railroads affected by this rule. FRA has also adopted the STB threshold for Class III railroad carriers as the size standard for railroad contractors.[30] FRA estimates that 703 railroads will be affected by the Amendments. This number equals the number of railroads that reported to FRA in 2011, minus those railroads that are tourist, scenic, excursion, or historic railroads and are not part of the general system (these railroads are exempt from the rule). Of those railroads, 44 are Class

[28] *See* 68 FR 24891 (May 9, 2003); 49 CFR part 209, Appendix C.

[29] For further information on the calculation of the specific dollar limit, please see 49 CFR part 1201.

[30] *See* 68 FR 24891 (May 9, 2003).

I, Class II, commuter, and intercity passenger railroads. By FRA's definition of a small entity, two commuter railroads would be considered to be small entities. The remaining 659 railroads are also assumed to be small railroads for the purpose of this assessment, for a total of 661 small entities subject to this rule. However, because of certain characteristics that these railroads typically have (most small railroads do not have territories with adjacent controlled tracks, but rather only single-track operations), there should not be any impact on the majority of them. Some small railroads, such as the tourist and historic railroads, which operate across the lines of other railroads, are not subject to the applicability of the final rule because they do not own the track over which they operate. They might be affected by the impact, although beneficial, of the requirements of the Amendments. The impacts on entities not directly subject to the regulation are not considered in this Regulatory Flexibility Analysis. Finally, other small railroads, if they do have more than a single track, typically have operations that are light enough such that the railroads have generally always performed the pertinent trackside work with the track and right-of-way taken out of service, or conducted the work during hours that the track is not used. Thus, although 661 small railroads will be subject to this rule, very few actually have operations that will be affected by this rulemaking. FRA does not believe that a substantial number of small entities will be affected.

FRA is uncertain as to the number of contractors that will be affected by the Amendments. FRA is aware that some railroads hire contractors to conduct some of the functions of roadway workers on their railroads. However, most of the cost savings associated with the burdens from the Amendments will ultimately get passed on to the pertinent railroad. In addition, at the proposed rule stage, FRA requested information related to contractors and the burdens that might impact them as a result of the proposed rule and received none. Hence, FRA is confident that the Amended Final Rule's requirements, which have not changed significantly from those proposed in the NPRM or the Final Rule published in November 2011, other than to reduce burdens, will not have an impact on any contractors that will perform track work on a small railroad. To the extent that any provisions of this rule do affect small entities, the effects are likely to be beneficial, as the Amendments only provides regulatory relief from the requirements originally imposed by the Final Rule. FRA does not believe the impact on any small entity will be significant.

No other small businesses (non-railroads) are expected to be impacted by the Amendments.

FRA certified that the Final Rule (76 FR 74586) was not expected to have a significant economic impact on a substantial number of small entities under 5 U.S.C. 605(b). Having made the determinations noted above, FRA certifies that the Final Rule Amendments will not have a significant economic impact on a substantial number of small entities under 5 U.S.C. 605(b).

*C. Paperwork Reduction Act*

The information collection requirements in this final rule associated with FRA's response to petitions for reconsideration remain unchanged from the previous publication of this final rule and are being submitted upon publication in the **Federal Register** for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* The sections that contain the current information collection requirements and the estimated time to fulfill each requirement are as follows, and also remain unchanged:

| CFR Section | Respondent universe | Total annual responses | Average time per response | Total annual burden hours |
|---|---|---|---|---|
| Form FRA F 6180.119—Part 214 Railroad Workplace Safety Violation Report. | 350 Safety Inspectors | 150 forms | 4 hours | 600 |
| 214.303—Railroad On-Track Safety Programs | | | | |
| —Amendments to Programs | 60 Railroads | 20 amend. + 584 amend. | 20 hours; 4 hrs | 2,736 |
| —Subsequent Years: New Programs | 5 New Railroads | 5 new prog | 250 hours | 1,250 |
| 214.313—Good Faith Challenges to On-Track Safety Rules. | 20 Railroads | 80 challenges | 4 hours per challenge | 320 |
| 214.315/335—Supervision + communication | | | | |
| —Regular Job Briefings | 50,000 Rdwy Workers | 16,350,000 brf | 2 minutes | 545,000 |
| —Adjacent-Track Safety Briefings (New) | 24,500 Rdwy Workers | 2,403,450 brf | 30 seconds | 20,029 |
| 214.321—Exclusive Track Occupancy: Working Limits | | | | |
| —Written authority to roadway worker in charge. | 8,583 Roadway Workers. | 700,739 authorities | 1 minute | 11,679 |
| 214.325—Train Coordination—Establishing Working Limits through Communication. | 50,00 Roadway Workers. | 36,500 comm | 15 seconds | 152 |
| 214.327—Inaccessible Track | | | | |
| —Working Limits on Non-controlled Track: Notifications. | 718 Railroads | 50,000 notifications | 10 minutes | 8,333 |
| 214.336—*Procedures for Adjacent-Track Movements Over 25 mph*—Notifications/Watchmen/Lookout Warnings. | 100 Railroads | 10,000 notific | 15 seconds | 42 |
| —Roadway Worker Communication with Train Engineers or Equipment Operators. | 100 Railroads | 3,000 comm | 1 minute | 50 |
| —*Procedures for Adjacent-Track Movements 25 mph or less*—Notifications/Watchmen/Lookout Warnings. | 100 Railroads | 3,000 notific | 15 seconds | 13 |
| —Roadway Worker Communication with Train Engineers or Equipment Operators. | 100 Railroads | 1,500 comm | 1 minute | 25 |

| CFR Section | Respondent universe | Total annual responses | Average time per response | Total annual burden hours |
|---|---|---|---|---|
| —Exceptions to the requirements in paragraphs (a), (b), and (c) for adjacent-controlled-track on-track safety: Work activities involving certain equipment and purposes—On-Track Job Safety Briefings. | 100 Railroads | 1,030,050 briefings | 15 seconds | 4,292 |
| 214.337—On-Track Safety Procedures for Lone Workers: Statements by Lone Workers. | 718 Railroads | 2,080,000 statements | 30 seconds | 17,333 |
| 214.343/345/347/349/351/353/355—training | 50,000 Rdwy Workers | 50,000 tr. RW | 4.5 hours | 225,000 |
| —Additional on-track safety training (New) | 35,000 Rdwy Workers | 35,000 tr. RW | 5 min | 2,917 |
| —Records of Training | 50,000 Roadway Workers. | 50,000 records | 2 min | 1,667 |
| 214.503—Good Faith Challenges; Procedures for Notification and Resolution | | | | |
| —Notifications for Non-Compliant Roadway Maintenance Machines or Unsafe Condition. | 50,000 Rdwy Workers | 125 notific | 10 minutes | 21 |
| —Resolution Procedures | 644 Railroads | 10 procedures | 2 hours | 20 |
| 214.505—Required Environmental Control and Protection Systems For New On-Track Roadway Maintenance Machines with Enclosed Cabs. | 644 Railroads/200 contractors. | 500 lists | 1 hour | 500 |
| —Designations/Additions to List | 644 Railroads/200 contractors. | 150 additions/designations. | 5 minutes | 13 |
| 214.507—A-Built Light Weight on New Roadway Maintenance Machines. | 644 Railroads | 1,000 stickers | 5 minutes | 83 |
| 214.511—Required Audible Warning Devices For New On-Track Roadway Maintenance Machines. | 644 Railroads | 3,700 identified mechanisms. | 5 minutes | 308 |
| 214.513—Retrofitting of Existing On-Track Roadway Maintenance Machines | | | | |
| —Identification of Triggering Mechanism—Horns. | 703 Railroads | 200 mechanisms | 5 minutes | 17 |
| 214.515—Overhead Covers For Existing On-Track Roadway Maintenance Machines. | 644 Railroads | 500 requests + 500 responses. | 10 minutes; 20 minutes | 250 |
| 214.517—Retrofitting of Existing On-Track Roadway Maintenance Machines Manufactured On or After Jan. 1, 1991. | 644 Railroads | 500 stencils | 5 minutes | 42 |
| 214.518—Safe and Secure Position for riders | | | | |
| —Positions identified by stencilings/markings/notices. | 644 Railroads | 1,000 stencils | 5 minutes | 83 |
| 214.523—Hi-Rail Vehicles—Inspections/Records | 644 Railroads | 2,000 records | 60 minutes | 2,000 |
| —Non-Complying Conditions | 644 Railroads | 500 tags + 500 reports | 10 min.; 15 min | 208 |
| 214.527—On-Track Roadway Maintenance Machine; Inspection for Compliance and Repair Schedules. | 644 Railroads | 550 tags + 550 reports | 5 min.; 15 min | 184 |
| 214.533—Schedule of Repairs Subject to Availability of Parts—Records of Compliance with this Section. | 644 Railroads | 250 records | 15 minutes | 63 |

All estimates include the time for reviewing instructions; searching existing data sources; gathering or maintaining the needed data; and reviewing the information. For information or a copy of the unchanged paperwork package submitted to OMB, contact Mr. Robert Brogan at 202–493–6292 or Ms. Kimberly Toone at 202–493–6132 or via email at the following addresses: *Robert.Brogan@dot.gov; Kimberly.Toone@dot.gov.* Organizations and individuals desiring to submit comments on the collection of information requirements should direct them to the Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503, Attention: FRA Desk Officer. Comments may also be sent via email to the Office of Management and Budget at the following address: *oira_submissions@omb.eop.gov. mailto:victor.angelo@fra.dot.gov.*

OMB is required to make a decision concerning the collection of information requirements contained in this final rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication.

FRA cannot impose a penalty on persons for violating information collection requirements which do not display a current OMB control number, if required. The current OMB control number for this collection of information is OMB No. 2130–0539.

*D. Federalism Implications*

Executive Order 13132, ''Federalism'' (64 FR 43255, Aug. 10, 1999), requires FRA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' are defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, the agency may not issue a regulation with federalism

implications that imposes substantial direct compliance costs and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or the agency consults with State and local government officials early in the process of developing the regulation. Where a regulation has federalism implications and preempts State law, the agency seeks to consult with State and local officials in the process of developing the regulation.

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132. This final rule would not have a substantial effect on the States or their political subdivisions; it would not impose any compliance costs; and it would not affect the relationships between the Federal government and the States or their political subdivisions, or the distribution of power and responsibilities among the various levels of government. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

However, this final rule could have preemptive effect by operation of law under certain provisions of the Federal railroad safety statutes, specifically the former Federal Railroad Safety Act of 1970, repealed and recodified at 49 U.S.C. 20106 (Section 20106). Section 20106 provides that States may not adopt or continue in effect any law, regulation, or order related to railroad safety or security that covers the subject matter of a regulation prescribed or order issued by the Secretary of Transportation (with respect to railroad safety matters) or the Secretary of Homeland Security (with respect to railroad security matters), except when the State law, regulation, or order qualifies under the ''essentially local safety or security hazard'' exception to Section 20106.

In sum, FRA has analyzed this final rule in accordance with the principles and criteria contained in Executive Order 13132. As explained above, FRA has determined that this final rule has no federalism implications, other than the possible preemption of State laws under Federal railroad safety statutes, specifically Section 20106. Accordingly, FRA has determined that preparation of a federalism summary impact statement for this final rule is not required.

*E. Environmental Impact*

FRA has evaluated this final rule in accordance with its ''Procedures for Considering Environmental Impacts'' (FRA's Procedures) (64 FR 28545, May 26, 1999) as required by the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), other environmental statutes, Executive Orders, and related regulatory requirements. FRA has determined that this final rule is not a major FRA action (requiring the preparation of an environmental impact statement or environmental assessment) because it is categorically excluded from detailed environmental review pursuant to section 4(c)(20) of FRA's Procedures. *See* 64 FR 28547 (May 26, 1999).

In accordance with section 4(c) and (e) of FRA's Procedures, the agency has further concluded that no extraordinary circumstances exist with respect to this regulation that might trigger the need for a more detailed environmental review. As a result, FRA finds that this final rule is not a major Federal action significantly affecting the quality of the human environment.

*F. Unfunded Mandates Reform Act of 1995*

Pursuant to Section 201 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 2 U.S.C. 1531), each Federal agency ''shall, unless otherwise prohibited by law, assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector (other than to the extent that such regulations incorporate requirements specifically set forth in law).'' Section 202 of the Act (2 U.S.C. 1532) further requires that ''before promulgating any general notice of proposed rulemaking that is likely to result in the promulgation of any rule that includes any Federal mandate that may result in expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year, and before promulgating any final rule for which a general notice of proposed rulemaking was published, the agency shall prepare a written statement'' detailing the effect on State, local, and tribal governments and the private sector. The final rule will not result in the expenditure, in the aggregate, of $140,800,000 or more (as adjusted annually for inflation) in any one year, and thus preparation of such a statement is not required.

*G. Energy Impact*

Executive Order 13211 requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' 66 FR 28355 (May 22, 2001). Under the Executive Order, a ''significant energy action'' is defined as any action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) That is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. FRA has evaluated this final rule in accordance with Executive Order 13211. FRA has determined that this final rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Consequently, FRA has determined that this final rule is not a ''significant energy action'' within the meaning of Executive Order 13211.

*H. Trade Impact*

The Trade Agreements Act of 1979 (Pub. L. 96–39, 19 U.S.C. 2501 *et seq.*) prohibits Federal agencies from engaging in any standards setting or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. FRA has assessed the potential effect of this final rule on foreign commerce and believes that its requirements are consistent with the Trade Agreements Act of 1979. The requirements imposed are safety standards, which, as noted, are not considered unnecessary obstacles to trade.

*I. Privacy Act*

Interested parties should be aware that anyone is able to search the electronic form of all written comments received into any agency docket by the name of the individual submitting the document (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Please see the privacy notice at *http://www.regulations.gov/#!privacyNotice.* You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *http://www.dot.gov/privacy.html.*

**List of Subjects in 49 CFR Part 214**

Occupational safety and health, Penalties, Railroad safety.

**The Rule**

For the reasons discussed in the preamble, FRA amends part 214 of title 49 of the Code of Federal Regulations as follows:

## PART 214—[AMENDED]

■ 1. The authority citation for part 214 is revised to read as follows:

**Authority:** 49 U.S.C. 20102–20103, 20107, 21301–21302, 21304; 28 U.S.C. 2461, note; and 49 CFR 1.89.

## Subpart C—Roadway Worker Protection

■ 2. Amend § 214.336 by:
■ a. Revising paragraph (a)(2),
■ b. Revising paragraph (a)(3) definitions of ''Adjacent controlled track'' and ''Minor correction,''
■ c. Revising the heading and introductory text of paragraph (b),
■ d. Revising paragraph (c),
■ e. Revising paragraph (e)(2),
■ f. Revising paragraph (e)(3)(i),
■ h. Revising Table 1, and
■ i. Revising Figure 1 to read as follows:

### § 214.336 On-track safety procedures for certain roadway work groups and adjacent tracks.

(a) * * *

(2) *Special circumstance arising in territories with at least three tracks, if an occupied track is between two adjacent controlled tracks.* If an occupied track has two adjacent controlled tracks, and one of these adjacent controlled tracks has one or more train or other on-track equipment movements authorized or permitted at a speed of 25 mph or less (or 40 mph or less for one or more passenger train or other passenger on-track equipment movements), and the other adjacent controlled track has one or more concurrent train or other on-track equipment movements authorized or permitted at a speed over 25 mph (or over 40 mph for one or more passenger train or other passenger on-track equipment movements), the more restrictive procedures in paragraph (b) of this section apply.

(3) * * *

*Adjacent controlled track* means a controlled track whose track center is spaced 19 feet or less from the track center of the occupied track.

* * * * *

*Minor correction* means one or more repairs of a minor nature, including, but not limited to, welding, spiking, anchoring, hand tamping, and joint bolt replacement, that are accomplished with hand tools or handheld, hand-supported, or hand-guided power tools. The term does not include machine spiking, machine tamping, or any similarly distracting repair.

* * * * *

(b) *Procedures for adjacent-controlled-track movements over 25 mph (or over 40 mph if passenger movements).* If a train or other on-track equipment is authorized to move on an adjacent controlled track at a speed greater than 25 mph, or at a speed greater than 40 mph for a passenger train or other passenger on-track equipment movement, each roadway worker in the roadway work group that is affected by such movement must comply with the following procedures:

* * * * *

(c) *Procedures for adjacent-controlled-track movements 25 mph or less (or 40 mph or less if passenger movements).* If a train or other on-track equipment is authorized or permitted to move on an adjacent controlled track at a speed of 25 mph or less, or at a speed of 40 mph or less for a passenger train or other passenger on-track equipment movement, each roadway worker in the roadway work group that is affected by such movement must comply with the procedures listed in paragraph (b) of this section, except that equipment movement on the rails of the occupied track and on-ground work performed exclusively between the rails (*i.e.,* not breaking the plane of the rails) of the occupied track may continue, provided that no on-ground work is performed within the areas 25 feet in front of and 25 feet behind any on-track, self-propelled equipment or coupled equipment permitted to move on the occupied track.

* * * * *

(e) * * *

(2) *Maintenance or repairs performed either alongside, or within the perimeter of, a roadway maintenance machine or coupled equipment on the occupied track.* (i) One or more roadway workers performing maintenance or repairs alongside a roadway maintenance machine or coupled equipment, provided that such machine or equipment would effectively prevent the worker from fouling the adjacent controlled track on the other side of such equipment, and that such maintenance or repairs are performed while positioned on a side of the occupied track as described in paragraph (e)(1)(i), (ii), or (iii) and Table 1 of this section.

(ii) One or more roadway workers on or under a roadway maintenance machine or coupled equipment performing maintenance or repairs within the perimeter of the machine or equipment, provided that no part of their person breaks the plane of the rail of the occupied track except when toward one of the sides of the occupied track as described in paragraph (e)(1)(i), (ii), or (iii) and Table 1 of this section. A boom or other equipment extending beyond the body of a roadway maintenance machine or coupled equipment toward an adjacent controlled track is not considered to be within the perimeter of the machine or coupled equipment.

(3) * * *

(i) A hi-rail vehicle or other rail-bound vehicle (other than a catenary maintenance tower vehicle) being used for inspection or minor correction purposes, provided that such vehicle is not coupled to one or more railroad cars. In accordance with § 214.315(a), where multiple hi-rail or rail-bound vehicles being used for inspection or minor correction are engaged in a common task, the on-track safety job briefing shall include discussion of the nature of the work to be performed to determine if adjacent-controlled-track on-track safety is necessary.

* * * * *

TABLE 1—SUMMARY OF ON-TRACK SAFETY PROCEDURES FOR CERTAIN ROADWAY WORK GROUPS AND ADJACENT TRACKS

| Example number/ diagram number (see figure 1) | "Side A" of the occupied track—the side from the vertical plane of the near running rail of the occupied track extending outward through to the fouling space of the adjacent controlled track (" 'No. 1' Track" or "No. 1") | | On or between the rails of the occupied track (" 'No. 2' track" or "number 2"), where on-track Safety Is Established through Working Limits | "Side B" of the occupied track—either (1) the side with no adjacent track or (2) the side from the vertical plane of the near running rail of the occupied track extending outward through to the fouling space of the adjacent controlled track (" 'number 3' track" or "number 3") | |
|---|---|---|---|---|---|
| | Method of On-Track Safety on Side A | Requirement | Requirements | Requirements | Method of on-track safety on side B |
| 1 ..... | Working limits or train approach warning. | Upon receiving a notification or warning for movement(s) ("movement notification or warning") for No. 1, cease work and occupy a predetermined place of safety ("PPOS") [1]. | Upon movement notification or warning for No. 1, cease work and occupy a PPOS, except work may continue during movement(s) on No. 1 auth'd. at 25 mph or less (or 40 mph or less for passenger train movements) if maintain 25′ spacing [2]. | Work [3] is not required to cease during movement(s) on No. 1. | Not applicable (N/A), because there is no adjacent track. |
| 2 ..... | Working limits ..... | Upon movement notification for No. 1, cease work and occupy a PPOS. Work [3] is not required to cease during movement(s) on No. 3. | Upon movement notification for No. 1 or No. 3, cease work and occupy a PPOS, except work may continue during movement(s) on No. 1 or No. 3 auth'd. at 25 mph or less (or at 40 mph or less for passenger train movements) if maintain 25′ spacing [2]. | Upon movement notification for No. 3, cease work and occupy a PPOS. Work [3] is not required to cease during movement(s) on No. 1. | Working limits. |
| 3 ..... | Working limits ..... | Upon movement notification for No. 1, cease work and occupy a PPOS. Work [3] is not required to cease during movement(s) on No. 3. | Upon movement notification for No. 1 or warning for No. 3, cease work and occupy a PPOS, except work may continue during movement(s) on No. 1 or No. 3 auth'd. at 25 mph or less (or at 40 mph or less for passenger train movements) if maintain 25′ spacing [2]. | Upon movement warning for No. 3 or notification for No. 1, cease work and occupy a PPOS. | Train approach warning. |
| 4 ..... | Train approach warning. | Upon movement warning for No. 1 or No. 3, cease work and occupy a PPOS. | Upon movement warning for No. 1 or No. 3, cease work and occupy a PPOS, except work may continue during movement(s) on No. 1 or No. 3 auth'd. at 25 mph or less (or at 40 mph or less for passenger train movements) if maintain 25′ spacing [2]. | Upon movement warning for No. 3 or No. 1, cease work and occupy safety PPOS. | Train approach warning. |
| 5 ..... | None, but with inter-track barrier. | Work is prohibited on No. 1 and up to barrier ("Side A1"). Work is not required to cease btwn. barrier and near running rail of occupied track ("Side A2") during movement(s) on No. 1. | Work is not required to cease during movement(s) on No. 1. | Work is not required to cease during movement(s) on No. 1. | N/A, because there is no adjacent track. |

TABLE 1—SUMMARY OF ON-TRACK SAFETY PROCEDURES FOR CERTAIN ROADWAY WORK GROUPS AND ADJACENT TRACKS—Continued

| Example number/ diagram number (see figure 1) | "Side A" of the occupied track—the side from the vertical plane of the near running rail of the occupied track extending outward through to the fouling space of the adjacent controlled track ("'No. 1' Track" or "No. 1") | | On or between the rails of the occupied track ("'No. 2' track" or "number 2"), where on-track Safety Is Established through Working Limits | "Side B" of the occupied track—either (1) the side with no adjacent track or (2) the side from the vertical plane of the near running rail of the occupied track extending outward through to the fouling space of the adjacent controlled track ("'number 3' track" or "number 3") | |
|---|---|---|---|---|---|
| | Method of On-Track Safety on Side A | Requirement | Requirements | Requirements | Method of on-track safety on side B |
| 6 ..... | None, but with inter-track barrier. | Work is prohibited on Side A1. Work[3] is not required to cease on Side A2 during movement(s) on No. 1 or No. 3. | Work is not required to cease during movement(s) on No. 1. Upon movement notification or warning for No. 3, cease work and occupy a PPOS, except work may continue during movement(s) on No. 3 auth'd. at 25 mph or less (or at 40 mph or less for passenger trains) if maintain 25′ spacing[2]. | Upon movement notification or warning for No. 3, cease work and occupy a PPOS. Work[3] is not required to cease during movement(s) on No. 1. | Working limits or train approach warning. |

[1] As used in the above table, a "predetermined place of safety" (or "PPOS") means a specific location that an affected roadway worker must occupy upon receiving a watchman/lookout's warning of approaching movement(s) ("warning") or a roadway worker in charge's ("RWIC's") notification of pending movement(s) on an adjacent track ("notification"), as designated during the on-track safety job briefing required by § 214.315. The PPOS may not be on a track, unless the track has working limits on it and no movements permitted within such working limits by the RWIC. Thus, under these circumstances, the space between the rails of the occupied track (No. 2 in this table) may be designated as a place to remain in position or to otherwise occupy upon receiving a warning or notification. The RWIC must determine any change to a PPOS, and communicate such change to all affected roadway workers through an updated on-track safety job briefing.

[2] On-ground work is prohibited in the areas 25′ in front of and 25′ behind equipment on the occupied track (No. 2), and must not break the plane of a rail on No. 2 towards a side of No. 2 unless work is permitted on that side. Note, however, that per § 214.336(a)(2), work would no longer be permitted to continue on or between the rails of the occupied track during movement(s) on an adjacent controlled track at 25 mph or less (or at 40 mph or less for passenger trains or other passenger on-track equipment movements) if there is a simultaneous movement on the other adjacent controlled track at more than 25 mph (or at more than 40 mph per hour for passenger train movements or other passenger on-track equipment movements).

[3] Work that does not break the plane of the near running rail of the occupied track (No. 2) is not required to cease during such movements; work that breaks the plane of the near running rail of the occupied track may also continue: 1) during the times that work is permitted on or between the rails of the occupied track in accordance with § 214.336(c) (Procedures for adjacent-controlled-track movements 25 mph or less, or 40 mph or less for passenger train movements or other passenger on-track equipment movements); or 2) if such work is performed alongside or within the perimeter of a roadway maintenance machine or coupled equipment in accordance with § 214.336(e)(2).

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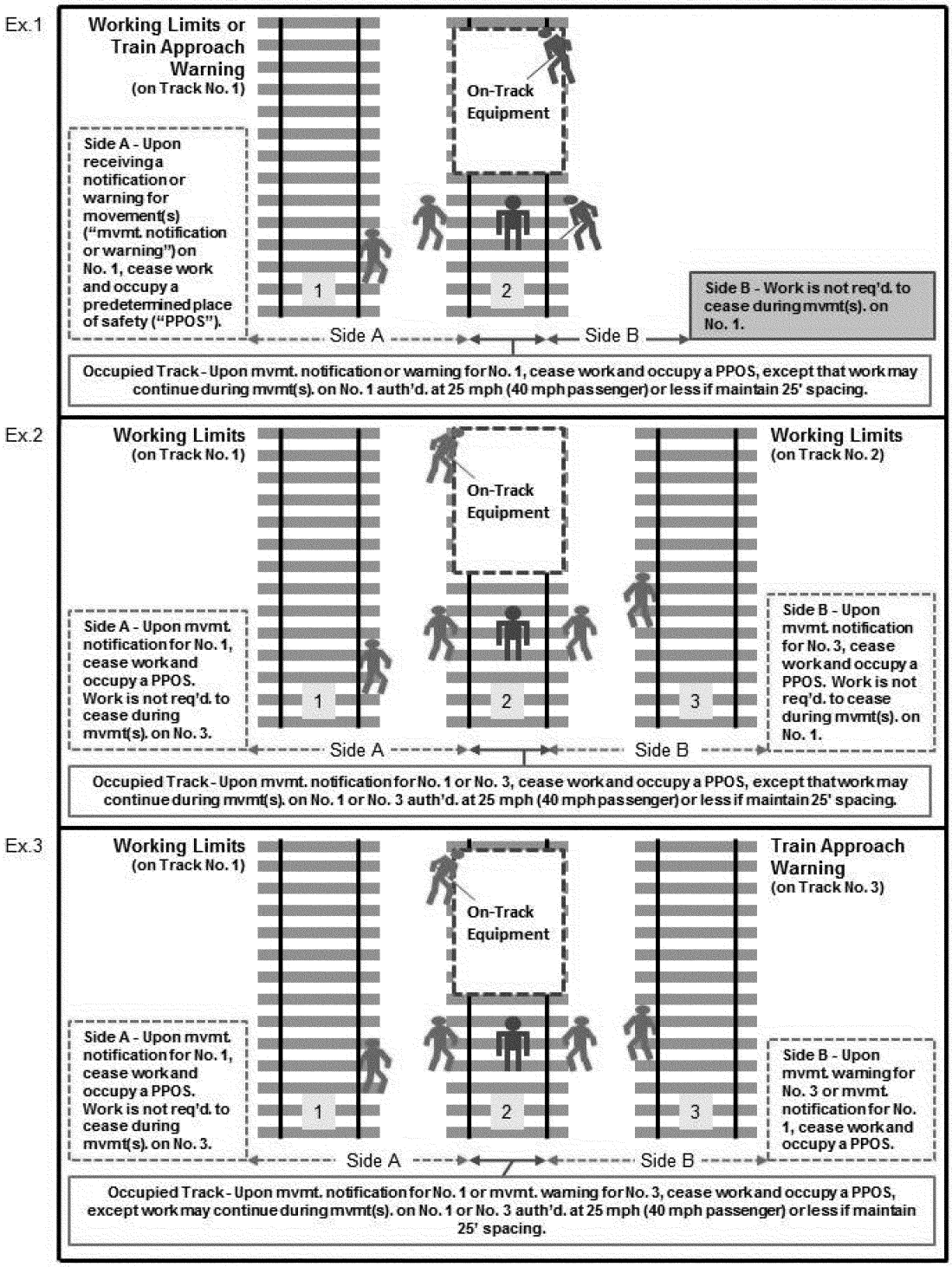
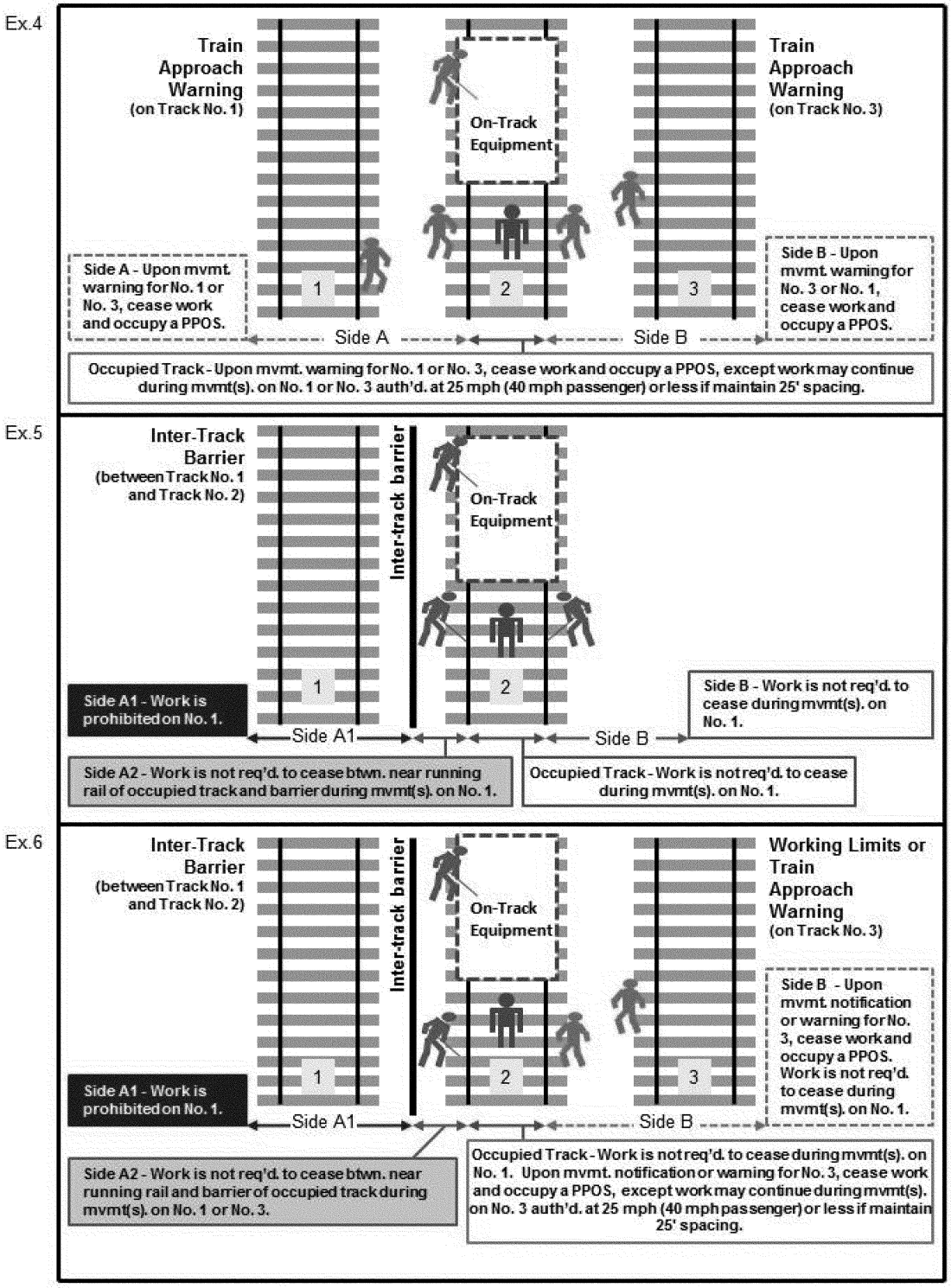
FIGURE 1 - EXAMPLES APPLYING § 214.336, ON-TRACK SAFETY PROCEDURES FOR CERTAIN ROADWAY WORK GROUPS AND ADJACENT TRACKS
(All tracks are controlled, with centerlines less than 19 feet apart.)






■ 3. Appendix A to part 214 is amended by removing the space before the superscripts for footnotes 1 and 2, revising the entry under Subpart C for § 214.315, revising the entry under Subpart C for § 214.336, and revising footnote 1 to read as follows:

## APPENDIX A TO PART 214—SCHEDULE OF CIVIL PENALTIES [1]

| Section [2] | Violation | Willful violation |
|---|---|---|
| * * * * * * | | |
| **Subpart C—Roadway Worker Protection Rule** | | |
| * * * * * * | | |
| 214.315 Supervision and communication: | | |
| (a) * * * | | |
| (2)–(4) Partial failure of employer to provide on-track safety job briefing | 2,000 | 4,000 |
| (b) Incomplete job briefing | 2,000 | 5,000 |
| (c)(i) Failure to designate roadway worker in charge of roadway work group | 2,000 | 5,000 |
| (ii) Designation of more than one roadway worker in charge of a roadway work group | 1,000 | 2,000 |
| (iii) Designation of non-qualified roadway worker in charge of roadway work group | 3,000 | 6,000 |
| (d)(i) Failure to notify roadway workers of on-track safety procedures in effect | 3,000 | 6,000 |
| (ii) Incorrect information provided to roadway workers regarding on-track safety procedures in effect | 3,000 | 6,000 |
| (iii) Failure to notify roadway workers of change in on-track safety procedures | 3,000 | 6,000 |
| (e)(i) Failure of lone worker to communicate with designated employee for daily job briefing | | 1,500 |
| (ii) Failure of employer to provide means for lone worker to receive daily job briefing | 3,000 | 6,000 |
| * * * * * * | | |
| 214.336 On-track safety procedures for certain roadway work groups and adjacent tracks: | | |
| (a) * * * | | |
| (2) Failure to implement the more restrictive procedure required by paragraph (b) during special circumstance of concurrent movement(s) on two adjacent controlled tracks where one movement is authorized or permitted at a speed over 25 mph (or over 40 mph for a passenger movement) | 1,500 | 3,000 |
| * * * * * * | | |
| (c) Failure to maintain 25-foot spacing between on-track, self-propelled equipment or coupled equipment and roadway workers(s) on the occupied track during an adjacent-controlled track movement at 25 mph or less (or at 40 mph or less for a passenger movement) | 2,000 | 4,000 |
| * * * * * * | | |

[1] A penalty may be assessed against an individual only for a willful violation. The Administrator reserves the right to assess a penalty of up to $105,000 for any violation where circumstances warrant. See 49 CFR part 209, appendix A. Failure to observe any condition(s) of an exception set forth in paragraph (e) of § 214.336 deprives the railroad or contractor of the benefit of the exception and makes the railroad or contractor, and any responsible individuals, liable for penalty under the particular regulatory provision(s) from which the exception would otherwise have granted relief.

[2] The penalty schedule uses section numbers from 49 CFR part 214. If more than one item is listed as a type of violation of a given section, each item is also designated by a ''penalty code,'' which is used to facilitate assessment of civil penalties, and which may or may not correspond to any subsection designation(s). For convenience, penalty citations will cite the CFR section and the penalty code, if any. FRA reserves the right, should litigation become necessary, to substitute in its complaint the CFR citation in place of the combined CFR and penalty code citation, should they differ.

Issued in Washington, DC, on December 27, 2013.

**Stacy Cummings,**

*Executive Director.*

[FR Doc. 2013–31417 Filed 1–9–14; 8:45 am]

BILLING CODE 4910–06–C

# Proposed Rules

Federal Register
Vol. 79, No. 7
Friday, January 10, 2014

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 39

**[Docket No. FAA–2013–1071; Directorate Identifier 2013–NM–204–AD]**

**RIN 2120–AA64**

## Airworthiness Directives; The Boeing Company Airplanes

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to adopt a new airworthiness directive (AD) for all The Boeing Company Model 777 airplanes. This proposed AD was prompted by reports of latently failed fuel shutoff valves discovered during fuel filter replacement. This proposed AD would require revising the maintenance or inspection program to include a new airworthiness limitation. We are proposing this AD to detect and correct latent failures of the fuel shutoff valve to the engine, which could result in the inability to shut off fuel to the engine and, in case of certain engine fires, an uncontrollable fire that could lead to wing failure.

**DATES:** We must receive comments on this proposed AD by February 24, 2014.

**ADDRESSES:** You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

### Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2013–1071; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

**FOR FURTHER INFORMATION CONTACT:** Rebel Nichols, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: (425) 917–6509; fax: (425) 917–6590; email: *rebel.nichols@faa.gov*.

**SUPPLEMENTARY INFORMATION:**

### Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–1071; Directorate Identifier 2013–NM–204–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

### Discussion

We have received reports of latently failed fuel shutoff valves discovered during fuel filter replacement. Deficiencies in the valve actuator design have resulted in latent failures of the fuel shutoff valve to the engine. This condition, if not detected and corrected, could result in latent failures of the fuel shutoff valve to the engine, which could result in the inability to shut off fuel to the engine and, in case of certain engine fires, an uncontrollable fire that could lead to wing failure.

### FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

### Proposed AD Requirements

This proposed AD would require revising the maintenance or inspection program to include a new airworthiness limitation.

This proposed AD would require revisions to certain operator maintenance documents to include new inspections. Compliance with these inspections is required by section 91.403(c) of the Federal Aviation Regulations (14 CFR 91.403(c)). For airplanes that have been previously modified, altered, or repaired in the areas addressed by these inspections, an operator might not be able to accomplish the inspections described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval of an alternative method of compliance (AMOC) in accordance with the provisions of paragraph (i) of this proposed AD. The request should include a description of changes to the proposed inspections that will ensure the continued operational safety of the airplane.

### Interim Action

We consider this proposed AD interim action. The manufacturer is currently developing a modification that will address the unsafe condition identified in this proposed AD. Once this modification is developed, approved, and available, we might consider additional rulemaking.

### Costs of Compliance

We estimate that this proposed AD affects 190 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

| Action | Labor cost | Parts cost | Cost per product | Cost on U.S. operators |
|---|---|---|---|---|
| Incorporating Airworthiness Limitation | 1 work-hour × $85 per hour = $85 | $0 | $85 | $16,150 |

## Authority for This Rulemaking

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

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

## Regulatory Findings

We determined that this 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 this 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),

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

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

## List of Subjects in 14 CFR Part 39

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

## 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 adding the following new airworthiness directive (AD):

**The Boeing Company:** Docket No. FAA–2013–1071; Directorate Identifier 2013–NM–204–AD.

**(a) Comments Due Date**

We must receive comments by February 24, 2014.

**(b) Affected ADs**

None.

**(c) Applicability**

This AD applies to all The Boeing Company Model 777–200, –200LR, –300, –300ER, and 777F series airplanes, certificated in any category.

**(d) Subject**

Joint Aircraft System Component (JASC) Code 2823, Fuel Selector/Shut-off Valve.

**(e) Unsafe Condition**

This AD was prompted by reports of latently failed fuel shutoff valves discovered during fuel filter replacement. We are issuing this AD to detect and correct latent failures of the fuel shutoff valve to the engine, which could result in the inability to shut off fuel to the engine and, in case of certain engine fires, an uncontrollable fire that could lead to wing failure.

**(f) Compliance**

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

**(g) Revision of Maintenance or Inspection Program**

Within 30 days after the effective date of this AD, revise the maintenance or inspection program, as applicable, to add airworthiness limitation number 28–AWL–MOV by incorporating the information specified in Figure 1 to paragraph (g) of this AD into the Airworthiness Limitations Section of the Instructions for Continued Airworthiness. The initial compliance time for accomplishing the actions specified in Figure 1 to paragraph (g) of this AD is within 7 days after accomplishing the maintenance or inspection program revision required by this paragraph.

FIGURE 1 TO PARAGRAPH (G) OF THIS AD: ENGINE SHUT-OFF VALVE (FUEL SPAR VALVE) MOV ACTUATOR INSPECTION

| AWL No. | Task | Interval | Applicability | Description |
|---|---|---|---|---|
| 28–AWL–MOV. | ALI | WEEKLY | ALL | Engine Shut-Off Valve (Fuel Spar Valve) MOV Actuator Inspection.<br>Concern: The MOV actuator design can result in airplanes operating with a failed MOV actuator that is not reported. A latently failed MOV actuator would prevent fuel shutoff to an engine. In the event of certain engine fires, the potential exists for an engine fire to be uncontrollable.<br>Perform an inspection of the Fuel Spar Valve MOV Actuator position (refer to Boeing AMM 28–22–00).<br>NOTE: The Fuel Spar Valve MOV Actuator is located behind latch panel 551 DB (left engine) and latch panel 651 DB (right engine). |

FIGURE 1 TO PARAGRAPH (G) OF THIS AD: ENGINE SHUT-OFF VALVE (FUEL SPAR VALVE) MOV ACTUATOR INSPECTION—Continued

| AWL No. | Task | Interval | Applicability | Description |
|---|---|---|---|---|
| | | | | 1. Make sure both Engine Control Switches are in the CUTOFF position.<br>2. Inspect the left engine fuel spar valve actuator located in the left rear spar.<br>a. Verify the manual override handle on the engine fuel spar valve actuator is in the CLOSED position.<br>b. Repair or replace any MOV actuator that is not in the CLOSED position (refer to Boeing Airplane Maintenance Manual, 28–22–02).<br>3. Inspect the right engine fuel spar valve actuator located in the right rear spar.<br>a. Verify the manual override handle on the engine fuel spar valve actuator is in the CLOSED position.<br>b. Repair or replace any MOV actuator that is not in the CLOSED position (refer to Boeing Airplane Maintenance Manual, 28–22–02). |

**(h) No Alternative Actions and Intervals**

After accomplishment of the maintenance or inspection program revision required by paragraph (g) of this AD, no alternative actions (e.g., inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (i)(1) of this AD.

**(i) Alternative Methods of Compliance (AMOCs)**

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

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

**(j) Related Information**

For more information about this AD, contact Rebel Nichols, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: (425) 917–6509; fax: (425) 917–6590; email: *rebel.nichols@faa.gov*.

Issued in Renton, Washington, on December 30, 2013.

**John P. Piccola,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2014–00234 Filed 1–9–14; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 39

**[Docket No. FAA–2008–1088; Directorate Identifier 2008–NE–15–AD]**

**RIN 2120–AA64**

## Airworthiness Directives; Dowty Propellers Propellers

*Correction*

In proposed rule document 2013–30882, appearing on pages 78290–78292, in the issue of Thursday, December 26, 2013, make the following correction:

On page 78290, in the first column, the subject heading is corrected to read as set forth above.

[FR Doc. C1–2013–30882 Filed 1–9–14; 8:45 am]

BILLING CODE 1505–01–D

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 39

**[Docket No. FAA–2013–0164; Directorate Identifier 2013–NE–10–AD]**

**RIN 2120–AA64**

## Airworthiness Directives; Austro Engine GmbH Engines

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to supersede airworthiness directive (AD) 2013–14–08 that applies to all Austro Engine GmbH model E4 engines. AD 2013–14–08 requires removing from service certain part number (P/N) waste gate controllers. Since we issued AD 2013–14–08 we received several reports of power loss events due to fracture of the waste gate controller lever. This proposed AD would require removing certain P/N waste gate controllers from service. We are proposing this AD to prevent failure of the waste gate controller lever, which could lead to damage to one or more engines, loss of thrust control, and damage to the airplane.

**DATES:** We must receive comments on this proposed AD by March 11, 2014.

**ADDRESSES:** You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this AD, contact Austro Engine GmbH, Rudolf-Diesel-Strasse 11, A–2700 Weiner Neustadt, Austria; phone: +43 2622 23000; fax: +43 2622 23000–2711; Internet: *www.austroengine.at.* You may

view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

**Examining the AD Docket**

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2013–0164; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the mandatory continuing airworthiness information, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

**FOR FURTHER INFORMATION CONTACT:** Frederick Zink, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7779; fax: 781–238–7199; email: *frederick.zink@faa.gov.*

**SUPPLEMENTARY INFORMATION:**

**Comments Invited**

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–0164; Directorate Identifier 2013–NE–10–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

**Discussion**

On July 10, 2013, we issued AD 2013–14–08, Amendment 39–17513 (78 FR 42677, July 17, 2013), (''AD 2013–14–08''), for all Austro Engine GmbH model E4 engines. AD 2013–14–08 requires removing from service certain P/N waste gate controllers. AD 2013–14–08 resulted from several reports of power loss events due to fracture of the waste gate controller lever. We issued AD 2013–14–08 to prevent failure of the waste gate controller lever, which could lead to damage to one or more engines, loss of thrust control, and damage to the airplane.

**Actions Since AD 2013–14–08 Was Issued**

Since we issued AD 2013–14–08, we received notification of additional waste gate controller P/Ns that require removal from service. Also since we issued AD 2013–14–08, the European Aviation Safety Agency (EASA) has issued AD 2013–0213, dated September 13, 2013, which requires removal and replacement of affected waste gate controllers. We also changed the unsafe condition statement in AD 2013–14–08 to clarify the relationship between the unsafe condition and the engine.

**Relevant Service Information**

We reviewed Austro Engine Mandatory Service Bulletin (MSB) No. MSB–E4–007/6, Revision 6, dated September 18, 2013. The service information describes procedures for removal and installation of the waste gate controllers.

**FAA's Determination**

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

**Proposed AD Requirements**

This proposed AD would retain all of the requirements of AD 2013–14–08. This proposed AD would expand the applicability by adding additional P/Ns of affected waste gate controllers.

**Costs of Compliance**

We estimate that this proposed AD would affect 128 engines installed on airplanes of U.S. registry. We also estimate that it would take about 0.5 hours per engine to comply with this proposed AD. The average labor rate is $85 per hour. Required parts cost about $231 per engine. Based on these figures, we estimate the total cost of this proposed AD to U.S. operators to be $35,008.

**Authority for This Rulemaking**

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

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

**Regulatory Findings**

We 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),

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

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

**List of Subjects in 14 CFR Part 39**

Air transportation, Aircraft, Aviation safety, Incorporation by reference, 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 airworthiness directive (AD) 2013–14–08, Amendment 39–17513 (78 FR 42677, July 17, 2013), and adding the following new AD:

**Austro Engine GmbH Engines:** Docket No. FAA–2013–0164; Directorate Identifier 2013–NE–10–AD.

**(a) Comments Due Date**

The FAA must receive comments on this AD action by March 11, 2014.

**(b) Affected ADs**

This AD supersedes AD 2013–14–08, Amendment 39–17513 (78 FR 42677, July 17, 2013).

**(c) Applicability**

This AD applies to all Austro Engine GmbH model E4 engines, with a waste gate controller, part number (P/N) E4A–41–120–000, Revision 060, or lower revision; or a waste gate controller, P/N E4B–41–120–000, Revision 010, or lower revision, installed.

**(d) Unsafe Condition**

This AD was prompted by engine power loss events due to fracture of the waste gate controller lever. We are issuing this AD to prevent failure of the waste gate controller lever, which could lead to damage to one or more engines, loss of thrust control, and damage to the airplane.

**(e) Compliance**

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

(2) At the next maintenance action for any reason, or within 110 flight hours after the effective date of this AD, or within three months after the effective date of this AD, whichever occurs first, remove from service waste gate controller, P/N E4A–41–120–000, Revision 060, or lower revision, and waste gate controller, P/N E4B–41–120–000, Revision 010 or lower revision.

**(f) Installation Prohibition**

After the effective date of this AD, do not install any waste gate controller, P/N E4A–41–120–000, Revision 060, or lower revision, or waste gate controller, P/N E4B–41–120–000, Revision 010, or lower revision, onto any engine, nor approve for return to service any engine that has either waste gate controller installed.

**(g) Alternative Methods of Compliance (AMOCs)**

The Manager, Engine Certification Office, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

**(h) Related Information**

(1) For more information about this AD, contact Frederick Zink, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7779; fax: 781–238–7199; email: *frederick.zink@faa.gov.*

(2) Refer to MCAI European Aviation Safety Agency AD 2013–0213, dated September 13, 2013, for more information. You may examine the MCAI on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2013-0164-0002.*

(3) Austro Engine Mandatory Service Bulletin No. MSB–E4–007/6, Revision 6, dated September 18, 2013, which is not incorporated by reference in this AD, can be obtained from Austro Engine GmbH, using the contact information in paragraph (h)(4) of this AD.

(4) For service information identified in this AD, contact Austro Engine GmbH, Rudolf-Diesel-Strasse 11, A–2700 Weiner Neustadt, Austria; phone: +43 2622 23000; fax: +43 2622 23000–2711; Internet: *www.austroengine.at.*

(5) You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on December 31, 2013.

**Colleen M. D'Alessandro,**

*Assistant Directorate Manager, Engine & Propeller Directorate, Aircraft Certification Service.*

[FR Doc. 2014–00169 Filed 1–9–14; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF JUSTICE

## Drug Enforcement Administration

## 21 CFR Part 1308

**[Docket No. DEA–385]**

## Schedules of Controlled Substances: Temporary Placement of Four Synthetic Cannabinoids Into Schedule I

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Notice of Intent.

**SUMMARY:** The Deputy Administrator of the Drug Enforcement Administration (DEA) is issuing this notice of intent to temporarily schedule four synthetic cannabinoids into Schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act (CSA). The substances are: quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB–22; QUPIC); quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB–22; 5F–PB–22); *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB–FUBINACA); and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB–PINACA). This action is based on a finding by the Deputy Administrator that the placement of these synthetic cannabinoids into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. Any final order will impose the administrative, civil, and criminal sanctions and regulatory controls applicable to Schedule I substances under the CSA on the manufacture, distribution, possession, importation, exportation, research, and conduct of instructional activities of these synthetic cannabinoids.

**DATES:** January 10, 2014.

**FOR FURTHER INFORMATION CONTACT:** Ruth A. Carter, Acting Chief, Policy Evaluation and Analysis Section, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone (202) 598–6812.

**SUPPLEMENTARY INFORMATION:** Any final order will be published in the **Federal Register** and may not be effective prior to February 10, 2014.

### Background

Section 201 of the CSA, 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into Schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid imminent hazard to the public safety. 21 U.S.C. 811(h). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308. The Attorney General has delegated his authority under 21 U.S.C. 811 to the Administrator of the DEA, who in turn has delegated her authority to the Deputy Administrator of the DEA. 28 CFR 0.100, 0.104, Appendix to Subpart R of Part 0, Sec. 12.

Section 201(h)(4) of the CSA (21 U.S.C. 811(h)(4)) requires the Deputy Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into Schedule I of the CSA.[1] As PB–22, 5F–

[1] Because the Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations, for purposes of this Notice of Intent, all subsequent references to ''Secretary'' have been replaced with ''Assistant Secretary.'' As set forth in a memorandum of understanding entered into by HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Assistant Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985.

PB–22, AB–FUBINACA, and ADB–PINACA are not currently listed in any schedule under the CSA, the DEA believes that the conditions of 21 U.S.C. 811(h)(1) have been satisfied. Any comments submitted by the Assistant Secretary in response to the notice transmitted to the Assistant Secretary on November 7, 2013, shall be taken into consideration before a final order is published. 21 U.S.C. 811(h)(4).

To make a finding that placing a substance temporarily into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Deputy Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA, 21 U.S.C. 811(c): the substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in Schedule I. 21 U.S.C. 811(h)(1). Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1). Available data and information for PB–22, 5F–PB–22, AB–FUBINACA, and ADB–PINACA indicate that these four synthetic cannabinoids have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

**Synthetic Cannabinoids**

Synthetic cannabinoids are a large family of compounds that are functionally (biologically) similar to delta9-tetrahydrocannabinol (THC), the main active ingredient in marijuana. Synthetic cannabinoids, however, are not organic but are chemicals created in a laboratory. Two of the synthetic cannabinoids currently controlled (CP–47,497 and cannabicyclohexanol) were first synthesized in the early 1980's for research purposes in the investigation of the cannabinoid system. JWH–018, JWH–073, and JWH–200 (temporarily scheduled on March 1, 2011 at 76 FR 11075 and permanently scheduled on July 9, 2012, by Section 1152 of the Food and Drug Administration Safety and Innovation Act (FDASIA), Pub. L. 112–144) were synthesized in the mid-1990s and studied to further advance the understanding of drug-receptor interactions regarding the cannabinoid system. Synthesized as research tools, no other known legitimate uses have been identified for these five synthetic cannabinoids.

According to forensic laboratory reports, the initial appearance of synthetic cannabinoids in herbal incense products in the United States occurred in November 2008 when U.S. Customs and Border Protection (CBP) first encountered products using brand names such as ''Spice.'' Prior to appearing on the U.S. market, synthetic cannabinoids were marketed in herbal incense products in several European countries. After experiencing numerous health-related incidents, some European countries banned these products/chemicals. According to CBP, a number of the synthetic cannabinoids appeared to originate from foreign sources.

Detailed chemical analyses by DEA and other agencies have found synthetic cannabinoids applied on plant material in herbal incense products marketed to the general public. Product analyses have found variations in both the type of synthetic cannabinoid and the amount of the substance found on the plant material.

The vast majority of cannabinoids are manufactured in Asia by individuals who are not bound by any manufacturing requirements or quality control standards. The bulk products are smuggled into the United States typically as misbranded imports. These chemicals are generally found in powder form or are dissolved in solvents, such as acetone, before being applied to the plant material comprising the ''herbal incense'' products. After local distributors apply the drug to the leafy material, they package it for retail distribution, ignoring any control mechanisms to prevent contamination or to ensure a consistent, uniform concentration of drug in each package. According to Internet discussion boards and law enforcement encounters, spraying or mixing the synthetic cannabinoids on plant material provides a vehicle for the most common route of administration- smoking (using a pipe, a water pipe, or rolling the drug-spiked plant material in cigarette papers). They are sold under hundreds of different brand names, including ''Spice,'' ''K2,'' ''Blaze,'' ''Red X Dawn,'' ''Paradise,'' ''Demon,'' ''Black Magic,'' ''Spike,'' ''Mr. Nice Guy,'' ''Ninja,'' ''Zohai,'' ''Dream,'' ''Genie,'' ''Sence,'' ''Smoke,'' ''Skunk,'' ''Serenity,'' ''Yucatan,'' ''Fire,'' and ''Crazy Clown.''

Law enforcement personnel have encountered dosage form and packaging operations in residential neighborhoods, garages, and warehouses. Throughout this process, there is no concern for preventing contamination of the product, consistent dosage, or the adverse health consequences that may occur from ingesting the drug. As proposed in the scientific literature, the risk of adverse health effects is further increased by the fact that similarly labeled products vary in the composition and concentration of synthetic cannabinoids applied on the plant material.

There is an incorrect assumption that these products are safe. Numerous states, local jurisdictions, and the international community have controlled many synthetic cannabinoids. These substances have no accepted medical use in the United States and have been reported to produce adverse health effects in those who abuse them.

PB–22, 5F–PB–22, AB–FUBINACA and ADB–PINACA are synthetic cannabinoids that have pharmacological effects similar to the Schedule I hallucinogen delta-9-tetrahydrocannabinol (THC). PB–22 and 5F–PB–22 were not reported in the scientific literature prior to their appearance on the illicit drug market. First appearing in a 2009 patent filed by the pharmaceutical manufacturer Pfizer, AB–FUBINACA was most recently reported in the scientific literature as a component of so-called ''herbal products'' purchased via the Internet in July 2012. ADB–PINACA was first encountered by law enforcement following reports of serious adverse events in Georgia and Colorado in August and September 2013, respectively.

From January through November 2013, according to the System to Retrieve Information from Drug Evidence (STRIDE)[2] there were 189 reports involving PB–22, 155 reports involving 5F–PB–22, and 42 reports involving AB–FUBINACA (Queried on December 18, 2013). From January through November 2013, the National Forensic Laboratory Information System (NFLIS)[3] registered 1,092 reports containing PB–22 in 29 states, 1,058 reports containing 5F–PB–22 in 25 states, 458 reports containing AB–FUBINACA in 17 states and 9 reports containing ADB–PINACA in one state

[2] STRIDE is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from the database are from the DEA, other federal agencies, and local law enforcement agencies.

[3] NFLIS is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories across the country.

(Queried on December 18, 2013). No reports in NFLIS or STRIDE were identified for PB–22 or 5F–PB–22 prior to February 2013. No reports in NFLIS or STRIDE were identified for AB–FUBINACA prior to June 2013 or for ADB–PINACA prior to August 2013.

**Factor 4. History and Current Pattern of Abuse**

Synthetic cannabinoids have been developed over the last 30 years as tools for investigating the cannabinoid system. Synthetic cannabinoids intended for illicit use were first reported in the United States in a November 2008 encounter, where a shipment of ''Spice'' was seized and analyzed by CBP in Dayton, Ohio. Additionally around the same time, in December 2008, JWH–018 and cannabicyclohexanol (CP–47,497 C8 homologue) were identified by German forensic laboratories. Since the initial identification of JWH–018, many additional synthetic cannabinoids have been found applied on plant material and encountered as designer drug products. The majority of the substances encountered on the illicit market have not been tested beyond preliminary pre-clinical laboratory screens before clandestine operators apply them on plant material.

JWH–018 was the first synthetic cannabinoid to be identified as a product adulterant in Germany in 2008. This substance was initially synthesized as a research tool to investigate the cannabinoid system. Since then, numerous other synthetic cannabinoids have been identified as product adulterants and law enforcement has seized bulk amounts of these substances. The first synthetic cannabinoids identified as being abused included JWH–018, JWH–200, JWH–073, CP–47,497 and CP–47,497 C8 homologue, followed shortly thereafter by new generations of synthetic cannabinoids that included AM2201 and others, and eventually UR–144, XLR11 and AKB48. JWH–018, JWH–073, JWH–200, CP–47,497, and CP–47,497 C8 were temporarily scheduled on March 1, 2011 (76 FR 11075), and later permanently placed in Schedule I by Section 1152 of FDASIA on July 9, 2012. Section 1152 of FDASIA amended the CSA by placing cannabimimetic agents and 26 specific substances (including 15 synthetic cannabinoids, 2 synthetic cathinones, and 9 synthetic phenethylamines of the 2C-series) in Schedule I. UR–144, XLR11 and AKB–48 were temporarily scheduled on May 16, 2013 (78 FR 28735). The most recent synthetic cannabinoids emerging as drugs of abuse include PB–22, 5F–PB–22, AB–FUBINACA, and ADB–PINACA. These four synthetic cannabinoids, along with UR–144, XLR11 and AKB–48, were not included among the 15 specific named synthetic cannabinoids, and do not fall under the definition of cannabimimetic agents, under FDASIA.

Synthetic cannabinoid products are marketed directly to adolescents and youth who appear to be the primary abusers of synthetic cannabinoids and synthetic cannabinoid-containing products. This is supported by law enforcement encounters and reports from emergency rooms; however, all age groups have been reported by media as abusing these substances and related products.

According to recent testimony given by the Deputy Director of the Office of National Drug Control Policy (ONDCP) to the United States Senate Caucus on International Narcotics Control (September 25, 2013), current drug testing misses significant populations of synthetic cannabinoid users. This testimony describes a study showing that in a sample of men 30 years old or younger within the District of Columbia parole and probation system, 39 percent of those who cleanly passed a traditional drug screen tested positive for synthetic cannabinoids. The study continued that between one-quarter and one-third of young men who were tested in the Washington, DC criminal justice system had positive test results for synthetic cannabinoids, regardless of whether they had failed or passed a traditional drug screen.

**Factor 5. Scope, Duration and Significance of Abuse**

Recently, increased exposure incidents have been documented by poison control centers in the United States as the abuse of synthetic cannabinoids has been associated with both acute and long-term public health and safety concerns. From January through November 2013, according to STRIDE there were 189 reports involving PB–22; 155 reports involving 5F–PB–22; and 42 reports involving AB–FUBINACA (Queried on December 18, 2013). From January through November 2013, NFLIS registered 1,092 reports containing PB–22 in 29 states (Arkansas, Arizona, Colorado, Connecticut, Florida, Georgia, Hawaii, Iowa, Kansas, Kentucky, Louisiana, Maryland, Minnesota, Missouri, North Dakota, Nebraska, New Hampshire, New Jersey, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Texas, Utah, Virginia, Wisconsin and Wyoming); 1,058 reports containing 5F–PB–22 in 25 states (Arkansas, Arizona, Colorado, Florida, Georgia, Iowa, Indiana, Kansas, Louisiana, Minnesota, Missouri, North Dakota, New Jersey, New Mexico, Nevada, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin and Wyoming); 458 reports containing AB–FUBINACA in 17 states (Arizona, Colorado, Florida, Georgia, Iowa, Indiana, Kansas, Louisiana, Minnesota, Missouri, North Dakota, New Jersey, Nevada, Ohio, Oklahoma, Pennsylvania and Texas); and 9 reports containing ADB–PINACA in one state (Colorado) (Queried on December 18, 2013). No reports in NFLIS or STRIDE were identified for PB–22 or 5F–PB–22 prior to February 2013. No reports in NFLIS or STRIDE were identified for AB–FUBINACA prior to June 2013 or for ADB–PINACA prior to August 2013.

ADB–PINACA was first encountered in the United States following reports of serious adverse events in Georgia on August 23, 2013. Reports of ADB–PINACA were not found in the scientific literature prior to its emergence on the designer drug market. The Georgia Bureau of Investigation (GBI) reported on September 12, 2013 that ADB–PINACA was detected in ''herbal incense'' products sold under the brand name ''Crazy Clown.'' It was later confirmed by the Centers for Disease Control and Prevention (CDC) as the substance responsible for severe adverse events in at least 22 persons who consumed the product. In addition, on August 30, 2013, the Colorado Department of Public Health and Environment (CDPHE) was notified by several hospitals of an increase in the number of patients visiting their emergency departments (EDs) with altered mental status after using synthetic marijuana. On September 8, 2013, CDPHE, with the assistance of CDC, began an epidemiologic investigation whereby 221 cases of severe illness due to ingestion of a synthetic cannabinoid were identified. Those that presented at emergency rooms in the Denver, Colorado area around September 1, 2013, had symptoms similar to those found in the August 2013 Georgia incident. Laboratory analysis of samples from the Colorado incident confirmed that the substance abused in the ''herbal incense'' products was ADB–PINACA.

The American Association of Poison Control Centers (AAPCC) reported receiving over 2,436 calls from January to November 2013, regarding exposures to products purportedly containing synthetic cannabinoids, although the data provided does not generally include biological sample testing that would confirm to which cannabinoids the user was exposed. A majority of

these exposure incidents resulted in individuals seeking medical attention at health care facilities.

**Factor 6. What, if Any, Risk There is to the Public Health**

The earliest reported encounter of PB–22 was by Finnish Customs (Tulli) in Helsinki who intercepted a consignment of 54 kilograms en route from China to Russia on October 27, 2012. From January through November 2013, CBP shared information related to synthetic cannabinoid shipments encountered at United States Ports of Entry and intended for destinations within the United States: PB–22—25 encounters involving 69.6 kg; 5F–PB–22—23 encounters involving 32.9 kg; and AB–FUBINACA—9 encounters involving 16.1 kg. The DEA has reported multiple encounters of large quantities of PB–22, 5F–PB–22 and/or AB–FUBINACA that have been confirmed by forensic laboratories (STRIDE).

In late August 2013, local law enforcement in Brunswick, Georgia reported that 22 persons ranging in age from 16 to 57 presented to emergency departments with severe adverse reactions after consuming a synthetic product called ''Crazy Clown.'' Adverse effects included the inability to stand, foaming at the mouth, violence towards police and paramedics and memory lapse. The substance responsible for these effects was later identified by the GBI as ADB–PINACA. In early September 2013, 221 patients presented to emergency departments in Colorado after having adverse reactions to a synthetic product labeled as ''Black Mamba.'' Adverse effects included having no gag reflex, inability to breathe on their own, hallucinations and psychotic episodes as described by nurses and attending physicians. The substance in the product consumed was identified as ADB–PINACA. In addition to the incidents in Georgia and Colorado, ADB–PINACA was also identified in exhibits of plant material labeled ''10X'' and ''20X'' submitted to a laboratory in Illinois on October 7, 2013.

Health warnings have been issued by numerous state public health departments and poison control centers describing adverse health effects associated with smoking (inhaling) synthetic cannabinoid products including, agitation, vomiting, tachycardia, elevated blood pressure, seizures, hallucinations, and non-responsiveness.

Medical examiner and postmortem toxicology reports demonstrate the involvement of 5F–PB–22 in the death of at least five individuals. These reports demonstrated that 5F–PB–22 was qualitatively identified in the blood and/or urine of all five of the deceased individuals. In addition, 5F–PB–22 intoxication was the sole cause of death in one case, while a second case stated that the cause of death was a fatal cardiac arrhythmia and/or fatal seizure in association with the use of 5F–PB–22.

Since abusers obtain these drugs through unknown sources, the identity, purity, and quantity of these substances is uncertain and inconsistent, thus posing significant adverse health risks to users. There are no recognized therapeutic uses of these substances in the United States.

**Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety**

Based on the above summarized data and information, the continued uncontrolled manufacture, distribution, importation, exportation, and abuse of PB–22, 5F–PB–22, AB–FUBINACA and ADB–PINACA pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for these synthetic cannabinoids in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in Schedule I. Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for PB–22, 5F–PB–22, AB–FUBINACA, and ADB–PINACA indicate that these four synthetic cannabinoids have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h), the Deputy Administrator, through a letter dated November 7, 2013, notified the Assistant Secretary of the DEA's intention to temporarily place these four synthetic cannabinoids in Schedule I.

**Conclusion**

This notice of intent initiates an expedited temporary scheduling action and provides the 30-day notice pursuant to section 201(h) of the CSA, 21 U.S.C. 811(h). In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Deputy Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily schedule four synthetic cannabinoids, quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB–22; QUPIC); quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB–22; 5F–PB–22); *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB–FUBINACA); and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB–PINACA), in Schedule I of the CSA, and finds that placement of these synthetic cannabinoids into Schedule I of the CSA is warranted in order to avoid an imminent hazard to the public safety.

Because the Deputy Administrator hereby finds that it is necessary to temporarily place these synthetic cannabinoids into Schedule I to avoid an imminent hazard to the public safety, any subsequent final order temporarily scheduling these substances will be effective on the date of publication in the **Federal Register**, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2). It is the intention of the Deputy Administrator to issue such a final order as soon as possible after the expiration of 30 days from the date of publication of this notice. PB–22, 5F–PB–22, AB–FUBINACA and ADB–PINACA will then be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, possession, importation, exportation, research, and conduct of instructional activities of a Schedule I controlled substance.

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done ''on the record after opportunity for a hearing'' conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

**Regulatory Matters**

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety.

As provided in this subsection, the Attorney General may, by order, schedule a substance in Schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this notice of intent. In the alternative, even assuming that this notice of intent might be subject to section 553 of the APA, the Deputy Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Although the DEA believes this notice of intent to issue a temporary scheduling order is not subject to the notice and comment requirements of section 553 of the APA, the DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Deputy Administrator will take into consideration any comments submitted by the Assistant Secretary with regard to the proposed temporary scheduling order.

Further, the DEA believes that this temporary scheduling action is not a ''rule'' as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

**List of Subjects in 21 CFR Part 1308**

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

Under the authority vested in the Attorney General by section 201(h) of the CSA, 21 U.S.C. 811(h), and delegated to the Deputy Administrator of the DEA by Department of Justice regulations (28 CFR 0.100, Appendix to Subpart R of Part 0), the Deputy Administrator hereby proposes that 21 CFR part 1308 be amended as follows:

## PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for Part 1308 continues to read as follows:

**Authority:** 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. Section 1308.11 is amended by adding paragraphs (h)(15) through (18) to read as follows:

**§ 1308.11 Schedule I**

* * * * *

(h) * * *

(15) quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate, its optical, positional, and geometric isomers, salts and salts of isomers—7222 (Other names: PB–22; QUPIC)

(16) quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate, its optical, positional, and geometric isomers, salts and salts of isomers—7225 (Other names: 5-fluoro-PB–22; 5F–PB–22)

(17) *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers—7012 (Other names: AB–FUBINACA)

(18) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers—7035 (Other names: ADB–PINACA)

Dated: January 6, 2014.

**Thomas M. Harrigan,**

*Deputy Administrator.*

[FR Doc. 2014–00217 Filed 1–9–14; 8:45 am]

BILLING CODE 4410–09–P

## DEPARTMENT OF HOMELAND SECURITY

## Coast Guard

## 33 CFR Parts 140 and 146

## 46 CFR Parts 4 and 109

**[Docket No. USCG–2013–1057]**

**RIN 1625–AB99**

## Marine Casualty Reporting on the Outer Continental Shelf

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes broadening the regulatory requirements for reporting marine casualties that occur on the U.S. Outer Continental Shelf (OCS). The limited reporting requirements currently applicable to foreign-flag OCS units in those waters would be replaced with the broader requirements currently applicable to U.S.-flag OCS units and to marine casualties occurring elsewhere in U.S. waters. The proposed changes would improve the Coast Guard's ability to collect and analyze casualty data for incidents on the OCS, in the interest of maintaining and improving safety on the OCS. This proposed rule would support the Coast Guard's maritime safety and stewardship missions.

**DATES:** Comments and related material must either be submitted to our online docket via *http://www.regulations.gov* on or before April 10, 2014 or reach the Docket Management Facility by that date. Comments sent to the Office of Management and Budget (OMB) on collection of information must reach OMB on or before April 10, 2014.

**ADDRESSES:** You may submit comments identified by docket number USCG–2013–1057 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section

below for instructions on submitting comments.

*Collection of Information Comments:* If you have comments on the collection of information discussed in section VI.D. of this notice of proposed rulemaking (NPRM), you must also send comments to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget. To ensure that your comments to OIRA are received on time, the preferred methods are by email to *oira_submission@omb.eop.gov* (include the docket number and ''Attention: Desk Officer for Coast Guard, DHS'' in the subject line of the email) or fax at 202–395–6566. An alternate, though slower, method is by U.S. mail to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, ATTN: Desk Officer, U.S. Coast Guard.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this proposed rule, call or email Mr. Dan Lawrence, Vessel and Facility Operating Standards Division (CG–OES–2), telephone 202–372–1382, email *James.D.Lawrence@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone 202–366–9826.

**SUPPLEMENTARY INFORMATION:**

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## I. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

### *A. Submitting Comments*

If you submit a comment, please include the docket number for this rulemaking (USCG–2013–1057), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. We recommend that you include your name and a mailing address, an email address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and insert ''USCG–2013–1057'' in the ''Search'' box. Click on ''Submit a Comment'' in the ''Actions'' column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period and may change this proposed rule based on your comments.

### *B. Viewing Comments and Documents*

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* and insert ''USCG–2013–1057 in the ''Search'' box. Click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

### *C. Privacy Act*

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

### *D. Public Meeting*

We do not plan to hold a public meeting. You may submit a request for one to the docket using one of the methods specified under **ADDRESSES**. In your request, explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

## II. Abbreviations

BSEE Bureau of Safety and Environmental Enforcement
COI Collection of information
DHS Department of Homeland Security
DP Dynamic positioning
E.O. Executive Order
FR Federal Register
MODU Mobile offshore drilling unit
NPRM Notice of proposed rulemaking
OCS Outer Continental Shelf
OIRA Office of Information and Regulatory Affairs
OMB Office of Management and Budget
§ Section symbol
U.S.C. United States Code

## III. Basis and Purpose

The legal basis for this rulemaking is 43 U.S.C. 1333(d)(1), which authorizes the Secretary of the Department in which the Coast Guard is operating to promulgate and enforce necessary and reasonable regulations relating to the promotion of safety of life and property on Outer Continental Shelf (OCS) units and adjacent waters. The Secretary's authority is delegated to the Coast Guard by Department of Homeland Security Delegation No. 0170.1 (90).

The purpose of this notice of proposed rulemaking (NPRM) is to propose changes to Coast Guard regulations to improve the Coast Guard's ability to capture data on casualties that occur on the U.S. OCS. That data is essential to analyze the effectiveness of current Coast Guard regulations on OCS safety and for any future improvements to those regulations.

## IV. Background

In 33 CFR subchapter N (33 CFR parts 140–147), the Coast Guard regulates OCS facilities, vessels, and other units engaged in OCS activities (collectively, ''OCS units'') on the U.S. OCS. *See* 33 CFR 140.3. The U.S. OCS includes ''all submerged lands lying seaward and outside of the area of 'lands beneath navigable waters' as defined in section 2(a) of the Submerged Lands Act (43 U.S.C. 1301(a)) and of which the subsoil and seabed appertain to the United

States and are subject to its jurisdiction and control.'' 33 CFR 140.10. OCS activity is defined as ''any offshore activity associated with exploration for, or development or production of, the minerals of the Outer Continental Shelf.'' 33 CFR 140.10. Subchapter N applies to offshore activity conducted by U.S.- or foreign-flag OCS units.[1]

Under 33 CFR 146.30, the owner, operator, and person in charge of an OCS facility (other than a mobile offshore drilling unit (MODU), see 33 CFR 146.1) must report to the Coast Guard as soon as possible any casualties involving death, injury to five or more persons in a single incident, incapacitation of any person for more than 72 hours, damage to primary lifesaving or firefighting equipment, and certain other property damage in excess of $25,000. Under 33 CFR 146.35, the initial notice of casualty report required in § 146.30 must be followed up in writing with, among other information, a description of the factors that may have contributed to the casualty, including any ''alcohol or drug involvement as specified in the vessel casualty reporting requirements of 46 CFR 4.05–12.'' 33 CFR 146.35(a)(7).

Under 33 CFR 146.303, the owner, operator, or person in charge of a vessel[2] (including a MODU) engaged in OCS activities must report to the Coast Guard as soon as possible casualties involving death, injury to five or more persons in a single incident, or the incapacitation of any person for more than 72 hours.

The Coast Guard also has existing marine casualty reporting regulations in 46 CFR part 4. Part 4 applies to any marine casualty that ''occurs upon the navigable waters of the United States, its territories or possessions'' or that involves ''any United States vessel wherever such casualty or accident occurs.'' 46 CFR 4.03–1(a). Generally, the navigable waters of the United States cover the U.S. territorial seas and internal waters, and not the waters of the U.S. OCS. 33 CFR 2.36(a).[3] Thus, part 4 applies to U.S.-flag OCS vessels, but, in general, does not apply to foreign-flag OCS vessels operating on the U.S. OCS.[4] Nor does part 4 apply to OCS facilities or other OCS units.

Under 46 CFR 4.05–1, ''immediately after the addressing of resultant safety concerns,'' a vessel's ''owner, agent, master, operator, or person in charge'' must report to the Coast Guard most casualties involving grounding, allision, loss of propulsion or vessel maneuverability, impacts to vessel seaworthiness or fitness for service or route, loss of life, injury requiring professional medical treatment, property damage in excess of $25,000, or ''significant harm to the environment'' as defined in 46 CFR 4.03–65. The initial report under § 4.05–1 must be followed within 5 days by a written report that must discuss any alcohol or drug involvement. *See* 46 CFR 4.05–10(a), 4.05–12(a).

Table 1 highlights the relative Coast Guard marine casualty reporting requirements of 33 CFR part 146 and 46 CFR part 4. (Please note that the Department of the Interior's Bureau of Safety and Environmental Enforcement (BSEE) also requires OCS lessees and right-of-way holders to report incidents addressed in BSEE regulations at 30 CFR 250.188. The BSEE's regulations cover only those OCS units that are permanently or semi-permanently attached to the seabed or subsoil of the OCS, not vessels. The Coast Guard and the BSEE work together to ensure that duplicative reporting is not required.)

TABLE 1—COAST GUARD MARINE CASUALTY REPORTING REQUIREMENTS

| Topic | Coast Guard—<br>33 CFR part 146 | Coast Guard—<br>46 CFR part 4 |
|---|---|---|
| Statutory authority | 43 U.S.C. 1333 | 43 U.S.C. 1333; 46 U.S.C. 2103, 2303a, 2306, 6101, 6301. |
| Applies to— | U.S. or foreign OCS unit* engaged in OCS activities.* 33 CFR 140.3, 146.1, 146.301. | U.S. or foreign vessel on U.S. navigable waters,* or U.S. vessel on any waters. 46 CFR 4.03–1. |
| Reportable casualties | Death<br>Injuries to 5+ persons<br>Incapacitation >72 hours; Property damage >$25,000 (facilities only)..<br><br>33 CFR 146.30, 146.303. | Vessel in distress/loss of communication with vessel.<br>Death<br>Injury<br>Property damage >$25,000<br>Grounding.<br>Allision.<br>Loss of—<br>• Main propulsion.<br>• Primary steering.<br>• Associated systems/components affecting maneuverability.<br>Impairment of—<br>• Vessel operation.<br>• Vessel components.<br>• Cargo.<br>Material/adverse impact to vessel's—<br>• Seaworthiness.<br>• Fitness for service.<br>• Fitness for route.<br>• Examples—fire, flooding, failure of/damage to fire extinguishing, lifesaving, auxiliary power, bilge pumping systems.<br>Significant harm to the environment (defined in 46 CFR 4.03–65).<br>46 CFR 4.04–1, 4.04–2, 4.05–1. |

[1] Foreign OCS units generally must employ only U.S. citizens or resident aliens engaged in OCS activities. *See* 33 CFR 141.15(a).

[2] ''*Vessel* means ''every description of watercraft or other artificial contrivance used, or capable of being used, as a means of transportation on water.'' 33 CFR 140.10.

[3] For the limited purpose of applying the Federal Water Pollution Control Act, 33 U.S.C. 1321 and 1322, ''navigable waters of the United States.'' also includes ''[o]ther waters over which the Federal Government may exercise Constitutional authority.'' 33 CFR 2.36(b).

[4] There is an exception to this general foreign-vessel exemption for certain foreign tank vessel casualties occurring outside U.S. navigable waters but within the U.S. Exclusive Economic Zone (including the U.S. OCS), in 46 CFR 4.05–2(b).

TABLE 1—COAST GUARD MARINE CASUALTY REPORTING REQUIREMENTS—Continued

| Topic | Coast Guard— 33 CFR part 146 | Coast Guard— 46 CFR part 4 |
|---|---|---|
| When to report | As soon as possible. 33 CFR 146.30, 146.303.. | Immediately after addressing resultant safety concerns. 46 CFR 4.05–1. |
| Subsequent reports | Within 10 days, describe possible contributing factors. 46 CFR 146.35, 146.303.. | Within 5 days, written casualty report required; must describe role of any alcohol/drug use. 46 CFR 4.05–10, 4.05–12. |
| Alcohol/drug testing | Required. 46 CFR 146.35, 146.303. | Required. 46 CFR 4.05–12. |

* TERMS USED IN TABLE:
U.S. navigable waters = in general, U.S. internal waters and 12-nautical mile wide zone of U.S.-adjacent waters (see 33 CFR 2.22, 2.36; 46 CFR 4.03–1).
OCS activities = any offshore activity associated with exploration for, or development or production of, the minerals of the Outer Continental Shelf (see 33 CFR 140.10).
OCS unit = a facility, vessel, or other unit engaged in OCS activities (see 33 CFR 140.10).

## V. Discussion of Proposed Rule

The effective formulation of Coast Guard policy to maintain a safe working environment on the U.S. OCS requires collecting and analyzing casualty data. However, our data collection is compromised because, today, there is a disparity between the general marine casualty reporting provisions of 46 CFR part 4 and the casualty reporting provisions of 33 CFR part 146, which apply only to OCS activities. Currently, foreign-flag OCS units must report casualties only under 33 CFR part 146, whereas U.S.-flag OCS units are subject to 33 CFR part 146 and also to the broader reporting requirements of 46 CFR part 4. We are concerned that some marine casualties on the U.S. OCS go unreported because, at present, much of the OCS activity on the U.S. OCS is conducted by foreign-flag OCS units.

To illustrate the difference in how U.S.- and foreign-flag OCS units are required to report casualties, consider dynamic positioning (DP) systems. OCS vessels increasingly use DP which, through the use of global positioning systems, operates vessel thrusters, steering, and main propulsion to keep the unit, albeit still underway, in a desired location, unanchored, while it engages in OCS activity. If a U.S.-flag OCS vessel loses its primary and backup DP capability so that it can no longer maintain its location, the loss is a reportable marine casualty because it reduces the vessel's maneuverability. *See* 46 CFR 4.05–1(a)(3).[5] However, the same incident on a foreign-flag OCS vessel is not reportable under 33 CFR 146.303 unless it results in death, multiple injuries, or an individual's lengthy incapacitation. This disparity between the reporting requirements of 33 CFR part 146 and 46 CFR part 4 prevents the Coast Guard from collecting data on many incidents that have significant safety implications for the U.S. OCS environment and the lives of U.S. citizens and resident aliens working there.

In April 2010, explosions on the *Deepwater Horizon,* a foreign-flag MODU, in Gulf of Mexico-U.S. OCS waters led to fire, the sinking of the MODU, 11 deaths, and the largest oil spill in U.S. history. In 2008, the *Deepwater Horizon* had two separate incidents involving flooding and total loss of power that a U.S.-flag MODU would have been required to report under 46 CFR 4.05–1, but which, under 33 CFR 146.303, did not constitute reportable marine casualties and were not investigated by the MODU's flag state or by the Coast Guard. Following the 2010 incident, Coast Guard investigators concluded that the casualty reporting requirements for foreign-flag OCS units found in 33 CFR part 146 were ''insufficient,'' and that, had the 2008 incidents been investigated, important contributing factors in the 2010 disaster could have been brought to light and remedied. The investigators recommended that the Coast Guard ''revise the current marine casualty reporting requirements and drug testing requirements for foreign-flag MODUs operating on the OCS and make them consistent with the requirements for U.S.-flag MODUs.''[6]

We do not suggest that the proposed rule by itself would have prevented the *Deepwater Horizon* disaster, but the proposed rule is in line with the investigators' recommendation. It would also place all OCS units, whether U.S flag. or foreign flag, on the same regulatory footing with respect to casualty reporting, thereby increasing the likelihood that we will have more complete casualty data for incidents occurring on the U.S. OCS.

We propose the following regulatory amendments.

In 33 CFR, proposed § 140.50 would effectively transfer marine casualty reporting requirements for OCS units from 33 CFR subchapter N to 46 CFR part 4. Section 140.50 would also refer regulated parties to other Coast Guard regulations that must be followed in the event an incident occurs that involves a ''commercial diving operation,'' a ''hazardous condition,'' or an ''occurrence which poses an imminent threat of oil pollution.'' We propose removing existing 33 CFR 146.30, 146.35, 146.40, 146.45, 146.301, and 146.303, all of which address marine casualties and accidents.

We propose amending 46 CFR 4.01–1 to state that, in general and with respect to the OCS, part 4 applies to all OCS units, not just OCS vessels.

In 46 CFR 4.03–1, we propose deleting the introductory language and modifying the existing language of paragraph (a) and the introductory language of paragraph of (b), for greater clarity, but without substantive change. We also propose adding a new paragraph (a)(3) so that the term ''marine casualty or accident'' specifically includes casualties or accidents involving OCS units engaged in OCS activities.

We propose adding 46 CFR 4.03–8 to define ''OCS unit'' as it is defined in 33 CFR 140.10, modified only to reflect the definitions of ''OCS activity'' and ''OCS facility'' found in § 140.10. Because 46 CFR part 4 currently lacks a general

[5] Not every DP incident constitutes a reportable marine casualty. Currently, DP incidents that do not rise to the level of a marine casualty do not need to be reported to the Coast Guard. The Coast Guard intends to develop a rulemaking to address DP incident reporting requirements and minimum DP system design and operating standards, and has published interim voluntary guidance for DP operations and the reporting of DP incidents (77 FR 26562; May 4, 2012).

[6] Report of Investigation into the Circumstances Surrounding the Explosion, Fire, Sinking and Loss of Eleven Crew Members Aboard the MOBILE OFFSHORE DRILLING UNIT *DEEPWATER HORIZON*— In the GULF OF MEXICO April 20–22, 2010, Volume I, pp. 92, 109 (Conclusion 5.I). With respect to drug testing, it is not a focus of this NPRM. However, by making all OCS units subject to the requirements of 46 CFR part 4, they would all be subject to that part's provisions for alcohol and drug testing in the wake of certain marine casualties, such as 46 CFR 4.05–12 and subpart 4.06.

definition for ''vessel,'' we propose adding new 46 CFR 4.03–9 to define ''vessel'' as it is defined in 1 U.S.C. 3 and 46 U.S.C. 2101 and to explain that, for the purposes of part 4, ''vessel'' includes OCS units unless regulatory text specifically excludes them.

We propose adding 46 CFR 4.05–1(a)(9)–(a)(11) to require notice in the event of any marine casualty listed in 46 CFR 4.03–1(a). As we propose in 33 CFR 140.50, we would also refer regulated parties to other Coast Guard regulations that must be followed in the event an incident occurs that involves a ''commercial diving operation,'' a ''hazardous condition,'' or an ''occurrence which poses an imminent threat of oil pollution.''

Finally, we propose amending 46 CFR 109.411 so that MODUs, like other OCS units, would be subject to the marine casualty and accident provisions of 46 CFR part 4, except insofar as existing 46 CFR 109.415 provides MODU-specific record retention requirements in the event of a casualty.

## VI. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on these statutes or executive orders.

### *A. Regulatory Planning and Review*

Executive Orders 13563 (''Improving Regulation and Regulatory Review'') and 12866 (''Regulatory Planning and Review'') direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget (OMB) has not reviewed it under that Order. Nonetheless, we developed an analysis of the costs and benefits of the proposed rule to ascertain its probable impacts on industry. We consider all estimates and analysis in this Regulatory Analysis to be preliminary and subject to change in consideration of public comments. A preliminary regulatory assessment follows:

The proposed rule would amend current Coast Guard regulations under which foreign-flag OCS units are subject only to the relatively limited marine casualty reporting requirements of 33 CFR subchapter N, while U.S.-flag OCS units are subject to the broader reporting requirements of 46 CFR part 4. The proposed amendments would place both U.S.- and foreign-flag OCS units under the 46 CFR part 4 reporting requirements.

Affected Population

A breakdown of the affected population appears below.

TABLE 2—FOREIGN VESSEL AND FLOATING FACILITY POPULATION

| Unit class | Frequency |
|---|---|
| Industrial Vessels [7] | 310 |
| Oil Recovery Vessels [8] | 9 |
| MODUs [9] | 73 |
| Vessel Subtotal | 319 |
| Floating OCS Facilities [10] | 28 |
| Total Vessels and Facilities | 420 |

All of the units affected by this proposed rule are foreign-flag. No U.S.-flag OCS units are affected by this proposed rule because they are currently covered by these requirements.

Costs

Forms CG–2692, CG–2692A, and CG–2692B

The proposed rule would require owners, operators, masters, or persons in charge of foreign-flag OCS units and U.S. OCS units, engaged in OCS activities, to provide timely notification by telephone or radio, or via third party, and complete the associated marine casualty reporting forms: Form CG–2692 and, as appropriate, Forms CG–2692A (Barge Addendum) and CG–2692B (Report of Required Chemical Drug and Alcohol Testing Following a Serious Marine Incident). The instructions on Form CG–2692 currently state that vessels need to report, ''A. All accidental groundings and any intentional grounding which also meets any of the other reporting criteria or creates a hazard to navigation, the environment, or the safety of the vessel; B. Loss of main propulsion or primary steering, or an associated component or control system, the loss of which causes a reduction of the maneuvering capabilities of the vessel. Loss means that systems, component parts, subsystems, or control systems do not perform the specified or required function; C. An occurrence materially and adversely affecting the vessel's seaworthiness or fitness for service or route including but not limited to fire, flooding, failure or damage to fixed fire extinguishing systems, lifesaving equipment or bilge pumping systems; D. Loss of life; E. An injury that requires professional medical treatment (beyond first aid) and, if a crewmember on a commercial vessel, that renders the individual unfit to perform routine duties; F. An occurrence not meeting any of the above criteria but resulting in damage to property in excess of $25,000. Damage cost includes the cost of labor and material to restore the property to the condition which existed prior to the casualty, but it does not include the cost of salvage, cleaning, gas freeing, drydocking or demurrage.'' The instructions also state for MODUs, ''3. MODUs are vessels and are required to report an accident that results in any of the events listed by Instruction 2–A through 2–F for vessels.'' The instructions continue for OCS facilities: ''4. All OCS facilities (except mobile offshore drilling units) engaged in mineral exploration, development or production activities on the Outer Continental Shelf of the U.S. are required by 33 CFR 146.30 to report accidents resulting in: A. Death; B. Injury to 5 or more persons in a single incident; C. Injury causing any person to be incapacitated for more than 72 hours; D. Damage affecting the usefulness of primary lifesaving or fire fighting equipment; E. Damage to the facility in excess of $25,000 resulting from a collision by a vessel; F. Damage to a floating OCS facility in excess of $25,000. 5. Foreign vessels engaged in mineral exploration, development or production on the U.S. Outer Continental Shelf, other than vessels already required to report by Instructions 2 and 3 above, are required by 33 CFR 146.303 to report casualties that result in any of the following: A. Death; B. Injury to 5 or more persons in a single incident; C. Injury causing any person to be incapacitated for more than 72 hours.'' Finally, Form CG–2692 has instructions for foreign vessels, ''5. Foreign vessels engaged in mineral

[7] Obtained via queries of the MISLE (Marine Information for Safety and Law Enforcement) database, maintained by the U.S. Coast Guard.

[8] Obtained via queries of the MISLE.

[9] Rigzone, *http://www.rigzone.com/data/utilization_region.asp*, accessed 9/25/2013.

[10] Obtained via queries of the MISLE.

exploration, development or production on the U.S. Outer Continental Shelf, other than vessels already required to report by Instructions 2 and 3 above, are required by 33 CFR 146.303 to report casualties that result in any of the following: A. Death; B. Injury to 5 or more persons in a single incident; C. Injury causing any person to be incapacitated for more than 72 hours.''

Under this proposed rule, Form CG–2692 would require both U.S.-flag and foreign-flag OCS units to report casualties beyond those required by existing regulatory requirements, which at present are limited to the relatively narrow casualty reporting requirements of 33 CFR part 146, instead of the broader reporting requirements of 46 CFR part 4 that apply to U.S.-flag OCS units. This NPRM proposes extending the 46 CFR part 4 requirements to foreign-flag OCS units. All U.S.-flag OCS vessels already comply with these requirements. The Coast Guard's Marine Information for Safety and Law Enforcement (MISLE) database contains 45 casualty incident reports from foreign-flag OCS units in 1 year, demonstrating some level of current compliance with the proposed requirements. However, experience with the *Deepwater Horizon* MODU in 2008 (before the 2010 casualty resulting in the loss of that MODU) indicates that not all foreign-flag OCS units are voluntarily reporting casualties. The proposed requirements are expected to result in a greater level of reporting by owners, operators, masters, or persons in charge of foreign-flag OCS units.

To estimate the greater level of reporting and associated costs that would be expected by owners, operators, masters, or persons in charge of foreign-flag OCS units under the proposed rule, we compared the relative number of reports from foreign-flag OCS units under other requirements to the number of reports from U.S.-flag OCS units. We extrapolated the ratio of reporting between U.S.- and foreign-flag MODUs under current regulations to project the level of additional reporting for foreign-flag MODUs under the proposal. We collected data from MISLE for all Forms CG–2692 received by the Coast Guard in 1 year. We have 391 forms reported by foreign-flag MODUs and 239 forms reported by U.S.-flag MODUs. Foreign-flag OCS units reported 346 incidents that are required to be reported by current regulations, and 45 reports for incidents voluntarily reported that would be required under the proposed rule. U.S.-flag OCS units reported 239 incidents, with 199 incidents of the same category as the 346 reported by foreign-flag OCS units, and 40 incidents of the same category as the 45 voluntary reports by foreign-flag OCS units. The foreign-flag OCS units reported approximately 63 percent of the current required reports (63 percent = [346/(346 + 199) × 100]). If we assume the ratio would remain the same for reports of incidents that would be required in the proposed regulation, foreign-flag OCS units would report approximately 70 incidents per year (70 = 40 × 346/199), or 25 more than the 45 per year currently being reported voluntarily.[11]

TABLE 2—FORM CG–2692 BASELINE REPORTING BEHAVIOR

| OCS Units | Currently required reporting for both foreign and U.S. | Other reporting | Total number of forms submitted |
|---|---|---|---|
| Foreign-flag | 346 | * 45 | 391 |
| U.S.-flag | 199 | ** 40 | 239 |

* Current voluntary reporting by foreign-flag OCS units.
** Currently required by U.S.-flag OCS units.

We assume the industry time needed to complete Form CG–2692 is 1 hour, based on ICR 1625–0001. Form CG–2692 is a machine-writable PDF form that can be transmitted by email, fax, or letter. The Coast Guard estimates that the cost to complete Form CG–2692 is $27.[12]

At a unit cost of $27, the 1-year industry cost for this proposed rule is $675 (= $27 × 25). The 10-year undiscounted industry cost is $6,750. The 10-year discounted industry cost is approximately $5,758 at a 3-percent discount rate, and $4,741 at a 7-percent discount rate.

We estimate that the government will incur costs to process these reports. We estimate that the average hourly wage rate is $42 dollars.[13] We estimate that the time to process the report is 1 hour. The 1-year cost for the government is approximately $1,050 (= $42 per hour × 1 hour × 25 reports). The 10-year undiscounted government cost is approximately $10,500. The 10-year discounted government cost is approximately $8,957 at a 3-percent discount rate, and $7,375 at a 7-percent discount rate.

The total private sector and government 10-year undiscounted cost for the proposed rule is approximately $17,250. Annualized costs (private sector and government) are approximately $1,725 at both 3- and 7-percent discount rates.

Chemical Testing

The requirements for chemical testing following a serious marine incident (as defined in 46 CFR 4.03–2) would be extended to foreign-flag OCS units engaged in OCS activities. The Coast Guard has identified two serious marine incidents in 2010, seven in 2011, and two in 2012 involving foreign-flag OCS units engaged in OCS activities. We do not expect that serious marine incidents, because of their nature, go unreported by owners, operators, masters, or persons in charge of foreign-flag OCS units. After each of these incidents, the owner, operator, master, or person in charge voluntarily submitted the required chemical testing of the involved crew members to the Coast Guard. We know that foreign-flag

[11] The ratio of foreign to domestic OCS required reports is: 346/199 = 1.74. If we assume that ratio holds and we have the number of domestic incidents required by the newly proposed regulation (40), then the equation is as follows: x/40 = 346/199 where x = foreign incidents that will now be required to be reported by the proposed regulation. That equation can then be converted to 199x = 40 × 346 = 13,840. Therefore, x = 13,840/199 = 69.6 foreign incidents that will now be reported. The equation can also be written as follows: 40 × 1.74 = 69.6 rounded to 70. If we add the 40 domestic incidents to the estimated 70 foreign incidents, we get a total of 110. 70/110 equals roughly 63% when rounding throughout the equation.

[12] The cost for completing Form CG–2692 is based on the fully loaded GS–03 out of government rate according to COMDTINST 7310.1N. The level of staff required to complete this form is equivalent to an administrative assistant.

[13] The cost for the government to process Form CG–2692/CG–2692A/CG–2692B is based on the fully loaded E–4 in government rate according to COMDTINST 7310.1N.

OCS units engaged in OCS activities currently report serious marine incidents and conduct post-incident chemical tests, and we expect that behavior to continue. Therefore, the Coast Guard estimates that industry would not incur additional costs to comply with the chemical testing provisions of this proposed rule.

Benefits

The proposed rule addresses the Coast Guard's concern that incidents involving foreign-flag OCS units are underreported. These incidents may not be ''serious marine incidents'' as defined in 46 CFR 4.03–2; nevertheless, it may be important for the Coast Guard to be aware of them. After the 2010 *Deepwater Horizon* incident—a serious marine incident in which 11 persons died and which resulted in an oil spill of national significance—the Coast Guard discovered that the *Deepwater Horizon* had two prior marine casualties in 2008, neither of which were ''serious marine incidents'' but which nevertheless pointed to problems with the *Deepwater Horizon's* safety and ability to respond to safety incidents. These two prior casualities in 2008 were not reported to the Coast Guard. This proposed rule would extend the marine casualty reporting requirements of 46 CFR part 4 to foreign-flag OCS units that currently are subject only to the relatively limited reporting requirements of 33 CFR part 146, essentially aligning the regulations with the current instructions of associated Forms CG–2692, CG–2692A and CG–2692B. The benefits of compliance would be improved maritime domain awareness. We have long recognized that provision of adequate maritime safety, security, and environmental protection requires timely reporting of casualties to provide the Coast Guard and other stakeholders with information needed to plan contingencies, evaluate risk, conduct trend analysis, and provide timely information.

*B. Small Entities*

Under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The proposed rule would not impact any U.S. entities. We estimate that 25 foreign-flag OCS units could incur an annual cost of $27. For these annual costs to have a significant economic impact on these entities, the foreign-flag OCS units would need to have annual revenues less than $2,700 per year.

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

We are interested in the potential impacts from this proposed rule on small businesses and we request public comment on these potential impacts. If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment to the Docket Management Facility at the address under **ADDRESSES**. In your comment, explain why, how, and to what degree you think this proposed rule would have an economic impact on you.

*C. Assistance for Small Entities*

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its potential effects on them, if any, and participate in the rulemaking. If you believe this proposed rule would affect your small business, organization, or governmental jurisdiction, and you have questions concerning its provisions or options for compliance, please submit a comment to the Docket Management Facility at the address under **ADDRESSES**. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard. Small businesses may also send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

*D. Collection of Information.*

This proposed rule would call for no new collection of information (COI) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) but would increase the number of affected facilities and the burden for an existing COI number 1625–0001, as described below.

*Title:* Marine Casualty Information & Periodic Chemical Drug and Alcohol Testing of Commercial Vessel Personnel

*OMB Control Number:* 1625–0001

*Summary of the Collection of Information:*

This proposed rule would require responses such as the preparation of written notification in the form of a CG–2692, Report of Marine Accident, Injury, or Death, and the maintenance of records. The collection of information would aid the regulated public in assuring safe practices.

*Need for Information:* We need this information to determine whether an entity is meeting the regulatory requirements.

*Proposed Use of Information:* We would use this information to capture data on casualties that occur on the U.S. OCS.

*Description of the Respondents:* The respondents are owners and operators of foreign-flag units engaged in OCS activities.

*Number of Respondents:* This collection of information applies to owners and operators of foreign-flag units engaged in OCS activities. We estimate the maximum number of respondents affected by this proposed rule to be 25 per year.

*Frequency of Response:* The development of the notification is only required if a marine casualty occurs as defined in these parts.

*Burden of Response:* We estimate that the development of the notification would take a given owner/operator 1 hour to complete the CG–2692.

*Estimate of Total Annual Burden:* We estimate the number of responses would increase by 25 per year. Therefore, the proposed rule would increase the annual burden by 25 hours.

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we will submit a copy of this proposed rule to the Office of Management and Budget (OMB) for its review of the collection of information.

We ask for public comment on the proposed collection of information to help us determine how useful the information is; whether it can help us perform our functions better; whether it is readily available elsewhere; how accurate our estimate of the burden of collection is; how valid our methods for determining burden are; how we can improve the quality, usefulness, and clarity of the information; and how we can minimize the burden of collection.

If you submit comments on the collection of information, submit them both to OMB and to the Docket Management Facility where indicated

under **ADDRESSES**, by the date under **DATES**.

You need not respond to a collection of information unless it displays a currently valid control number from OMB. Before the Coast Guard could enforce the collection of information requirements in this proposed rule, OMB would need to approve the Coast Guard's request to collect this information.

*E. Federalism*

A rule has implications for federalism under Executive Order 13132, Federalism, if it has 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. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132. Our analysis is explained below.

Congress specifically granted the authority to regulate artificial islands, installations, and other devices permanently or temporarily attached to the Outer Continental Shelf (OCS) and in the waters adjacent thereto as it relates to the safety of life to the Secretary of the Department in which the Coast Guard is operating. 43 U.S.C. 1333(d)(1) states that the Secretary ''shall have the authority to promulgate and enforce such reasonable regulations with respect to lights and other warning devices, safety equipment, and other matters relating to the promotion of safety of life and property on the artificial islands, installations, and other devices . . . as he may deem necessary.'' As this proposed rule would improve the Coast Guard's ability to collect and analyze casualty data for incidents on the OCS in order to maintain and improve safety of life on OCS installations, it falls within the scope of authority Congress granted exclusively to the Secretary. This authority has been delegated to the Coast Guard and is exercised in this rulemaking, and the States may not regulate within this category of marine casualty reporting. Therefore, the rule is consistent with the principles of federalism and preemption requirements in Executive Order 13132.

While it is well settled that States may not regulate in categories in which Congress intended the Coast Guard to be the sole source of a vessel's obligations, the Coast Guard recognizes the key role that State and local governments may have in making regulatory determinations. Additionally, for rules with implications and preemptive effect, Executive Order 13132 specifically directs agencies to consult with State and local governments during the rulemaking process.

Therefore, the Coast Guard invites State and local governments and their representative national organizations to indicate their desire for participation and consultation in this rulemaking process by submitting comments to this NPRM. In accordance with Executive Order 13132, the Coast Guard will provide a federalism impact statement to document: (1) The extent of the Coast Guard's consultation with State and local officials who submit comments to this proposed rule; (2) a summary of the nature of any concerns raised by State or local governments and the Coast Guard's position thereon; and (3) a statement of the extent to which the concerns of State and local officials have been met. We will also report to the Office of Management and Budget any written communications with the States.

*F. Unfunded Mandates Reform Act*

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any 1 year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

*G. Taking of Private Property*

This proposed rule would not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

*H. Civil Justice Reform*

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

*I. Protection of Children*

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

*J. Indian Tribal Governments*

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

*K. Energy Effects*

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

*L. Technical Standards*

The National Technology Transfer and Advancement Act (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

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

*M. Environment*

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. A preliminary environmental analysis checklist supporting this determination is

available in the docket where indicated under the ''Public Participation and Request for Comments'' section of this preamble. This rule is likely to be categorically excluded under section 2.B.2, figure 2–1, paragraphs (34)(a) and (d) of the Instruction. This proposed rule involves regulations which are editorial and regulations concerning documentation and equipping of vessels. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

**List of Subjects**

*33 CFR Part 140*

Continental shelf, Incorporation by reference, Investigations, Marine safety, Occupational safety and health, Penalties, Reporting and recordkeeping requirements.

*33 CFR Part 146*

Continental shelf, Marine safety, Occupational safety and health, Reporting and recordkeeping requirements, Vessels.

*46 CFR Part 4*

Administrative practice and procedure, Drug testing, Investigations, Marine safety, Nuclear vessels, Radiation protection, Reporting and recordkeeping requirements, Safety, Transportation.

*46 CFR Part 109*

Incorporation by reference, Marine safety, Occupational safety and health, Oil and gas exploration, Reporting and recordkeeping requirements, Vessels.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR parts 140 and 146 and 46 CFR parts 4 and 109 as follows:

## TITLE 33—NAVIGATION AND NAVIGABLE WATERS

## PART 140—GENERAL

■ 1. The authority citation for part 140 continues to read as follows:

**Authority:** 43 U.S.C. 1333, 1348, 1350, 1356; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 140.50 to read as follows:

### § 140.50 Marine casualties or accidents.

With respect to any marine casualty or accident, as defined in 46 CFR 4.03–1, each unit is subject to the other definitions and requirements contained in 46 CFR part 4. In addition, with respect to a marine casualty or accident involving—

(a) A ''commercial diving operation'' as defined in 46 CFR 197.204, the unit is subject to 46 CFR 197.484 and 197.486;

(b) A ''hazardous condition'' as defined in 33 CFR 160.204, the unit is subject to 33 CFR 160.215; and

(c) An ''occurrence which poses an imminent threat of oil pollution'' as defined in 33 CFR 135.303, the unit is subject to 33 CFR 135.305 and 135.307.

## PART 146—OPERATIONS

■ 3. The authority citation for part 146 continues to read as follows:

**Authority:** 33 U.S.C. 1223, 1226; 43 U.S.C. 1333, 1348, 1350, 1356; Sec. 109, Pub. L. 109–347, 120 Stat. 1884; Department of Homeland Security Delegation No. 0170.1.

### §§ 146.30–146.45 [Removed]

■ 4. Remove §§ 146.30, 146.35, 146.40, and 146.45.

## Subpart D [Removed and Reserved]

■ 5. Remove and reserve subpart D, consisting of §§ 146.301 and 146.303.

## TITLE 46—SHIPPING

## PART 4—MARINE CASUALTIES AND INVESTIGATIONS

■ 6. The authority citation for part 4 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 43 U.S.C. 1333; 46 U.S.C. 2103, 2303a, 2306, 6101, 6301, and 6305; 50 U.S.C. 198; Department of Homeland Security Delegation No. 0170.1. Subpart 4.40 issued under 49 U.S.C. 1903(a)(1)(E).

■ 7. Amend § 4.01–1 by designating the existing text as paragraph (a) and adding paragraph (b) to read as follows:

### § 4.01–1 Scope of regulation.

* * * * *

(b) This part applies to any Outer Continental Shelf (OCS) unit as defined in 46 CFR 4.03–8, and every provision of this part is applicable to OCS units unless the provision explicitly states that OCS units are excepted.

■ 7. Amend § 4.03–1 by removing the introductory text and by revising paragraph (a) and the introductory text of paragraph (b) to read as follows:

### § 4.03–1 Marine casualty or accident.

(a) As used in this part, *marine casualty or accident* means any casualty or accident, involving any vessel other than a public vessel, or any Outer Continental Shelf (OCS) unit, as follows:

(1) A U.S.- or foreign-flag vessel on the navigable waters of the United States or its territories or possessions;

(2) A U.S.-flag vessel on any waters;

(3) A U.S.-flag or foreign-flag OCS unit that is engaged in an ''OCS activity'' as defined in 33 CFR 140.10; or

(4) A foreign-flag tank vessel operating in waters subject to the jurisdiction of the United States, including the Exclusive Economic Zone, when the casualty or accident involves significant harm to the environment or material damage affecting the seaworthiness or efficiency of the vessel.

(b) As used in paragraph (a) of this section, ''any casualty or accident'' applies to any event caused by or involving a vessel and includes, but is not limited to, the following:

* * * * *

■ 8. Add § 4.03–8 to read as follows:

### § 4.03–8 OCS unit, OCS facility.

(a) As used in this part, ''OCS unit'' means any U.S. or foreign Outer Continental Shelf (OCS) facility as defined in this section, and any vessel, rig, platform, or other vehicle or structure, installation, or device, U.S. or foreign-flag, engaged directly in any offshore activity associated with exploration for, or development or production of, the minerals of the OCS, or in support of and in waters adjacent to any unit directly so engaged. The term includes a mobile offshore drilling unit when in contact with the seabed of the OCS for exploration or exploitation of subsea resources. The term does not include any pipeline or deepwater port (as the term ''deepwater port'' is defined in section 3(10) of the Deepwater Port Act of 1974 (33 U.S.C. 1502)).

(b) As used in this part, ''OCS facility'' means any artificial island, installation, or other device permanently or temporarily attached to the subsoil or seabed of the OCS, erected for the purpose of exploring for, developing, or producing resources therefrom; any vehicle, structure, installation, or device engaged in OCS activities and located in the waters adjacent to such a facility; or any such installation or other device (other than a ship or vessel) for the purpose of transporting such resources.

■ 9. Add § 4.03–9 to read as follows:

### § 4.03–9 Vessel.

As used in this part, ''vessel'' includes every description of watercraft or other artificial contrivance used, or capable of being used, as a means of transportation on water; it also includes any ''OCS unit'' as defined in § 4.03–8 of this subpart, unless the text explicitly states that such an OCS unit is excepted.

■ 10. Amend § 4.05–1 as follows:

■ a. In paragraph (a)(6), after the words ''to perform his or her routine duties;'', remove the word ''or'';

■ b. In paragraph (a)(7), after the words ''drydocking, or demurrage'', remove the

punctuation mark ''.'' and add, in its place, the punctuation mark '';'';

■ c. In paragraph (a)(8), after the words ''as defined in § 4.03–65'', remove the punctuation mark ''.'' and add, in its place, the text ''; or''; and

■ d. Add new paragraphs (a)(9), (a)(10), and (a)(11) to read as follows:

**§ 4.05–1 Notice of Marine Casualty.**

(a) * * *

(9) Any occurrence that constitutes a ''marine casualty or accident'' as defined in 46 CFR 4.03–1 or that involves a marine casualty described in this paragraph (a), and that involves a ''commercial diving operation'' as defined in 46 CFR 197.204; in which case the notification required by this section is also subject to 46 CFR 197.484 and 197.486;

(10) Any occurrence that constitutes a ''marine casualty or accident'' as defined in 46 CFR 4.03–1 or that involves a marine casualty described in this paragraph (a), and that involves a ''hazardous condition'' as defined in 33 CFR 160.204; in which case the notification required by this section is also subject to 33 CFR 160.215; or

(11) Any occurrence that constitutes a ''marine casualty or accident'' as defined in 46 CFR 4.03–1 or that involves a marine casualty described in this paragraph (a), and that involves an ''occurrence which poses an imminent threat of oil pollution'' as defined in 33 CFR 135.303; in which case the notification required by this section is also subject to 33 CFR 135.305 and 135.307.

* * * * *

## PART 109—OPERATIONS

■ 11. The authority citation for part 109 continues to read as follows:

**Authority:** 43 U.S.C. 1333; 46 U.S.C. 3306, 6101, 10104; Department of Homeland Security Delegation No. 0170.1.

■ 12. Revise § 109.411 to read as follows:

**§ 109.411 Notice and reporting of casualty.**

Except insofar as § 109.415 of this part provides specific record retention requirements for mobile offshore drilling units, each unit is subject to the marine casualty and reporting requirements of 33 CFR 140.50 and 46 CFR part 4.

Dated: January 3, 2014.

**J.C. Burton,**

*Captain, U.S. Coast Guard, Director of Inspections & Compliance.*

[FR Doc. 2014–00278 Filed 1–9–14; 8:45 am]

BILLING CODE 9110–04–P

## DEPARTMENT OF HOMELAND SECURITY

## Coast Guard

## 33 CFR Part 165

**[Docket Number USCG–2013–0935]**

## Regulated Navigation Areas and Limited Access Areas Waterway Management; Apra Harbor, Guam

**AGENCY:** Coast Guard, DHS.

**ACTION:** Advance notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is considering revising and consolidating existing Regulated Navigation Areas, Security Zones and Safety Zones currently in place in Apra Harbor, Guam. This action is intended to replace a number of redundant, potentially confusing and outdated navigation regulations with a cogent regulatory framework. The goal is to better meet the needs of the community today and ensure the safe and efficient use of the harbor by clarifying and streamlining requirements thereby reducing vessel operator confusion while transiting the waters of Apra Harbor, Guam. We are soliciting comments related to navigation in Apra Harbor, Guam including ways the Coast Guard can streamline the regulations in place while promoting safety on the waterway.

**DATES:** Comments and related material must be received by the Coast Guard on or before March 11, 2014. Public meetings will be held from 12 p.m. to 2 p.m. and from 6 p.m. to 8 p.m. on January 22, 2014.

**ADDRESSES:** The public meetings will be held at the Port Authority Guam Building, 1026 Cabras Highway, Piti, Guam. Documents mentioned in this preamble are part of Docket Number USCG–2013–0935. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Open Docket Folder'' on the line associated with this rulemaking. The following link will take you directly to the docket: *http://www.regulations.gov/#!docketDetail;=USCG–2013–0935.* If you do not have access to the Internet, you may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

You may submit comments, identified by docket number, using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* (202) 493–2251.

(3) *Mail or Delivery:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202–366–9329.

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments. To avoid duplication, please use only one of these three methods.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this document, call or email Mr. Terry Rice, Fourteenth Coast Guard District, U. S. Coast Guard; telephone (808) 535–3264, email *terry.l.rice1@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone (202) 366–9826.

**SUPPLEMENTARY INFORMATION:**

### Table of Acronyms

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
ESQD Explosive Safe Quantity Distance
FR Federal Register
NPRM Notice of Proposed Rulemaking
RNA Regulated Navigation Area

### A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

*1. Submitting Comments*

If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at *http://www.regulations.gov,* or by fax, mail, or hand delivery, but please use only one of these means. If you submit a

comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Submit a Comment'' on the line associated with this rulemaking.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

*2. Viewing Comments and Documents*

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this document. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

*3. Privacy Act*

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

*4. Public Meeting*

We plan to hold two public meetings. The first meeting will be on January 22, 2014 at noon at Port Authority Guam, 1026 Cabras Highway, Piti, Guam. The second meeting will be on January 22, 2014 at 6 p.m. at Port Authority Guam, 1026 Cabras Highway, Piti, Guam. We plan to post the minutes and a written summary of the meeting, including all comments made at the meeting, in the docket. For information on facilities or services for individuals with disabilities or to request special assistance at the public meeting, contact the person named in the **FOR FURTHER INFORMATION CONTACT** section, above.

*5. Regulatory History and Information*

Navigational regulations of Apra Harbor have been in place in various forms dating back to the era of U.S. Navy administration of Guam. Some of the regulations predate the promulgation of the Ports and Waterways Safety Act of 1972, were initially included in 33 CFR Parts 127 and 128, and subsequently re-codified in 33 CFR Part 165 on July 8, 1982 as part of a regulatory reorganization effort. The regulations in part 165 were subsequently amended in 1986, 1990, 1996, 1998 and 2003. Between 1972 and 2003 four Regulated Navigation Areas, three Security Zones and two Safety Zones were created and/or amended. One of the Security Zones was subsequently deleted, another changed to a Safety Zone, and an additional safety zone created.

*Apra Harbor safety zones regulations in 33 CFR 165.1401* were last amended in 1990 (55 FR 18725, May 4, 1990). These zones were established as security zones in 1972 (37 FR 10800, 31 May 1972); amended in 1975 (40 FR 1016, Jan. 6, 1975); codified in 33 CFR 127.1401 (a) and (b) in 1982 as part of a regulatory reorganization effort (47 FR 29569, 29667, July 8, 1982); and were subsequently disestablished and re-established as safety zones in 1990 (55 FR 18725, May 4, 1990).

*Apra Outer Harbor regulated navigation area regulations in 33 CFR 165.1402* were established by 33 CFR part 165 (47 FR 29660, July 8, 1982), and amended in 1996, and subsequently again in 1998 (63 FR 35533, June 30, 1998).

*Apra Outer Harbor regulated navigation area regulations in 33 CFR 165.1404* were first established in 33 CFR part 128 in 1972 (37 FR 10800, May 31, 1972). They were moved to 33 CFR part 165 in 1982 (47 FR 29569, July 8, 1982), and amended in 1996 (61 FR 33660, June 28, 1996; and subsequently in 1998 (63 FR 35524, June 30, 1998].

*Apra Harbor Security Zone C in 33 CFR 165.1404* was promulgated in 1990 (55 FR 18724, May 4, 1990).

*Regulated Navigation Areas and Security Zones regulations in 33 CFR 165.1405* regarding; Designated Escorted Vessels-Philippine Sea and Apra Harbor Guam (including Cabras Island Channel) were established in 2003 (68 FR 4383, Jan. 29, 2003).

*6. Basis and Purpose*

The legal basis for this rulemaking is the Coast Guard's authority to establish regulated navigation areas and other limited access areas: 33 U.S.C 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–6,160.5; Pub L. 107–295, 116 Stat. 2064; and Department of Homeland Security Delegation No. 0170.1.

Currently there are four Regulated Navigation Areas (RNA), one Security Zone and two Safety Zones within and approaching Apra Harbor. These regulations, included in 33 CFR 165.1401, 165.1402, 165.1404 and 165.1405, while intended to improve the safety and security of Apra Harbor and the mariners operating therein, are potentially confusing, overlapping, and do not adequately address current needs. The purpose of this ANPRM is to solicit comments on how to revise and simplify the current rules, taking into account relevant safety and security navigational requirements for the waters of Apra Harbor (including approaches). This proposed rulemaking will create a regulatory scheme that ensures the needs of all stakeholders are addressed in a concise, understandable format.

*7. Discussion*

As noted, the regulatory scheme in Apra Harbor does not meet current needs. A thorough review and consolidation of the Regulated Navigation Areas and Limited Access Areas (Safety or Security Zones) will simplify harbor transit communication, lessen confusion regarding harbor transit requirements, and address current safety and security concerns of all stakeholders.

A *Regulated Navigation Area* is a water area within a defined boundary for which regulations for vessels navigating within the area have been established. See 33 CFR 165.10.

A *Safety Zone* is a water area, shore area, or water and shore area to which, for safety or environmental purposes, access is limited to authorized persons, vehicles, or vessels. It may be stationary and described by fixed limits or it may be described as a zone around a vessel in motion. See 33 CFR 165.20.

A *Security Zone* is an area of land, water, or land and water which is so designated by the Captain of the Port or District Commander for such time as necessary to prevent damage or injury to any vessel or waterfront facility, to safeguard ports, harbors, territories, or

waters of the United States or to secure the observance of the rights and obligations of the United States. See 33 CFR 165.30.

The Coast Guard is considering:

• Consolidating the existing four RNAs, (33 CFR 165.1405(a)(1), (a)(2), (a)(4) and 165.1402(a)), into one Regulated Navigational Area that addresses the waters of the Apra Harbor Channel entrance and all waters of the Apra Harbor outer harbor.

• Expanding the radius of the existing Kilo Wharf Safety Zone (33 CFR 165.1401(b)) into a series of two or three safety zone radius options based upon the volume and type of cargo transferred at Kilo Wharf, thereby optimizing harbor operations viability and personal safety.

• Removing Hotel Wharf Safety Zones A and B (33 CFR 165.1405.1(a) and (b)) due to obsolescence.

• Retaining Security Zone C, Buoy 702 (33 CFR 165.1404). This zone surrounds a permanent mooring buoy reserved for specific vessels.

**B. Information Requested**

Public participation is requested to assist in determining the optimal way forward. The Coast Guard is seeking to identify what problems mariners and the public are experiencing with the current regulatory scheme, including but not limited to: The impacts of existing safety and security zones; suggestions for regulatory amendment to improve navigation while assuring safety concerns are adequately addressed; and potential impacts if the Kilo Wharf Safety Zone is amended to include a flexible expansion capability during periods of increased munitions cargo volume operations. The Coast Guard also seeks to determine the viability of alternative vessel transit and cargo operations methodologies (e.g., night vs. daylight cargo transfers, or alteration of charter operator schedules or locations).

Again, the Coast Guard seeks input for aid in developing a proposed rule. Please submit any comments or concerns you may have in accordance with the ''submitting comments'' section above.

This document is issued under the authority of 5 U.S.C. 552(a); 33 CFR 1.05–1, and 1.05–30.

Dated: December 18, 2013.

**C.B. Thomas,**

*Rear Admiral, U.S. Coast Guard, Commander, Fourteenth Coast Guard District.*

[FR Doc. 2014–00280 Filed 1–9–14; 8:45 am]

BILLING CODE 9110–04–P

**DEPARTMENT OF AGRICULTURE**

**Forest Service**

**36 CFR Part 242**

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**50 CFR Part 100**

**[Docket No. FWS–R7–SM–2013–0065; FXFR13350700640–145–FF07J00000]**

**RIN 1018–AZ67**

## Subsistence Management Regulations for Public Lands in Alaska—2015–16 and 2016–17 Subsistence Taking of Fish and Shellfish Regulations

**AGENCY:** Forest Service, Agriculture; Fish and Wildlife Service, Interior.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would establish regulations for fish and shellfish seasons, harvest limits, methods and means related to taking of fish and shellfish for subsistence uses during the 2015–2016 and 2016–2017 regulatory years. The Federal Subsistence Board (Board) is on a schedule of completing the process of revising subsistence taking of fish and shellfish regulations in odd-numbered years and subsistence taking of wildlife regulations in even-numbered years; public proposal and review processes take place during the preceding year. The Board also addresses customary and traditional use determinations during the applicable cycle. When final, the resulting rulemaking will replace the existing subsistence fish and shellfish taking regulations. This proposed rule would also amend the general regulations on subsistence taking of fish and wildlife.

**DATES:** *Public meetings:* The Federal Subsistence Regional Advisory Councils will hold public meetings to receive comments and make proposals to change this proposed rule on several dates between February 11 and March 21, 2014, and then hold another round of public meetings to discuss and receive comments on the proposals, and make recommendations on the proposals to the Federal Subsistence Board, on several dates between August 19 and October 24, 2014. The Board will discuss and evaluate proposed regulatory changes during a public meeting in Anchorage, AK, in January 2015. See **SUPPLEMENTARY INFORMATION** for specific information on dates and locations of the public meetings.

*Public comments:* Comments and proposals to change this proposed rule must be received or postmarked by March 28, 2014.

**ADDRESSES:** *Public meetings:* The Federal Subsistence Board and the Federal Subsistence Regional Advisory Councils' public meetings will be held at various locations in Alaska. See **SUPPLEMENTARY INFORMATION** for specific information on dates and locations of the public meetings.

*Public comments:* You may submit comments by one of the following methods:

• *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov* and search for FWS–R7–SM–2013–0065, which is the docket number for this rulemaking.

• *By hard copy:* U.S. mail or hand-delivery to: USFWS, Office of Subsistence Management, 1011 East Tudor Road, MS 121, Attn: Theo Matuskowitz, Anchorage, AK 99503–6199, or hand delivery to the Designated Federal Official attending any of the Federal Subsistence Regional Advisory Council public meetings. See **SUPPLEMENTARY INFORMATION** for additional information on locations of the public meetings.

We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Review Process section below for more information).

**FOR FURTHER INFORMATION CONTACT:** Chair, Federal Subsistence Board, c/o U.S. Fish and Wildlife Service, Attention: Gene Peltola, Office of Subsistence Management; (907) 786–3888 or *subsistence@fws.gov.* For questions specific to National Forest System lands, contact Steve Kessler, Regional Subsistence Program Leader, USDA, Forest Service, Alaska Region; (907) 743–9461 or *skessler@fs.fed.us.*

**SUPPLEMENTARY INFORMATION:**

**Background**

Under Title VIII of the Alaska National Interest Lands Conservation Act (ANILCA) (16 U.S.C. 3111–3126), the Secretary of the Interior and the Secretary of Agriculture (Secretaries) jointly implement the Federal Subsistence Management Program. This program provides a preference for take of fish and wildlife resources for subsistence uses on Federal public lands and waters in Alaska. The Secretaries published temporary regulations to carry out this program in the **Federal Register** on June 29, 1990 (55 FR 27114), and final regulations were published in the **Federal Register** on May 29, 1992 (57 FR 22940). The Program has subsequently amended

these regulations a number of times. Because this program is a joint effort between Interior and Agriculture, these regulations are located in two titles of the Code of Federal Regulations (CFR): Title 36, ''Parks, Forests, and Public Property,'' and Title 50, ''Wildlife and Fisheries,'' at 36 CFR 242.1–28 and 50 CFR 100.1–28, respectively. The regulations contain subparts as follows: Subpart A, General Provisions; Subpart B, Program Structure; Subpart C, Board Determinations; and Subpart D, Subsistence Taking of Fish and Wildlife.

Consistent with subpart B of these regulations, the Secretaries established a Federal Subsistence Board to administer the Federal Subsistence Management Program. The Board comprises:

- A Chair appointed by the Secretary of the Interior with concurrence of the Secretary of Agriculture;
- The Alaska Regional Director, U.S. Fish and Wildlife Service;
- The Alaska Regional Director, U.S. National Park Service;
- The Alaska State Director, U.S. Bureau of Land Management;
- The Alaska Regional Director, U.S. Bureau of Indian Affairs;
- The Alaska Regional Forester, U.S. Forest Service; and
- Two public members appointed by the Secretary of the Interior with concurrence of the Secretary of Agriculture.

Through the Board, these agencies and public members participate in the development of regulations for subparts C and D, which, among other things, set forth program eligibility and specific harvest seasons and limits.

In administering the program, the Secretaries divided Alaska into 10 subsistence resource regions, each of which is represented by a Regional Advisory Council. The Regional Advisory Councils provide a forum for rural residents with personal knowledge of local conditions and resource requirements to have a meaningful role in the subsistence management of fish and wildlife on Federal public lands in Alaska. The Regional Advisory Council members represent varied geographical, cultural, and user interests within each region.

**Public Review Process—Comments, Proposals, and Public Meetings**

The Federal Subsistence Regional Advisory Councils have a substantial role in reviewing this proposed rule and making recommendations for the final rule. The Federal Subsistence Board, through the Federal Subsistence Regional Advisory Councils, will hold public meetings on this proposed rule at the following locations in Alaska, on the following dates:

| | | |
|---|---|---|
| Region 1—Southeast Regional Council | Anchorage | March 11, 2014. |
| Region 2—Southcentral Regional Council | Anchorage | March 11, 2014. |
| Region 3—Kodiak/Aleutians Regional Council | TBD | March 20, 2014. |
| Region 4—Bristol Bay Regional Council | Naknek | February 11, 2014. |
| Region 5—Yukon–Kuskokwim Delta Regional Council | Bethel | March 5, 2014. |
| Region 6—Western Interior Regional Council | Aniak | February 25, 2014. |
| Region 7—Seward Peninsula Regional Council | Nome | March 18, 2014. |
| Region 8—Northwest Arctic Regional Council | Kotzebue | February 18, 2014. |
| Region 9—Eastern Interior Regional Council | Fairbanks | March 6, 2014. |
| Region 10—North Slope Regional Council | Barrow | February 12, 2014. |

During April 2014, the written proposals to change the subpart D, take of fish and shellfish, regulations and subpart C, customary and traditional use, determinations, will be compiled and distributed for public review.

During the 30-day public comment period, which is presently scheduled to end on May 23, 2014, written public comments will be accepted on the distributed proposals.

The Board, through the Regional Advisory Councils, will hold a second series of public meetings in August through October 2014, to receive comments on specific proposals and to develop recommendations to the Board at the following locations in Alaska, on the following dates:

| | | |
|---|---|---|
| Region 1—Southeast Regional Council | Sitka | September 17, 2014 |
| Region 2—Southcentral Regional Council | Kenai | October 14, 2014 |
| Region 3—Kodiak/Aleutians Regional Council | Cold Bay | September 9, 2014 |
| Region 4—Bristol Bay Regional Council | Dillingham | October 21, 2014 |
| Region 5—Yukon–Kuskokwim Delta Regional Council | Bethel | October 14, 2014 |
| Region 6—Western Interior Regional Council | McGrath | October 28, 2014 |
| Region 7—Seward Peninsula Regional Council | Nome | October 7, 2014 |
| Region 8—Northwest Arctic Regional Council | TBD | October 8, 2014 |
| Region 9—Eastern Interior Regional Council | TBD | October 23, 2014 |
| Region 10—North Slope Regional Council | TBD | August 19, 2014 |

A notice will be published of specific dates, times, and meeting locations in local and statewide newspapers prior to both series of meetings. Locations and dates may change based on weather or local circumstances. The amount of work on each Regional Advisory Council's agenda determines the length of each Regional Advisory Council meeting.

The Board will discuss and evaluate proposed changes to the subsistence management regulations during a public meeting scheduled to be held in Anchorage, Alaska, in January 2015. The Federal Subsistence Regional Advisory Council Chairs, or their designated representatives, will present their respective Councils' recommendations at the Board meeting. Additional oral testimony may be provided on specific proposals before the Board at that time. At that public meeting, the Board will deliberate and take final action on proposals received that request changes to this proposed rule.

Proposals to the Board to modify the general fish and wildlife regulations, fish and shellfish harvest regulations, and customary and traditional use determinations must include the following information:

a. Name, address, and telephone number of the requestor;

b. Each section and/or paragraph designation in this proposed rule for which changes are suggested, if applicable;

c. A description of the regulatory change(s) desired;

d. A statement explaining why each change is necessary;

e. Proposed wording changes; and

f. Any additional information that you believe will help the Board in evaluating the proposed change.

The Board immediately rejects proposals that fail to include the above information, or proposals that are beyond the scope of authorities in § _____.24, subpart C (the regulations governing customary and traditional use determinations), and §§ _____.25, _____.27, and _____.28, subpart D (the general and specific regulations governing the subsistence take of fish and shellfish). If a proposal needs clarification, prior to being distributed for public review, the proponent may be contacted, and the proposal could be revised based on their input. Once distributed for public review, no additional changes may be made as part of the original submission. During the January 2015 meeting, the Board may defer review and action on some proposals to allow time for cooperative planning efforts, or to acquire additional needed information. The Board may elect to defer taking action on any given proposal if the workload of staff, Regional Advisory Councils, or the Board becomes excessive. These deferrals may be based on recommendations by the affected Regional Advisory Council(s) or staff members, or on the basis of the Board's intention to do least harm to the subsistence user and the resource involved. A proponent of a proposal may withdraw the proposal provided it has not been considered, and a recommendation has not been made, by a Regional Advisory Council. The Board may consider and act on alternatives that address the intent of a proposal while differing in approach.

*Tribal Consultation and Comment*

As expressed in Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments,'' the Federal officials that have been delegated authority by the Secretaries are committed to honoring the unique government-to-government political relationship that exists between the Federal Government and Federally Recognized Indian Tribes (Tribes) as listed in 75 FR 60810 (October 1, 2010). Consultation with Alaska Native corporations is based on Public Law 108–199, div. H, Sec. 161, Jan. 23, 2004, 118 Stat. 452, as amended by Public Law 108–447, div. H, title V, Sec. 518, Dec. 8, 2004, 118 Stat. 3267, which provides that: ''The Director of the Office of Management and Budget and all Federal agencies shall hereafter consult with Alaska Native corporations on the same basis as Indian tribes under Executive Order No. 13175.''

The Alaska National Interest Lands Conservation Act does not provide specific rights to Tribes for the subsistence taking of wildlife, fish, and shellfish. However, because tribal members are affected by subsistence fishing, hunting, and trapping regulations, the Secretaries, through the Board, will provide Federally recognized Tribes and Alaska Native corporations an opportunity to consult on this proposed rule.

The Board will engage in outreach efforts for this proposed rule, including a notification letter, to ensure that Tribes and Alaska Native corporations are advised of the mechanisms by which they can participate. The Board provides a variety of opportunities for consultation: Proposing changes to the existing rule; commenting on proposed changes to the existing rule; engaging in dialogue at the Regional Council meetings; engaging in dialogue at the Board's meetings; and providing input in person, by mail, email, or phone at any time during the rulemaking process. The Board will commit to efficiently and adequately providing an opportunity to Tribes and Alaska Native corporations for consultation in regard to subsistence rulemaking.

The Board will consider Tribes' and Alaska Native corporations' information, input, and recommendations, and address their concerns as much as practicable.

**Developing the 2015–16 and 2016–17 Fish and Shellfish Seasons and Harvest Limit Regulations**

Subpart C and D regulations are subject to periodic review and revision. The Board currently completes the process of revising subsistence take of fish and shellfish regulations in odd-numbered years and wildlife regulations in even-numbered years; public proposal and review processes take place during the preceding year. The Board also addresses customary and traditional use determinations during the applicable cycle.

The text of three final rules form the text of this proposed rule for the 2013–15 subparts C and D regulations:

The text of the proposed amendments to 36 CFR 242.24 and 242.25 and 50 CFR 100.24 and 100.25 is the final rule for the 2012–2014 regulatory period for wildlife (77 FR 35482; June 13, 2012).

The text of the proposed amendments to 36 CFR 242.27 and 50 CFR 100.27 is the final rule for the 2013–15 regulatory period for fish and shellfish (78 FR 19107; March 29, 2013).

The text of the proposed amendments to 36 CFR 242.28 and 50 CFR 100.28 is the final rule for the 2011–13 regulatory period for fish and shellfish (76 FR 12564; March 8, 2011).

These regulations will remain in effect until subsequent Board action changes elements as a result of the public review process outlined above in this document.

**Compliance With Statutory and Regulatory Authorities**

*National Environmental Policy Act*

A Draft Environmental Impact Statement that described four alternatives for developing a Federal Subsistence Management Program was distributed for public comment on October 7, 1991. The Final Environmental Impact Statement (FEIS) was published on February 28, 1992. The Record of Decision (ROD) on Subsistence Management for Federal Public Lands in Alaska was signed April 6, 1992. The selected alternative in the FEIS (Alternative IV) defined the administrative framework of an annual regulatory cycle for subsistence regulations.

A 1997 environmental assessment dealt with the expansion of Federal jurisdiction over fisheries and is available at the office listed under **FOR FURTHER INFORMATION CONTACT**. The Secretary of the Interior, with concurrence of the Secretary of Agriculture, determined that expansion of Federal jurisdiction does not constitute a major Federal action significantly affecting the human environment and, therefore, signed a Finding of No Significant Impact.

*Section 810 of ANILCA*

An ANILCA § 810 analysis was completed as part of the FEIS process on the Federal Subsistence Management Program. The intent of all Federal subsistence regulations is to accord subsistence uses of fish and wildlife on public lands a priority over the taking of fish and wildlife on such lands for other purposes, unless restriction is necessary to conserve healthy fish and wildlife populations. The final § 810 analysis determination appeared in the April 6, 1992, ROD and concluded that the Federal Subsistence Management Program, under Alternative IV with an annual process for setting subsistence regulations, may have some local impacts on subsistence uses, but will not likely restrict subsistence uses significantly.

During the subsequent environmental assessment process for extending fisheries jurisdiction, an evaluation of

the effects of this rule was conducted in accordance with § 810. That evaluation also supported the Secretaries' determination that the rule will not reach the ''may significantly restrict'' threshold that would require notice and hearings under ANILCA § 810(a).

*Paperwork Reduction Act*

An agency may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. This proposed rule does not contain any new collections of information that require OMB approval. OMB has reviewed and approved the collections of information associated with the subsistence regulations at 36 CFR 242 and 50 CFR 100, and assigned OMB Control Number 1018–0075, which expires February 29, 2016.

*Regulatory Planning and Review (Executive Order 12866)*

The Office of Management and Budget (OMB) has determined that this proposed rule is not significant and has not reviewed this rule under Executive Order 12866. OMB bases its determination upon the following four criteria:

(a) Whether the rule will have an annual effect of $100 million or more on the economy or adversely affect an economic sector, productivity, jobs, the environment, or other units of the government.

(b) Whether the rule will create inconsistencies with other agencies' actions.

(c) Whether the rule will materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients.

(d) Whether the rule raises novel legal or policy issues.

*Regulatory Flexibility Act*

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 et seq.) requires preparation of flexibility analyses for rules that will have a significant effect on a substantial number of small entities, which include small businesses, organizations, or governmental jurisdictions. In general, the resources to be harvested under this rule are already being harvested and consumed by the local harvester and do not result in an additional dollar benefit to the economy. However, we estimate that two million pounds of meat are harvested by subsistence users annually and, if given an estimated dollar value of $3.00 per pound, this amount would equate to about $6 million in food value statewide. Based upon the amounts and values cited above, the Departments certify that this rulemaking will not have a significant economic effect on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

*Small Business Regulatory Enforcement Fairness Act*

Under the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801 et seq.), this rule is not a major rule. It does not have an effect on the economy of $100 million or more, will not cause a major increase in costs or prices for consumers, and does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

*Executive Order 12630*

Title VIII of ANILCA requires the Secretaries to administer a subsistence priority on public lands. The scope of this program is limited by definition to certain public lands. Likewise, these regulations have no potential takings of private property implications as defined by Executive Order 12630.

*Unfunded Mandates Reform Act*

The Secretaries have determined and certify pursuant to the Unfunded Mandates Reform Act, 2 U.S.C. 1502 et seq., that this rulemaking will not impose a cost of $100 million or more in any given year on local or State governments or private entities. The implementation of this rule is by Federal agencies and there is no cost imposed on any State or local entities or tribal governments.

*Executive Order 12988*

The Secretaries have determined that these regulations meet the applicable standards provided in §§ 3(a) and 3(b)(2) of Executive Order 12988, regarding civil justice reform.

*Executive Order 13132*

In accordance with Executive Order 13132, the proposed rule does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment. Title VIII of ANILCA precludes the State from exercising subsistence management authority over fish and wildlife resources on Federal lands unless it meets certain requirements.

*Executive Order 13175*

The Alaska National Interest Lands Conservation Act, Title VIII, does not provide specific rights to tribes for the subsistence taking of wildlife, fish, and shellfish. However, the Secretaries, through the Board, will provide Federally recognized Tribes and Alaska Native corporations an opportunity to consult on this proposed rule. Consultation with Alaska Native corporations are based on Public Law 108–199, div. H, Sec. 161, Jan. 23, 2004, 118 Stat. 452, as amended by Public Law 108–447, div. H, title V, Sec. 518, Dec. 8, 2004, 118 Stat. 3267, which provides that: ''The Director of the Office of Management and Budget and all Federal agencies shall hereafter consult with Alaska Native corporations on the same basis as Indian tribes under Executive Order No. 13175.''

The Secretaries, through the Board, will provide a variety of opportunities for consultation: commenting on proposed changes to the existing rule; engaging in dialogue at the Regional Council meetings; engaging in dialogue at the Board's meetings; and providing input in person, by mail, email, or phone at any time during the rulemaking process.

*Executive Order 13211*

This Executive Order requires agencies to prepare Statements of Energy Effects when undertaking certain actions. However, this proposed rule is not a significant regulatory action under E.O. 13211, affecting energy supply, distribution, or use, and no Statement of Energy Effects is required.

**Drafting Information**

Theo Matuskowitz drafted these regulations under the guidance of Gene Peltola of the Office of Subsistence Management, Alaska Regional Office, U.S. Fish and Wildlife Service, Anchorage, Alaska. Additional assistance was provided by:

- Daniel Sharp, Alaska State Office, Bureau of Land Management;
- Clarence Summers, Alaska Regional Office, National Park Service;
- Dr. Glenn Chen, Alaska Regional Office, Bureau of Indian Affairs;
- Jerry Berg and Jack Lorrigan, Alaska Regional Office, U.S. Fish and Wildlife Service; and
- Steve Kessler, Alaska Regional Office, U.S. Forest Service.

**List of Subjects**

*36 CFR Part 242*

Administrative practice and procedure, Alaska, Fish, National forests, Public lands, Reporting and recordkeeping requirements, Wildlife.

*50 CFR Part 100*

Administrative practice and procedure, Alaska, Fish, National

forests, Public lands, Reporting and recordkeeping requirements, Wildlife.

**Proposed Regulation Promulgation**

For the reasons set out in the preamble, the Federal Subsistence Board proposes to amend 36 CFR part 242 and 50 CFR part 100 for the 2015–16 and 2016–17 regulatory years.

The text of the proposed amendments to 36 CFR 242.24 and 242.25 and 50 CFR 100.24 and 100.25 is the final rule for the 2012–2014 regulatory period for wildlife (77 FR 35482; June 13, 2012).

The text of the proposed amendments to 36 CFR 242.27 and 50 CFR 100.27 is the final rule for the 2013–15 regulatory period for fish and shellfish (78 FR 19107; March 29, 2013).

The text of the proposed amendments to 36 CFR 242.28 and 50 CFR 100.28 is the final rule for the 2011–13 regulatory period for fish and shellfish (76 FR 12564; March 8, 2011).

Dated: December 13, 2013.

**Gene Peltola,**

*Assistant Regional Director, U.S. Fish and Wildlife Service, Acting Chair, Federal Subsistence Board.*

Dated: December 13, 2013.

**Steve Kessler,**

*Subsistence Program Leader, USDA—Forest Service.*

[FR Doc. 2014–00239 Filed 1–9–14; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 52

**[EPA–R10–OAR–2013–0418, FRL–9905–30–Region 10]**

## Approval and Promulgation of Implementation Plans; Idaho

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to partially approve the May 9, 2013, State Implementation Plan (SIP) submittal from Idaho to revise the SIP to update the incorporation by reference of Federal air quality regulations into the SIP and make minor edits and clarifications. The EPA is proposing to grant limited approval, as SIP strengthening, to a portion of the submittal that incorporates by reference updates to the Federal nonattainment new source review (nonattainment NSR) requirements that have been recently remanded to the EPA by a court. In addition, the EPA is proposing to partially disapprove Idaho's incorporation by reference of two provisions of the Federal prevention of significant deterioration (PSD) permitting rules that have been recently vacated in a separate decision by a court. Finally, we are proposing to take no action on Idaho's incorporation by reference of another provision of the Federal PSD permitting rules that has been the subject of a court action. Upon final action, the Idaho SIP would incorporate by reference certain Federal regulations as of July 1, 2012.

**DATES:** Comments must be received on or before February 10, 2014.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–R10–OAR–2013–0418, by any of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: R10-Public_Comments@epa.gov.*
- *Mail:* Kristin Hall, EPA Region 10, Office of Air, Waste and Toxics (AWT–107), 1200 Sixth Avenue, Suite 900, Seattle WA, 98101.
- *Hand Delivery:* EPA Region 10 Mailroom, 9th floor, 1200 Sixth Avenue, Suite 900, Seattle WA, 98101. Attention: Kristin Hall, Office of Air, Waste and Toxics, AWT—107. Such deliveries are only accepted during normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID No. EPA–R10–OAR–2013–0418. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Office of Air, Waste and Toxics, EPA Region 10, 1200 Sixth Avenue, Seattle WA, 98101.

**FOR FURTHER INFORMATION CONTACT:** Kristin Hall at: (206) 553–6357, *hall.kristin@epa.gov*, or the above EPA, Region 10 address.

**SUPPLEMENTARY INFORMATION:** Throughout this document wherever ''we'', ''us'' or ''our'' is used, it is intended to refer to the EPA. Information is organized as follows:

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## I. Background

Section 110 of the Clean Air Act (CAA) specifies the general requirements for states to submit SIPs to attain and maintain the National Ambient Air Quality Standards (NAAQS) and the EPA's actions regarding approval of those SIPs. On May 9, 2013, the State of Idaho submitted a SIP revision to the EPA to account for regulatory changes adopted by Idaho on several different dates. Idaho incorporates by reference (IBR) various portions of Federal regulations codified in the Code of Federal Regulations (CFR) into the Rules for the

Control of Air Pollution in Idaho (IDAPA 58.01.01). Idaho then submits parts of IDAPA 58.01.01 to the EPA for approval into the Federally-approved Idaho SIP (generally those provisions that relate to the criteria pollutants regulated under section 110 of the CAA for which the EPA has promulgated NAAQS or other specific requirements of section 110). To ensure that its rules remain consistent with the EPA requirements, Idaho generally updates the IBR citations in IDAPA 58.01.01 on an annual basis and submits a SIP revision to reflect any changes made to the Federal regulations during that year. Idaho's current SIP includes the approved incorporation by reference of specific Federal regulations, revised as of July 1, 2010, at IDAPA 58.01.01.107 ''Incorporation by Reference.''

## II. Analysis of State Submittal

### *A. Summary of Submittal*

On May 9, 2013, Idaho submitted several state dockets (rulemakings) for approval by the EPA. We note that the dockets also include revisions to Idaho's regulations relating to its title V operating permits program, hazardous air pollutants (referred to as ''toxic air pollutants'' in Idaho regulations), and other air quality-related requirements that do not implement section 110 of the CAA. Idaho submitted the revisions to these regulations for information purposes only, in order to provide a complete record of the rule revisions in each of the identified dockets. In the cover letter to the May 9, 2013, submittal Idaho specifically stated that the identified provisions were not being submitted to update Idaho's SIP. Below, we describe the rule changes submitted to the EPA for approval and provide our analysis of the revisions.

1. $PM_{2.5}$ PSD IBR Update

Docket 58–0101–1101 ''$PM_{2.5}$ PSD IBR'' revises IDAPA 58.01.01.107.03 ''Documents Incorporated by Reference'' to add the EPA final rule for Prevention of Significant Deterioration for Particulate Matter Less than 2.5 Micrometers ($PM_{2.5}$)—Increments, Significant Impact Levels and Significant Monitoring Concentration (2010 PSD $PM_{2.5}$ Implementation Rule) (October 20, 2010, 75 FR 64864) codified at 40 CFR parts 51 and 52. Idaho incorporated these Federal requirements by reference separately from its annual IBR update because the EPA's final rule became effective after the State's annual IBR update in 2010, but before its annual IBR update in 2011. Although Idaho requested approval of this docket, it has been superseded by the annual IBR updates for 2011 and 2012, described below. Therefore, we are acting on only the most recently adopted and submitted version of Idaho's regulations (namely, the 2012 Federal Rule IBR Update). Further action on this docket is not necessary because this version of the regulations is no longer in effect.

2. 2011 Federal Rule IBR Update

Docket 58–0101–1103 ''2011 Federal Rule IBR'' revises IDAPA 58.01.01.107.03 ''Documents Incorporated by Reference'' to update the citation dates for specific provisions incorporated by reference into the Idaho SIP as of July 1, 2011. Although Idaho requested approval of this docket, it has been superseded by the annual IBR update for 2012, described below. Therefore, we are acting on only the most recently adopted and submitted version of Idaho's regulations (namely, the 2012 Federal Rule IBR Update). Further action on this docket is not necessary because this version of the regulations is no longer in effect.

3. Housekeeping Revisions

Docket 58–0101–1201 ''Housekeeping Revisions'' revises IDAPA 58.01.01.006 ''General Definitions'' to clarify the definition of ''Modification'' with respect to the use of an alternative fuel or raw material, if the stationary source is specifically designed to accommodate such fuel or raw material before January 6, 1975 and use of such fuel or raw material is not specifically prohibited in a permit. The EPA is proposing to approve this revision because it has been clarified by adding the specific date of January 6, 1975, and aligns with the Federal definition of ''major modification'' at 40 CFR 51.166(b)(2)(i).

Docket 58–0101–1201 also revises the definition of ''Significant'' at IDAPA 58.01.01.006 ''General Definitions'' to include $PM_{2.5}$. Specifically, the revision defines a net emissions increase or the potential of a source to emit $PM_{2.5}$ as ''significant'' if the rate of emissions would equal or exceed 10 tons per year of direct $PM_{2.5}$ emissions; or, with respect to specific precursors to $PM_{2.5}$, 40 tons per year of sulfur dioxide emissions, or 40 tons per year of nitrogen oxides emissions. The EPA is proposing to approve this revised definition because it is the same as the Federal definition of significant at 40 CFR 51.166(b)(23)(i).

Docket 58–0101–1201 also revises the definition of ''Significant Contribution'' in IDAPA 58.01.01.006 ''General Definitions'' to include an increase in ambient concentrations of $PM_{2.5}$ which would exceed 0.3 micrograms per cubic meter, annual average, and 1.2 micrograms per cubic meter, twenty-four hour average. The EPA is proposing to approve this revision because it adopts the Federal ''significant impact levels'' for $PM_{2.5}$ as set forth in 40 CFR 51.165(b)(2) and, as a definition, has a legal affect only as otherwise provided in regulations. As discussed in Section II.B.2 below, certain Federal regulations related to significant impact levels were recently vacated by a court. However, 40 CFR 51.165(b)(2) was not vacated and remains in effect. Please see Section II.B.2 for a detailed discussion.

It is important to note that since we most recently approved revisions to IDAPA 58.01.01.006 ''General Definitions,'' new definitions have been added at paragraphs (49), (50), (51), (66), (67), (114), and (116). As a result, the paragraphs in this section have been renumbered. We are not at this time acting on these new definitions because they were not part of the submittal, but we are proposing to approve the renumbering of the section to reflect the current paragraph numbers for ''Modification'' (68), ''Significant'' (106), and ''Significant Contribution'' (107), and for all previously approved definitions in this section.

The docket also makes minor changes to IDAPA 58.01.01.220 ''General Exemption Criteria for Permit to Construct Exemptions'' and IDAPA 58.01.01.222 ''Category II Exemptions'' to clarify the applicability of these provisions. The revision to IDAPA 58.01.01.220 is approvable because it makes clear that an exemption under IDAPA 58.01.01.220 may be used by Category I sources if they meet the criteria in both IDAPA 58.01.01.221 and 223. Similarly, an exemption under IDAPA 58.01.01.220 may be used by Category II sources if they meet the criteria in both IDAPA 58.01.01.222 and 223. The revision to IDAPA 58.01.01.222 ''Category II Exemptions'' is approvable because it clarifies the additional criteria that a pilot plant in subparagraph (01)(e) must meet in order to satisfy the exemption criteria. Therefore, we are proposing to approve the submitted revisions to IDAPA 58.01.01.220 and IDAPA 58.01.01.222.

Finally, this docket revises IDAPA 58.01.01.792 ''Emissions Standards for Nonmetallic Mineral Processing Plants Subject to 40 CFR 60 Subpart OOO'' and IDAPA 58.01.01.794 ''Permit Requirements'' as they relate to nonmetallic mineral processing plant. Idaho submitted a previous version of IDAPA 58.01.01.792 and 58.01.01.794 to the EPA as a SIP revision, but the EPA has not yet taken action on that SIP revision. See 75 FR 72719 (November

26, 2010). The EPA intends to take action on both submitted revisions to IDAPA 58.01.01.792 and 58.01.01.794 in a separate rulemaking.

4. 2012 Federal Rule IBR Update

Docket 58–0101–1203 ''2012 Federal Rule IBR Update'' revises IDAPA 58.01.01.107 ''Incorporations by Reference'' in several ways. First, the revision updates to July 1, 2012 the citation dates of specific provisions incorporated by reference in IDAPA 58.01.01.107.03 ''Documents Incorporated by Reference.'' Second, the revision repeals certain provisions that are no longer necessary to incorporate by reference. Finally, the revision adds the incorporation by reference of 40 CFR part 70 (State Operating Programs) and renumbers the subparagraphs in the rule.

Subparagraph (a) of IDAPA 58.01.01.107.03 incorporates by reference the Requirements for Preparation, Adoption, and Submittal of Implementation Plans, 40 CFR part 51, with the exception of certain visibility-related provisions, revised as of July 1, 2012. Idaho's update to the incorporation by reference of 40 CFR part 51 includes nonattainment NSR requirements at 40 CFR 51.165. For the reasons discussed in Section II.B.1 below, the EPA is proposing to grant limited approval, as SIP strengthening, to the portion of Idaho's submittal that incorporates by reference updates to the Federal nonattainment NSR requirements at 40 CFR 51.165.

Subparagraphs (b) through (e) and (o) as renumbered, incorporate by reference the following provisions revised as of July 1, 2012: (b) National Primary and Secondary Ambient Air Quality Standards, 40 CFR part 50; (c) Approval and Promulgation of Implementation Plans, 40 CFR part 52, including the Federal PSD permitting rules at 40 CFR 52.21; (d) Ambient Air Monitoring Reference and Equivalent Methods, 40 CFR part 53; (e) Ambient Air Quality Surveillance, 40 CFR part 58; and (o) Determining Conformity of Federal Actions to State or Federal Implementation Plans, 40 CFR part 93, Subpart A, Sections 93.100 through 93.129, although certain subsections are specifically excluded from the State's incorporation by reference. These provisions relate to the criteria pollutants regulated under section 110 of title I of the CAA or other specific requirements of section 110 and, with the exceptions discussed in Section II.B.2 below, make the Idaho SIP consistent with Federal law. The EPA is proposing to approve the revisions to IDAPA 58.01.01.107.03 (b) through (e) and (o) as renumbered, with the following exceptions. We are proposing to disapprove Idaho's incorporation by reference of two provisions of the Federal PSD permitting rules at 40 CFR 52.21 revised by the 2010 PSD $PM_{2.5}$ Implementation Rule (October 20, 2010, 75 FR 64864). Provisions of this rule were recently vacated by a court, as discussed in Section II.B.2 below. We are also proposing to take no action on Idaho's incorporation by reference of a provision of 40 CFR 52.21 revised by the Biogenic Carbon Dioxide ($CO_2$) Deferral Rule that is currently the subject of a judicial challenge, as described in Section II.B.3 below (July 20, 2011, 76 FR 43490).

This docket also repealed subparagraphs (o), (p), and (q) (prior to renumbering) of IDAPA 58.01.01.107.03. Subparagraph (o) incorporated by reference the final rule for Primary National Ambient Air Quality Standards for Sulfur Dioxide, now codified at 40 CFR part 50, 40 CFR part 53, and 40 CFR part 58. Subparagraph (p) incorporated by reference the final rule for Prevention of Significant Deterioration and Title V Greenhouse Gas Tailoring Rule, now codified at 40 CFR part 51, 40 CFR part 52, and 40 CFR part 70. Subparagraph (q) incorporated by reference the 2010 PSD $PM_{2.5}$ Implementation Rule, now codified at 40 CFR part 51 and 40 CFR part 52. Idaho's annual IBR update has since captured the CFR changes made by these three Federal rules, and Idaho has therefore repealed these subparagraphs. We are proposing to approve the repeal of IDAPA 58.01.01.107.03 subparagraphs (o), (p), and (q) (prior to renumbering).

Subparagraphs (f) through (m) of IDAPA 58.01.01.107.03 as renumbered, incorporate by reference the following provisions as of July 1, 2012: (f) Standards of Performance for New Stationary Sources, 40 CFR part 60; (g) National Emission Standards for Hazardous Air Pollutants, 40 CFR part 61; (h) National Emission Standards for Hazardous Air Pollutants for Source Categories, 40 CFR part 63; (i) Compliance Assurance Monitoring, 40 CFR part 64; (j) State Operating Permit Programs, 40 CFR part 70; (k) Permits, 40 CFR part 72; (l) Sulfur Dioxide Allowance System, 40 CFR part 73; and (m) Protection of Stratospheric Ozone, 40 CFR part 82. Consistent with past approvals of the Idaho SIP, we are proposing to not approve the portion of the May 9, 2013, submittal that revises IDAPA 58.01.01.107.03(f) through (m) as renumbered, because these provisions implement other CAA requirements that are not requirements of a SIP under section 110 of the CAA.

*B. Effect of Court Decisions Vacating and Remanding Certain Federal Rules*

1. $PM_{2.5}$ Nonattainment NSR Provisions

On January 4, 2013, the U.S. Court of Appeals in the District of Columbia, in *Natural Resources Defense Council (NRDC)* v. *EPA,* 706 F.3d 428 (DC Cir.), issued a decision that remanded the EPA's 2007 and 2008 rules implementing the 1997 $PM_{2.5}$ NAAQS. Relevant here, the EPA's 2008 implementation rule addressed by the Court decision, ''Implementation of New Source Review (NSR) Program for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$)'' (the 2008 NSR $PM_{2.5}$ Rule),[1] promulgated NSR requirements for implementation of $PM_{2.5}$ in both nonattainment areas (nonattainment NSR) and attainment/unclassifiable areas (PSD). The Court concluded that the EPA had improperly based the implementation rule for the 1997 $PM_{2.5}$ NAAQS solely upon the requirements of part D, subpart 1 of the CAA, and had failed to address the requirements of part D, subpart 4, which establishes additional provisions for particulate matter nonattainment areas. The Court ordered the EPA to ''repromulgate these rules pursuant to Subpart 4 consistent with this opinion.'' *Id.* at 437. As a result of the Court's decision, the EPA withdrew its guidance for implementing the 2006 $PM_{2.5}$ NAAQS[2] because the guidance was based largely on the remanded rule promulgated to implement the 1997 $PM_{2.5}$ NAAQS.[3] The EPA is currently engaged in rulemaking to address the remand from the Court.

In the interim, however, states and the EPA still need to proceed with implementation of the $PM_{2.5}$ NAAQS in a timely and effective fashion in order to meet statutory obligations under the CAA and to assure the protection of public health intended by those NAAQS. In light of the Court's remand of the 2008 NSR $PM_{2.5}$ Rule, the EPA is not prepared at this time to grant full approval to Idaho's incorporation by reference into the Idaho SIP of the Federal nonattainment NSR requirements at 40 CFR 51.165, but instead proposes to grant limited

[1] 73 FR 28321 (May 16, 2008).

[2] Memorandum from Stephen D. Page, Implementation Guidance for the 2006 24-Hour Fine Particulate ($PM_{2.5}$) National Ambient Air Quality Standards (Mar. 2, 2012).

[3] Memorandum from Stephen D. Page, Withdrawal of Implementation Guidance for the 2006 24-Hour Fine Particle ($PM_{2.5}$) National Ambient Air Quality Standards (Jun. 6, 2013).

approval, as SIP strengthening, of this aspect of Idaho's submittal.

The EPA is in the process of evaluating the requirements of subpart 4 as they pertain to nonattainment NSR. In particular, subpart 4 includes section 189(e) of the CAA, which requires the control of major stationary sources of $PM_{10}$ precursors (and hence under the Court decision, $PM_{2.5}$ precursors) ''except where the Administrator determines that such sources do not contribute significantly to $PM_{10}$ levels which exceed the standard in the area.'' The evaluation of which precursors need to be controlled to achieve the standard in a particular area is typically conducted in the context of the State's preparing and the EPA's reviewing of an area's attainment plan SIP. In this case, there is only one designated $PM_{2.5}$ nonattainment area in Idaho, the portion of Franklin County which is part of the cross border Logan, Utah-Idaho nonattainment area for the 2006 24-hour $PM_{2.5}$ NAAQS. Idaho submitted an attainment plan for this area in Idaho (referred to here as ''Franklin County'') on December 14, 2012. On December 26, 2013, the EPA proposed limited approval of the road sanding and woodstove control measures in this plan (78 FR 78315).

In light of the Court's decision in *NRDC* v. *EPA,* and the need to evaluate Idaho's submittal for Franklin County in conjunction with the SIP submittal for the Utah portion of the Logan Utah-Idaho nonattainment area, the EPA is not proposing to make a determination regarding whether Idaho's December 2012 SIP submittal for Franklin County satisfies all of the statutory nonattainment planning requirements for the 2006 $PM_{2.5}$ NAAQS. For similar reasons, and because the EPA is not evaluating in this action Idaho's analysis as to which precursors need to be controlled in the Idaho portion of the Logan Utah-Idaho nonattainment area, the EPA cannot approve as fully complying with the CAA a nonattainment NSR SIP that may address only a subset of the scientific precursors recognized by the EPA. On the other hand, while we have not yet determined if Idaho's submittal for Franklin County contains all of the elements necessary to satisfy the CAA requirements for $PM_{2.5}$ nonattainment areas when evaluated under subpart 4, the revisions proposed in this action to 40 CFR 51.165 (including without limitation the regulation of $PM_{10}$ and $PM_{2.5}$ condensable emissions) represent a strengthening of the currently approved Idaho SIP. Therefore, the EPA is proposing to grant limited approval of the nonattainment NSR provisions in Idaho's 2012 IBR Update.

Because the EPA has not yet proposed revisions to the nonattainment NSR permitting requirements in response to the remand, the EPA is not evaluating at this time whether Idaho's submittal for Franklin County will require additional revisions to satisfy the subpart 4 requirements. Once the EPA repromulgates the Federal $PM_{2.5}$ regulations with respect to nonattainment NSR permitting in response to the *NRDC* v. *EPA* remand, the EPA will consider whether a limited disapproval should also be finalized.[4]

2. $PM_{2.5}$ PSD Provisions

As discussed above in Section II.A.4, IDAPA 58.01.01.107.03(c) incorporates by reference the Federal PSD permitting rules at 40 CFR 52.21. The current Idaho SIP incorporates 40 CFR 52.21 by reference as of July 1, 2010. Docket Number 58–0101–1203 updates the incorporation by reference date of the PSD permitting rules to July 1, 2012, and thus includes revisions to 40 CFR 52.21(i) (relating to the significant monitoring concentration (SMC)) and 40 CFR 52.21(k) (relating to the significant impact level (SIL)) that added a SMC and SIL for $PM_{2.5}$ as part of the 2010 PSD $PM_{2.5}$ Implementation Rule.

On January 22, 2013, the U.S. Court of Appeals for the District of Columbia, in *Sierra Club* v. *EPA,* 703 F.3d 458 (D.C. Cir. 2013), issued, with respect to the SMC, a judgment that, inter alia, vacated the provisions adding the $PM_{2.5}$ SMC to the Federal regulations at 51.166(i)(5)(i)(c) and 52.21(i)(5)(i)(c). In its decision, the Court held that the EPA did not have the authority to use SMCs to exempt permit applicants from the statutory requirement in section 165(e)(2) of the CAA that ambient monitoring data for $PM_{2.5}$ be included in all PSD permit applications. Thus, although the $PM_{2.5}$ SMC was not a required element of a state's PSD program, where a state PSD program contains such a provision and allows issuance of new permits without requiring ambient $PM_{2.5}$ monitoring data, such application of the vacated SMC would be inconsistent with the Court's opinion and the requirements of section 165(e)(2) of the CAA.

At the EPA's request, the decision also vacated and remanded to the EPA for further consideration the portions of the 2010 PSD $PM_{2.5}$ Implementation Rule that revised 40 CFR 51.166 and 40 CFR 52.21 related to SILs for $PM_{2.5}$. The EPA requested this vacatur and remand of two of the three provisions in the EPA regulations that contain SILs for $PM_{2.5}$ because the wording of these two SIL provisions (40 CFR 51.166(k)(2) and 40 CFR 52.21(k)(2)) is inconsistent with the explanation of when and how SILs should be used by permitting authorities that we provided in the preamble to the **Federal Register** publication when we promulgated these provisions. The third SIL provision (40 CFR 51.165(b)(2)) was not vacated and remains in effect. We also note that the Court's decision does not affect the PSD increments for $PM_{2.5}$ promulgated as part of the 2010 PSD $PM_{2.5}$ Implementation Rule. The EPA recently amended its regulations to remove the vacated $PM_{2.5}$ SILs and SMC provisions from the PSD regulations (December 9, 2013, 78 FR 73698). The EPA will initiate a separate rulemaking in the future regarding the $PM_{2.5}$ SILs that will address the Court's remand. In the meantime, the EPA is advising states to begin preparations to remove the vacated provisions from state PSD regulations.

In response to the vacatur of the EPA regulations as they relate to the $PM_{2.5}$ SMC and the $PM_{2.5}$ SILs, Idaho submitted a letter to the EPA, dated October 18, 2013, clarifying that it will not apply either the $PM_{2.5}$ SMC provisions at 40 CFR 52.21(i)(5)(i)(c) or the $PM_{2.5}$ SIL provisions at 40 CFR 52.21(k)(2) in Idaho's implementation of the PSD program. In addition, the October 18, 2013 letter states that Idaho intends to remove the vacated provisions to ensure consistency with Federal law as soon as practicable. Therefore, we are proposing to partially disapprove the Idaho submittal with respect to the incorporation by reference at IDAPA 58.01.01.107.03(c) of the vacated provisions of 40 CFR 52.21 (namely, 40 CFR 52.21(i)(5)(i)(c) and 40 CFR 52.21(k)(2)).

3. PSD Deferral of Certain Emissions From Biogenic Sources

In 2011, the EPA revised the definition of ''subject to regulation'' at 40 CFR 52.21(b)(49)(ii)(*a*) to defer for three years (until July 21, 2014) PSD permitting requirements to $CO_2$ emissions from bioenergy and other biogenic stationary sources (Deferral for $CO_2$ Emissions from Bioenergy and Other Biogenic Sources under the Prevention of Significant Deterioration (PSD) and Title V Programs; Final Rule

[4] As discussed above, Idaho's submittal also includes revisions to the Idaho SIP to update the incorporation by reference of the Federal PSD permitting rule at 40 CFR 52.21. Because the requirements of subpart 4 only pertain to nonattainment areas, the EPA does not consider the portions of the 2008 NSR $PM_{2.5}$ Rule that address requirements for $PM_{2.5}$ attainment and unclassifiable areas (including PSD permitting rules) to be affected by the court's opinion in *NRDC* v. *EPA.*

(July 20, 2011, 76 FR 43490) (Biogenic $CO_2$ Deferral Rule). Idaho's update to incorporate by reference the EPA's PSD permitting rules as of July 1, 2012, includes this revision to 40 CFR 52.21(b)(49)(ii)(*a*). On July 12, 2013, the U.S. Court of Appeals for the District of Columbia, in *Center for Biological Diversity* v. *EPA,* No. 11–1101 (D.C. Cir. July 12, 2013), vacated the Biogenic $CO_2$ Deferral Rule. At this time, the Court has not issued the mandate in this case and the vacatur is therefore not in effect. In light of this situation, we are proposing to take no action on Idaho's incorporation by reference of the revision to 40 CFR 52.21(b)(49)(ii)(*a*) at this time.

The EPA is proposing to approve all other aspects of Idaho's incorporation by reference of 40 CFR 52.21 as of July 1, 2012 in IDAPA 58.01.01.107.03(c), other than those discussed in Sections II.B.2 and II.B.3 of this proposal.

## III. Proposed Action

The EPA is proposing to partially approve the May 9, 2013, submittal from Idaho to update the incorporation by reference of Federal air quality regulations into the SIP and make minor edits and clarifications. Specifically, we are proposing to approve the revisions to IDAPA 58.01.01.107.03 ''Incorporations by Reference,'' except as noted below; IDAPA 58.01.01.006 ''General Definitions;'' IDAPA 58.01.01.220 ''General Exemption Criteria for Permit to Construct Exemptions;'' and IDAPA 58.01.01.222 ''Category II Exemption.'' The EPA is proposing to grant limited approval, as SIP strengthening, to a portion of the submittal that incorporates by reference updates to the Federal nonattainment NSR requirements at 40 CFR 51.165 that have been recently remanded to the EPA by a court.

We are proposing to partially disapprove the revision to IDAPA 58.01.01.107.03(c) as it relates to the incorporation by reference of specific vacated provisions at 40 CFR 52.21 (namely, 40 CFR 52.21(i)(5)(i)(c) and 40 CFR 52.21(k)(2)). We are proposing to take no action on the revision to IDAPA 58.01.01.107.03(c) as it relates to the incorporation by reference of the vacated revision to 40 CFR 52.21(b)(49)(ii)(*a*). Upon final action, the Idaho SIP would incorporate by reference specific Federal regulations as of July 1, 2012.

## IV. Statutory and Executive Order Reviews

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

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

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

### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Particulate matter, and Reporting and recordkeeping requirements.

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

Dated: December 30, 2013.

**Michelle L. Pirzadeh,**

*Acting Regional Administrator, Region 10.*

[FR Doc. 2014–00274 Filed 1–9–14; 8:45 am]

BILLING CODE 6560–50–P

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 745

**[EPA–R06–OPPT–2013–0398; FRL–9905–14–Region 6]**

## Lead-Based Paint Renovation, Repair and Painting, and Pre-Renovation Education Activities in Target Housing and Child Occupied Facilities; Oklahoma; Notice of Self-Certification Program Authorization, and Request for Public Comment on Self-Certification

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Self-certification program authorization and request for comments.

**SUMMARY:** This document announces that on March 25, 2013, the State of Oklahoma was deemed authorized under section 404(a) of the Toxic Substances Control Act (TSCA), to administer and enforce requirements for a renovation, repair and painting program (RRP) and a lead-based paint pre-renovation education program (PRE) in accordance with 406(b) of TSCA. This document also announces that EPA is seeking comment during a 45-day public comment period on the State of Oklahoma's self-certification. This document also announces that the authorization of the Oklahoma 402(c)(3) and 406(b) programs, which was deemed authorized by regulation and statute on March 25, 2013, will continue without further notice unless EPA, based on its own review and/or comments received during the comment period, disapproves this Oklahoma program application.

**DATES:** Comments identified by Docket Control Number EPA–R06–OPPT–2013–0398, must be received on or before February 24, 2014.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Section I of this notice.

**SUPPLEMENTARY INFORMATION:** To ensure proper receipt by EPA, it is important that you identify Docket Control Number EPA–R06–OPPT–2013–0398 in

the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** Cindy Parker, Toxics Section, Toxics, Pesticides and Underground Storage Tanks Branch, Multimedia Planning and Permitting Division, United States Environmental Protection Agency, 1445 Ross Avenue, Ste 1200, Dallas, Texas 75202–2733. The telephone number where Ms. Parker can be reached is: (214) 665–7291. Ms. Parker can be contacted via electronic mail at *parker.cindy@epa.gov.mailto*:

**SUPPLEMENTARY INFORMATION:**

## Table of Contents

I. General Information
II. Background
III. State Program Description Summaries
IV. Federal Overfiling
V. Withdrawal of Authorization

## I. General Information

### *A. Does this action apply to me?*

This action is directed to the public in general, to entities offering Lead Safe Renovation courses, and to firms and individuals engaged in renovation and remodeling activities of pre-1978 housing and child-occupied facilities in the State of Oklahoma. Individuals and firms falling under the North American Industrial Classification System (NAICS) codes 231118, 238210, 238220, 238320, 531120, 531210, 53131, e.g., General Building Contractors/Operative Builders, Renovation Firms, Individual Contractors, and Special Trade Contractors like Carpenters, Painters, Drywall Workers and Plumbers, ''Home Improvement'' Contractors, as well as Property Management Firms and some Landlords are also affected by these rules. This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed here could also be affected. The NAICS codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

### *B. How can I get additional information, including copies of this document or other related documents?*

1. Electronically: you may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at *http://www.epa.gov/* or from *http://www.regulations.gov/*. You can also go directly to the **Federal Register** listings at *http://www.gpoaccess.gov/fr/*.

2. In person: you may read this document, and certain other related documents, by visiting the Oklahoma Department of Environmental Quality, Central Records, 707 North Robinson Street, Oklahoma City, Oklahoma 73102. You should arrange your visit to the ODEQ office by contacting Rhonda Craig, 405–702–0152, or by email at *Rhonda.Craig@deq.ok.gov*. You may also read this document, and certain other related documents, by visiting the United States Environmental Protection Agency, Region 6 Office, 1445 Ross Avenue, Ste 700, Dallas, TX 75202. You should arrange your visit to the EPA office by contacting the technical person listed under **FOR FURTHER INFORMATION CONTACT**. Also, EPA has established an official record for this action under Docket Control Number EPA–R06–OPPT–2013–0398. The official record consists of the documents specifically referenced in this action, this notice, the State of Oklahoma 402(c)(3) and 406(b) program authorization applications, documents related to EPA's offer to consult with any affected Tribes in Oklahoma, any public comments received during an applicable comment period, and other information related to this action.

### *C. How and to whom do I submit comments?*

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is important that you identify Docket Identification Number EPA–R06–OPPT–2013–0398 in the subject line on the first page of your response.

Submit your comments, by one of the following methods:

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

2. *By mail:* Submit your comments and hearing requests to: Cindy Parker, Toxics Section, 6PD–T, United States Environmental Protection Agency, 1445 Ross Avenue, Ste 1200, Dallas, Texas 75202–2733.

3. *By person or courier:* Deliver your comments and hearing requests to: Cindy Parker, Toxics Section, Multimedia Planning and Permitting Division, United States Environmental Protection Agency, 1445 Ross Avenue, Ste 700, Dallas, Texas 75202–2733. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding federal holidays.

4. *By fax:* 214–665–6655.

5. *By email:* You may submit your comments and hearing requests electronically by email to: *parker.cindy@epa.gov,* or mail your computer disk to the address identified above. Do not submit any information electronically that you consider Confidential Business Information (CBI). Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on standard disks in Microsoft Word or ASCII file format.

*Instructions:* Direct your comments to Docket ID Number EPA–R06–OPPT–2013–0398. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters or any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

*Docket:* All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either

electronically in *http://www.regulations.gov* or in hard copy.

*D. How should I handle CBI information that I want to submit to the agency?*

Do not submit this information to EPA through *regulations.gov* or email. Clearly mark on each page the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM that you mail to EPA as CBI, and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. If you have any questions about CBI or the procedures for claiming CBI, please consult the technical person identified 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 use.
3. Provide copies of any technical information and/or data you use that support your views.
4. If you estimate potential burden or costs, explain how you arrive 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 notice.
8. To ensure proper receipt by EPA, identify the Docket Control Number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

## II. Background

*A. What action is the agency taking?*

EPA is announcing that the State of Oklahoma on March 25, 2013, was deemed authorized under section 404(a) of TSCA, 15 U.S.C. 2684(a) and 40 CFR 745.324(d)(2), to administer and enforce requirements for a renovation, repair and painting program in accordance with section 402(c)(3) of TSCA, 15 U.S.C. 2682(c)(3), and a lead-based paint pre-renovation education program in accordance with section 406(b) of TSCA, 15 U.S.C. 2686(b). This notice also announces that EPA is seeking comment on Oklahoma's self-certification. The 402(c)(3) program ensures that training providers are accredited to teach renovation classes, that individuals performing renovation activities are properly trained and certified as renovators, that firms are certified as renovation firms, and that specific work practices are followed during renovation activities. The 406(b) program ensures that owners and occupants of target housing are provided information concerning potential hazards of lead-based paint exposure before certain renovations are begun.

On March 25, 2013, Oklahoma submitted an application under section 404 of TSCA requesting authorization to administer and enforce requirements for a renovation, repair and painting program in accordance with section 402(c)(3) of TSCA, and a pre-renovation education program in accordance with section 406(b) of TSCA, and submitted a self-certification that these programs are at least as protective as the federal programs and provide for adequate enforcement. Therefore, pursuant to section 404(a) of TSCA, and 40 CFR 745.324(d)(2), the Oklahoma renovation program and pre-renovation education program are deemed authorized as of the date of submission and until such time as the Agency disapproves the program application or withdraws program authorization. Pursuant to section 404(b) of TSCA and 40 CFR 745.324(e)(2), EPA is providing notice and an opportunity for public comment on Oklahoma's self-certification. The authorization of the Oklahoma 402(c)(3) and 406(b) programs, which were deemed authorized by EPA on March 25, 2013, will continue without further notice unless EPA, based on its own review and/or comments received during the comment period, disapproves one or both of these Oklahoma program applications. Oklahoma is not authorized to carry out its RRP or PRE programs in ''Indian Country'', as defined in 18 USC 1151. Therefore, this action has no effect on Indian country. EPA retains the authority to implement and administer the RRP and PRE programs on these lands.

In accordance with the EPA policy on Consultation and Coordination with Indian Tribes, EPA Region 6 has offered government-to-government consultation to all Tribes within the State of Oklahoma. Any requested consultations will be conducted in accordance with the policy and completed by the date of the end of the public comment period February 24, 2014. Tribal consultation will be conducted in accordance with the EPA policy on Consultation and Coordination with Indian Tribes (*www.epa.gov/tribal/consultation/consult-policy.htm*).

*B. What is EPA's authority for taking this action?*

On October 28, 1992, the Housing and Community Development Act of 1992, Public Law 102–550, became law. Title X of that statute was the Residential Lead-Based Paint Hazard Reduction Act of 1992. That Act amended TSCA (15 U.S.C. 2601 et seq.) by adding Title IV (15 U.S.C. 2681–2692), entitled ''Lead Exposure Reduction.'' On April 22, 2008, EPA promulgated the final TSCA section 402(c)(3) regulations governing renovation activities. *See* 73 FR 21692. These regulations require that in order to do renovation activities for compensation, renovators must first be properly trained and certified, must be associated with a certified renovation firm, and must follow specific work practice standards, including recordkeeping requirements. In addition, the rule prescribes requirements for the training and certification of dust sampling technicians. On June 1, 1998, EPA promulgated the final TSCA section 406(b) regulations governing pre-renovation education requirements in target housing. *See* 63 FR 29908. This program ensures that owners and occupants of target housing are provided information concerning potential hazards of lead-based paint exposure before certain renovations are begun on that housing. In addition to providing general information on the health hazards associated with exposure to lead, EPA developed the lead hazard information pamphlet. This pamphlet advises owners and occupants to take appropriate precautions to avoid exposure to lead-contaminated dust and debris that are sometimes generated during renovations. EPA believes that regulation of renovation activities and the distribution of the pamphlet will help to reduce the exposures that cause serious lead poisonings, especially in children under age 6, who are particularly susceptible to the hazards of lead.

Under section 404 of TSCA, a state may seek authorization from EPA to administer and enforce its own pre-renovation education program or renovation, repair and painting program in lieu of the federal programs. The

regulations governing the authorization of a state program under both sections 402 and 406 of TSCA are codified at 40 CFR Part 745, subpart Q. States that choose to apply for program authorization must submit a complete application to the appropriate regional EPA office for review. Those applications will be reviewed by EPA within 180 days of receipt of the complete application. To receive EPA approval, a state must demonstrate that its program is at least as protective of human health and the environment as the federal program, and provides for adequate enforcement, as required by Section 404(b) of TSCA. EPA's regulations at 40 CFR Part 745, subpart Q, provide the detailed requirements a state program must meet in order to obtain EPA approval. A state may choose to certify that its own pre-renovation education program or renovation, repair and painting program meets the requirements for EPA approval, by submitting a letter signed by the Governor or Attorney General stating that the program is at least as protective of human health and the environment as the federal program and provides for adequate enforcement. Upon submission of such a certification letter, the program is deemed authorized pursuant to TSCA section 404(a) and 40 CFR 745.324(d)(2). This authorization becomes ineffective, however, if EPA disapproves the application or withdraws the program authorization.

## III. State Program Description Summaries

A. The following excerpt is from the renovation, repair and painting program description submitted in Oklahoma's self-certification application:

The Oklahoma Department of Environmental Quality (DEQ) submits this application with the intent of self-certifying for authorization of the federal Renovation, Repair and Painting (RRP) program, along with the Pre-Renovation Education program. The Department of Environmental Quality (DEQ) currently administers a comprehensive lead-based paint (LBP) management program in Oklahoma with the authority of the ''Oklahoma LBP Management Act'' (Act), 27A Okla Stat. (O.S.) § 2–12–101 *et seq.* The LBP Management Rules, Okla. Admin. Code (OAC) 252:110–1–1 *et seq.* (Chapter 110) were adopted to fulfill the mandates of the Act. The Chapter 110 rules establish mechanisms for certification of individuals and firms, accreditation of training providers, and implementation of performance standards for LBP services. Chapter 110 was updated, and a new Subchapter 15 was added in 2012 to allow the DEQ to seek delegation of the RRP program.

In general, the RRP provisions in 40 CFR Part 745 Subpart E were incorporated by reference into the Oklahoma Administrative Code. The items not incorporated by reference are those that are otherwise mandated by the Act, or that were modified to blend the RRP program into the existing state program. The differences are minor and all concern the accreditation of training providers.

The LBP/RRP program is administered by the Air Quality Division of the DEQ. The point of contact for this program is Randall Ward, Environmental Programs Manager, who can be reached by mail at Oklahoma Department of Environmental Quality, Air Quality Division, P.O. Box 1677, 707 N. Robinson, Oklahoma City, OK 73101–1677, by telephone at (405) 702–4128 or by fax at (405) 702–4101.

Public rulemaking hearings for the adoption of the RRP program were held in conjunction with approval of the revised Chapter 110 rules, and the rules were affirmatively approved by the Oklahoma State Legislature and the Governor on May 1, 2012. Public hearings were noticed in accordance with the Oklahoma Administrative Procedures Act, and were held on January 19, 2011; July 20, 2011; and October 5, 2011 before the Oklahoma Air Quality Council. The rules were approved by the Council on October 5, 2011, and after another public hearing on February 24, 2012 were approved by Oklahoma Environmental Quality Board.

The Air Quality Division (AQD) has existed (within the Oklahoma State Department of Health and later within the DEQ) since 1971. The LBP Program is administered by the AQD and staffed by the Technical Resources and Projects Section. The various LBP program duties (enforcement, compliance, inspections, certification, accreditation, public education) are accomplished through the efforts of three full-time equivalent employees.

For both LBP activity training and the RRP training, the Oklahoma LBP Management Rules (Rules) incorporate by reference the federal accreditation requirements in 40 CFR 745.225, except for those subsections that address application dates, accreditation deadlines, accredited training courses, programs that offer only refresher courses, renewal timelines, and renewal deadlines. In addition to providing the various dates, timelines and deadlines not incorporated by reference from the federal rule, the Rules limit accreditation to educational institutions and government agencies that offer ongoing and continuous LBP training programs. In addition to the incorporations by reference, Oklahoma rules provide for provisional accreditation, OAC 252:110–9–5. A stakeholder task force strongly recommended an on-site evaluation of the training prior to issuing final accreditation in order to ensure that the training organization operates according to the information given in the accreditation application. Provisional accreditation allows the training facility to provide training under the conditions outlined in OAC 252:110–9–5. EPA rules do not provide for an on-site evaluation of the training program prior to the issuance of final accreditation. Therefore, Oklahoma's provisional accreditation is essentially equivalent to EPA's final accreditation. DEQ further ensures quality training by requiring an on-site evaluation before final accreditation is issued.

Refresher courses can be accredited only if the training program has received accreditation for the initial discipline-specific training course. Programs that have been accredited by another state or agency must apply for and receive accreditation from DEQ before conducting or advertising a training course in Oklahoma. An accredited training program must notify the DEQ of course offerings, significant changes in the program, course cancellations, and personnel changes. Annual renewal is required and is based on documented implementation of compliance updates as well as satisfactory course and instructor evaluations.

The Oklahoma RRP program is identical to the federal program except for the accreditation requirements.

*Program Elements*

a. Public Information and Outreach

Program information (applications, regulations, statutes, lists of certified contractors, educational materials, etc.) is mailed to customers upon request. Increasingly, most of this information can be obtained through the Internet. The LBP Program pages are contained in the ''Air Quality'' subset of the DEQ Home Page (*http://www.deq.state.ok.us*). As program resources allow, and dependent on public demand, public outreach and education activities are performed.

b. Accreditation of Training Providers

The federal program for accreditation of LBP training providers is established in 40 CFR 745.225. DEQ incorporated this federal rule by reference in OAC

252:110–5–1(2) with the following exceptions.

745.225(a)(2), which refers to application dates,

745.225(a)(3), which refers to accreditation deadlines,

745.225(f)(1), which refers to timelines for renewal of accreditation of training programs, and

745.225(f)(2), which refers to renewal accreditation deadlines.

27A O.S. 2–12–303(D) establishes an annual renewal year for accreditations from September 1 through August 31. Likewise, accreditation timelines are established in OAC 252:110–7–2(c). In addition to incorporating by reference 745.225(f)(3) and (f)(4), DEQ provides criteria for re-accreditation of training programs at OAC 252:110–9–7.

745.225(b)(3), which refers to accredited training courses, and

745.225(e)(5), which refers to training programs offering refresher training courses.

These federal rules permit a training program to offer refresher courses only. Per the eligibility requirements established in OAC 252:110–9–1, ''Training programs shall not receive accreditation for a refresher course if they do not also receive accreditation for the discipline-specific initial training course.'' This section also limits accreditation to ''educational institutions and government agencies''.

c. Certification of Individuals and Firms

Under the federal RRP program as incorporated by reference in the Oklahoma regulations, individuals receive their certification by completing courses at accredited training providers. RRP firms are certified by the state using the federal procedure except for the transition period from EPA to Oklahoma delegation. In that period, EPA certified firms may transfer their certification to Oklahoma without payment of fees until the certification expires.

d. Enforcement and Compliance

The Oklahoma RRP program will rely heavily upon DEQ's Complaints system. Since 1993 the state-wide complaints program has allowed citizens access to a toll-free hotline and local Environmental Program Specialists who can provide assistance and information. The complaints system is also important to the LBP activities programs as it allows industry competitors access to an anonymous reporting system.

Although the DEQ prefers education and compliance assistance for small businesses, the LBP/RRP program is fully supported by the DEQ's enforcement authority. DEQ has the statutory authority to perform inspections, pursue enforcement actions, and assess penalties.

Authority To Enter

State law (27A O.S. § 2–3–501) grants the authority for duly authorized representatives of the DEQ to enter, through consent or warrant, any private or public property where lead-based paint activities or training may occur to conduct inspections, take samples, and review records. Further, the Oklahoma LBP Management Act grants DEQ the power to enforce the rules, collect samples for enforcement purposes, and otherwise exercise the incidental powers necessary for enforcement. See 27A O.S. § 2–12–202(B). DEQ has further addressed the issue of entrance for inspection purposes in OAC 252:110–7–3(c), whereby holders of DEQ issued ''authorizations'' (such as certifications and accreditations) have a duty to allow DEQ representatives the right to inspect.

Enforcement Remedies

All environmental programs administered by DEQ are designed to focus agency efforts on assisting the regulated community with the common goal of compliance with environmental regulations. Article III, Part 5 of the ''Oklahoma Environmental Quality Code,'' (27A O.S. § 2–1–102, *et seq.*), provides for the general enforcement of the DEQ rules, permits, and orders and extends to all programs administered by the DEQ (27A O.S. § 2–3–506(D)). The aforementioned remedies are in addition to those found in other Oklahoma law, including criminal statutes contained in Title 21 of the Oklahoma Statutes. The civil enforcement remedies include:

i. Letters and Notices

Notices of Violation. 27A O.S. § 2–3–502(A).

ii. Penalty Authority

The DEQ may issue Administrative Compliance Orders, which may include administrative penalties for past violations and stipulated penalties for violations of Orders, and which may specify compliance requirements and schedules and/or corrective action (27A O.S. § 2–3–502(B)). After notice and opportunity for an administrative hearing, the DEQ may revoke, modify or suspend the holder's license in part or in whole (27A O.S. § 2–3–502(D)). The DEQ may also seek injunctive relief to compel compliance with or prevent violation of any section of the Code or any license or order issued pursuant thereto (27A O.S. § 2–3–504(A)(4)). Violations may be punished by monetary penalties assessed in administrative proceedings (27A O.S. § 2–3–502(K)), or in civil proceedings (27A O.S. § 2–3–504(A)(2)), not to exceed $10,000.00 per day of noncompliance.

iii. Criminal Authority

The DEQ may request either the Attorney General or the district attorney of the appropriate district court of Oklahoma to criminally prosecute anyone who violates the Code, rules promulgated thereunder, or orders issued, or conditions of permits, licenses, certificates or other authorizations prescribed pursuant thereto (27A O.S. § 2–3–504(I)). Such violations are misdemeanors, punishable by a fine of not less than $200.00 for each violation and not more than $10,000.00 for each violation and/or by imprisonment in the county jail for not more than six months (27A O.S. § 2–3–504(A)(1)). In addition, anyone who knowingly makes a false statement in, or omits material data from, any application for a permit, license, certificate or other authorization, or any notice, analyses or report required by the Code, rules promulgated thereunder, or permit, license, certificate or other authorization issued pursuant thereto, or who knowingly alters any sample may be guilty of a misdemeanor and subject to a fine of not more than $5,000.00 for each such violation (27A O.S. § 2–3–505). Criminal sanctions may also be imposed pursuant to Oklahoma's Penal Code. For example, persons who make false statements when advertising a service can be guilty of a misdemeanor under 21 O.S. § 1502. Whether a violation will be recommended for criminal prosecution is a case-by-case decision to be based upon the willfulness and severity of the violation as well as the effect on human health and the environment.

B. The following summary is an excerpt from Oklahoma's renovation, repair and painting program self-certification application:

Because the Oklahoma Lead-Based Paint program already included EPA-approved training provider elements that are considerably more stringent than the federal program, Oklahoma chose to maintain that portion of the Lead-Based Paint program for use with the new RRP program. The differences include: Requirements that only educational institutions and government agencies may become accredited; providers must offer on-going programs that include both initial and refresher

training; and requirements for inspections, annual reviews, and renewal. Fees for training providers were also modified so that the annual renewal would not lead to a fee increase over the EPA program.

During the public hearings before the Air Quality Council, concerns were raised that the DEQ RRP program would cause financial hardship on renovation firms and training providers that were already approved by EPA at the time of delegation approval and might have several years left before they were required to renew under the EPA program. In response, the proposed rules were amended to include transition language exempting EPA-approved firms and training providers from fees until the expiration of their EPA-approval.

The Oklahoma RRP program will utilize the existing accreditation structure of inspections and close review to ensure a quality training system. The existing DEQ enforcement system will also apply to the RRP program, but for the RRP firms and their work practices, much of the enforcement will come through the DEQ complaint system. The complaint system uses a toll-free state wide number, strict timelines for response and investigation, and referral to the various DEQ divisions for expert follow-up. The DEQ complaint system is well-established and has proven effective in all programs, including the Oklahoma LBP activities program. The activities program provides a network of individuals and firms throughout the state that also self-monitor to assist in compliance.

## IV. Federal Overfiling

Section 404(b) of TSCA makes it unlawful for any person to violate, or fail or refuse to comply with, any requirement of an approved state program. Therefore, EPA reserves the right to exercise its enforcement authority under TSCA against a violation of, or a failure or refusal to comply with, any requirement of an authorized state program.

## V. Withdrawal of Authorization

Pursuant to section 404(c) of TSCA, the EPA Administrator may withdraw authorization of a State or Indian tribal renovation, repair and painting program, and/or a lead-based paint pre-renovation education program, after notice and opportunity for corrective action, if the program is not being administered or enforced in compliance with standards, regulations, and other requirements established under the authorization. The procedures U.S. EPA will follow for the withdrawal of an authorization are found at 40 CFR 745.324(I).

## List of Subjects in 40 CFR 745

Environmental protection, Hazardous substances, Lead poisoning, Reporting and recordkeeping requirements.

Dated: December 19, 2013.

**Ron Curry,**

*Regional Administrator, Region 6.*

[FR Doc. 2014–00270 Filed 1–9–14; 8:45 am]

BILLING CODE 6560–50–P

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## 42 CFR Part 100

**RIN 0906–AB00**

## National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice of public hearing.

**SUMMARY:** This document announces a public hearing to receive information and views on the Notice of Proposed Rulemaking (NPRM) entitled ''National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table.''

**DATES:** The public hearing will be held on January 13, 2014, from 10:30 a.m.–12 p.m. (EDT).

**ADDRESSES:** The public hearing will be held in Conference Room 10–65 in the Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

**FOR FURTHER INFORMATION CONTACT:** Dr. Vito Caserta, Acting Director, Division of Vaccine Injury Compensation, at 855–266–2427 or by email *vcaserta@hrsa.gov.*

**SUPPLEMENTARY INFORMATION:** The National Childhood Vaccine Injury Act of 1986, Title III of Public Law 99–660, as amended (42 U.S.C. 300aa–10 et seq.), established the National Vaccine Injury Compensation Program (VICP) for persons found to be injured by vaccines. The Secretary has taken the necessary initial steps to propose to amend the Vaccine Injury Table to add intussusception as an injury associated with rotavirus vaccines.

The NPRM was published in the **Federal Register**, July 24, 2013: 78 FR 44512. The public comment period closes January 21, 2014.

A public hearing will be held during the 180-day public comment period. This hearing is to provide an open forum for the presentation of information and views concerning all aspects of the NPRM by interested persons.

In preparing a final regulation, the Secretary will consider the administrative record of this hearing along with all other written comments received during the comment period specified in the NPRM. Individuals or representatives of interested organizations are invited to participate in the public hearing in accord with the schedule and procedures set forth below.

The hearing will be held on January 13, 2014, beginning at 10:30 a.m. and ending at 12 p.m. (EDT) in Conference Room 10–65 in the Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Upon entering the Parklawn Building, persons who wish to attend the hearing will be required to call Ms. Andrea Herzog at (301) 443–6634 to be escorted to Conference Room 10–65.

The public can also join the meeting via audio conference call:

Audio Conference Call: Dial 800–369–3104 and provide the following information:

Leader's Name: Dr. Vito Caserta

Password: HRSA

The presiding officer representing the Secretary, HHS will be Dr. Vito Caserta, Acting Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau (HSB), Health Resources and Services Administration.

Persons who wish to participate are requested to file a notice of participation with the Department of Health and Human Services (HHS) on or before January 9, 2014. The notice should be mailed to the Division of Vaccine Injury Compensation, HSB, Room 11C–26, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857 or emailed to *aherzog@hrsa.gov.* To ensure timely handling, any outer envelope or the subject line of an email should be clearly marked ''VICP NPRM Hearing.'' The notice of participation should contain the interested person's name, address, email address, telephone number, any business or organizational affiliation of the person desiring to make a presentation, a brief summary of the presentation, and the approximate time requested for the presentation. Groups that have similar interests should consolidate their comments as part of one presentation. Time available for the hearing will be allocated among the persons who properly file notices of participation. If time permits, interested parties attending the hearing who did not submit notice of participation in advance will be allowed to make an oral presentation at the conclusion of the hearing.

Persons who find that there is insufficient time to submit the required information in writing may give oral notice of participation by calling Andrea Herzog, Division of Vaccine Injury Compensation, at (301) 443–6634, no later than January 9, 2014.

After reviewing the notices of participation and accompanying information, HHS will schedule each appearance and notify each participant by mail, email, or telephone of the time allotted to the person(s) and the approximate time the person's oral presentation is scheduled to begin.

Written comments and transcripts of the hearing will be made available for public inspection as soon as they have been prepared, on weekdays (federal holidays excepted) between the hours of 8:30 a.m. and 5 p.m. (EDT) at the Division of Vaccine Injury Compensation, Room 11C–26, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Dated: January 6, 2014.

**Kathleen Sebelius,**

*Secretary.*

[FR Doc. 2014–00199 Filed 1–9–14; 8:45 am]

**BILLING CODE 4165–15–P**

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## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

### 50 CFR Part 17

**[Docket Nos. FWS–R8–ES–2012–0100; FWS–R8–ES–2012–0074; 4500030113]**

**RIN 1018–AZ21; RIN 1018–AY07**

## Endangered and Threatened Wildlife and Plants; Endangered Status for the Sierra Nevada Yellow-Legged Frog and the Northern Distinct Population Segment of the Mountain Yellow-Legged Frog, and Threatened Status for the Yosemite Toad and Designation of Critical Habitat

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Proposed rules; reopening of the comment periods.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), announce the reopening of the public comment period on our April 25, 2013, proposed rule to list the Sierra Nevada yellow-legged frog and the northern distinct population segment (DPS) of the mountain yellow-legged frog (populations that occur north of the Tehachapi Mountains) as endangered species, and the Yosemite toad as a threatened species under the Endangered Species Act of 1973, as amended (Act). We are also reopening the public comment period on our April 25, 2013, proposed rule to designate critical habitat for these species. We also announce the availability of a draft economic analysis (DEA) of the proposed designation of critical habitat for the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad and an amended required determinations section of the proposal. We are also announcing the location and time of a public hearing to receive public comments on the proposals, as well as the times and locations of two public meetings. We are reopening the comment periods to allow all interested parties an opportunity to comment simultaneously on the proposed rules, the associated DEA, and the amended required determinations section. Comments previously submitted need not be resubmitted, as they will be fully considered in preparation of the final rule.

**DATES:** We will consider comments on the proposed rules published April 25, 2013 (78 FR 24472 and 78 FR 24516) received or postmarked on or before March 11, 2014. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** section, below) must be received by 11:59 p.m. Eastern Time on the closing date.

*Public Hearing:* We will hold a public hearing on these proposed rules in Sacramento, California, on January 30, 2014, at 1:00 p.m. and again at 6:00 p.m. (see **ADDRESSES**).

*Public Meetings:* We will hold two public meetings to provide information on these proposed rules in Bridgeport, California, on January 8, 2014, from 1:00 p.m. to 3:00 p.m. and in Fresno, California, on January 13, 2014, from 1:00 p.m. to 3:00 p.m. (see **ADDRESSES**).

**ADDRESSES:**

*Document availability:* You may obtain copies of the proposed rules and the associated documents of the draft economic analysis on the internet at *http://www.regulations.gov* at Docket No. FWS–R8–ES–2012–0100 and Docket No. FWS–R8–ES–2012–0074 or by mail from the Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

*Written comments:* You may submit written comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* Search for Docket No. FWS–R8–ES–2012–0100 (the docket number for the proposed listing rule) or FWS–R8–ES–2012–0074 (the docket number for the proposed critical habitat rule).

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R8–ES–2012–0100 (if commenting on the proposed listing rule) or FWS–R8–ES–2012–0074 (if commenting on the proposed critical habitat rule); Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Comments section below for more information).

*Public informational sessions and public hearing:* The public informational sessions and hearing will be held at Mono County Board of Supervisors Chambers in the Mono County Courthouse, State Highway 395 North, Bridgeport, CA 93517, and the Fresno County Board of Supervisors Chambers in the Hall of Records, Room 301, 2281 Tulare Street, Fresno, CA 93721. The hearing will be held at the Sacramento Horsemen's Association, 3200 Longview Drive, Sacramento, CA 9582. People needing reasonable accommodations in order to attend and participate in the public hearing should contact Jennifer Norris, Field Supervisor, Sacramento Fish and Wildlife Office, as soon as possible (see **FOR FURTHER INFORMATION CONTACT**).

**FOR FURTHER INFORMATION CONTACT:** Jennifer Norris, Field Supervisor, U.S. Fish and Wildlife Service, Sacramento Fish and Wildlife Office, 2800 Cottage Way Room W–2605, Sacramento CA 95825; by telephone 916–414–6600; or by facsimile 916–414–6712. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

**SUPPLEMENTARY INFORMATION:**

### Public Comments

We will accept written comments and information during this reopened comment period on our proposed rule to list the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog as endangered species, and the Yosemite toad as a threatened species, that was published in the **Federal Register** on April 25, 2013 (78 FR 24472). We will consider information and recommendations from all interested parties. We are particularly interested in comments concerning:

(1) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to these species, and regulations that may be addressing those threats.

(2) Additional information concerning the historical and current status, range, distribution, and population size of these species, including the locations of any additional populations of these species.

(3) Any information on the biological or ecological requirements of these species, and ongoing conservation measures for these species and their habitats.

(4) The factors that are the basis for making a listing determination for a species under section 4(a) of the Act (16 U.S.C. 1531 *et seq.*), which are:

(a) The present or threatened destruction, modification, or curtailment of its habitat or range;

(b) Overutilization for commercial, recreational, scientific, or educational purposes;

(c) Disease or predation;

(d) The inadequacy of existing regulatory mechanisms; or

(e) Other natural or manmade factors affecting its continued existence.

(5) Land use designations and current or planned activities in the areas occupied by the species, and possible impacts of these activities on these species.

(6) Information on the projected and reasonably likely impacts of climate change on the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad.

(7) Input on whether we should retain the northern and southern DPSs of the mountain yellow-legged frog in the final rule or should we combine the two DPSs into one listed entity for the species.

We will also accept written comments and information during this reopened comment period on our proposed designation of critical habitat for the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad, which was published in the **Federal Register** on April, 25, 2013 (78 FR 24516), our DEA of the proposed designation, and the amended required determinations provided in this document. We will consider information and recommendations from all interested parties. We are particularly interested in comments concerning:

(1) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act (16 U.S.C. 1531 *et seq.*), including whether there are threats to these species from human activity, the degree of which can be expected to increase due to the designation, and whether that increase in threat outweighs the benefit of designation such that the designation of critical habitat is not prudent.

(2) Specific information on:

(a) The amount and distribution of Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and Yosemite toad, and their habitats;

(b) What may constitute ''physical or biological features essential to the conservation of the species,'' within the geographical range currently occupied by the species;

(c) Where these features are currently found;

(d) Whether any of these features may require special management considerations or protection;

(e) Which areas currently occupied contain features essential to the conservation of these species should be included in the designation, and why; and

(f) Which areas not currently occupied are essential for the conservation of these species, and why.

(3) Land use designations and current or planned activities in the areas occupied by the species or proposed to be designated as critical habitat, and possible impacts of these activities on these species and their proposed critical habitats.

(4) Information on the projected and reasonably likely impacts of climate change on the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad, and on their proposed critical habitats and whether the critical habitat may adequately account for these potential effects. We also seek information on special management considerations or protection that may be needed in the proposed critical habitat areas, including management for the potential effects of climate change.

(5) Any probable economic, national security, or other relevant impacts that may result from designating any area as critical habitat that may be included in the final designation. We are particularly interested in any impacts on small entities, and the benefits of including or excluding areas from the proposed designation that are subject to these impacts.

(6) Information on the extent to which the description of probable economic impacts in the DEA is complete and accurate, and specifically:

(a) Whether there are incremental costs of critical habitat designation (for example, costs attributable solely to the designation of critical habitat for the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad) that have not been appropriately identified or considered in our economic analysis, including costs associated with future administrative costs or project modifications that may be required by Federal agencies related to section 7 consultation under the Act; and

(b) Whether there are additional project modifications that may result from the designation of critical habitat for the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad, and what those potential project modifications might represent.

(7) The likelihood of adverse social reactions to the designation of critical habitat as discussed in the DEA and how the consequences of such reactions, if likely to occur, would relate to the conservation and regulatory benefits of the proposed critical habitat designation.

(8) Whether any specific areas proposed for critical habitat designation should be considered for exclusion under section 4(b)(2) of the Act, and whether the benefits of potentially excluding any specific area outweigh the benefits of including that area under section 4(b)(2) of the Act.

(9) Whether our approach to designating critical habitat could be improved or modified in any way to provide for greater public participation and understanding, or to assist us in accommodating public concerns and comments.

If you submitted comments or information on the proposed rule (78 FR 24516) during either of the previous comment periods from April 25, 2013, to June 24, 1013, or July 19, 2013, to November 18, 2013, please do not resubmit them. We will incorporate them into the public record as part of this comment period, and we will fully consider them in the preparation of our final determination. Our final determination concerning critical habitat will take into consideration all written comments and any additional information we receive during the comment periods. On the basis of public comments, we may, during the development of our final determination, find that areas proposed are not essential, are appropriate for exclusion under section 4(b)(2) of the Act, or are not appropriate for exclusion.

You may submit your comments and materials concerning the proposed rules or DEA by one of the methods listed in **ADDRESSES**. We request that you send

comments only by the methods described in **ADDRESSES**.

If you submit a comment via *http://www.regulations.gov,* your entire comment—including any personal identifying information—will be posted on the Web site. We will post all hardcopy comments on *http://www.regulations.gov* as well. If you submit a hardcopy comment that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documentation we used in preparing the proposed listing, proposed critical habitat, and DEA, will be available for public inspection on *http://www.regulations.gov* at Docket Number FWS–R8–ES–2012–0100 for the proposed listing and Docket Number FWS–R8–ES–2012–0074 for the proposed critical habitat, or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**). You may obtain copies of the proposed rule to designate critical habitat and the DEA on the Internet at *http://www.regulations.gov* at Docket Number FWS–R8–ES–2012–0100 for the proposed listing and Docket Number FWS–R8–ES–2012–0074 for the proposed critical habitat, or by mail from the Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT** section).

## Background

It is our intent to discuss only those topics directly relevant to the designation of critical habitat for Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad in this document. For more information on previous Federal actions concerning the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad, refer to the proposed designation of critical habitat published in the **Federal Register** on April 25, 2013 (78 FR 24516). For more information on the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad or its habitat, refer to the proposed listing rule published in the **Federal Register** on April 25, 2013 (78 FR 24472). Both are available online at *http://www.regulations.gov* (at Docket Number FWS–R8–ES–2012–0074 for the listing and Docket Number FWS–R8–ES–2012–0100 for the critical habitat designation) or from the Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

On April 24, 2013, we published a proposed rule to designate critical habitat for the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad (78 FR 24516). We proposed to designate approximately 447,341 hectares (1,105,400 acres) as critical habitat for the Sierra Nevada yellow-legged frog in Butte, Plumas, Lassen, Sierra, Nevada, Placer, El Dorado, Amador, Calaveras, Alpine, Mariposa, Mono, Madera, Tuolumne, Fresno, and Inyo Counties, California as critical habitat; approximately 89,637 hectares (221,498 acres) as critical habitat for the northern DPS mountain yellow-legged frog in Fresno and Tulare Counties, California; and approximately 303,889 hectares (750,926 acres) as critical habitat for Yosemite toad in Alpine, Tuolumne, Mono, Mariposa, Madera, Fresno, and Inyo Counties, California. That proposal had an initial 60-day comment period, ending June 24, 2013; however, we reopened the comment period from July 19, 2013, to November 18, 2013 (78 FR 45122). We anticipate submitting for publication in the **Federal Register** a final critical habitat designation for Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad on or before April 25, 2014, if we finalize our proposed rule to list the species under the Act.

### *Critical Habitat*

Section 3 of the Act defines critical habitat as the specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features essential to the conservation of the species and that may require special management considerations or protection, and specific areas outside the geographical area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. If the proposed rule is made final, section 7 of the Act will prohibit destruction or adverse modification of critical habitat by any activity funded, authorized, or carried out by any Federal agency. Federal agencies proposing actions affecting critical habitat must consult with us on the effects of their proposed actions, under section 7(a)(2) of the Act.

## Consideration of Impacts Under Section 4(b)(2) of the Act

Section 4(b)(2) of the Act requires that we designate or revise critical habitat based upon the best scientific data available, after taking into consideration the economic impact, impact on national security, or any other relevant impact of specifying any particular area as critical habitat. We may exclude an area from critical habitat if we determine that the benefits of excluding the area outweigh the benefits of including the area as critical habitat, provided such exclusion will not result in the extinction of the species.

When considering the benefits of inclusion for an area, we consider among other factors, the additional regulatory benefits that an area would receive through the analysis under section 7 of the Act addressing the destruction or adverse modification of critical habitat as a result of actions with a Federal nexus (activities conducted, funded, permitted, or authorized by Federal agencies), the educational benefits of identifying areas containing essential features that aid in the recovery of the listed species, and any ancillary benefits triggered by existing local, State or Federal laws as a result of the critical habitat designation.

When considering the benefits of exclusion, we consider, among other things, whether exclusion of a specific area is likely to incentivize or result in conservation; the continuation, strengthening, or encouragement of partnerships; and the implementation of a management plan. In the case of the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad, the benefits of critical habitat include public awareness of the presence of these species, and the importance of habitat protection. Where a Federal nexus exists, critical habitat would benefit the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad though increased habitat protection due to protection from adverse modification or destruction of critical habitat. In practice, situations with a Federal nexus exist primarily on Federal lands or for projects undertaken by Federal agencies. We have not proposed to exclude any areas from critical habitat.

### *Draft Economic Analysis*

The purpose of the DEA is to identify and analyze the potential economic impacts associated with the proposed critical habitat designation for the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad. The DEA separates conservation measures into two distinct categories according to ''without critical habitat'' and ''with critical habitat'' scenarios. The ''without

critical habitat'' scenario represents the baseline for the analysis, considering protections otherwise afforded to the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad (e.g., under the Federal listing and other Federal, State, and local regulations). The ''with critical habitat'' scenario describes the incremental impacts specifically due to designation of critical habitat for the species. In other words, these incremental conservation measures and associated economic impacts would not occur but for the designation of critical habitat. Conservation measures implemented under the baseline (without critical habitat) scenario are described qualitatively within the DEA, but economic impacts associated with these measures are not quantified. Economic impacts are only quantified for conservation measures implemented specifically due to the designation of critical habitat (i.e., incremental impacts). For a further description of the methodology of the analysis, see Chapter 2, ''Framework for the Analysis,'' of the DEA.

The DEA provides estimated costs of the foreseeable potential economic impacts of the proposed critical habitat designation for the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad over the next 17 years. This timeframe was determined to be the appropriate period for analysis because planning information is not available for most activities to forecast activity levels for projects beyond a 17-year timeframe. The DEA identifies potential incremental costs as a result of the proposed critical habitat designation. These incremental costs are associated with the designation of critical habitat and are above those baseline costs attributed to listing.

The DEA quantifies economic impacts of the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad conservation efforts associated with the following categories of activity: (1) Fish stocking/persistence; (2) dams and water diversions; (3) grazing; (4) fuels management; (5) timber harvests; (6) recreation; and (7) habitat and species management.

The DEA concludes that incremental impacts resulting from the critical habitat designation are limited to the administrative costs of considering adverse modification in section 7 consultation. Estimating the impact of a regulation on future outcomes is inherently uncertain, as well as estimating the timing and duration of the administrative costs associated with section 7 consultation. Due to the uncertainty in the specifics of how Federal agencies will fulfill their section 7 requirements, cost estimates were calculated for a low-end scenario (single range-wide consultation) and a high-end scenario (project-by-project consultation). The DEA estimates total potential incremental economic impacts in areas proposed as critical habitat over the next 17 years (2014 to 2030) to be approximately $630,000 ($60,000 annualized) under the low-end scenario and approximately $1.5 million ($140,000 annualized) under the high-end scenario. These impact estimates are in present-value terms and apply a 7 percent discount rate (Industrial Economics Incorporated 2013, p. 4–1).

Under the low-end scenario, costs related to dams and water diversions represent approximately 75 percent of overall incremental impacts, while costs for grazing and timber harvest activities represent approximately 8 and 5 percent of forecast impacts, respectively. In the high-end scenario, costs related to timber harvest activities represent approximately 49 percent of overall incremental impacts, with dams and water diversion activities representing 32 percent, and grazing activities representing 15 percent.

As we stated earlier, we are soliciting data and comments from the public on the DEA, as well as all aspects of the proposed rules and our amended required determinations. We may revise the proposed rules or supporting documents to incorporate or address information we receive during the public comment period. In particular, we may exclude an area from critical habitat if we determine that the benefits of excluding the area outweigh the benefits of including the area, provided the exclusion will not result in the extinction of the species.

**Required Determinations—Amended**

In our April 25, 2013, proposed rule (78 FR 24516), we indicated that we would defer our determination of compliance with several statutes and executive orders until the information concerning potential economic impacts of the designation and potential effects on landowners and stakeholders became available in the DEA. We have now made use of the DEA data to make these determinations. In this document, we affirm the information in our proposed rule concerning Executive Order (E.O.) 12866 (Regulatory Planning and Review), E.O. 13132 (Federalism), E.O. 12988 (Civil Justice Reform), the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), and the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951). However, based on the DEA data, we are amending our required determinations concerning the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), E.O. 12630 (Takings), and E.O. 13211 (Energy, Supply, Distribution, and Use).

*Regulatory Flexibility Act (5 U.S.C. 601 et seq.)*

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (i.e., small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities. Based on our DEA of the proposed designation, we provide our analysis for determining whether the proposed rule would result in a significant economic impact on a substantial number of small entities. Based on comments we receive, we may revise this determination as part of our final rulemaking.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine

if potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

To determine if the proposed designation of critical habitat for the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad would affect a substantial number of small entities, we considered the number of small entities affected within particular types of economic activities, such as fish stocking, dams and water diversions, grazing, fuels management, timber harvest activities, and recreation. In order to determine whether it is appropriate for our agency to certify that this proposed rule would not have a significant economic impact on a substantial number of small entities, we considered each industry or category individually. In estimating the numbers of small entities potentially affected, we also considered whether their activities have any Federal involvement. Critical habitat designation does not affect activities that do not have any Federal involvement; designation of critical habitat only affects activities conducted, funded, permitted, or authorized by Federal agencies. If the proposed listing is made final, in areas where the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, or the Yosemite toad is present, Federal agencies will be required to consult with us under section 7(a)(2) of the Act on activities they fund, permit, or implement that may affect the species. If we finalize this proposed critical habitat designation, consultations to avoid the destruction or adverse modification of critical habitat would be incorporated into that consultation process.

In the DEA, we evaluated the potential economic effects on small entities resulting from implementation of conservation actions related to the proposed designation of critical habitat for the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad. Because the Service, the National Park Service, and the U.S. Forest Service are the only entities with expected direct compliance costs related to fish stocking, grazing, fuels management, and recreation, and these agencies are not considered small entities, this rule will not result in any impact to small entities regarding these activities. This rule has the potential to impact four small entities that operate dams and water diversion for power generation, and the impact is expected to range from 0.0003 to 0.01 percent of the entities' reported annual revenues. This rule also has the potential to impact small entities engaged in timber harvest activities on Federal lands. Given the limited information available to specifically determine which small entities may be impacted, we conservatively estimate that approximately 358 small entities associated with timber harvest activities may be impacted by this rule. While there is insufficient information to accurately quantify the impact to these small entities, we anticipate that approximately 4 percent of these entities will be impacted in any given year, and that the magnitude of impact will be small, as it is limited to the minor administrative costs of consultation. Please refer to the DEA of the proposed critical habitat designation for a more detailed discussion of potential economic impacts.

The Service's current understanding of the requirements under the RFA, as amended, and following recent court decisions, is that Federal agencies are only required to evaluate the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself, and therefore, not required to evaluate the potential impacts to indirectly regulated entities. The regulatory mechanism through which critical habitat protections are realized is section 7 of the Act, which requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried by the Agency is not likely to adversely modify critical habitat. Therefore, under these circumstances only Federal action agencies are directly subject to the specific regulatory requirement (avoiding destruction and adverse modification) imposed by critical habitat designation. Under these circumstances, it is our position that only Federal action agencies will be directly regulated by this designation. Federal Agencies are not small entities and, to this end, there is no requirement under the RFA to evaluate the potential impacts to entities not directly regulated. Therefore, because no small entities are directly regulated by this rulemaking, the Service certifies that, if promulgated, the proposed critical habitat designation will not have a significant economic impact on a substantial number of small entities.

In summary, we have considered whether the proposed designation would result in a significant economic impact on a substantial number of small entities. For the above reasons and based on currently available information, we certify that, if promulgated, the proposed critical habitat designation would not have a significant economic impact on a substantial number of small business entities. Therefore, an initial regulatory flexibility analysis is not required.

*Executive Order 12630 (Takings)*

In accordance with E.O. 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of designating critical habitat for the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad in a takings implications assessment. As discussed above, the designation of critical habitat affects only Federal actions. Although private parties that receive Federal funding, assistance, or require approval or authorization from a Federal agency for an action may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. The economic analysis found that no significant economic impacts are likely to result from the designation of critical habitat for the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad. Because the Act's critical habitat protection requirements apply only to Federal agency actions, few conflicts between critical habitat and private property rights should result from this designation. Based on information contained in the DEA and described within this document, it is not likely that economic impacts to a property owner would be of a sufficient magnitude to support a takings action. Therefore, the takings implications assessment concludes that this designation of critical habitat for the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad does not pose significant takings implications for lands within or affected by the designation.

*Energy Supply, Distribution, or Use—Executive Order 13211*

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. OMB has provided guidance for

implementing this Executive Order that outlines nine outcomes that may constitute ''a significant adverse effect'' when compared to not taking the regulatory action under consideration. The DEA finds that impacts to the energy industry from this rule are expected to be limited to additional administrative costs. Thus, based on information in the DEA, energy-related impacts associated with the Sierra Nevada yellow-legged frog, the northern DPS of the mountain yellow-legged frog, and the Yosemite toad within critical habitat are not expected. As such, the designation of critical habitat is not expected to significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

## Authors

The primary authors of this document are the staff members of the Sacramento Fish and Wildlife Office, Pacific Southwest Region, U.S. Fish and Wildlife Service.

## Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: December 13, 2013.

**Rachel Jacobson,**

*Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.*

[FR Doc. 2014–00281 Filed 1–8–14; 11:15 am]

**BILLING CODE 4310–55–P**

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## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

## 50 CFR Part 300

**[Docket No. 130722647–3647–01]**

**RIN 0648–BD55**

## International Fisheries; Pacific Tuna Fisheries; Fishing Restrictions for Pacific Bluefin Tuna in the Eastern Pacific Ocean

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

**ACTION:** Proposed rule; request for comments.

**SUMMARY:** NMFS is proposing regulations under the Tuna Conventions Act to implement Resolution C–13–02 of the Inter-American Tropical Tuna Commission (IATTC or the Commission) by specifying limits on U.S. commercial catch of Pacific bluefin tuna from the eastern Pacific Ocean (EPO) waters of the IATTC Convention Area in 2014. This action is necessary for the United States to satisfy its obligations as a member of the IATTC.

**DATES:** Comments on the proposed rule and the initial regulatory flexibility analysis must be submitted in writing by February 10, 2014. A public hearing will be held from 1 p.m. to 4 p.m. PDT, February 10, 2014, in Long Beach, CA.

**ADDRESSES:** You may submit comments on this document, identified by NOAA–NMFS–2013–0119, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *http://www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2013-0119,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Amber Rhodes, NMFS West Coast Office, 501 W. Ocean Blvd., Suite 4200, Long Beach, CA 90802. Include the identifier ''NOAA–NMFS–2013–0119'' in the comments.
- *Public hearing:* The public is welcome to attend a public hearing and offer comments on this proposed rule from 1 p.m. to 4 p.m. PDT, February 10, 2014 at 501 W. Ocean Boulevard, Suite 4200, Long Beach, CA 90802. The public may also participate in the public hearing via conference line: 1–888–323–9701, passcode 11543.

*Instructions:* Comments must be submitted by one of the above methods to ensure they are received, documented, and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (e.g., name, address, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word or Excel, WordPerfect, or Adobe PDF file formats only.

Copies of the draft Regulatory Impact Review (RIR) and other supporting documents are available via the Federal eRulemaking Portal: *http://www.regulations.gov,* docket NOAA–NMFS–2013–0119 or contact with the Regional Administrator, Will Stelle, NMFS West Coast Regional Office, 7600 Sand Point Way, NE., Bldg 1, Seattle, WA 98115–0070, or *RegionalAdministrator.WCRHMS@noaa.gov.*

**FOR FURTHER INFORMATION CONTACT:** Amber Rhodes, NMFS, 562–980–3231, or Heidi Taylor, NMFS, 562–980–4039.

**SUPPLEMENTARY INFORMATION:**

## Background on the IATTC

The United States is a member of the IATTC, which was established under the 1949 Convention for the Establishment of an Inter-American Tropical Tuna Commission. The full text of the 1949 Convention is available at: *http://www.iattc.org/PDFFiles/IATTC_convention_1949.pdf.*

The IATTC facilitates scientific research into, as well as conservation and management of, highly migratory species of fish in the IATTC Convention Area (defined as the waters of the EPO). Since 1998, conservation resolutions adopted by the IATTC have further defined the Convention Area as the area bounded by the coast of the Americas, the 50° N. and 50° S. parallels, and the 150° W. meridian. The IATTC has maintained a scientific research and fishery monitoring program for many years, and regularly assesses the status of tuna and billfish stocks in the EPO to determine appropriate catch limits and other measures deemed necessary to prevent overexploitation of these stocks and to promote sustainable fisheries. Current IATTC member countries include: Belize, Canada, China, Chinese Taipei (Taiwan), Colombia, Costa Rica, Ecuador, El Salvador, the European Union, France, Guatemala, Japan, Kiribati, the Republic of Korea, Mexico, Nicaragua, Panama, Peru, the United States, Vanuatu, and Venezuela. Bolivia, Honduras, Indonesia and the Cook Islands are cooperating non-members.

## International Obligations of the United States Under the Convention

As a Contracting Party to the 1949 Convention and a member of the IATTC, the United States is legally bound to implement IATTC resolutions. The Tuna Conventions Act (16 U.S.C. 951–962 and 971 *et seq.*) directs the Secretary of Commerce, after approval by the Secretary of State, to promulgate such regulations as may be necessary to implement resolutions adopted by the IATTC. The Secretary's authority to promulgate such regulations has been delegated to NMFS.

**Pacific Bluefin Tuna Resolution**

At its 85th Meeting, in June 2013, the IATTC adopted Resolution C–13–02, ''Measures for the Conservation and Management of Bluefin Tuna in the Eastern Pacific Ocean,'' which is the subject of this rulemaking; it was approved by the Secretary of State, thereby prompting implementation by NMFS.

The main objective of Resolution C–13–02 is to conserve Pacific bluefin tuna (*Thunnus orientalis*) by setting limits on the commercial catch of Pacific bluefin tuna in the IATTC Convention Area for 2014. Recognizing the need to reduce fishing mortality of Pacific bluefin tuna throughout its pan-Pacific range, the IATTC first adopted catch limits for Pacific bluefin tuna in the EPO for calendar years 2012 and 2013 with Resolution C–12–09. NMFS implemented the resolution via rulemaking for the United States in 2013 (see final rule at 78 FR 33240, June 4, 2013). As with Resolution C–12–09, Resolution C–13–02 includes two catch limits: (1) A Commission-wide limit for all commercial fishing vessels of all IATTC member countries and cooperating non-member countries (collectively known as CPCs) fishing in the EPO and (2) a catch limit of 500 metric tons for commercial vessels of each CPC with a historical record of Pacific bluefin catch from the EPO—such as the United States—to allow these nations some opportunity to catch Pacific bluefin tuna, notwithstanding the shared Commission-wide catch limit. For 2014, the Commission-wide catch limit is 5,000 metric tons and the catch limit for each CPC with a history of Pacific bluefin tuna catch is 500 metric tons.

Resolution C–13–02 reaffirms ''. . . that it is necessary to take precautionary management measures throughout the range of the resource to contribute to the stability of the stock of Pacific bluefin tuna.'' In 2011, NMFS determined overfishing is occurring on Pacific bluefin tuna (76 FR 28422, May 17, 2011). Based on the results of a 2012 stock assessment conducted by the International Scientific Committee for Tuna and Tuna-like Species in the North Pacific Ocean (ISC), NMFS determined Pacific bluefin tuna was not only experiencing overfishing but was also overfished (78 FR 41033, July 9, 2013). In 2012, the Commission for the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (WCPFC) adopted a conservation and management measure for Pacific bluefin tuna to ensure that the level of fishing mortality does not increase (CMM 2012–06). The WCPFC met in December 2013 and adopted a resolution called Conservation and Management Measure for Pacific Bluefin tuna (CMM–2013–09) and the IATTC will convene in the summer of 2014 to discuss the future management of Pacific bluefin tuna. Future conservation measures for Pacific bluefin tuna are expected to be based in part on information and advice from the ISC and the IATTC's scientific staff.

**Pacific Bluefin Tuna Catches**

While Pacific bluefin tuna catch by U.S. commercial vessels fishing in the EPO exceeded 1,000 metric tons in the early 1990's, catches have remained below 500 metric tons for more than a decade. The U.S. commercial catch of Pacific bluefin tuna for the years 1999 to 2012 in the EPO can be found in Table 1 below. The average annual Pacific bluefin tuna catch as determined by landings receipts of U.S. commercial vessels fishing in the EPO from 2007 to 2011 represents only two percent of the average annual landings for all fleets fishing in the EPO during that period (for information on Pacific bluefin tuna harvests in the EPO, see: *http://isc.ac.affrc.go.jp/pdf/ISC12pdf/ISC12_Plenary_Report-FINAL.pdf*).

TABLE 1—U.S. COMMERCIAL ANNUAL CATCH OF PACIFIC BLUEFIN TUNA IN THE EPO

| Year | Pacific bluefin tuna catch (metric tons) |
|---|---|
| 1999 | 186 |
| 2000 | 313 |
| 2001 | 196 |
| 2002 | 11 |
| 2003 | 36 |
| 2004 | 10 |
| 2005 | 207 |
| 2006 | 1 |
| 2007 | 45 |
| 2008 | 1 |
| 2009 | 415 |
| 2010 | 1 |
| 2011 | 118 |
| 2012 | *42 |

Source: Highly Migratory Species Stock Assessment and Fishery Evaluation: *http://www.pcouncil.org/highly-migratory-species/stock-assessment-and-fishery-evaluation-safe-documents/current-hms-safe-document/.*

*Preliminary PacFIN estimate of 2012 Pacific bluefin tuna landings by United States, extracted February 22, 2013.

**Proposed Regulations for Pacific Bluefin Tuna for 2014**

Under this proposed rule, once Pacific bluefin tuna catch limits have been reached, NMFS will prohibit any further targeting, retaining on board, transshipping, or landing of Pacific bluefin tuna in the Convention Area, because these activities can be effectively verified for enforcement purposes. Therefore, targeting, retaining on board, transshipping, or landing of Pacific bluefin tuna by all U.S. commercial vessels in the IATTC Convention Area shall be prohibited for the remainder of 2014 when the Commission-wide commercial catch limit of 5,000 metric tons of Pacific bluefin tuna is reached, and the 500 metric tons commercial catch limit of Pacific bluefin tuna is reached by the U.S. fleet. If the U.S. commercial fishing fleet has not caught 500 metric tons of Pacific bluefin tuna in the Convention Area in 2014 when the Commission-wide 5,000 metric tons catch limit is reached, then the U.S. commercial fleet may continue to target, retain, transship, or land Pacific bluefin tuna until the 500 metric ton limit is reached. The U.S. commercial fleet may continue to target, retain, transship, or land more than the 500 metric tons of Pacific bluefin tuna in 2014 unless and until the Commission-wide catch limit of 5,000 metric tons is reached.

**Announcement of the Limit Being Reached**

To ensure that the total catch of Pacific bluefin tuna taken from the IATTC Convention Area does not exceed the Commission-wide catch limit for 2014, NMFS will report U.S. catch to the IATTC Director on a monthly basis. The IATTC Director will inform CPCs when 50 percent of the Commission-wide limit is reached. The Director will likewise send similar notices when 60, 70, and 80 percent of the Commission-wide limit is reached. When 90 percent is reached, the Director will send the corresponding notice to all CPCs, with a projection of when the 5,000 metric ton Commission-wide limit will be reached, at which time CPCs are expected to take the necessary internal measures to avoid exceeding the limit. NMFS will provide updates on Commission-wide and U.S. catches to the public via the highly migratory and coastal pelagic species listservs and the West Coast Region Web site: *http://www.westcoast.fisheries.noaa.gov/fisheries/migratory_species/bluefin_tuna_harvest_status.html.* Additionally, NMFS will report preliminarily estimated Pacific bluefin tuna catch between monthly intervals if and when catches approach the limits to help participants in the U.S. commercial fishery plan for the possibility of the catch limit being reached.

When NMFS is informed that the 5,000 metric ton Commission-wide limit has been met (based on information provided by the IATTC Director) and that the 500 metric ton catch limit is expected to be reached before the end of 2014 (based on landings receipts, data submitted in logbooks, and other available fishery information), NMFS will publish a notice in the **Federal Register** announcing that the targeting, retaining, transshipping or landing for Pacific bluefin tuna will be prohibited on a specified effective date through December 31, 2014. Upon that effective date, a commercial fishing vessel of the United States may not be used to target, retain on board, transship, or land Pacific bluefin tuna captured in the Convention Area during the period specified in the announcement, with the exception that any Pacific bluefin tuna already on board a fishing vessel on the effective date may be retained on board, transshipped, and/or landed, to the extent authorized by applicable laws and regulations, provided that they are landed within 14 days after the effective date. NMFS anticipates limits to catches of Pacific bluefin tuna in the EPO to be included in future resolutions by the IATTC.

**Classification**

The NMFS Assistant Administrator has determined that this proposed rule is consistent with the Tuna Conventions Act and other applicable laws. This proposed rule has been determined to be not significant for purposes of Executive Order 12866. Additionally, while there are no new collection-of-information requirements associated with this action that are subject to the Paperwork Reduction Act, existing collection-of-information requirements associated with the Fishery Management Plan for U.S. West Coast Fisheries for Highly Migratory Species still apply. These requirements have been approved by the Office of Management and Budget under Control Number 0648–0204. The initial regulatory flexibility analysis is summarized in the following paragraphs.

The main objective of this proposed rule is to establish catch limits to contribute to the conservation of the Pacific bluefin tuna stock. This rule would apply to owners and operators of U.S. commercial fishing vessels that catch Pacific bluefin tuna in the IATTC Convention Area. Each vessel that would be affected is considered a small business according to the Small Business Administration's revised size standards (78 FR 37398, June 20, 2013), which increased the size standard for Finfish Fishing from $ 4.0 to 19.0 million, Shellfish Fishing from $ 4.0 to 5.0 million, and Other Marine Fishing from $4.0 to 7.0 million. Pacific bluefin tuna do not serve as the primary target species for any U.S. commercial vessels, but rather are incidentally or opportunistically caught by U.S. commercial vessels fishing in the EPO. Therefore, the action is not expected to have a significant or disproportional economic impact on these small business entities.

NMFS will publish a notice in the **Federal Register** announcing that restrictions will be effective from the dates specified through the end of the calendar year. NMFS will take reasonable actions to inform vessel owners in advance of publishing, in a **Federal Register** announcement, the effective date for the restrictions on targeting, retaining, transshipping, or landing Pacific bluefin tuna captured in the IATTC Convention Area. In the event that the limit on Pacific bluefin tuna catch is reached in 2014, it will be the responsibility of the commercial vessel owner to ensure that no further targeting of Pacific bluefin tuna occurs, and that no more Pacific bluefin tuna are retained on board, transshipped, or landed after the specified dates published in the **Federal Register** notice announcing that the annual limit is expected to be reached.

While this proposed rule does not mandate any new ''reporting'' or ''recordkeeping'' requirements for the public, some compliance costs may be associated with the regulations if the restrictions on targeting, retaining, transshipping, or landing Pacific bluefin tuna captured in the IATTC Convention Area becomes effective in 2014 as a result of the commercial catch limits being reached. The Pacific bluefin tuna commercial catch limits are not expected to result in closing fishing of Pacific bluefin tuna in the Convention Area to U.S. commercial vessels because annual U.S. catches of Pacific bluefin tuna have not reached 500 metric tons in more than a decade. In the event of a closure under this rule, the cost of compliance would be *de minimis.* Compliance costs could consist of returning incidentally caught bluefin tuna to the ocean, forgoing associated profits, and potentially losing fishing opportunity if bluefin are available to the U.S. fleet during the time a closure is in place.

The U.S. catch of Pacific bluefin tuna in the EPO represents a relatively minor component of the overall catch of Pacific bluefin tuna from the EPO. The average annual U.S. catch of Pacific bluefin tuna was 113 metric tons for 1999 through 2012. Table 1 (above) illustrates U.S. commercial catch of bluefin tuna in the EPO for the years 1999 to 2012. Pacific bluefin tuna is commercially caught by U.S. vessels fishing in the EPO on an irregular basis. Most of the landings are made by small coastal purse seine vessels operating in the Southern California Bight with limited additional landings made by the drift gillnet fleet that targets swordfish and thresher shark. Lesser amounts of Pacific bluefin tuna are caught by surface hook and line and longline gear (typically less than .05 metric tons per year for these gear types combined). The number of purse seine vessels that have landed tuna in California averaged 197 annually from 1981 through 1990. However, from 2000 to 2013, six small purse seiners have been registered with the IATTC to target Pacific bluefin tuna in the Convention Area each year. The landings data suggests that they opportunistically targeted Pacific bluefin tuna in alternate years since 2001. The decline in the number of domestic vessels is correlated in part with the relocation of large cannery operations.

NMFS compared the effects of the Pacific bluefin tuna restrictions imposed by this rule to a no action alternative. Under the no action alternative, there would be no limit on U.S. commercial catches of Pacific bluefin tuna in the IATTC Convention Area. It is unlikely that any benefit to U.S. commercial fisheries would be gained from not implementing Resolution C–13–02 as recent trends in Pacific bluefin tuna catch data indicate that it is unlikely that the U.S. catch limit will be reached. However, failing to adopt this rule would result in the United States not satisfying its international obligations as a member of the IATTC. Furthermore, implementing Resolution C–13–02 could benefit the conservation of Pacific bluefin tuna by limiting catches if the fish were to become abundantly available to U.S. commercial vessels fishing in the EPO in 2014.

**List of Subjects in 50 CFR Part 300**

Administrative practice and procedure, Fish, Fisheries, Fishing, Marine resources, Reporting and recordkeeping requirements, Treaties.

Dated: January 7, 2014.

**Alan D. Risenhoover,**

*Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.*

For the reasons set out in the preamble, 50 CFR part 300 is proposed to be amended as follows:

## PART 300—INTERNATIONAL FISHERIES REGULATIONS

■ 1. The authority citation for 50 CFR part 300, continues to read as follows:

**Authority:** 16 U.S.C. 951–961 et seq.

■ 2. In § 300.24, paragraph (u) is added to read as follows:

**§ 300.24 Prohibitions.**

* * * * *

(u) Use a United States commercial fishing vessel in the IATTC Convention Area in contravention of § 300.25(h)(4)

■ 3. In § 300.25, paragraph (h) is added to read as follows:

**§ 300.25 Eastern Pacific fisheries management.**

* * * * *

(h) *Pacific bluefin tuna commercial catch limits in the eastern Pacific Ocean.* (1) For the calendar year 2014, all commercial fishing vessels of IATTC member countries and cooperating non-member countries collectively are subject to a limit of 5,000 metric tons of Pacific bluefin tuna that may be captured, retained, and landed in the Convention Area.

(2) Notwithstanding the collective 5,000 metric ton limit, in calendar year 2014 commercial vessels of the United States may capture, retain, transship, or land up to 500 metric tons of Pacific bluefin tuna.

(3) After NMFS determines that the limits under paragraphs (h)(1) and (2) of this section are expected to be reached by a future date, and at least 7 calendar days in advance of that date, NMFS will publish a notice of closure in the **Federal Register** announcing the effective date that additional targeting, retaining on board, transshipping or landing Pacific bluefin tuna in the Convention Area shall be prohibited as described in paragraph (h)(4) of this section.

(4) Beginning on the date announced in the notice of closure published under paragraph (h)(3) of this section through the end of the calendar year, a commercial fishing vessel of the United States may not be used to target, retain on board, transship, or land Pacific bluefin tuna captured in the Convention Area, with the exception that any Pacific bluefin tuna already on board a fishing vessel on the effective date of the notice may be retained on board, transshipped, and/or landed, to the extent authorized by applicable laws and regulations, provided such tuna is landed within 14 days after the effective date published in the notice of closure.

[FR Doc. 2014–00269 Filed 1–9–14; 8:45 am]

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 648

**[Docket No. 130903775–4002–01]**

**RIN 0648–BD65**

### Fisheries of the Northeastern United States; Atlantic Mackerel, Squid, and Butterfish Fisheries; Specifications and Management Measures

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

**ACTION:** Proposed rule, request for comments.

**SUMMARY:** NMFS proposes the specifications for the 2014 fishing year for butterfish, as well as other management measures for the species managed under the Atlantic Mackerel, Squid, and Butterfish Fishery Management Plan. NMFS previously set specifications for longfin squid and *Illex* squid for 3 years in 2012 (2012–2014) and, therefore, new specifications will not be included in this year's specification rulemaking. Likewise, NMFS set specifications for mackerel for 3 years in 2013 (2013–2015), and new specifications will also not be included in this action. The proposed specifications for butterfish would increase the butterfish acceptable biological catch by 8 percent and would increase the butterfish landings limit by 24 percent compared to 2013. This action also proposes to increase the butterfish Phase 3 trip limit from 500 lb (0.23 mt) to 600 lb (0.27 mt) for longfin squid/butterfish moratorium permit holders; establish a 236-mt cap on river herring (blueback and alewife) and shad (American and hickory) catch in the mackerel fishery; and raise the post-closure possession limit for longfin squid to 15,000 lb (6.80 mt) for vessels targeting *Illex* squid.

**DATES:** Public comments must be received by February 10, 2014.

**ADDRESSES:** Copies of supporting documents used by the Mid-Atlantic Fishery Management Council (Council), including the Environmental Assessment (EA) and Regulatory Impact Review (RIR)/Initial Regulatory Flexibility Analysis (IRFA), are available from: Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, Suite 201, 800 N. State Street, Dover, DE 19901. The EA/RIR/IRFA is accessible via the Internet at *http://www.nero.noaa.gov.*

You may submit comments, identified by NOAA–NMFS–2013–0172, by any one of the following methods:

• *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2013-0172,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments. Mail: Submit written comments to NOAA Fisheries, Northeast Regional Office, 55 Great Republic Dr, Gloucester, MA 01930. Mark the outside of the envelope ''Comments on 2014 MSB Specifications.''

*Instructions:* Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

**FOR FURTHER INFORMATION CONTACT:** Aja Szumylo, Fishery Policy Analyst, 978–281–9195, fax 978–281–9135.

**SUPPLEMENTARY INFORMATION:**

### Background

This rule proposes specifications, which are the combined suite of commercial and recreational catch levels established for one or more fishing years. The specification process also allows for the modification of a select number of management measures, such as closure thresholds, gear restrictions, and possession limits. The Council's process for establishing specifications relies on provisions within the Atlantic Mackerel, Squid,

and Butterfish (MSB) Fishery Management Plan (FMP) and its implementing regulations, as well as requirements established by the Magnuson–Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Specifically, section 302(g)(1)(B) of the Magnuson-Stevens Act states that the Scientific and Statistical Committee (SSC) for each Regional Fishery Management Council shall provide its Council ongoing scientific advice for fishery management decisions, including recommendations for acceptable biological catch (ABC), preventing overfishing, maximum sustainable yield, and achieving rebuilding targets. The ABC is a level of catch that accounts for the scientific uncertainty in the estimate of the stock's defined overfishing level (OFL). The Council's SSC met on May 15 and 16, 2013, confirming 2014 specifications for *Illex* squid, longfin squid, and Atlantic mackerel (mackerel) and recommending ABCs for the 2014 butterfish specifications. As previously mentioned, NMFS set the specifications for longfin squid and *Illex* squid for 3 years in 2012 (77 FR 51858; August 27, 2012) and for mackerel in 2013 (78 FR 3346; January 16, 2013). Information on these specifications are not included in this action and can be found in the final rules for those actions, as referenced above.

The MSB FMP's implementing regulations require the involvement of a monitoring committee in the specification process for each species. The monitoring committees' role has largely been to recommend any reduction in catch limits from the SSC-recommended ABCs to offset management uncertainty, and to recommend other management measures (e.g., gear and/or possession restrictions) needed for the efficient management of the fisheries. The MSB Monitoring Committee met on May 28, 2013, to discuss specification related recommendations for the 2014 butterfish fishery, changes in management measures in the squid and butterfish fisheries, and the establishment of the river herring/shad (RH/S) cap in the mackerel fishery.

Following the SSC and MSB Monitoring Committee meetings, the Council considered the committees' recommendations and public comments at its June 2013, meeting in Eatontown, NJ, and made their specification recommendations. The Council submitted these recommendations, along with the required analyses, for agency review on August 15, 2013, with final submission on December 18, 2013. NMFS must review the Council's recommendations to ensure that they comply with the FMP and applicable law, and conduct notice-and-comment rulemaking to propose and implement the final recommendations.

The MSB regulations require the specification of annual catch limits (ACL) and accountability measure (AM) provisions for mackerel and butterfish (both squid species are exempt from the ACL/AM requirements because they have a life cycle of less than 1 year). In addition, the regulations require the specification of domestic annual harvest (DAH), domestic annual processing (DAP), and total allowable level of foreign fishing (TALFF), along with joint venture processing for (JVP) and commercial and recreational annual catch totals (ACT) for mackerel, the butterfish mortality cap in the longfin squid fishery, and initial optimum yield (IOY) for both squid species.

**2014 Proposed Specifications for Butterfish**

Table 1 outlines all of the proposed butterfish specifications for the 2014 fishing year, which are further explained below.

TABLE 1—PROPOSED SPECIFICATIONS, IN METRIC TONS (MT), FOR BUTTERFISH FOR THE 2014 FISHING YEAR

| Specifications | Butterfish (mt) |
|---|---|
| OFL | 18,200. |
| ABC | 9,100. |
| ACL | 8,190. |
| Commercial ACT | 7,084. |
| DAH/DAP | 3,200. |
| JVP | 0. |
| TALFF | 0. |
| Butterfish Mortality Cap. | 3,884. |
| RSA | Up to 2 percent of ACT (164 mt). |

Most recent assessments of the butterfish resource do not provide conclusive advice on the status of the butterfish resource in order to make a determination of whether or not the stock is overfished. A new assessment is underway and expected to be finalized in January 2014. To address this, NOAA's Northeast Fisheries Science Center (NEFSC) expanded its fall trawl survey data (i.e., the survey that best samples butterfish) to a range of total swept area biomass based on ranges of reasonable assumptions regarding catchability, and also investigated likely fishing mortalities from various catch levels. The results of this strongly supported that a catch of 9,100 mt would be extremely unlikely to cause overfishing if the 2014 biomass of butterfish is similar to butterfish biomass over 2006–2012.

Additional NEFSC analysis examined the range of probable fishing mortalities that would result from relatively conservative assumptions about butterfish biomass. This analysis suggested that catches of 18,200 mt would only lead to overfishing under the most extreme assumptions (i.e., assuming that the entire Atlantic butterfish stock falls within the bounds of the NEFSC's fall trawl survey area, and that the survey catches 100 percent of the butterfish in each sample location). The SSC therefore adopted 18,200 mt as a proxy OFL and recommended an ABC of 9,100 mt (50 percent of the OFL, and an 8-percent increase from the 2013 ABC). The relatively large 50-percent buffer accounts for uncertainty in the evaluation of fishing mortality associated with the catch levels. A detailed summary of the SSC's rationale for its 2014 butterfish ABC recommendation is available in its May 2013 Report (available, along with other materials from the SSC discussion, at: *http://www.mafmc.org/ssc-meeting-documents*).

The Council recommended setting the butterfish ACL equal to the ABC, and establishing a 10-percent buffer between ACL and ACT for management uncertainty, which would result in an ACT of 8,190 mt. From this amount, the Council recommended setting the DAH and DAP at 3,200 mt and the butterfish discard cap in the longfin fishery at 3,884 mt. The remaining 1,106 mt of the ACT allows for discards in other fisheries to minimize the likelihood of an ACL overage. Since up to 3 percent of the ACL for butterfish may be set aside for scientific research, the Council recommended setting aside up to 2 percent of the butterfish ACT (i.e., 164 mt). This allocation would be accounted for within the 1,106-mt unallocated portion of the ACT that covers butterfish discards in other fisheries.

NMFS proposes specifications, consistent with the Council's recommendation, that would set the butterfish ABC/ACL at 9,100 mt, the ACT at 8,190 mt, the DAH and DAP at 3,200 mt, and the butterfish mortality cap on the longfin squid fishery at 3,884 mt. Additionally, consistent with MSB regulations, NMFS is proposing zero TALFF for butterfish in 2014. Butterfish TALFF is only specified to address bycatch by foreign fleets targeting mackerel TALFF. Because no mackerel TALFF was allocated for the 2013–2015 fishing years, butterfish TALFF is also proposed to be set at zero for 2014.

Consistent with 2013, NMFS proposes that the 2014 butterfish mortality cap be allocated by Trimester, as follows:

TABLE 2—PROPOSED TRIMESTER ALLOCATION OF BUTTERFISH MORTALITY CAP ON THE LONGFIN SQUID FISHERY FOR 2014

| Trimester | Percent | Metric tons |
|---|---|---|
| I (Jan–Apr) ..... | 65 | 2,525 |
| II (May–Aug) ..... | 3.3 | 128 |
| III (Sep–Dec) .... | 31.7 | 1,231 |
| Total ..... | 100 | 3,884 |

This action also proposes to increase the butterfish possession limit in Phase 3 of the directed butterfish fishery. Currently, NMFS manages the directed butterfish fishery in three phases. Table 3 shows the phases and possession limits, and the fishery moves from Phase 1, to Phase 2, and to Phase 3 when catch reaches specified thresholds throughout the year. When NMFS projects the butterfish harvest to reach the catch threshold for Phase 3, the trip limit for all limited access permit holders is currently reduced to 500 lb (0.23 mt) to avoid quota overages, but the incidental trip limit remains at 600 lb (0.27 mt). This action would increase the Phase 3 possession limit from 500 lb (0.23 mt) to 600 lb (0.27 mt) to allow for consistency with the current incidental butterfish trip limit.

TABLE 3—THREE-PHASE BUTTERFISH MANAGEMENT SYSTEM

| Phase | Longfin squid/butterfish moratorium permit trip limit | | Squid/butterfish incidental catch permit trip limit |
|---|---|---|---|
| | ≥3 inch (7.62 cm) mesh | <3 inch (7.62 cm) mesh | |
| 1 ..... | Unlimited ..... | 2,500 lb (1.13 mt) ..... | 600 lb (0.27 mt). |
| 2 ..... | 5,000 lb (2.27 mt) ..... | 2,500 lb (1.13 mt) ..... | 600 lb (0.27 mt). |
| 3 ..... | 600 lb (0.27 mt) ..... | 600 lb (0.27 mt) ..... | 600 lb (0.27 mt). |

Consistent with 2013, NMFS proposes the following quota thresholds to reduce the trip limits for Phases 2 and 3 (Tables 4 and 5):

TABLE 4—PROPOSED BUTTERFISH THRESHOLDS FOR REDUCING TRIP LIMITS FOR PHASE 2

| Months | Trip limit reduction threshold (percent) | Butterfish harvest (metric tons) |
|---|---|---|
| Jan–Feb ... | 40 | 1,658 |
| Mar–Apr ... | 47 | 1,838 |
| May–Jun .. | 55 | 2,044 |
| Jul–Aug .... | 63 | 2,249 |
| Sept–Oct .. | 71 | 2,455 |
| Nov–Dec .. | 78 | 2,635 |

TABLE 5—PROPOSED BUTTERFISH THRESHOLDS FOR REDUCING TRIP LIMITS FOR PHASE 3

| Months | Trip limit reduction threshold (percent) | Butterfish harvest (metric tons) |
|---|---|---|
| Jan–Feb ... | 58 | 2,121 |
| Mar–Apr ... | 64 | 2,275 |
| May–Jun .. | 71 | 2,455 |
| Jul–Aug .... | 78 | 2,635 |
| Sept–Oct .. | 85 | 2,815 |
| Nov–Dec .. | 91 | 2,969 |

*Proposed River Herring and Shad Catch Cap in the Mackerel Fishery*

This action proposes a river herring and shad (RH/S) catch cap in the mackerel fishery. In order to limit RH/S catch, Amendment 14 to the FMP (proposed rule published August 29, 2013, 78 FR 53404; partial approval by Secretary on November 7, 2013) includes the provision to allow the Council to set a RH/S cap. However, the actual value of the cap must be set through annual specifications. As such, this action proposes the Council's recommended RH/S catch cap of 236 mt. This amount represents the estimated median amount of RH/S that would have been caught, had the commercial mackerel fishery landed its current quota of 33,821 mt for each year during 2005–2012 based on analysis of observer and landings. RH/S caught on all trips that land 20,000 lb (9.07 mt) or more of mackerel would count against the cap. Once NMFS estimates that directed mackerel trips have caught 95 percent of the 236-mt RH/S cap, then the directed mackerel fishery would close, and NMFS would institute a 20,000-lb mackerel trip limit, as currently occurs if the directed mackerel fishery closes. The improved reporting and monitoring requirements proposed in Amendment 14 would enable monitoring of the RH/S cap. This proposed RH/S cap amount should create a strong incentive for the fleet to avoid RH/S, would allow for the possibility of the full mackerel quota to be caught if the fleet can avoid RH/S, and would likely reduce RH/S catches over time, compared to what would occur without a cap, given recent data.

**Longfin Squid Possession Limit Increase**

This action proposes to increase the Trimester II longfin squid post-closure possession limit for longfin squid/butterfish moratorium permit holders from 2,500 lb (1.13 mt) to 15,000 lb (6.80 mt) for vessels targeting *Illex* squid if they are fishing seaward of the *Illex* mesh exemption line and have more than 10,000 lb (4.54 mt) of *Illex* onboard. In recent years, fishermen are reporting that, to remain in compliance with longfin squid regulations, they sometimes have to discard large quantities of longfin squid while *Illex* fishing during longfin squid Trimester II after that trimester closes (i.e., from July 10–August 31 in 2012). Increasing the longfin squid possession limit to accommodate the multi-day nature of *Illex* fishing trips would reduce the potential for high levels of regulatory discarding of longfin on such trips. Requiring a minimal *Illex* possession requirement of 15,000 lb (6.80 mt) should help ensure that vessels are actually *Illex* fishing when they utilize this provision, and restricting the proposed possession limit increase to areas beyond the *Illex* mesh exemption line should help prevent vessels returning from *Illex* fishing from targeting longfin squid in inshore areas after a Trimester II closure. This action does not propose changes for the post-closure possession limit for longfin squid during Trimesters I (January 1–April 30) or III (September 1–December 31). The post-closure possession limit for longfin squid would remain 2,500 lb (1.13 mt) during those Trimesters.

**Corrections**

This proposed rule also contains minor corrections to existing regulations, and would reinstate

regulations that were inadvertently deleted in previous rulemakings. NMFS proposes these adjustments under the authority of section 305(d) to the Magnuson-Stevens Act, which provides that the Secretary of Commerce may promulgate regulations necessary to ensure that amendments to an FMP are carried out in accordance with the FMP and the Magnuson-Stevens Act. These adjustments, which are identified and described below, are necessary to clarify current regulations or the intent of the FMP and would not change the intent of any regulations.

NMFS proposes to clarify the coordinates at § 648.23(a)(3) to more accurately define the *Illex* exemption line. Most significantly, this action proposes to create a southern boundary for the exemption by extending the southernmost point eastward until it intersects with the boundary of the Exclusive Economic Zone. In addition, this rule proposes to reinstate the coordinates for the MSB bottom trawling restricted areas (i.e., Oceanographer Canyon and Lydonia Canyon) at § 648.23(a)(4), which were inadvertently deleted in previous rulemaking.

**Classification**

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the Atlantic Mackerel, Squid, and Butterfish FMP; other provisions of the Magnuson-Stevens Act; and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

The Council prepared an IRFA, as required by section 603 of the Regulatory Flexibility Act (RFA). The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A summary of the analysis follows. A copy of this analysis is available from the Council or NMFS (see **ADDRESSES**) or via the Internet at *http://www.nero.noaa.gov.*

*Statement of Objective and Need*

This action proposes 2014 specifications for butterfish, along with management measures for the longfin squid, butterfish, and mackerel fisheries. A complete description of the reasons why this action is being considered, and the objectives of and legal basis for this action, are contained in the preamble to this proposed rule and are not repeated here.

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

On June 20, 2013, the Small Business Administration (SBA) issued a final rule revising the small business size standards for several industries effective July 22, 2013 (78 FR 37398). The rule increased the size standard for Finfish Fishing from $4.0 to $19.0 million, Shellfish Fishing from $4.0 to $5.0 million, and Other Marine Fishing from $4.0 to $7.0 million. NMFS has reviewed the analyses prepared for this action in light of the new size standards. Under the former, lower size standards, all entities subject to this action were considered small entities, thus they all would continue to be considered small under the new standards.

The proposed measures in the 2014 MSB Specifications and Management Measures could affect any vessel holding an active Federal permit to fish for Atlantic mackerel, longfin squid, *Illex* squid, or butterfish. Having different size standards for different types of marine fishing activities creates difficulties in categorizing businesses that participate in more than one of these activities. For now, the short-term approach is to classify a business entity into the SBA defined categories based on which activity produced the highest gross revenue. In this case, Atlantic mackerel is the only species with significant recreational fishing, and in 2012, the charter boat industry harvested only 10,000 lb (4.54 mt). Based on these assumptions, the finfish size standard would apply, and the business is considered large, only if revenues are greater than $19 million. As such, all of the potentially affected businesses are considered small entities under the standards described in NMFS guidelines, because they have gross receipts that do not exceed $19 million annually. Based on permit data for 2013, 2,441 commercial or charter vessels possessed MSB permits for the 2013 fishing year, and similar numbers of vessels are expected to have MSB permits for 2014. Many vessels participate in more than one of these fisheries; therefore, permit numbers are not additive.

Although it is possible that some entities, based on rules of affiliation, would qualify as large business entities, due to lack of reliable ownership affiliation data NMFS cannot apply the business size standard at this time. NMFS is currently compiling data on vessel ownership that should permit a more refined assessment and determination of the number of large and small entities for future actions. For this action, since available data are not adequate to identify affiliated vessels, each operating unit is considered a small entity for purposes of the RFA, and, therefore, there is no differential impact between small and large entities. Therefore, there are no disproportionate economic impacts on small entities. Section 6.7 in Amendment 14 describes the vessels, key ports, and revenue information for the MSB fisheries; therefore, that information is not repeated here.

*Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements*

There are no new reporting or recordkeeping requirements contained in any of the alternatives considered for this action. In addition, there are no Federal rules that duplicate, overlap, or conflict with this proposed rule.

*Minimizing Significant Economic Impacts on Small Entities*

Proposed Actions

The proposed RH/S catch cap in the mackerel fishery has the potential to limit the fishery from achieving its full mackerel quota if the RH/S encounter rates are high, but it is very unlikely that the fishery would close before exceeding the levels of landings experienced since 2010, when landings have been less than 11,000 mt. Limiting catches of river herring and shad has the potential to benefit those species, although the extent of this benefit is unknown because overall abundance information for these species is not available.

The butterfish DAH proposed in this action (3,200 mt) represents a 24-percent increase over the 2013 DAH (2,570 mt). The proposed increase in the DAH has the potential to slightly increase revenue for permitted vessels.

In addition, this action proposes a slightly higher trip limit in Phase 3 of the directed butterfish fishery, in order to simplify the regulations and have this limit match the incidental trip limit of 600 lb (0.27 mt). This increase should also have positive economic impacts on the fishery.

The only proposed adjustment to the longfin squid fishery is an increase to the Trimester II longfin squid post-closure possession limit for longfin squid/butterfish moratorium permit holders from 2,500 lb (1.13 mt) to 15,000 lb (6.80 mt) for vessels targeting *Illex*. This measure should reduce regulatory discarding and provide a small amount of additional revenue; thus, it would have positive economic impacts to the *Illex* fishery.

**Alternatives to the Proposed Rule**

The Council analysis evaluated four alternatives to the proposed specifications for butterfish. Of the three the Council did not select, two alternatives would have resulted in lower 2014 specifications. The first of these is the No Action alternative (status quo), which would have set the butterfish ABC at 8,400 mt and resulted in an ACT of 7,560 mt, a DAH and DAP of 2,570 mt, and a butterfish mortality cap at 3,884 mt. The other alternative (the most restrictive) would have set the ABC at 25 percent lower than the proposed alternative (6,825 mt), resulting in an ACT of 6,143 mt, a DAH and DAP of 2,400 mt, and a butterfish mortality cap at 2,913 mt. These alternatives could generate the lowest revenues of all of the considered alternatives. The fourth alternative (the least restrictive) would have set the ABC at 25 percent higher than the proposed alternative (11,375 mt), resulting in an ACT of 10,238 mt, a DAH and DAP of 5,248 mt, and a butterfish mortality cap at 3,884 mt. This alternative could generate increased revenue if more butterfish became available to the fishery. These three alternatives were not selected because they were all inconsistent with the ABC recommended by the SSC.

The Council considered four alternatives for the RH/S catch cap in the mackerel fishery. Aside from the No Action (status quo) alternative, which would not have implemented a catch cap in the fishery because there is currently no cap in place, the Council considered one alternative that would have set the RH/S catch cap at 119 mt (most restrictive) and one alternative that would have set the RH/S catch cap at 456 mt (least restrictive). If the catch cap were set at 119 mt, there would be the greatest likelihood that the cap level could restrict mackerel fishing, whereas setting the RH/S cap at 456 mt would be the least likely to be restrictive. Any cap would be more likely to close the fishery compared to no cap (status quo), the proposed alternative (RH/S cap of 236 mt) would most likely assist in the recovery of RH/S stocks while allowing the mackerel fishery to continue, assuming low RH/S catch rates.

With regards to matching Phase 3 and the incidental trip limits in the butterfish fishery, the Council considered two other alternatives in addition to the proposed alternative (i.e., increasing the Phase 3 trip limit from 500 lb (0.23 mt) to 600 lb (0.27 mt), to match the incidental limit). One alternative was the No Action alternative, which would have unnecessarily continued the regulatory confusion by requiring two different possession limits based on permit type. The other alternative would have lowered the incidental limit to 500 lb (0.23 mt) to match the current Phase 3 limit, which potentially could have the effect of converting currently retained butterfish catch into discards. The proposed alternative would resolve this confusion over different trip limits, while continuing to discourage directed fishing.

The Council considered three alternatives related to the post-closure possession limit of longfin squid in the *Illex* fishery. The most restrictive alternative considered was the No Action (status quo) alternative, which would continue the current longfin squid trip limit of 2,500 lb (1.13 mt) in Trimester 3. The proposed alternative, which would increase the possession limit to 15,000 lb (6.80 mt), is the least restrictive alternative. The other alternative considered would have increased the longfin squid possession limit to 10,000 lb (4.54 mt). Compared to the other two alternatives, the status quo alternative would continue to result in high levels of regulatory discards of longfin squid and would result in lower revenues than the other alternatives considered. Although the other two alternatives would both result in previously discarded longfin squid being landed, the proposed alternative with its higher possession limit would result in the highest potential revenue.

**List of Subjects in 50 CFR Part 648**

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: January 6, 2014.

**Alan D. Risenhoover,**

*Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.*

For the reasons set out in the preamble, 50 CFR part 648 is proposed to be amended as follows:

## PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

**Authority:** 16 U.S.C. 1801 *et seq.*

■ 2. In § 648.23, paragraph (a)(3) is revised and paragraph (a)(4) is added to read as follows:

**§ 648.23 Mackerel, squid, and butterfish gear restrictions.**

* * * * *

(a) * * *

(3) *Illex fishery.* Seaward of the following coordinates, connected in the order listed by straight lines except otherwise noted, otter trawl vessels possessing longfin squid harvested in or from the EEZ and fishing for *Illex* during the months of June, July, August, in Trimester II, and September in Trimester III are exempt from the longfin squid gear requirements specified in paragraph (a)(2) of this section, provided that landward of the specified coordinates they do not have available for immediate use, as defined in paragraph (b) of this section, any net, or any piece of net, with a mesh size less than 1⅞ inches (48 mm) diamond mesh in Trimester II, and 2⅛ inches (54 mm) diamond mesh in Trimester III, or any piece of net, with mesh that is rigged in a manner that is prohibited by paragraph (a)(2) of this section.

| Point | N. lat. | W. long. |
|---|---|---|
| M0 | 43°58.0′ | [1] |
| M1 | 43°58.0′ | 67°22.0′ |
| M2 | 43°50.0′ | 68°35.0′ |
| M3 | 43°30.0′ | 69°40.0′ |
| M4 | 43°20.0′ | 70°00.0′ |
| M5 | 42°45.0′ | 70°10.0′ |
| M6 | 42°13.0′ | 69°55.0′ |
| M7 | 41°00.0′ | 69°00.0′ |
| M8 | 41°45.0′ | 68°15.0′ |
| M9 | 42°10.0′ | [2] 67°10.0′ |
| M10 | 41°18.6′ | [2] 66°24.8′ |
| M11 | 40°55.5′ | 66°38.0′ |
| M12 | 40°45.5′ | 68°00.0′ |
| M13 | 40°37.0′ | 68°00.0′ |
| M14 | 40°30.0′ | 69°00.0′ |
| M15 | 40°22.7′ | 69°00.0′ |
| M16 | 40°18.7′ | 69°40.0′ |
| M17 | 40°21.0′ | 71°03.0′ |
| M18 | 39°41.0′ | 72°32.0′ |
| M19 | 38°47.0′ | 73°11.0′ |
| M20 | 38°04.0′ | 74°06.0′ |
| M21 | 37°08.0′ | 74°46.0′ |
| M22 | 36°00.0′ | 74°52.0′ |
| M23 | 35°45.0′ | 74°53.0′ |
| M24 | 35°28.0′ | 74°52.0′ |
| M25 | 35°28.0′ | ([3]) |

[1] The intersection of 43°58.0′ N. latitude and the US-Canada Maritime Boundary.

[2] Points M9 and M10 are intended to fall along and are connected by the US-Canada Maritime Boundary.

[3] The intersection of 35°28.0′ N. latitude and the outward limit of the US EEZ.

(4) *Mackerel, squid, and butterfish bottom trawling restricted areas*—(i) *Oceanographer Canyon.* No permitted mackerel, squid, or butterfish vessel may fish with bottom trawl gear in the Oceanographer Canyon or be in the Oceanographer Canyon unless transiting. Vessels may transit this area provided the bottom trawl gear is stowed in accordance with the provisions of paragraph (b) of this section. Oceanographer Canyon is defined by straight lines connecting the following points in the order stated

(copies of a chart depicting this area are available from the Regional Administrator upon request):

OCEANOGRAPHER CANYON

| Point | N. lat. | W. long. |
|---|---|---|
| OC1 | 40°10.0′ | 68°12.0′ |
| OC2 | 40°24.0′ | 68°09.0′ |
| OC3 | 40°24.0′ | 68°08.0′ |
| OC4 | 40°10.0′ | 67°59.0′ |
| OC1 | 40°10.0′ | 68°12.0′ |

(ii) *Lydonia Canyon.* No permitted mackerel, squid, or butterfish vessel may fish with bottom trawl gear in the Lydonia Canyon or be in the Lydonia Canyon unless transiting. Vessels may transit this area provided the bottom trawl gear is stowed in accordance with the provisions of paragraph (b) of this section. Lydonia Canyon is defined by straight lines connecting the following points in the order stated (copies of a chart depicting this area are available from the Regional Administrator upon request):

LYDONIA CANYON

| Point | N. lat. | W. long. |
|---|---|---|
| LC1 | 40°16.0′ | 67°34.0′ |
| LC2 | 40°16.0′ | 67°42.0′ |
| LC3 | 40°20.0′ | 67°43.0′ |
| LC4 | 40°27.0′ | 67°40.0′ |
| LC5 | 40°27.0′ | 67°38.0′ |
| LC1 | 40°16.0′ | 67°34.0′ |

* * * * *

■ 3. In § 648.24, paragraph (b)(7) is added and paragraph (c)(1)(iii) is revised to read as follows:

**§ 648.24 Fishery closures and accountability measures.**

* * * * *

(b) * * *

(7) *River herring and shad catch cap.* NMFS shall close the directed mackerel fishery in the EEZ when the Regional Administrator projects that 95 percent of the river herring/shad catch cap has been harvested.

(c) * * *

(1) * * *

(iii) *Phase 3.* NMFS shall subsequently reduce the trip limit for vessels issued longfin squid/butterfish moratorium permits to 600 lb (0.27 mt), regardless of minimum mesh size, when butterfish harvest is projected to reach the relevant phase 3 trip limit reduction threshold. The NMFS Regional Administrator may adjust the butterfish trip limit during phase 3 of the directed butterfish fishery anywhere from 250 lb (0.11 mt) to 750 lb (0.34 mt) to ensure butterfish harvest does not exceed the specified DAH.

* * * * *

■ 4. In § 648.26, paragraphs (b) and (d)(3) are revised to read as follows:

**§ 648.26 Mackerel, squid, and butterfish possession restrictions.**

* * * * *

(b) *Longfin squid.* (1) Unless specified in paragraph (b)(2) of this section, during a closure of the directed fishery for longfin squid vessels may not fish for, possess, or land more than 2,500 lb (1.13 mt) of longfin squid per trip at any time, and may only land longfin squid once on any calendar day, which is defined as the 24-hr period beginning at 0001 hours and ending at 2400 hours. If a vessel has been issued a longfin squid incidental catch permit (as specified at § 648.4(a)(5)(ii)), then it may not fish for, possess, or land more than 2,500 lb (1.13 mt) of longfin squid per trip at any time and may only land longfin squid once on any calendar day, unless such a vessel meets the criteria outlined in paragraph (b)(2) of this section.

(2) During a closure of the directed fishery for longfin squid for Trimester II, a vessel with a longfin squid/butterfish moratorium permit that is on a directed *Illex* squid fishing trip (i.e., possess over 10,000 lb (4.54 mt) of *Illex*) and is seaward of the coordinates specified at § 648.23 (a)(3), may possess up to 15,000 lb (6.80 mt) of longfin squid. Once landward of the coordinates specified at § 648.23 (a)(3), such vessels must stow all fishing gear, as specified at § 648.23(b), in order to possess more than 2,500 lb (1.13 mt) of longfin squid per trip.

* * * * *

(d) * * *

(3) *Phase 3.* When butterfish harvest is projected to reach the trip limit reduction threshold for phase 3 (as described in § 648.24), all vessels issued a longfin squid/butterfish moratorium permit, regardless of mesh size used, may not fish for, possess, or land more than 600 lb (0.27 mt) of butterfish per trip at any time, and may only land butterfish once on any calendar day, which is defined as the 24-hr period beginning at 0001 hours and ending at 2400 hours. If a vessel has been issued a longfin squid/butterfish incidental catch permit (as specified at § 648.4(a)(5)(ii)), it may not fish for, possess, or land more than 600 lb (0.27 mt) of butterfish per trip at any time.

[FR Doc. 2014–00265 Filed 1–9–14; 8:45 am]

BILLING CODE 3510–22–P

# Notices

Federal Register
Vol. 79, No. 7
Friday, January 10, 2014

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

### Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@omb.eop.gov* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

**Food and Nutrition Service**

*Title:* Enhancing Completion Rates for Supplemental Nutrition Assistance Program (SNAP) Quality Control Reviews.

*OMB Control Number:* 0584–NEW.

*Summary of Collection:* Section 17 [7 U.S.C. 2026] (a)(1) of the Food and Nutrition Act of 2008 provides general legislative authority for the planned data collection. It authorizes the Secretary of the U.S. Department of Agriculture to enter into contracts with private institutions to undertake research that will help to improve the administration and effectiveness of the Supplemental Nutrition Assistance Program (SNAP) in delivering nutrition-related benefits. The SNAP Quality Control (QC) system requires States to conduct monthly quality control reviews of households participating in SNAP to assess the validity of SNAP cases, and, ultimately, the payment error rate for SNAP. The completion rate of sampled QC reviews has decreased nationally over the last few decades. In response to this overall decline and inter-State variation in SNAP QC completion rates, the current study seeks to identify the factors associated with incomplete QC reviews in active SNAP cases and to identify best practices related to completing SNAP QC reviews.

*Need and Use of the Information:* The Food and Nutrition Service will collect information through four instruments: a semi-structured interview protocol for QC directors and supervisors, a semi-structured interview protocol for QC reviewers, a survey instrument for QC directors and supervisors, and a survey instrument for QC reviewers. The purpose of this information collection is to identify the factors that consistently lead to incomplete cases among active SNAP QC case reviews and identify possible means to enhance completion rates. If the data is not collected, USDA will not have critical information for assessing the causes of incomplete QC reviews and improving the integrity of the QC process.

*Description of Respondents:* State, Local or Tribal Government; Federal Government.

*Number of Respondents:* 1,050.

*Frequency of Responses:* Reporting: On occasion; Other (1 time).

*Total Burden Hours:* 307.

**Food and Nutrition Service**

*Title:* WIC Nutrition Services and Administration (NSA) Costs Study.

*OMB Control Number:* 0584–NEW.

*Summary of Collection:* The Healthy, Hunger-Free Kid Act of 2010 (Pub. L. 111–296, Sec 305) mandates programs under its authorization to cooperate with U.S. Department of Agriculture (USDA) program research and evaluation activities. The mandate applies to Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) agencies. The WIC Program regulations (7 CFR part 246) delegate administration of the WIC Program to the USDA's Food and Nutrition Service (FNS). The operational component of the WIC Program is funded through the nutrition services and administration (NSA) portion of State Agency grants; however, these NSA costs have not been examined since a Government Accountability Office (GA)) study conducted in 2000. To better understand the sources that contribute to the variation in NSA costs, FNS seeks to ensure that all States operate the WIC Program in an effective and efficient manner. The National WIC NSA cost Study will provide an updated assessment of the types and categories of costs charged to WIC NSA grants, and the factors that influence the variation in these costs among State and local agencies.

*Need and Use of the Information:* The purpose of the WIC NSA Cost Study is to provide FNS with an updated assessment of the amounts and categories of costs charged to WIC NSA grants and to increase the understanding of why there is such cost variation among State and local agencies. A better understanding of these areas will enable FNS to more efficiently and effectively administer the WIC Program. If the data is not collected it would negatively impact the ability of FNS to carry out its federal mandate of managing the WIC program in the most effective and efficient way possible.

*Description of Respondents:* State, Local or Tribal Government; Federal Government.

*Number of Respondents:* 6,236.

*Frequency of Responses:* Reporting: On occasion; Other (1 time).

*Total Burden Hours:* 2,580.

**Charlene Parker,**

*Departmental Information Collection Clearance Officer.*

[FR Doc. 2014–00207 Filed 1–9–14; 8:45 am]

**BILLING CODE 3410–30–P**

## DEPARTMENT OF AGRICULTURE

### Submission for OMB Review; Comment Request

The Department of Agriculture will submit the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, Washington, DC; New Executive Office Building, 725—17th Street NW., Washington, DC 20503. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602.

Comments regarding these information collections are best assured of having their full effect if received by February 10, 2014. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

**Agricultural Marketing Service**

*Title:* Cotton Classing, Testing, and Standards.

*OMB Control Number:* 0581–0008.

*Summary of Collection:* The U.S. Cotton Standards Act, 7 U.S.C. 51 53 and 55, authorizes the USDA to supervise the various activities directly associated with the classification or grading of cotton, cotton linters, and cottonseed based on official USDA Standards. The Cotton and Tobacco Program of the Agricultural Marketing Service carries out this supervision and is responsible for the maintenance of the functions to which these forms relate. USDA is the only Federal agency authorized to establish and promote the use of the official cotton standards of the U.S. in interstate and foreign commerce and to supervise the various activities associated with the classification or grading of cotton, cotton linters, and cottonseed based on official USDA standards.

*Need and Use of the Information:* The Agricultural Marketing Service uses the following forms to collection information:

Form FD–210 is submitted by owners of cotton to request cotton classification services. The request contains information for USDA to ascertain proper ownership of the samples submitted, to distribute classification results, and bill for services. Information about the origin and handling of the cotton is necessary in order to properly evaluate and classify the samples.

Form CN–246 is submitted by cotton gins and warehouses seeking to serve as licensed samplers. Licenses issued by the USDA–AMS Cotton Program authorize the warehouse/gin to draw and submit samples to insure the proper application of standards in the classification of cotton and to prevent deception in their use.

Form CN–383 is a package of forms designated as CN–383–a through CN–383–k that is submitted by cotton producers, ginners, warehousemen, cooperatives, manufacturers, merchants, and crushers interested in acquiring cotton classification standards and round testing services.

*Description of Respondents:* Business or other for-profit.

*Number of Respondents:* 993.

*Frequency of Responses:* Reporting: Annually; on occasion.

*Total Burden Hours:* 141.

**Agricultural Marketing Service**

*Title:* Cotton Classification and Market News Service.

*OMB Control Number:* 0581–0009.

*Summary of Collection:* The Cotton Statistics and Estimates Act, 7 U.S. Code 471–476, authorizes the Secretary of Agriculture to collect and publish annually statistics or estimates concerning the grades and staple lengths of stocks of cotton. In addition, Agricultural Marketing Service (AMS) collects, authenticates, publishes, and distributes timely information of the market supply, demand, location, and market prices for cotton (7 U.S.C. 473B). This information is needed and used by all segments of the cotton industry.

*Need and Use of the Information:* AMS will collect information on the quality of cotton in the carryover stocks along with the size or volume of the carryover. Growers use this information in making decisions relative to marketing their present crop and planning for the next one; cotton merchants use the information in marketing decisions; and the mills that provide the data also use the combined data in planning their future purchase to cover their needs. Importers of U.S. cotton use the data in making their plans for purchases of U.S. cotton. AMS and other government agencies are users of the compiled information.

*Description of Respondents:* Business or other for-profit.

*Number of Respondents:* 826.

*Frequency of Responses:* Reporting: On occasion; weekly; annually.

*Total Burden Hours:* 653.

**Agricultural Marketing Service**

*Title:* Reporting Forms under Milk Marketing Order Programs.

*OMB Control Number:* 0581–0032.

*Summary of Collection:* Agricultural Marketing Service (AMS) oversees the administration of the Federal Milk Marketing Orders authorized by the Agricultural Marketing Agreement Act of 1937, as amended. The Act is designed to improve returns to producers while protecting the interests of consumers. The Federal Milk Marketing Order regulations require places certain requirements on the handling of milk in the area it covers. Currently, there are 10 milk marketing orders regulating the handling of milk in the respective marketing areas.

*Need and Use of the Information:* The information collected is needed to administer the classified pricing system and related requirements of each Federal Order. Forms are used for reporting purposes and to establish the quantity of milk received by handlers, the pooling status of the handler, and the class-use of the milk used by the handler and the butterfat content and amounts of other components of the milk. Without the monthly information, the market administrator would not have the information to compute each

monthly price nor know if handlers were paying producers on dates prescribed in the order. Penalties are imposed for violation of the order, such as the failure to pay producers by the prescribed dates.

*Description of Respondents:* Business or other for-profit; not-for-profit institutions; individuals or households; farms.

*Number of Respondents:* 690.

*Frequency of Responses:* Recordkeeping; Reporting: On occasion; quarterly; monthly; annually.

*Total Burden Hours:* 20,343.

**Agricultural Marketing Service**

*Title:* Reporting and Recordkeeping Requirements for 7 CFR part 29.

*OMB Control Number:* 0581–0056.

*Summary of Collection:* The Fair and Equitable Tobacco Reform Act of 2004 (7 U.S.C. 518) eliminated price supports and marketing quotas for all tobacco beginning with the 2005 crop year. Mandatory inspection and grading of domestic and imported tobacco was eliminated as well as the mandatory pesticide testing of imported tobacco and the tobacco Market News Program. The Tobacco Inspection Act (U.S.C. 511) requires that all tobacco sold at designated auction markets in the U.S. be inspected and graded. Provision is also made for interested parties to request inspection, pesticide testing and grading services on an ''as needed'' basis.

*Need and Use of the Information:* Information is collected through various forms and other documents for the inspection and certification process. Upon receiving request information from tobacco dealers and/or manufacturers, tobacco inspectors will pull samples and apply U.S. Standard Grades to samples to provide a Tobacco Inspection Certificate (TB–92). Also, samples can be submitted to a USDA laboratory for pesticide testing and a detailed analysis is provided to the customer.

*Description of Respondents:* Business or other for-profit.

*Number of Respondents:* 50.

*Frequency of Responses:* Recordkeeping; reporting; on occasion.

*Total Burden Hours:* 3,851.

**Charlene Parker,**

*Departmental Information Collection Clearance Officer.*

[FR Doc. 2014–00205 Filed 1–9–14; 8:45 am]

BILLING CODE 3410–02–P

## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

**[Docket Number FSIS–2013–0051]**

**RIN 0583–AD40**

### 2014 Rate Changes for the Basetime, Overtime, Holiday, and Laboratory Services Rates

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Notice.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is announcing the 2014 rates it will charge meat and poultry establishments, egg products plants, and importers and exporters for providing voluntary, overtime, and holiday inspection and identification, certification, and laboratory services. The 2014 basetime, overtime, holiday, and laboratory services rates will be applied on the first FSIS pay period approximately 30 days after the publication of this notice, which begins on February 9, 2014.

**DATES:** FSIS will charge the rates announced in this notice beginning February 9, 2014.

**FOR FURTHER INFORMATION CONTACT:** For further information contact Michael Toner, Director, Budget Division, Office of Management, FSIS, U.S. Department of Agriculture, Room 2159, South Building, 1400 Independence Avenue SW., Washington, DC 20250–3700; Telephone: (202) 690–8398, Fax: (202) 690–4155.

**SUPPLEMENTARY INFORMATION:**

**Background**

On April 12, 2011, FSIS published a final rule amending its regulations to establish formulas for calculating the rates it charges meat and poultry establishments, egg products plants, and importers and exporters for providing voluntary, overtime, and holiday inspection and identification, certification, and laboratory services (76 FR 20220).

In the final rule, FSIS stated that it would use the formulas to calculate the annual rates, publish the rates in **Federal Register** notices prior to the start of each calendar year, and apply the rates on the first FSIS pay period at the beginning of the calendar year.

This notice provides the 2014 rates, which will be applied starting on February 9, 2014.

**2014 Rates and Calculations**

The following table lists the 2014 Rates per hour, per employee, by type of service:

| Service | 2014 Rate (estimates rounded to reflect billable quarters) |
|---|---|
| Basetime | $55.16 |
| Overtime | 69.56 |
| Holiday | 84.00 |
| Laboratory | 68.79 |

The regulations state that FSIS will calculate the rates using formulas that include the Office of Field Operations (OFO) and Office of International Affairs (OIA) inspection program personnel's previous fiscal year's regular direct pay and regular hours (9 CFR 391.2, 391.3, 391.4, 590.126, 590.128, 592.510, 592.520, and 592.530). In 2013, an Agency reorganization eliminated the OIA program office and transferred all of its inspection program personnel to OFO. The calculations below include the portion of the previous fiscal year's OIA inspection program personnel's pay and hours but are identified in the calculations as ''OFO inspection program personnel's'' pay and hours.

FSIS determined the 2014 rates using the following calculations:

*Basetime Rate* = The quotient of dividing the Office of Field Operations (OFO) inspection program personnel's previous fiscal year's regular direct pay by the previous fiscal year's regular hours, plus the quotient multiplied by the calendar year's percentage of cost of living increase, plus the benefits rate, plus the travel and operating rate, plus the overhead rate, plus the allowance for bad debt rate.

The calculation for the 2014 basetime rate per hour per program employee is:

[FY 2013 OFO Regular Direct Pay divided by the previous fiscal year's Regular Hours ($463,542,338/16,407,854)] = $28.25 + ($28.25 * 2.0% (calendar year 2014 Cost of Living Increase)) = $28.82 + $9.08 (benefits rate) + $.66 (travel and operating rate) + $16.61 (overhead rate) + $.02 (bad debt allowance rate) = $55.18(rounded to $55.16).[1]

*Overtime Rate* = The quotient of dividing the Office of Field Operations (OFO) inspection program personnel's previous fiscal year's regular direct pay by the previous fiscal year's regular hours, plus that quotient multiplied by the calendar year's percentage of cost of living increase, multiplied by 1.5 (for overtime), plus the benefits rate, plus the travel and operating rate, plus the overhead rate, plus the allowance for bad debt rate.

[1] FSIS can bill basetime, overtime, and holiday rates on the quarter hour. Accordingly, the 2014 basetime and overtime rates were rounded down so that the rates can equally be divided by 4 (to 2 decimal places).

The calculation for the 2014 overtime rate per hour per program employee is:

[FY 2013 OFO Regular Direct Pay divided by previous fiscal year's Regular Hours ($463,542,338/16,407,854)] = $28.25 + ($28.25 * 2.0% (calendar year 2014 Cost of Living Increase)) = $28.82 * 1.5 = $43.22 + $9.08 (benefits rate) + $.66 (travel and operating rate) + $16.61 (overhead rate) + $.02 (bad debt allowance rate) = $69.59 (rounded to $69.56).[2]

*Holiday Rate* = The quotient of dividing the Office of Field Operations (OFO) inspection program personnel's previous fiscal year's regular direct pay by the previous fiscal year's regular hours, plus that quotient multiplied by the calendar year's percentage of cost of living increase, multiplied by 2 (for holiday pay), plus the benefits rate, plus the travel and operating rate, plus the overhead rate, plus the allowance for bad debt rate.

The calculation for the 2014 holiday rate per hour per program employee calculation is:

[FY 2013 OFO Regular Direct Pay divided by Regular Hours ($463,542,338/16,407,854)] = $28.25 + ($28.25 * 2.0% (calendar year 2014 Cost of Living Increase)) = $28.82 * 2 = $57.64 + $9.08 (benefits rate) + $.66 (travel and operating rate) + $16.61 (overhead rate) + $.02 (bad debt allowance rate) = $84.00.

*Laboratory Services Rate* = The quotient of dividing the Office of Public Health Science (OPHS) previous fiscal year's regular direct pay by the OPHS previous fiscal year's regular hours, plus the quotient multiplied by the calendar year's percentage cost of living increase, plus the benefits rate, plus the travel and operating rate, plus the overhead rate, plus the allowance for bad debt rate.

The calculation for the 2014 laboratory services rate per hour per program employee is:

[FY 2013 OPHS Regular Direct Pay/OPHS Regular hours ($22,997,979/552,947)] = $41.59 + ($41.59 * 2.0% (calendar year 2014 Cost of Living Increase)) = $42.42 + $9.08 (benefits rate) + $.66 (travel and operating rate) + $16.61 (overhead rate) + $.02 (bad debt allowance rate) = $68.79.

[2] *Ibid.*

**Calculations for the Benefits, Travel and Operating, Overhead, and Allowance for Bad Debt Rates**

These rates are components of the basetime, overtime, holiday, and laboratory services rates formulas.

*Benefits Rate:* The quotient of dividing the previous fiscal year's direct benefits costs by the previous fiscal year's total hours (regular, overtime, and holiday), plus that quotient multiplied by the calendar year's percentage cost of living increase. Some examples of direct benefits are health insurance, retirement, life insurance, and Thrift Savings Plan basic and matching contributions.

The calculation for the 2014 benefits rate per hour per program employee is:

[FY 2013 Direct Benefits/ (Total Regular hours + Total Overtime hours + Total Holiday hours) ($172,028,218/19,333,483)] = $8.90 + ($8.90 * 2.0% (calendar year 2014 Cost of Living Increase) = $9.08.

*Travel and Operating Rate:* The quotient of dividing the previous fiscal year's total direct travel and operating costs by the previous fiscal year's total hours (regular, overtime, and holiday), plus that quotient multiplied by the calendar year's percentage of inflation.

The calculation for the 2014 travel and operating rate per hour per program employee is:

[FY 2013 Total Direct Travel and Operating Costs/(Total Regular hours + Total Overtime hours + Total Holiday hours) ($12,600,122/19,333,483)] = $.65 + ($.65 * 1.7% (2014 Inflation) = $.66.

*Overhead Rate:* The quotient of dividing the previous fiscal year's indirect costs plus the previous fiscal year's information technology (IT) costs in the Public Health Data Communication Infrastructure System Fund plus the previous fiscal year's Office of Management Program cost in the Reimbursable and Voluntary Funds plus the provision for the operating balance less any Greenbook costs (i.e., costs of USDA support services prorated to the service component for which fees are charged) that are not related to food inspection by the previous fiscal year's total hours (regular, overtime, and holiday) worked across all funds, plus the quotient multiplied by the calendar year's percentage of inflation.

The calculation for the 2014 overhead rate per hour per program employee is:

[FY 2013 Total Overhead/(Total Regular hours + Total Overtime hours + Total Holiday hours) ($315,684,199.17/19,333,483)] = $16.33 + ($16.33 * 1.7% (2014 Inflation) = $16.61.

*Allowance for Bad Debt Rate* = Previous fiscal year's total allowance for bad debt (for example, debt owed that is not paid in full by plants and establishments that declare bankruptcy) divided by previous fiscal year's total hours (regular, overtime, and holiday) worked.

The 2014 calculation for bad debt rate per hour per program employee is:

[FY 2013 Total Bad Debt/(Total Regular hours + Total Overtime hours + Total Holiday hours) = ($288,994/19,333,483)] = $.02.

**Additional Public Notification**

FSIS will announce this notice online through the FSIS Web page located at *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/federal-register-notices.* FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Constituent Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/wps/portal/fsis/programs-and-services/email-subscription-service.* Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250–9410 or call (202) 720–5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Dated: January 3, 2014.

**Alfred V. Almanza,**

*Administrator.*

[FR Doc. 2014–00372 Filed 1–8–14; 4:15 pm]

**BILLING CODE 3410–DM–P**

## DEPARTMENT OF COMMERCE

### Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

*Agency:* National Oceanic and Atmospheric Administration (NOAA).

*Title:* Mandatory Shrimp Vessel and Gear Characterization Survey.

*OMB Control Number:* 0648–0542.

*Form Number(s):* NA.

*Type of Request:* Regular submission (extension of a current information collection).

*Number of Respondents:* 1,529.

*Average Hours Per Response:* 20 minutes.

*Burden Hours:* 510.

*Needs and Uses:* This request is for extension of a current information collection.

The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) authorizes the Gulf of Mexico Fishery Management Council (Council) to prepare and amend fishery management plans for any fishery in waters under its jurisdiction. National Marine Fisheries Service (NMFS) manages the shrimp fishery in the waters of the Gulf of Mexico under the Shrimp Fishery Management Plan (FMP). The regulations for the Gulf Shrimp Vessel and Gear Characterization Form may be found at 50 CFR 622.51(a)(3).

Owners or operators of vessels applying for or renewing a commercial vessel moratorium permit for Gulf shrimp must complete an annual Gulf Shrimp Vessel and Gear Characterization Form. The form will be provided by NMFS at the time of permit application and renewal. Compliance with this reporting requirement is required for permit issuance and renewal.

Through this form, NMFS is collecting census-level information on fishing vessel and gear characteristics in the Gulf of Mexico Exclusive Economic Zone (EEZ) shrimp fishery to conduct analyses that will improve fishery management decision-making in this fishery; ensure that national goals, objectives, and requirements of the Magnuson-Stevens Act, National Environmental Policy Act (NEPA), Regulatory Flexibility Act (RFA), Endangered Species Act (ESA), and Executive Order (E.O.) 12866 are met; and quantify achievement of the performance measures in the NMFS' Operating Plans. This information is vital in assessing the economic, social, and environmental effects of fishery management decisions and regulations on individual shrimp fishing enterprises, fishing communities, and the nation as a whole.

*Affected Public:* Business or other for-profit organizations.

*Frequency:* Annually.

*Respondent's Obligation:* Mandatory.

*OMB Desk Officer: OIRA_Submission@omb.eop.gov.*

Copies of the above information collection proposal can be obtained by calling or writing Jennifer Jessup, Departmental Paperwork Clearance Officer, (202) 482–0336, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov.*

Dated: January 7, 2014.

**Gwellnar Banks,**

*Management Analyst, Office of the Chief Information Officer.*

[FR Doc. 2014–00233 Filed 1–9–14; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### Bureau of Industry and Security

### Order Temporarily Denying Export Privileges

3K Aviation Consulting & Logistics, a/k/a 3K Havacilik Ve Danismanlik SAN. TIC. LTD. ST., Biniciler Apt. Savas Cad. No. 18/5, Sirinyali Mah. 07160, Antalya, Turkey

and

Sonmez Apt. No. 4/5 1523 Sokak, Sirinyali Mah. 07160, Antalya, Turkey

Huseyin Engin Borluca, Biniciler Apt. Savas Cad. No. 18/5, Sirinyali Mah. 07160, Antalya, Turkey

and

Sonmez Apt. No. 4/5 1523 Sokak, Sirinyali Mah. 07160, Antalya, Turkey)

Adaero International Trade, LLC, 2326 17th Avenue, Rockford, IL 61104

and

IDTM B 1 Blok, Kat 14 No: 439, Yesilkoy, Istanbul, Turkey

Recep Sadettin Ilgin, 2326 17th Avenue, Rockford, IL 61104

and

IDTM B 1 Blok, Kat 14 No: 439, Yesilkoy, Istanbul, Turkey

Pouya Airline, a/k/a Pouya Air, Mehrebad Airport, Tehran, Iran

*Respondents.*

Pursuant to Section 766.24 of the Export Administration Regulations (the ''Regulations'' or ''EAR''),[1] the Bureau of Industry and Security (''BIS''), U.S. Department of Commerce, through its Office of Export Enforcement (''OEE''), has requested that I issue an Order temporarily denying, for a period of 180 days, the export privileges under the EAR of: 3K Aviation Consulting & Logistics, also known as 3K Havacilik Ve Danismanlik SAN. TIC. LTD. ST.; Huseyin Engin Boluca (3K Aviation Consulting & Leasing's founder and director); Adaero International Trade, LLC; Recep Sadettin Ilgin (Adaero International Trade's managing director); and Pouya Airline, also known as Pouya Air.

Pursuant to Section 766.24, BIS may issue an order temporarily denying a respondent's export privileges upon a showing that the order is necessary in the public interest to prevent an ''imminent violation'' of the Regulations. 15 CFR 766.24(b)(1) and 776.24(d). ''A violation may be 'imminent' either in time or degree of likelihood.'' 15 CFR 766.24(b)(3). BIS may show ''either that a violation is about to occur, or that the general circumstances of the matter under investigation or case under criminal or administrative charges demonstrate a likelihood of future violations.'' *Id.* As to the likelihood of future violations, BIS may show that the violation under investigation or charge ''is significant, deliberate, covert and/or likely to occur again, rather than technical or negligent[.]'' *Id.* A ''lack of information

[1] The EAR is currently codified at 15 CFR Parts 730–774 (2013). The EAR are issued under the Export Administration Act of 1979, as amended (50 U.S.C. app. 2401–2420 (2000)) (''EAA''). Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 8, 2013 (78 FR 49107 (Aug. 12, 2013)), has continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701, *et seq.*) (2006 & Supp. IV 2010).

establishing the precise time a violation may occur does not preclude a finding that a violation is imminent, so long as there is sufficient reason to believe the likelihood of a violation.'' *Id.*

In its request, BIS has presented evidence that, in December 2013, two U.S.-origin General Electric CF6 aircraft engines [2] bearing manufacturer's serial numbers (''MSN'') 695244 and 705112 were transported on behalf of Adaero International Trade, LLC to 3K Aviation Consulting & Logistics (''3K Aviation''), which is located in Turkey. Additionally, BIS has been notified that 3K Aviation is preparing to immediately re-export the engines to Iran without the U.S. Government authorization required by Section 746.7 of the EAR. BIS was further notified that Pouya Airline, an Iranian cargo airline, is scheduled to transport both engines from Turkey to Iran on January 7, 2014.

I find that the evidence presented by BIS demonstrates that a violation of the Regulations is imminent in both time and degree of likelihood. As such, a TDO is needed to give notice to persons and companies in the United States and abroad that they should cease dealing with the Respondents in export transactions involving items subject to the EAR. Such a TDO is consistent with the public interest to preclude future violations of the EAR.

Accordingly, I find that a TDO naming 3K Aviation Consulting & Logistics, Huseyin Engin Borluca, Adaero International Trade, Recep Sadettin Ilgin, and Pouya Airline is necessary, in the public interest, to prevent an imminent violation of the EAR.

This Order is being issued on an *ex parte* basis without a hearing based upon BIS's showing of an imminent violation in accordance with Section 766.24 of the Regulations.

*It is therefore ordered:*

*First,* that 3K AVIATION CONSULTING & LOGISTICS, A/K/A 3K HAVACILIK VE DANISMANLIK SAN. TIC. LTD. ST., Biniciler Apt. Savas Cad. No. 18/5, Sirinyali Mah. 07160, Antalya, Turkey, and Sonmez Apt. No. 4/5 1523 Sokak, Sirinyali Mah. 07160, Antalya, Turkey; HUSEYIN ENGIN BORLUCA, Biniciler Apt. Savas Cad. No. 18/5, Sirinyali Mah. 07160, Antalya, Turkey, and Sonmez Apt. No. 4/5 1523 Sokak, Sirinyali Mah. 07160, Antalya, Turkey; ADAERO INTERNATIONAL TRADE, LLC, 2326 17th Avenue, Rockford, IL 61104, and IDTM B1 Blok, KAT 14 No. 439, Ysilkoy, Istanbul, Turkey; RECEP SADETTIN ILGIN, 2326 17th Avenue, Rockford, IL 61104, and IDTM B1 Blok, KAT 14 No. 439, Ysilkoy, Istanbul, Turkey; and POUYA AIRLINE, a/k/a POUYA AIR, Mehrebad Airport, Tehran, Iran; and when acting for or on their behalf, any successors or assigns, agents, or employees (each a ''Denied Person'' and collectively the ''Denied Persons'') may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Export Administration Regulations (''EAR''), or in any other activity subject to the EAR including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR.

*Second,* that no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of a Denied Person any item subject to the EAR;

B. Take any action that facilitates the acquisition or attempted acquisition by a Denied Person of the ownership, possession, or control of any item subject to the EAR that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby a Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from a Denied Person of any item subject to the EAR that has been exported from the United States;

D. Obtain from a Denied Person in the United States any item subject to the EAR with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the EAR that has been or will be exported from the United States and which is owned, possessed or controlled by a Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by a Denied Person if such service involves the use of any item subject to the EAR that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

*Third,* that, after notice and opportunity for comment as provided in section 766.23 of the EAR, any other person, firm, corporation, or business organization related to a Denied Person by affiliation, ownership, control, or position of responsibility in the conduct of trade or related services may also be made subject to the provisions of this Order.

In accordance with the provisions of Section 766.24(e) of the EAR, the Respondents may, at any time, appeal this Order by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202–4022.

In accordance with the provisions of Section 766.24(d) of the EAR, BIS may seek renewal of this Order by filing a written request not later than 20 days before the expiration date. The Respondents may oppose a request to renew this Order by filing a written submission with the Assistant Secretary for Export Enforcement, which must be received not later than seven days before the expiration date of the Order.

A copy of this Order shall be served on the Respondents and shall be published in the **Federal Register**.

This Order is effective upon issuance and shall remain in effect for 180 days.

Dated: January 3, 2014.

**David W. Mills,**

*Assistant Secretary of Commerce for Export Enforcement.*

[FR Doc. 2014–00229 Filed 1–9–14; 8:45 a.m.]

BILLING CODE P

[2] The engines are items subject to the Regulations, classified under Export Control Classification Number 9A991.d, and controlled for anti-terrorism reasons.

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–552–802]**

### Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Initiation and Preliminary Results of Changed Circumstances Review

**AGENCY:** Enforcement and Compliance, formerly Import Administration, International Trade Administration, Department of Commerce.

**SUMMARY:** In response to a request for a changed circumstances review (''CCR'')

of Gallant Ocean (Vietnam) Co., Ltd. (''Gallant Ocean'') and its subsidiary, Gallant Ocean (Quang Ngai), Co. Ltd. (''Quang Ngai''), the Department of Commerce (''Department'') is initiating a CCR of the antidumping duty order on certain frozen warmwater shrimp from the Socialist Republic of Vietnam (''Vietnam''). We have preliminarily determined that Gallant Dachan Seafood Co., Ltd. (''Dachan'') is the successor-in-interest to Quang Ngai, and, as a result, should be accorded the same treatment previously accorded to Quang Ngai. Interested parties are invited to comment on these preliminary results.

**DATES:** *Effective Date:* January 10, 2014.

**FOR FURTHER INFORMATION CONTACT:** Ricardo Martinez Rivera or Bob Palmer, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: at (202) 482–4532 or (202) 482–9068, respectively.

**SUPPLEMENTARY INFORMATION:**

## Background

The Department published the antidumping duty order on certain frozen warmwater shrimp from Vietnam on February 1, 2005.[1] In the fourth administrative review, we granted Gallant Ocean a separate rate.[2] In the sixth administrative review (*i.e.,* February 1, 2010, through January 31, 2011), Gallant Ocean acquired Quang Ngai, and in that review and in the seventh administrative review, we assigned Quang Ngai a separate rate (*i.e.,* zero percent).[3] On October 31, 2013,[4] Gallant Ocean informed the Department that it had reduced ownership in Quang Ngai and changed its name, and petitioned the Department to conduct a CCR to confirm that Dachan is the successor-in-interest to Quang Ngai, for purposes of determining antidumping duties due as a result of the *Order.*[5]

## Scope of the Order

The merchandise subject to the order is certain frozen warmwater shrimp. The product is currently classified under the following Harmonized Tariff Schedule of the United States item numbers: 0306.17.00.03, 0306.17.00.06, 0306.17.00.09, 0306.17.00.12, 0306.17.00.15, 0306.17.00.18, 0306.17.00.21, 0306.17.00.24, 0306.17.00.27, 0306.17.00.40, 1605.21.10.30, and 1605.29.10.10. The written description of the scope of the order is dispositive. A full description of the scope of the order is available in the accompanying Issues and Decision Memorandum.[6]

## Initiation and Preliminary Results of Changed Circumstances Review

Pursuant to section 751(b)(1) of the Tariff Act of 1930, as amended (''the Act''), and 19 CFR 351.216, the Department will conduct a CCR upon a request from an interested party for a review of an antidumping duty order which shows changed circumstances sufficient to warrant a review of the order. The information submitted by Gallant Ocean supporting its claim that Dachan is the successor-in-interest to Quang Ngai, demonstrates changed circumstances sufficient to warrant such a review.[7]

In accordance with the above-referenced regulation, the Department is initiating a CCR to determine whether Dachan is the successor-in-interest Quang Ngai. In determining whether one company is the successor-in-interest to another, the Department examines a number of factors including, but not limited to, changes in management, production facilities, supplier relationships, and customer base.[8] Although no single factor will necessarily provide a dispositive indication of succession, generally, the Department will consider one company to be a successor-in-interest to another company if its resulting operation is similar to that of its predecessor.[9] Thus, if the evidence demonstrates that with respect to the production and sale of the subject merchandise, the new company operates as the same business entity as the prior company, the Department will assign the new company the cash-deposit rate of its predecessor.[10]

In its October 31, 2013, submission, Gallant Ocean provided information to demonstrate that Dachan is the successor-in-interest to Quang Ngai. Specifically, the record in this review indicates: (1) That, except for the financial manager, management which operated Dachan is the same which operated Quang Ngai;[11] (2) Dachan retained the same physical address and equipment as Quang Ngai and that production continued uninterrupted;[12] (3) that Dachan continued to purchase raw shrimp and packing materials from the same suppliers;[13] (4) that Dachan continued to supply the same U.S. customer base.[14] Under these circumstances, the Department preliminarily finds that Dachan operates as the same business entity as Quang Ngai. Given the continuity described above, we have preliminarily determined that no material change has occurred with respect to Quang Ngai's management, production facilities, suppliers, or customer base as a result of the name change to Dachan.

When it concludes that expedited action is warranted, the Department may publish the notice of initiation and preliminary results for a CCR concurrently.[15] We have determined that expedition of this CCR is warranted because we have the information necessary to make a preliminary finding

[1] *See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam,* 70 FR 5152 (February 1, 2005) (''*Order*'').

[2] *See Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Final Results and Partial Rescission of Antidumping Duty Administrative Review,* 75 FR 47771 (August 9, 2010).

[3] *See Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Final Results and Final Partial Rescission of Antidumping Duty Administrative Review,* 77 FR 55800, 55802 (September 11, 2012), unchanged in *Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Amended Final Results and Partial Final Rescission of Antidumping Duty Administrative Review,* 77 FR 64102, 64103 (October 18, 2012); see also *Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Final Results and Final Partial Rescission of Antidumping Duty Administrative Review,* 78 FR 56211–14 (September 12, 2013).

[4] This changed circumstances review was originally filed on September 30, 2013, within the seventh administrative review for frozen shrimp from Vietnam. Pursuant to instructions from the Department, Gallant Ocean re-filed this changed circumstances review on October 31, 2013.

[5] *See* Letter from Gallant Ocean, dated October 31, 2013, at 3.

[6] For a full description of the scope of the *Order, see* Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Issues and Decision Memorandum for the Final Results, (''Issues and Decision Memorandum'') dated September 6, 2013.

[7] *See* 19 CFR 351.216(d); *see also Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review: Carbon and Certain Alloy Steel Wire Rod From Mexico,* 75 FR 67685 (November 3, 2010).

[8] *See Industrial Phosphoric Acid From Israel; Final Results of Antidumping Duty Changed Circumstances Review,* 59 FR 6944 (February 14, 1994).

[9] *See Brass Sheet and Strip From Canada; Final Results of Antidumping Duty Administrative Review,* 57 FR 20460 (May 13, 1992).

[10] *Id.; Notice of Final Results of Changed Circumstances Antidumping Duty Administrative Review: Polychloroprene Rubber From Japan,* 67 FR 58 (January 2, 2002); *see also Ball Bearings and Parts Thereof from France: Final Results of Changed-Circumstances Review,* 75 FR 34688 (June 18, 2010) (the Department found successorship where the company changed its ownership structure, but made only minor changes to its operations, management, supplier relationships, and customer base).

[11] *See* Letter from Gallant Ocean, dated October 31, 2013, at 4 and Exhibit 4.

[12] *See id.,* at 5, and Exhibits 1 and 2.

[13] *See id.,* at 5, and Exhibit 5.

[14] *See id.,* at 5–6, and Exhibit 5.

[15] *See* 19 CFR 351.221(c)(3)(ii); *see also Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review: Canned Pineapple Fruit From Thailand,* 69 FR 30878 (June 1, 2004).

already on the record.[16] In this case, we preliminarily find that Dachan is the successor-in-interest to Quang Ngai and, as such, is entitled to Quang Ngai's cash-deposit rate with respect to entries of subject merchandise.

Should our final results remain the same as these preliminary results, effective the date of publication of the final results, we will instruct U.S. Customs and Border Protection to assign entries of merchandise produced or exported by Dachan the antidumping duty cash-deposit rate applicable to Quang Ngai.

**Public Comment**

Any interested party may request a hearing within 14 days of publication of this notice, in accordance with 19 CFR 351.310(c). Interested parties may submit case briefs and/or written comments no later than 30 days after the date of publication of this notice. Rebuttal briefs and rebuttals to written comments, which must be limited to issues raised in such briefs or comments, may be filed not later than 5 days after the case briefs. Any hearing, if requested, will normally be held two days after rebuttal briefs are due, in accordance with 19 CFR 351.310(d)(1). Parties who submit case briefs or rebuttal briefs in this CCR are requested to submit with each argument (1) a statement of the issue and (2) a brief summary of the argument with an electronic version included. Consistent with 19 CFR 351.216(e), we will issue the final results of this CCR no later than 270 days after the date on which this review was initiated or within 45 days of publication of these preliminary results if all parties agree to our preliminary finding.

We are issuing and publishing this initiation and preliminary results notice in accordance with sections 751(b)(1) and 777(i)(1) of the Act and 19 CFR 351.216 and 351.221(c)(3).

Dated: January 3, 2014.

**Christian Marsh,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

[FR Doc. 2014–00194 Filed 1–9–14; 8:45 am]

**BILLING CODE 3510–DS–P**

[16] *See Ball Bearings and Parts Thereof from Japan: Initiation and Preliminary Results of Changed Circumstances Review,* 71 FR 14679 (March 23, 2006).

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–405–803]**

### Purified Carboxymethylcellulose From Finland: Final Results of Antidumping Duty Administrative Review; 2011–2012

**AGENCY:** Enforcement and Compliance, formerly Import Administration, International Trade Administration, Department of Commerce.

**SUMMARY:** On August 7, 2013, the Department of Commerce (the Department) published the *Preliminary Results* of the 2011–2012 administrative review of the antidumping duty order on Purified Carboxymethylcellulose from Finland.[1] This review covers one respondent, CP Kelco Oy and CP Kelco, Inc. (collectively, CP Kelco). The petitioner in this proceeding is the Aqualon Company, a division of Hercules Incorporated (Petitioner). For these final results of review, we continue to find that CP Kelco made sales of subject merchandise to the United States at less than normal value (NV).

**DATES:** *Effective Date:* January 10, 2014.

**FOR FURTHER INFORMATION CONTACT:** Tyler Weinhold or Robert James, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Room 7850, Washington, D.C. 20230; telephone (202) 482–1121 or (202) 482–0649, respectively.

**SUPPLEMENTARY INFORMATION:**

**Background**

On August 7, 2013, the Department published the *Preliminary Results.* We invited parties to comment on the *Preliminary Results.* In response, we received a case brief from CP Kelco on September 16, 2013.[2] Petitioner filed a rebuttal brief on September 20, 2013.[3]

**Period of Review (POR)**

The POR is July 1, 2011, through June 30, 2012.

[1] *See Purified Carboxymethylcellulose from Finland: Notice of Preliminary Results of Antidumping Duty Administrative Review; 2011–2012,* 78 FR 50028 (August 16, 2013) (*Preliminary Results*), and the accompanying Decision Memorandum (Preliminary Decision Memorandum).

[2] *See* case brief from CP Kelco, ''Purified Carboxymethylcellulose from Finland; Case Brief'' (September 16, 2013) (CP Kelco's Case Brief).

[3] *See* rebuttal brief from Petitioner, ''Purified Carboxymethylcellulose from Finland; Rebuttal Brief'' (September 20, 2013) (Petitioner's Rebuttal Brief).

**Scope of the Order**

The merchandise covered by this order is all purified carboxymethylcellulose (CMC).[4] The merchandise subject to this order is classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheading 3912.31.00.

**Tolling of Deadlines**

As explained in the memorandum from the Assistant Secretary for Enforcement and Compliance, the Department has exercised its discretion to toll deadlines for the duration of the closure of the Federal Government from October 1, through October 16, 2013. *See* Memorandum for the Record from Paul Piquado, Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Shutdown of the Federal Government'' (October 18, 2013). Therefore, all deadlines in this segment of the proceeding have been extended by 16 days. If the new deadline falls on a non-business day, in accordance with the Department's practice, the deadline will become the next business day. The revised deadline for the final results of this review is now January 2, 2014.

**Analysis of Comments Received**

All issues raised in the case and rebuttal briefs by parties to this antidumping investigation are addressed in the Issues and Decision Memorandum. A list of the issues raised is attached to this notice as Appendix I. We have analyzed all interested party comments and have made no changes to the *Preliminary Results* for these final results.

[4] For a full description of the scope of the order, *see* Memorandum from Richard Weible, Director, Office VI, Antidumping and Countervailing Duty Operations, to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, ''Issues and Decision Memorandum for the Final Results of the 2011 to 2012 Administrative Review of the Antidumping Duty Order on Purified Carboxymethylcellulose from Finland'' (Issues and Decision Memorandum), which is dated concurrently with these final results and incorporated herein by reference. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (IA ACCESS). IA ACCESS is available to registered users at *http://iaaccess.trade.gov* and in the Central Records Unit (CRU), Room 7046 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/.* The signed Issues and Decision Memorandum and the electronic versions of the Issues and Decision Memorandum are identical in content.

**Final Results of Review**

We determine that the following dumping margin exists for the period July 1, 2011, through June 30, 2012:

| Manufacturer/exporter | Weighted-average dumping margin (percentage) |
|---|---|
| CP Kelco Oy | 3.40 |

**Assessment Rates**

Pursuant to section 751(a)(2)(A) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.212(b), the Department will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. For assessment purposes, we calculated importer (or customer)-specific assessment rates for merchandise subject to this review. Where appropriate, we calculated an *ad valorem* rate for each importer (or customer) by dividing the total dumping margins for reviewed sales to that party by the total entered values associated with those transactions. For duty assessment rates calculated on this basis, we will direct CBP to assess the resulting *ad valorem* rate against the entered customs values for the subject merchandise. Where appropriate, we calculated a per-unit rate for each importer (or customer) by dividing the total dumping margins for reviewed sales to that party by the total sales quantity associated with those transactions. For duty-assessment rates calculated on this basis, we will direct CBP to assess the resulting per-unit rate against the entered quantity of the subject merchandise. Where an importer (or customer)-specific assessment rate is *de minimis* (*i.e.,* less than 0.50 percent), the Department will instruct CBP to assess that importer (or customer's) entries of subject merchandise without regard to antidumping duties, in accordance with 19 CFR 351.106(c)(2). The Department intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review.

The Department clarified its automatic assessment regulation on May 6, 2003. *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003). This clarification will apply to entries of subject merchandise during the POR produced by the company included in these final results of review for which the reviewed company did not know their merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate un-reviewed entries at the all-others rate if there is no rate for the intermediate company involved in the transaction.

**Cash Deposit Requirements**

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of these final results, consistent with section 751(a)(1) of the Act: (1) For the company covered by this review, the cash deposit will be the rate listed above; (2) if the exporter is not a firm covered in this review, but was covered in a previous review or the original less than fair value (LTFV) investigation, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original LTFV investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this or any previous review conducted by the Department, the cash deposit rate will continue to be 6.65 percent, which is the all-others rate established in the LTFV investigation. *See Notice of Antidumping Duty Order; Purified Carboxymethylcellulose From Finland; Mexico, the Netherlands and Sweden,* 70 FR 39734 (July 11, 2005). These deposit requirements, when imposed, shall remain in effect until further notice.

**Notification to Importers**

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 the subsequent assessment of doubled antidumping duties.

**Administrative Protective Order**

This notice also serves as a reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: January 2, 2014.

**Christian Marsh,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

## Appendix I

**List of Topics Discussed in the Accompanying Issues and Decision Memorandum**

Issue: Authority To Conduct a Differential Pricing Analysis and Apply an Alternative Comparison Methodology

[FR Doc. 2014–00173 Filed 1–9–14; 8:45 am]

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## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–351–841]**

### Polyethylene Terephthalate Film, Sheet, and Strip From Brazil: Final Results of Antidumping Duty Administrative Review; 2011–2012

**AGENCY:** Enforcement and Compliance, formerly Import Administration, International Trade Administration, Department of Commerce.

**SUMMARY:** On August 16, 2013, the Department of Commerce (the Department) published the *Preliminary Results* of the 2011–2012 administrative review of the antidumping duty order on Polyethylene Terephthalate Film, Sheet, and Strip (PET film) from Brazil.[1] This review covers one respondent, Terphane Ltda., and Terphane's U.S. affiliate, Terphane, Inc. (collectively, Terphane). The petitioners in this proceeding are Mitsubishi Polyester Film, Inc. and SKC, Inc. (collectively, Petitioners). For these final results of review we continue to find that Terphane had no reviewable entries of PET film subject to the order.

**DATES:** *Effective Date:* January 10, 2014.

**FOR FURTHER INFORMATION CONTACT:** Tyler Weinhold or Robert James, AD/

[1] *See Polyethylene Terephthalate Film, Sheet and Strip From Brazil: Preliminary Results of Antidumping Duty Administrative Review; 2011–2012,* 78 FR 50029 (August 16, 2013) (*Preliminary Results*), and accompanying Decision Memorandum (Preliminary Decision Memorandum).

CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Room 7850, Washington, DC 20230; telephone (202) 482–1121 or (202) 482–0649, respectively.

**SUPPLEMENTARY INFORMATION:**

## Background

On August 7, 2013, the Department published the *Preliminary Results.* We invited interested parties to comment on the *Preliminary Results.* In response, we received a case brief from Petitioner on September 16, 2013. Terphane filed a rebuttal brief on September 23, 2013.

## Period of Review (POR)

The POR is July 1, 2011, through June 30, 2012.

## Scope of the Order

The products covered by this order are all gauges of raw, pre-treated, or primed PET film, whether extruded or co-extruded. PET film is classifiable under subheading 3920.62.00.90 of the Harmonized Tariff Schedule of the United States.[2]

## Tolling of Deadlines

As explained in the memorandum from the Assistant Secretary for Enforcement and Compliance, the Department has exercised its discretion to toll deadlines for the duration of the closure of the Federal Government from October 1, through October 16, 2013.[3] Therefore, all deadlines in this segment of the proceeding have been extended by 16 days. If the new deadline falls on a non-business day, in accordance with the Department's practice, the deadline will become the next business day. The revised deadline for the final results of this review is now January 2, 2014.

## Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this antidumping investigation are addressed in the Issues and Decision Memorandum. A list of the issues raised is attached to this notice as Appendix I. We have analyzed all interested party comments and have made no changes to the *Preliminary Results* for these final results.

## Final Determination of No Shipments

Based on information Terphane submitted after the initiation of this administrative review and information collected from U.S. Customs and Border Protection (CBP), the Department has determined that the record evidence indicates that Terphane had no reviewable entries during the POR. In addition, the Department finds that it is not appropriate to rescind the review with respect to Terphane but, rather, to complete the review with respect to Terphane and issue appropriate instructions to CBP based on the final results of this review, as is our current practice for companies which had no shipments during the POR.[4]

## Assessment Rates

The Department clarified its ''automatic assessment'' regulation on May 6, 2003. This clarification will apply to entries of subject merchandise during the POR produced by companies included in these final results of review for which these companies did not know that the merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate un-reviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[5] We intend to issue assessment instructions directly to CBP 15 days after publication of the final results of this review.

## Notification to Importers

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 the subsequent assessment of doubled antidumping duties.

## Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: January 2, 2014.

**Christian Marsh,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

## Appendix I

**List of Topics Discussed in the Accompanying Issues and Decision Memorandum**

Issue 1: Whether to Rescind or to Complete the Administrative Review

Issue 2: Whether to Structure the Final Results, and Resulting Customs Instructions to Allow for Subsequent Revision In Light of Pending Litigation

[FR Doc. 2014–00174 Filed 1–9–14; 8:45 am]

BILLING CODE 3510–DS–P

[2] For a full description of the scope of the order, *see* ''Issues and Decision Memorandum for the Final Results of the 2011 to 2012 Administrative Review of the Antidumping Duty Order on Polyethylene Terephthalate Film, Sheet, and Strip from Brazil,'' from Richard Weible, Director, Office VI, to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations (Issues and Decision Memorandum), dated concurrently with these final results and incorporated herein by reference. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (IA ACCESS). IA ACCESS is available to registered users at *http://iaaccess.trade.gov* and in the Central Records Unit (CRU), Room 7046 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/.* The signed Issues and Decision Memorandum and the electronic versions of the Issues and Decision Memorandum are identical in content.

[3] See Memorandum for the Record from Paul Piquado, Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Shutdown of the Federal Government'' (October 18, 2013).

[4] *See, e.g., Certain Frozen Warmwater Shrimp From Thailand: Preliminary Results of Antidumping Duty Administrative Review and Intent To Revoke the Order (in Part); 2011–2012,* 78 FR 15686 (March 12, 2013) and the accompanying Decision Memorandum, at 7 to 8, unchanged in *Certain Frozen Warmwater Shrimp From Thailand: Final Results of Antidumping Duty Administrative Review, Partial Rescission of Review, and Revocation of Order (in Part); 2011–2012,* 78 FR 42497 (July 16, 2013); *Polyester Staple Fiber From Taiwan: Final Results of Antidumping Duty Administrative Review; 2011–2012,* 78 FR 38938, 38939 (June 28, 2013); *Certain Frozen Warmwater Shrimp From India: Final Results of Antidumping Duty Administrative Review and Final No Shipment Determination; 2011–2012,* 78 FR 42492, 42493 (July 16, 2013); and *Polyethylene Retail Carrier Bags From Thailand: Final Results of Antidumping Duty Administrative Review; 2011–2012,* 78 FR 50376, 50377 (August 19, 2013).

[5] For a full discussion of this clarification, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–570–918]**

### Steel Wire Garment Hangers From the People's Republic of China: Final Results of Expedited Sunset Review of the Antidumping Duty Order

**AGENCY:** Enforcement and Compliance, formerly Import Administration, International Trade Administration, Department of Commerce.

**SUMMARY:** On September 3, 2013, the Department of Commerce (''the Department'') initiated the first five-year (''sunset'') review of the antidumping duty order on steel wire garment hangers from the People's Republic of China (''PRC'') pursuant to section 751(c) of the Tariff Act of 1930, as amended (''the Act''). On the basis of a notice of intent to participate and an adequate substantive response filed on behalf of the domestic interested parties, as well as a lack of response from respondent interested parties, the Department conducted an expedited sunset review of the antidumping duty order, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2). As a result of this sunset review, the Department finds that revocation of the antidumping duty order on steel wire garment hangers from the PRC would be likely to lead to continuation or recurrence of dumping at the levels indicated in the ''Final Results of Review'' section of this notice.

**DATES:** *Effective Date:* January 10, 2014.

**FOR FURTHER INFORMATION CONTACT:** Bob Palmer, Enforcement and Compliance, Office V, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–9068.

**SUPPLEMENTARY INFORMATION:**

### Background

On September 3, 2013, the Department initiated the first sunset review of the antidumping duty order on steel wire garment hangers from the PRC, pursuant to section 751(c) of the Act and 19 CFR 351.218(c)(1).[1] The Department received a notice of intent to participate from M&B Metal Products Company, Inc., Innovative Fabrication LLP/Indy Hanger, and US Hanger Co., LLC (collectively, ''the domestic interested parties'') within the deadline specified in 19 CFR 351.218(d)(1)(i).[2] The domestic interested parties claimed interested party status under section 771(9)(C) of the Act, as manufacturers of a domestic like product in the United States.

We received a complete substantive response from the domestic interested parties within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[3] We received no responses from respondent interested parties. As a result, the Department conducted an expedited sunset review of the *Order,* pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2).

### Scope of the Order

The merchandise that is subject to the *Order* is steel wire garment hangers, fabricated from carbon steel wire, whether or not galvanized or painted, whether or not coated with latex or epoxy or similar gripping materials, and/or whether or not fashioned with paper covers or capes (with or without printing) and/or nonslip features such as saddles or tubes. These products may also be referred to by a commercial designation, such as shirt, suit, strut, caped, or latex (industrial) hangers. Specifically excluded from the scope of the order are wooden, plastic, and other garment hangers that are not made of steel wire. Also excluded from the scope of the order are chrome-plated steel wire garment hangers with a diameter of 3.4 mm or greater. The products subject to the order are currently classified under U.S. Harmonized Tariff Schedule (''HTSUS'') subheadings 7326.20.0020, 7323.99.9060, and 7323.99.9080.

Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive.

### Analysis of Comments Received

All issues raised in this review are addressed in the ''Issues and Decision Memorandum for the Expedited Sunset Review of the Antidumping Duty Order on Steel Wire Garment Hangers from the People's Republic of China'' (''Decision Memorandum'') from James C. Doyle, Director, Office V, Antidumping and Countervailing Duty Operations, to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, dated concurrently with and hereby adopted by this notice. The issues discussed in the Decision Memorandum include the likelihood of continuation or recurrence of dumping and the magnitude of the margins likely to prevail if the order was to be revoked. Parties may find a complete discussion of all issues raised in the review and the corresponding recommendations in this public memorandum which is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Services System (''IA ACCESS''). Access to IA ACCESS is available in the Central Records Unit room 7046 of the main Commerce building. In addition, a complete version of the Decision Memorandum can be accessed directly on the Web at *http://trade.gov/enforcement.* The signed Decision Memorandum and the electronic versions of the Decision Memorandum are identical in content.

### Final Results of Review

We determine that revocation of the *Order* would be likely to lead to continuation or recurrence of dumping, with the following dumping margin magnitudes likely to prevail:

| Exporter | Weighted-average deposit rate (percent) |
|---|---|
| Shanghai Wells Hanger Co., Ltd | 15.83 |
| Shaoxing Metal Companies: | |
| Shaoxing Gangyuan Metal Manufacured Co., Ltd. | |
| Shaoxing Andrew Metal Manufactured Co., Ltd. | |
| Shaoxing Tongzhou Metal Manufactured Co., Ltd | 94.78 |
| Jiangyin Hongji Metal Products Co., Ltd | 55.31 |
| Shaoxing Meideli Metal Hanger Co., Ltd | 55.31 |
| Shaoxing Dingli Metal Clothes-horse Co., Ltd | 55.31 |
| Shaoxing Liangbao Metal Manufactured Co. Ltd | 55.31 |
| Shaoxing Zhongbao Metal Manufactured Co. Ltd | 55.31 |
| Shangyu Baoxiang Metal Manufactured Co. Ltd | 55.31 |
| Zhejiang Lucky Cloud Hanger Co., Ltd | 55.31 |
| Pu Jiang County Command Metal Products Co., Ltd | 55.31 |
| Shaoxing Shunji Metal Clothes-horse Co., Ltd | 55.31 |
| Ningbo Dasheng Hanger Ind. Co., Ltd | 55.31 |
| Jiaxing Boyi Medical Device Co., Ltd | 55.31 |
| Yiwu Ao-Si Metal Products Co., Ltd | 55.31 |

[1] *See Initiation of Five-Year (''Sunset'') Review,* 78 FR 54237 (September 3, 2013); *see also Notice of Antidumping Duty Order: Steel Wire Garment Hangers from the People's Republic of China,* 73 FR 58111 (October 6, 2008) (''*Order*'').

[2] *See* Letter from domestic interested parties, re: ''Five-Year Review of Steel Wire Garment Hangers from China—Intent to Participate,'' dated September 11, 2013.

[3] *See* Letter from domestic interested parties, re: ''Five-Year Review of Steel Wire Garment Hangers from China—Substantive Response of Domestic Producers to Notice of Initiation,'' dated September 30, 2013.

| Exporter | Weighted-average deposit rate (percent) |
|---|---|
| Shaoxing Guochao Metallic Products Co., Ltd | 55.31 |
| PRC-Wide Rate | 187.25 |

**Notice Regarding Administrative Protective Order (''APO'')**

This notice also serves as 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 notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This sunset review and notice are in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act.

Dated: January 2, 2013.

**Christian Marsh,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

[FR Doc. 2014–00170 Filed 1–9–14; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–570–909]**

### Certain Steel Nails From the People's Republic of China: Continuation of Antidumping Duty Order

**AGENCY:** Enforcement and Compliance, formerly Import Administration, International Trade Administration, Department of Commerce.

**SUMMARY:** As a result of the determinations by the Department of Commerce (the ''Department'') and the International Trade Commission (the ''ITC'') that revocation of the antidumping duty order on certain steel nails (''nails'') from the People's Republic of China (''PRC'') would likely lead to a continuation or recurrence of dumping and material injury to an industry in the United States, the Department is publishing a notice of continuation of the antidumping duty order.

**DATES:** *Effective Date:* January 10, 2014.

**FOR FURTHER INFORMATION CONTACT:** Jerry Huang, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: 202–482–4047.

**SUPPLEMENTARY INFORMATION:**

**Background**

On July 1, 2013, the Department initiated a sunset review of the antidumping duty order on nails from the PRC, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the ''Act'').[1] As a result of its review, the Department determined that revocation of the antidumping duty order on nails from the PRC would likely lead to a continuation or recurrence of dumping and, therefore, notified the ITC of the magnitude of the margins likely to prevail should the order be revoked.[2] On December 26, 2013, the ITC published its determination, pursuant to section 751(c) of the Act, that revocation of the antidumping duty order on nails from the PRC would likely lead to a continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[3]

*Scope of the Order*

The merchandise covered by the order includes certain steel nails having a shaft length up to 12 inches. Certain steel nails include, but are not limited to, nails made of round wire and nails that are cut. Certain steel nails may be of one piece construction or constructed of two or more pieces. Certain steel nails may be produced from any type of steel, and have a variety of finishes, heads, shanks, point types, shaft lengths and shaft diameters. Finishes include, but are not limited to, coating in vinyl, zinc (galvanized, whether by electroplating or hot dipping one or more times), phosphate cement, and paint. Head styles include, but are not limited to, flat, projection, cupped, oval, brad, headless, double, countersunk, and sinker. Shank styles include, but are not limited to, smooth, barbed, screw threaded, ring shank and fluted shank styles. Screw-threaded nails subject to this proceeding are driven using direct force and not by turning the fastener using a tool that engages with the head. Point styles include, but are not limited to, diamond, blunt, needle, chisel and no point. Finished nails may be sold in bulk, or they may be collated into strips or coils using materials such as plastic, paper, or wire. Certain steel nails subject to the order are currently classified under the Harmonized Tariff Schedule of the United States (''HTSUS'') subheadings 7317.00.55, 7317.00.65 and 7317.00.75.

Excluded from the scope of the order are steel roofing nails of all lengths and diameter, whether collated or in bulk, and whether or not galvanized. Steel roofing nails are specifically enumerated and identified in ASTM Standard F 1667 (2005 revision) as Type I, Style 20 nails. Also excluded from the scope are the following steel nails: (1) Non-collated (i.e., hand-driven or bulk), two-piece steel nails having plastic or steel washers (caps) already assembled to the nail, having a bright or galvanized finish, a ring, fluted or spiral shank, an actual length of 0.500″ to 8″, inclusive; and an actual shank diameter of 0.1015″ to 0.166″, inclusive; and an actual washer or cap diameter of 0.900″ to 1.10″, inclusive; (2) Non-collated (i.e., hand-driven or bulk), steel nails having a bright or galvanized finish, a smooth, barbed or ringed shank, an actual length of 0.500″ to 4″, inclusive; an actual shank diameter of 0.1015″ to 0.166″, inclusive; and an actual head diameter of 0.3375″ to 0.500″, inclusive; (3) Wire collated steel nails, in coils, having a galvanized finish, a smooth, barbed or ringed shank, an actual length of 0.500″ to 1.75″, inclusive; an actual shank diameter of 0.116″ to 0.166″, inclusive; and an actual head diameter of 0.3375″ to 0.500″, inclusive; and (4) Non-collated (i.e., hand-driven or bulk), steel nails having a convex head (commonly known as an umbrella head), a smooth or spiral shank, a galvanized finish, an actual length of 1.75″ to 3″, inclusive; an actual shank diameter of 0.131″ to 0.152″, inclusive; and an actual head diameter of 0.450″ to 0.813″, inclusive.

Also excluded from the scope of the order are corrugated nails. A corrugated nail is made of a small strip of corrugated steel with sharp points on one side. Also excluded from the scope of the order are fasteners suitable for use in powder-actuated hand tools, not threaded and threaded, which are currently classified under HTSUS 7317.00.20 and 7317.00.30. Also excluded from the scope of the order are thumb tacks, which are currently classified under HTSUS 7317.00.10.00.

Also excluded from the scope of the order are certain brads and finish nails that are equal to or less than 0.0720 inches in shank diameter, round or rectangular in cross section, between

[1] *See Initiation of Five-Year (''Sunset'') Review,* 78 FR 39256 (July 1, 2013).

[2] *See Certain Steel Nails From the People's Republic of China: Final Results of Expedited First Sunset Review of the Antidumping Duty Order,* 78 FR 69644 (November 20, 2013).

[3] *See Steel Nails From China: Determination,* 78 FR 78382 (December 26, 2013); *see also Steel Nails From China: Investigation No. 731–TA–1114,* USITC Publication 4442 (December 2013).

0.375 inches and 2.5 inches in length, and that are collated with adhesive or polyester film tape backed with a heat seal adhesive. Also excluded from the scope of the order are fasteners having a case hardness greater than or equal to 50 HRC, a carbon content greater than or equal to 0.5 percent, a round head, a secondary reduced-diameter raised head section, a centered shank, and a smooth symmetrical point, suitable for use in gas-actuated hand tools. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

*Continuation of the Order*

As a result of the determinations by the Department and the ITC that revocation of the antidumping duty order would likely lead to a continuation or recurrence of dumping and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act, the Department hereby orders the continuation of the antidumping order on nails from the PRC. U.S. Customs and Border Protection will continue to collect antidumping duty cash deposits at the rates in effect at the time of entry for all imports of subject merchandise. The effective date of the continuation of the order will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act, the Department intends to initiate the next five-year review of the order not later than 30 days prior to the fifth anniversary of the effective date of continuation. This five-year (''sunset'') review and this notice are in accordance with section 751(c) of the Act and published pursuant to section 777(i)(1) of the Act.

Dated: January 6, 2014.

**Paul Piquado,**

*Assistant Secretary for Enforcement and Compliance.*

[FR Doc. 2014–00263 Filed 1–9–14; 8:45 am]

BILLING CODE 3510–DS–P

## DEPARTMENT OF COMMERCE

### National Institute of Standards and Technology

**[Docket No.: 130212127–3999–04]**

### Proposed Establishment of a Federally Funded Research and Development Center

**AGENCY:** National Institute of Standards and Technology (NIST), Commerce.

**ACTION:** Notice.

**SUMMARY:** The National Institute of Standards and Technology (NIST), Department of Commerce, intends to sponsor a Federally Funded Research and Development Center (FFRDC) to facilitate public-private collaboration for accelerating the widespread adoption of integrated cybersecurity tools and technologies. NIST published three notices in the **Federal Register** advising the public of the agency's intention to sponsor an FFRDC and requesting comments from the public. This notice provides NIST's analysis of the comments related to NIST's proposed establishment of the FFRDC received in response to those notices. These responses, as well as NIST's responses to the many acquisition-related comments and questions received in response to the three notices will be posted on FedBizOpps.

**DATES:** NIST published portions of a draft Request for Proposals for public comment in December 2013.

**ADDRESSES:** NIST's responses to acquisition-related comments and question and the draft Request for Proposals will be published for public comment at *www.fbo.gov.*

**FOR FURTHER INFORMATION CONTACT:** Keith Bubar via email at *Keith.Bubar@nist.gov* or telephone 301–975–8329 or Keith Bubar, NIST, 100 Bureau Drive, Mail Stop 1640, Gaithersburg, MD 20899–1640.

**SUPPLEMENTARY INFORMATION:** NIST has identified the need to support the mission of the National Cybersecurity Center of Excellence (NCCoE) through the establishment of an FFRDC. In evaluating the need for the FFRDC, NIST determined that no existing alternative sources can effectively meet the unique needs of NIST. The proposed NCCoE FFRDC will have three primary purposes: (1) Research, Development, Engineering and Technical support; (2) Program/Project Management focused on increasing the effectiveness and efficiency of cybersecurity applications, prototyping, demonstrations, and technical activities; and (3) Facilities Management. The proposed NCCoE FFRDC may also be utilized by other federal agencies.

The FFRDC will be established under the regulations found at 48 CFR 35.017.

*Comments Received and Responses:* The following is a summary and analysis of the comments received during the public comment period and NIST's responses to them. NIST received comments from a total of 46 commenters. NIST received three comments opposed to establishing the proposed FFRDC. In addition, NIST received two comments opposed to government spending in general, but not specifically directed toward the proposed FFRDC. Finally, NIST received a total of 73 additional comments/questions from 43 commenters, centered on the proposed acquisition and other related topics.

A summary of the public comments opposing the establishment of the FFRDC, along with NIST's responses to each, are as follows:

*Comment:* Two commenters stated that hundreds of private sector firms are capable of performing the tasks described in the notice.

*Response:* NIST is aware of the vast cybersecurity research, development, engineering, technical, program/project management and facilities management capabilities available in the private sector. The NCCoE meets its unique mission of increasing the rate of adoption of more secure technologies by establishing broad consortia of academic, government, and private sector organizations whose engineers work side-by-side at the center. While potentially having the appropriate technical capabilities, private sector firms motivated by profit and future competitive opportunities would not provide the same level of objectivity as an organization managing an FFRDC.

*Comment:* One commenter stated that a Request for Information or draft Request for Proposals (RFP) would likely yield numerous responses from qualified private sector firms.

*Response:* NIST intends to publish a draft RFP to allow prospective offerors an opportunity to ask questions and provide comments.

*Comment:* Two commenters stated that any concerns about organizational conflicts of interest within the private sector can be resolved through industry divestitures and other methods, and can be fully addressed and prevented through provisions in the current acquisition system.

*Response:* As established under the Federal Acquisition Regulation (FAR), FFRDCs are designed to prevent potential conflicts of interest from occurring and to allow for the independence and objectivity necessary to collaborate effectively with a broad consortium of technical organizations. By establishing an FFRDC, potential conflicts of interest will be avoided as the FFRDC operator will not be motivated by potential competitive advantages or profit, ensuring a level playing field for all collaborators on NCCoE activities. The FFRDC operator could potentially have access to the intellectual property of a large number of possibly competing companies collaborating on NCCoE activities. The

access to intellectual property of many companies could present conflicts of interest for an organization that does not meet the provisions of FAR 35.017(a)(3).

*Comment:* One commenter stated that NIST has not adequately demonstrated that there are no existing contract vehicles or FFRDCs available to meet its needs.

*Response:* Through conducting market research, NIST determined that neither a standard services contractor nor an existing FFRDC can adequately meet NIST's requirement for supporting the NCCoE. Review of the 40 existing FFRDCs indicated that only one incorporated cybersecurity in its mission and vision statement, Carnegie Mellon Software Engineering Institute (SEI), sponsored by the U.S. Army. SEI's stated mission is to ''advance the technologies and practices needed to acquire, develop, operate, and sustain software systems that are innovative, affordable, trustworthy, and enduring.'' SEI identifies its competencies as including software engineering and research, computer security, emerging software technologies, and acquisition solutions. SEI's mission statement and the focus of its current staff are significantly narrower than the NCCoE's requirement to execute applied research and collaborate with industry, academia, and government to accelerate the adoption of solutions based on existing commercial-off-the-shelf products. The use of SEI to support the mission of the NCCoE would result in a significant limitation on the range of services that could be performed and the range of use cases to be undertaken.

*Comment:* Two commenters stated that NIST has not clearly stated the basis, purpose and mission of the FFRDC.

*Response:* In the forthcoming draft RFP, NIST will articulate its requirement for the FFRDC with greater specificity, and prospective offerors will have the opportunity to ask questions and submit comments.

*Comment:* One commenter stated that creating a new FFRDC would expose NIST to significant cost vulnerabilities and potential criticism from Congress and others.

*Response:* The competition for an Indefinite Delivery Indefinite Quantity (IDIQ) contract, the contracting mechanism to be used for the FFRDC, occurs at the base contract level. The nature of an IDIQ contract does allow for future actions within the scope of the contract to be awarded without further competition. However, NIST will review the scope of work thoroughly to identify areas that require clarification prior to release of the RFP, and the IDIQ contract will be competed to the maximum extent practicable. NIST will negotiate the cost, terms and conditions of all task orders with the FFRDC operator before performance commences. By using a task order based IDIQ contract, NIST will balance scope and cost control while allowing for the flexibility to address the needs of the NCCoE.

NIST has posted a notice to the Federal Business Opportunities (FBO) Web site with the official responses to each comment received in response to the previous three **Federal Register** notices, including those comments summarized above. The FBO Reference Number for this notice is *NCCoE_FFRDC–FRN_4.* NIST published portions of a draft Request for Proposals for public comment in December 2013.

Dated: January 6, 2014.

**Willie E. May,**

*Associate Director for Laboratory Programs.*

[FR Doc. 2014–00260 Filed 1–9–14; 8:45 am]

**BILLING CODE 3510–13–P**

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XD042**

### Pacific Fishery Management Council; Online Webinar

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

**ACTION:** Notice of online webinar.

**SUMMARY:** The Pacific Fishery Management Council's (Pacific Council's) Scientific and Statistical Committee (SSC) Groundfish Subcommittee will hold an online webinar to review data-poor overfishing limit (OFL) estimates for kelp greenling in Oregon and Washington, new OFL estimates for the Washington stock of cabezon, and other business in preparation for the SSC's March 2014 meeting. The online SSC Groundfish Subcommittee webinar is open to the public.

**DATES:** The SSC Groundfish Subcommittee webinar will commence at 1 p.m. PST, Thursday, January 30, 2014 and continue until 3 p.m. or as necessary to complete business for the day.

**ADDRESSES:** To attend the SSC Groundfish Subcommittee webinar, please join online at *https://www.joinwebinar.com* and enter the webinar ID: 701–764–215, as well as your name and email address. Once you have joined the webinar, choose either your computer's audio or select ''Use Telephone.'' To join the audio teleconference using a telephone, call the toll number 1 (646) 307–1721 and enter 799–773–093 when prompted for the audio code. If you do not select ''Use Telephone,'' you will be connected to audio using your computer's microphone and speakers (VolP). A headset is recommended. System requirements for PC-based attendees: Windows 7, Vista, or XP; for Mac-based attendees: Mac OS X 10.5 or newer; and for mobile attendees: iPhone, iPad, Android phone, or Android tablet (see the GoToMeeting Webinar Apps). If you experience technical difficulties and would like assistance, please contact Mr. Kris Kleinschmidt at (503) 820–2280. Public comments during the webinar will be received from attendees at the discretion of the SSC Groundfish Subcommittee chair.

**FOR FURTHER INFORMATION CONTACT:** Mr. John DeVore, Pacific Council; telephone: (503) 820–2280.

**SUPPLEMENTARY INFORMATION:** The specific objectives of the SSC Groundfish Subcommittee webinar are to review data-poor OFL estimates for kelp greenling in Oregon and Washington, new OFL estimates for the Washington stock of cabezon, and review or discuss other items necessary to prepare for the March 2014 SSC meeting in Sacramento, CA. No management actions will be decided in this webinar.

Although non-emergency issues not identified in the webinar agenda may come before the webinar participants for discussion, those issues may not be the subject of formal action during this webinar. Formal action at the webinar will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the webinar participants' intent to take final action to address the emergency.

**Special Accommodations**

This meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820–2280 at least 5 days prior to the webinar date.

Dated: January 7, 2014.

**Tracey L. Thompson,**

*Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2014–00241 Filed 1–9–14; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XD050**

### Fisheries of the South Atlantic, Gulf of Mexico, and Caribbean; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

**ACTION:** Notice of SEDAR Steering Committee meeting.

**SUMMARY:** The SEDAR Steering Committee will meet via webinar. See **SUPPLEMENTARY INFORMATION.**

**DATES:** The Steering Committee webinar will be held on January 30, 2014, from 2 p.m. to 4 p.m., EST.

**ADDRESSES:** The webinar will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact John Carmichael at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request meeting information at least 24 hours in advance.

*SEDAR address:* 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405.

**FOR FURTHER INFORMATION CONTACT:** John Carmichael, SEDAR Program Manager; telephone: (843) 571–4366; email: *john.carmichael@safmc.net.* Andrea Grabman, SEDAR Administrative Assistant; telephone: (843) 571–4366; email: *Andrea.Grabman@safmc.net.*

**SUPPLEMENTARY INFORMATION:** This meeting is being held to consider items discussed by the SEDAR Steering Committee at its prior meeting, held on October 1–2, 2013. Because several Steering Committee members were not allowed to attend that meeting due to the Federal Government shutdown, the Committee did not take final action on the agenda topics.

Items to discuss at this meeting:

1. SEDAR process: workshops, participation, and best practices.
2. SEDAR project scheduling: improving planning and scheduling efficiency.
3. SEDAR assessment schedule.

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 intent to take final action to address the emergency.

**Special Accommodations**

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the SEDAR office (see **ADDRESSES**) at least 10 business days prior to the meeting.

**Note:** The times and sequence specified in this agenda are subject to change.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: January 7, 2014.

**Tracey L. Thompson,**

*Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2014–00242 Filed 1–9–14; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XA840**

### Marine Mammals; File No. 16479

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

**ACTION:** Notice; receipt of application for permit amendment.

**SUMMARY:** Notice is hereby given that The Pacific Whale Foundation [Responsible Party: Gregory Kaufman], 300 Maalaea Road, Suite 211, Wailuku, HI 96793, has applied for an amendment to Scientific Research Permit No. 16479–01.

**DATES:** Written, telefaxed, or email comments must be received on or before February 10, 2014.

**ADDRESSES:** The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the *Features* box on the Applications and Permits for Protected Species home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 16479 from the list of available applications.

These documents are also available upon written request or by appointment in the following offices:

Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376; and

Pacific Islands Region, NMFS, 1601 Kapiolani Blvd., Rm 1110, Honolulu, HI 96814–4700; phone (808) 944–2200; fax (808) 973–2941.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

**FOR FURTHER INFORMATION CONTACT:** Amy Hapeman or Kristy Beard, (301) 427–8401.

**SUPPLEMENTARY INFORMATION:** The subject amendment to Permit No. 16479–01 is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (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 (16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

Permit No. 16479, issued on September 18, 2012 (77 FR 59594), authorizes the permit holder to conduct vessel-based research on humpback whales in waters around Maui, Hawaii to quantify the potential for near misses between vessels and humpback whales (*Megaptera novaeangliae*), and define the probability of 'surprise encounters' with humpback whales. Up to 567 humpback whales may be approached annually for photo-identification and behavioral observation and up to 240 Hawaiian insular false killer whales (*Pseudorca crassidens*) may be incidentally harassed during research. A minor amendment (No. 01) to the permit was issued on August 23, 2013, authorizing the field season to start in December versus January of each permit year. The Permit Holder is requesting the permit be amended to authorize research activities (approaches for

photo-identification and behavioral observation) on the false killer whales to study their occurrence, distribution, movement, site fidelity, abundance, social organization, home ranges, and life history. The number of takes authorized for the stock would not change. The permit expires on June 1, 2017.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activities proposed are consistent with the Proposed Action Alternative in the Environmental Assessment (EA) on Effects of Issuing Marine Mammal Scientific Research Permit No. 16479 (NMFS 2012). Based on the analyses in the EA, NMFS determined that issuance of the permit would not significantly impact the quality of the human environment and that preparation of an environmental impact statement was not required. That determination is documented in a Finding of No Significant Impact (FONSI), signed on September 17, 2012. That EA and FONSI are available upon request. A new FONSI will be prepared for this action.

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.

Dated: January 7, 2014.

**P. Michael Payne,**

*Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2014–00228 Filed 1–9–14; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XW11**

### Marine Mammals; File No. 14514

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

**ACTION:** Notice; issuance of permit amendment.

**SUMMARY:** Notice is hereby given that a major amendment to Permit No. 14514 has been issued to the University of Florida, Aquatic Animal Program, College of Veterinary Medicine, Gainesville, FL 32610 (Thomas Waltzek, Responsible Party).

**ADDRESSES:** The permit amendment and related documents are available for review upon written request or by appointment in the following offices:

Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376; and

Southeast Region, NMFS, 263 13th Avenue South, Saint Petersburg, FL 33701; phone (727) 824–5312; fax (727) 824–5309.

**FOR FURTHER INFORMATION CONTACT:** Amy Sloan or Jennifer Skidmore, (301) 427–8401.

**SUPPLEMENTARY INFORMATION:** On September 17, 2013, notice was published in the **Federal Register** (78 FR 57133) that a request for an amendment Permit No. 14514 to receive, import, and export marine mammal specimens for scientific research had been submitted by the above-named applicant. The requested permit amendment has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (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.*), the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*).

Permit No. 14514–01 authorizes an increase the number of animals from which pinniped samples may be received, imported, or exported from 100 to 700 animals per year for additional studies on viral pathogens (adenovirus and herpesvirus). The permit amendment also authorizes personnel changes.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

As required by the ESA, issuance of this permit was based on a finding that such permit: (1) Was applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: January 6, 2014.

**P. Michael Payne,**

*Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2014–00180 Filed 1–9–14; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XC766**

### Marine Mammals; File No. 17429

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

**ACTION:** Notice; issuance of permit.

**SUMMARY:** Notice is hereby given that a permit has been issued to Sea Life Park Hawaii, 41–202 Kalanianaole Highway, Waimanalo, HI 96795 (Jerry Pupillo, Responsible Party), to maintain non-releasable Hawaiian monk seals (*Monachus schauinslandi*) in captivity for enhancement purposes.

**DATES:** Written, telefaxed, or email comments must be received on or before February 10, 2014.

**ADDRESSES:** The permit and related documents are available for review upon written request or by appointment in the following offices:

Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376; and

Pacific Islands Region, NMFS, 1601 Kapiolani Blvd., Room 1110, Honolulu, HI 96814–4700; phone (808) 944–2200; fax (808) 973–2941.

**FOR FURTHER INFORMATION CONTACT:** Amy Sloan or Jennifer Skidmore, (301) 427–8401.

**SUPPLEMENTARY INFORMATION:** On August 20, 2013, notice was published in the **Federal Register** (78 FR 51146) that a request for a permit to conduct enhancement on the species identified above had been submitted by the above-named applicant. The requested permit has been issued 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).

Permit No. 17429–00 authorizes Sea Life Park Hawaii to continue to maintain and provide routine animal husbandry and veterinary care for one non-releasable adult Hawaiian monk seal and up to an additional three seals (four total, considering future non-releasable seals) at the monk seal exhibit at Sea Life Park Hawaii. Sea Life Park will maintain in permanent captivity seals removed from the wild under separate permits for stranding response and enhancement and are deemed non-releasable to the wild. The animals will be made available for scientific studies by researchers whose research protocols are approved by the Sea Life Park Hawaii Curator and staff veterinarian and authorized under separate permits. A public conservation and education lecture will be conducted daily concerning the status of Hawaiian monk seals, and educational descriptive signs with current information are on display at the monk seal exhibit. The permit expires November 30, 2018.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: January 6, 2014.

**P. Michael Payne,**

*Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2014–00181 Filed 1–9–14; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Telecommunications and Information Administration

**[Docket Number: 131219999–3999–02]**

**RIN 0660–XC008**

### First Responder Network Authority; National Environmental Policy Act Implementing Procedures and Categorical Exclusions

*Correction*

In notice document 2013–31493 appearing on pages 639 through 642 in the issue of Monday, January 6, 2014 make the following correction:

On page 639, in the second column, under the **DATES** heading, in the third line ''February 5, 2013'' should read ''February 5, 2014''.

[FR Doc. C1–2013–31493 Filed 1–9–14; 8:45 am]

**BILLING CODE 1505–01–D**

## COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

### Procurement List Deletions

**AGENCY:** Committee for Purchase From People Who Are Blind or Severely Disabled.

**ACTION:** Deletions from the Procurement List.

**SUMMARY:** This action deletes products and services from the Procurement List previously furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

**DATES:** *Effective Date:* 2/10/2014.

**ADDRESSES:** Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 10800, Arlington, Virginia 22202–4149.

**FOR FURTHER INFORMATION CONTACT:** Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov*.

**SUPPLEMENTARY INFORMATION:**

#### Deletions

On 11/29/2013 (78 FR 71582–71583), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products and services listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

#### Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products and services deleted from the Procurement List.

#### End of Certification

Accordingly, the following products and services are deleted from the Procurement List:

*Products*

Stamp Pad Ink

*NSN:* 7510–01–316–7516—Refill Ink—Black 2 oz. roll-on.
*NPA:* Arbor Products, Inc., Houston, TX.
*Contracting Activity:* General Services Administration, New York, NY.

*NSN:* 8950–01–079–6942—Paprika, Ground.
*NSN:* 8950–01–254–2691—Garlic Powder.
*NSN:* 8950–00–NSH–0205—Pepper, Black, Ground, Restaurant Grind, 5 lb.
*NPA:* CDS Monarch, Webster, NY.
*Contracting Activity:* Defense Logistics Agency Troop Support, Philadelphia, PA.

*Services*

*Service Types/Location:* Grounds Maintenance Service, Janitorial Service, William Jefferson Clinton Birthplace Home NHS, 117 S. Hervey St., Hope, AR.
*NPA:* Rainbow of Challenges, Inc., Hope, AR.
*Contracting Activity:* National Park Service, MWR Regional Contracting, Omaha, NE.

**Barry S. Lineback,**

*Director, Business Operations.*

[FR Doc. 2014–00237 Filed 1–9–14; 8:45 am]

**BILLING CODE 6353–01–P**

## COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

### Procurement List, Proposed Additions and Deletions

**AGENCY:** Committee for Purchase From People Who Are Blind or Severely Disabled.

**ACTION:** Proposed additions to and deletions from the Procurement List.

**SUMMARY:** The Committee is proposing to add products to the Procurement List that will be furnished by a nonprofit agency employing persons who are blind or have other severe disabilities, and deletes products and a service previously furnished by such agencies.

*Comments Must be Received on or Before:* 2/10/2014.

**ADDRESSES:** Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 10800, Arlington, Virginia 22202–4149.

*For Further Information or To Submit Comments Contact:* Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

**SUPPLEMENTARY INFORMATION:** This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

**Additions**

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products listed below from the nonprofit agency employing persons who are blind or have other severe disabilities.

The following products are proposed for addition to the Procurement List for production by the nonprofit agency listed. These products are being proposed as part of the eyewear products proposed for addition to the Procurement List in the **Federal Register** at 78 FR 75911 and published on Friday, December 13, 2013. Comments received from the public, to-date, as a result of the eyewear proposed at 78 FR 75911, are considered inclusive of the eyewear products proposed here.

*Products*

*NSN:* 6650–00–NIB–0009—Flat Top 28, Bifocal, Single Vision, Plastic, Clear.
*NSN:* 6650–00–NIB–0010—Flat Top 28, Bifocal, Plastic, Clear.
*NSN:* 6650–00–NIB–0011—Flat Top 35, Bifocal, Clear.
*NSN:* 6650–00–NIB–0012—Clear Plastic Round 25 and Round 28.
*NSN:* 6650–00–NIB–0013—Flat Top 7 × 28, Plastic, Clear.
*NSN:* 6650–00–NIB–0014—Flat Top 8 × 35, Plastic, Clear.
*NSN:* 6650–00–NIB–0015—Progressives, (VIP, Adaptar, Freedom, Image), Plastic, Clear.
*NSN:* 6650–00–NIB–0016—Lenticular Aspheric, Single Vision, Plastic, Clear.
*NSN:* 6650–00–NIB–0017—Flat Top-Round Aspheric Lenticular, Plastic, Clear.
*NSN:* 6650–00–NIB–0018—Executive Bifocal, Plastic, Clear.
*NSN:* 6650–00–NIB–0019—Single Vision, Glass, Clear.
*NSN:* 6650–00–NIB–0020—Flat Top 28, Bifocal, Glass, Clear.
*NSN:* 6650–00–NIB–0021—Flat Top 35, Bifocal, Glass, Clear.
*NSN:* 6650–00–NIB–0022—Flat Top 7 × 28, Trifocal, Glass, Clear.
*NSN:* 6650–00–NIB–0023—Flat Top 8 × 35, Trifocal, Glass, Clear.
*NSN:* 6650–00–NIB–0024—Progressives, (VIP, Adaptar, Freedom), Glass, Clear.
*NSN:* 6650–00–NIB–0025—Executive Bifocal, Glass, Clear.
*NSN:* 6650–00–NIB–0026—Single Vision, Polycarbonate, Clear.
*NPA:* Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC.
*Contracting Activity:* NETWORK CONTRACTING OFFICE 8, TAMPA, FL.
*Coverage:* C-List for 100% of the requirements of Bay Pines Healthcare System, Bay Pines, FL and the James A. Haley Veterans Hospital, Tampa, FL as aggregated by Network Contracting Office 8, Tampa, FL.

**Deletions**

The following products and service are proposed for deletion from the Procurement List:

*Products*

*NSN:* 7530–00–281–5907—Folder, File, Paperboard, Heavy Duty, ⅓ Cut Tab, Clear Sleeve, Kraft, Letter.
*NPA:* L.C. Industries for the Blind, Inc., Durham, NC.
*Contracting Activity:* GENERAL SERVICES ADMINISTRATION, NEW YORK, NY.
*NSN:* 7530–01–554–7679—DVD Label Refill.
*NPA:* North Central Sight Services, Inc., Williamsport, PA.
*Contracting Activity:* GENERAL SERVICES ADMINISTRATION, NEW YORK, NY.

*Service*

*Service Type/Location:* Janitorial/Custodial Service, Social Security Administration Building, 50 North Third Street, Chambersburg, PA.
*Contracting Activity:* GENERAL SERVICES ADMINISTRATION, FPDS AGENCY COORDINATOR, WASHINGTON, DC.

**Barry S. Lineback,**

*Director, Business Operations.*

[FR Doc. 2014–00238 Filed 1–9–14; 8:45 am]

**BILLING CODE 6353–01–P**

## BUREAU OF CONSUMER FINANCIAL PROTECTION

### Notice of Availability of Certain Revised Consumer Information Publications

**AGENCY:** Bureau of Consumer Financial Protection.

**ACTION:** Notice of availability.

**SUMMARY:** The Bureau of Consumer Financial Protection (Bureau or CFPB) announces the availability of three revised consumer publications, including a consumer information brochure and two booklets required under the Real Estate Settlement Procedures Act (RESPA), Regulation X, the Truth in Lending Act (TILA), and Regulation Z. These publications are titled: *What You Should Know About Home Equity Lines of Credit,* the *Consumer Handbook on Adjustable-Rate Mortgages,* and the *Shopping for Your Home Loan: Settlement Cost Booklet.*

**ADDRESSES:** The revised consumer publications are available for download on the Bureau's Web site at *www.consumerfinance.gov/learnmore* and can also be found in the Catalog of U.S. Government Publications (*http://catalog.gpo.gov*), maintained by Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

**FOR FURTHER INFORMATION CONTACT:** Lea Mosena, Legal Division; Susan Haag, Office of Financial Education; and Richard Arculin, Office of Regulations, *CFPB_reginquiries@cfpb.gov* or (202) 435–7700.

**SUPPLEMENTARY INFORMATION:** Pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), Public Law 111–203, the CFPB is responsible for three consumer information publications related to mortgage and home equity line of credit transactions, titled: (1) *What You Should Know About Home Equity Lines of Credit* (HELOC Brochure); (2) *Consumer Handbook on Adjustable-Rate Mortgages* (CHARM Booklet); and (3) *Shopping for Your Home Loan, Settlement Cost Booklet* (Settlement Cost Booklet). The HELOC Brochure and CHARM booklet were formerly published by the Board of Governors of the Federal Reserve System (Board). The Settlement Cost Booklet was formerly published by the Department of Housing and Urban Development (HUD).

The CFPB is making technical and conforming changes to each of the three publications in conjunction with the January 2014 effective dates for many provisions of the Bureau's rulemakings regulating practices in mortgage origination and servicing. A description of the changes in each publication follows.

The Bureau views the publications as part of the Bureau's broader mission to educate consumers about consumer financial products. The Bureau intends to revise the publications and develop other educational materials that will be accessible on its public Web site. The Bureau therefore expects to consider further revisions to these publications in the future, in particular to reflect changes to disclosure requirements for mortgage credit transactions under TILA and for real estate settlements under RESPA, pursuant to the Bureau's Integrated Mortgage Disclosures under the Real Estate Settlement Procedures Act (Regulation X) and the Truth in Lending Act (Regulation Z) final rule issued on November 20, 2013.

Those who provide these publications may, at their option, immediately begin using the revised HELOC Brochure, CHARM Booklet, or Settlement Cost Booklet, or suitable substitutes to comply with the requirements in Regulations X and Z. The Bureau understands, however, that some may wish to use their existing stock of publications. Therefore, those who provide these publications may use earlier versions of these publications until existing supplies are exhausted.

When reprinting these publications, the most recent version should be used.

**HELOC Brochure**

The Home Equity Loan Consumer Protection Act of 1988, Public Law 100–709, amended TILA to require creditors to give consumers, among other disclosures, an educational brochure on home-equity plans at the time an application is provided. Specifically, TILA section 127A requires that, in addition to certain other disclosures, when a consumer is applying to open an account under any open-end consumer credit plan secured by the consumer's principal dwelling, ''the creditor or other person providing such disclosures to the consumer shall provide (1) a pamphlet published by the Bureau pursuant to section 4 of the Home Equity Consumer Protection Act of 1988; or (2) any pamphlet which provides substantially similar information to the information described in such section, as determined by the Bureau.'' 15 U.S.C. 1637a(e).

Prior to the Dodd-Frank Act, the Board implemented this requirement in 12 CFR 226.5b(e) and developed and published the HELOC Brochure to consumers with basic information about the features of a home equity line of credit and what to look for and compare when shopping for credit. Under the Dodd-Frank Act, the responsibility for the HELOC Brochure transferred to the CFPB. Under the CFPB's Regulation Z, at the time an application for a HELOC is provided to the consumer, a creditor must provide certain disclosures and ''the home equity brochure entitled 'What You Should Know About Home Equity Lines of Credit' or a suitable substitute.'' 12 CFR 1026.40(e).

To reflect the transfer to the CFPB and ensure consistency with the Bureau's rulemakings regulating practices in mortgage origination and servicing, many of which take effect in January 2014, the CFPB has made technical and conforming changes to the HELOC Brochure. Specifically, the revised publication adds a reference to the requirement that lenders must provide borrowers with a list of housing counselors in their area, CFPB contact information, and updates to other Federal agency contact information. It also adds CFPB resources for consumers including information about how consumers can submit a complaint to the Bureau, a link to the Bureau's online ''Ask CFPB'' tool to find answers to questions about mortgages and other financial topics, and a link to an online tool to find local HUD-approved housing counseling agencies.

**CHARM Booklet**

In 1987, the Board revised Regulation Z, to require special disclosures for closed-end ARMs secured by the borrower's principal dwelling with a term greater than one year. 52 FR 48665 (Dec. 24, 1987). The Board and the Federal Home Loan Bank Board (predecessor to the former Office of Thrift Supervision (OTS)) developed the CHARM booklet in 1987 to fulfill that requirement and educate consumers about the features and risks associated with adjustable-rate mortgages. Under the Dodd-Frank Act, the responsibility for the CHARM Booklet transferred to the Bureau. Under 12 CFR 1026.19(b)(1), the ''booklet titled Consumer Handbook on Adjustable Rate Mortgages, or a suitable substitute'' must generally be given to consumers at the time an application for an adjustable-rate mortgage is provided or before the consumer pays a non-refundable fee, whichever is earlier.

To reflect the transfer to the CFPB and ensure consistency with the Bureau's rulemakings regulating practices in mortgage origination and servicing that take effect in January 2014, the CFPB has made technical and conforming changes to the CHARM Booklet. The key revisions to the CHARM booklet include: (1) Removing references to certain fees and product types that are no longer permitted, such as prepayment penalties on adjustable-rate mortgages; (2) adding information about the lender's obligation to consider the borrower's ability to repay the loan, provide disclosure of interest rate adjustments, and ensure a borrower has received homeownership counseling before making a negative amortization loan; and (3) adding CFPB contact information and resources for consumers and updates to other federal agency contact information. The CFPB resources added include: information about how consumers can submit a complaint to the Bureau; a link to the Bureau's online ''Ask CFPB'' tool to find answers to questions about mortgages and other financial topics; and a link to an online tool to find local HUD-approved housing counseling agencies.

**Settlement Cost Booklet/Special Information Booklet**

In its enactment in 1974, RESPA required the provision of ''special information booklets'' to help persons borrowing money to finance the purchase of residential real estate to understand better the nature and costs of real estate settlement services. Public Law 93–553. Since 1976, HUD implemented this requirement by publishing the Settlement Cost Booklet.

The Dodd-Frank Act amended RESPA, among other things, to transfer to the Bureau the responsibility for ''a booklet to help consumers applying for federally related mortgage loans to understand the nature and costs of real estate settlement services.'' 12 U.S.C. 2604. Under 12 CFR 1024.6, lenders are directed to provide a copy of the special information booklet to each person who has submitted a written application for certain federally related mortgage loans within 3 business days after receiving the application. To reflect the transfer to the CFPB and ensure consistency with the Bureau's rulemakings regulating practices in mortgage origination and servicing that take effect in January 2014, the CFPB has made technical and conforming changes to the Settlement Cost Booklet. Specifically, the CFPB has revised the booklet to add information about new servicing protections for consumers, including servicer obligations to (1) respond promptly to consumer requests for information and notices of errors, (2) provide mortgage payoff statements and monthly billing information, and (3) contact delinquent consumers regarding options to avoid foreclosure. As with the HELOC Brochure and CHARM Booklet, the revised Settlement Cost Booklet also adds CFPB contact information and resources for consumers, and updates other federal agency contact information. The CFPB resources added include: information about how consumers can submit a complaint to the Bureau; a link to the Bureau's online ''Ask CFPB'' tool to find answers to questions about mortgages and other financial topics; and a link to an online tool to find local HUD-approved housing counseling agencies. These changes obviate the relevance of the permissible chang.es stated in 12 CFR 1024.6(d)(1)(ii) and the last sentence of 12 CFR 1024.6(d)(2) for those using the revised Settlement Cost Booklet.

The CFPB is hereby publishing this notice of availability regarding the revised HELOC Brochure, CHARM Booklet, and Settlement Cost Booklet to provide appropriate notice of the revisions.

Dated: January 6, 2014.

**Richard Cordray,**

*Director, Bureau of Consumer Financial Protection.*

[FR Doc. 2014–00272 Filed 1–9–14; 8:45 am]

BILLING CODE 4810–AM–P

## DEPARTMENT OF DEFENSE

### Office of the Secretary

### Base Closure and Realignment

**AGENCY:** Office of Economic Adjustment, DoD.

**ACTION:** Notice.

**SUMMARY:** This notice is provided pursuant to section 2905(b)(7)(B)(ii) of the Defense Base Closure and Realignment Act of 1990. It provides the point of contact, address, and telephone number for the Local Redevelopment Authority (LRA) for the Pueblo Chemical Depot, Colorado. The Pueblo Depot Activity Development Authority was recognized as the LRA by the Secretary of Defense, acting through the Department of Defense, Office of Economic Adjustment (OEA) on June 29, 1995. The Army Surplus Property Notice for the Pueblo Chemical Depot was published in the **Federal Register** on December 20, 2013 (78 FR 77108). Representatives of state and local governments, homeless providers, and other parties interested in the redevelopment of the installation should contact this LRA.

**FOR FURTHER INFORMATION CONTACT:** The following point of contact information will also be published simultaneously in a newspaper of general circulation in the area of the installation. Director, Office of Economic Adjustment, Office of the Secretary of Defense, 2231 Crystal Drive, Suite 520, Arlington, VA 22202–4704, (703) 697–2123.

**SUPPLEMENTARY INFORMATION:**

**Local Redevelopment Authority (LRA)**

*Colorado*

Installation: Name: Pueblo Chemical Depot.

LRA Name: Pueblo Depot Activity Development Authority.

Point of Contact: Mr. Russell A. DeSalvo, President and CEO.

Address: Post Office Box 11467, Pueblo, Colorado, CO 81001–0467.

Phone: (719) 947–3770.

Email address: *rdesalvo@PuebloPlex.com.*

Dated: January 7, 2014.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 2014–00254 Filed 1–9–14; 8:45 am]

BILLING CODE 5001–06–P

## DEPARTMENT OF DEFENSE

### Office of the Secretary

### Response Systems to Adult Sexual Assault Crimes Panel; Notice of Federal Advisory Committee Meeting

**AGENCY:** Department of Defense.

**ACTION:** Notice of meeting.

**SUMMARY:** The Department of Defense is publishing this notice to announce the following Federal Advisory Committee meeting of the Response Systems to Adult Sexual Assault Crimes Panel. This meeting is open to the public.

**DATES:** A meeting of the Response Systems to Adult Sexual Assault Crimes Panel (''the Panel'') will be held Thursday, January 30, 2014 from 8:30 a.m. to 5:00 p.m.

**ADDRESSES:** The George Washington University Law School, Faculty Conference Center, 5th Floor, 716 20th Street NW., Washington, DC 20052.

**FOR FURTHER INFORMATION CONTACT:** Ms. Terri Saunders, Deputy Staff Director, Response Systems Panel, One Liberty Center, 875 N. Randolph Street, Suite 150, Arlington, VA 22203. Email: *terri.a.saunders.civ@mail.mil.* Phone: (703) 693–3829. Web site: *http://responsesystemspanel.whs.mil.*

**SUPPLEMENTARY INFORMATION:** This public meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

*Purpose of the Meeting:* At this meeting, the Panel will deliberate on the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112–239), Section 576(a)(1) requirement to conduct an independent review and assessment of the systems used to investigate, prosecute, and adjudicate crimes involving adult sexual assault and related offenses under 10 U.S.C. 920 (article 120 of the Uniform Code of Military Justice), for the purpose of developing recommendations regarding how to improve the effectiveness of such systems. The Panel is interested in written and oral comments from the public, including non-governmental organizations, relevant to this tasking.

**Agenda**

*January 30, 2014*

- 8:30 a.m.–8:40 a.m. Comments from the Panel Chair
- 8:40 a.m.–12:30 p.m. Perspectives on Commanders in the Military Justice Process from Retired and Former Military Commanders
- 12:30 p.m.–1:00 p.m. Lunch
- 1:00 p.m.–1:15 p.m. Public Comment
- 1:15 p.m.–1:45 p.m. Role of the Commander Subcommittee Report to Panel
- 1:45 p.m.–5:00 p.m. Panel Deliberations

*Availability of Materials for the Meeting:* A copy of the agenda or any updates to the agenda for the January 30, 2014 meeting, as well as other materials presented in the meeting, may be obtained at the meeting or from the Panel's Web site at: *http://responsesystemspanel.whs.mil.*

*Public's Accessibility to the Meeting:* Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. Seating is limited and is on a first-come basis.

*Special Accommodations:* Individuals requiring special accommodations to access the public meeting should contact the Deputy Staff Director at *terri.a.saunders.civ@mail.mil* at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

*Procedures for Providing Public Comments:* Pursuant to 41 CFR 102–3.105(j) and 102–3.140, and section 10(a)(3) of the Federal Advisory Committee Act of 1972, the public or interested organizations may submit written comments to the Panel about its mission and topics pertaining to this public session. Written comments must be received by the Deputy Staff Director at least five (5) business days prior to the meeting date so that they may be made available to the Panel for their consideration prior to the meeting. Written comments should be submitted via email to the address for the Deputy Staff Director given in this notice in the following formats: Adobe Acrobat or Microsoft Word. Please note that since the Panel operates under the provisions of the Federal Advisory Committee Act, as amended, all written comments will be treated as public documents and will be made available for public inspection. If members of the public are interested in making an oral statement, a written statement must be submitted along with a request to provide an oral statement. Oral presentations by members of the public will be permitted between 1:00 p.m. and 1:15 p.m. January 30, 2014 in front of the Panel. The number of oral presentations to be made will depend on the number of requests received from members of the public on a first-come basis. After reviewing the requests for

oral presentation, the Chairperson and the Designated Federal Officer will, having determined the statement to be relevant to the Panel's mission, allot five minutes to persons desiring to make an oral presentation.

*Committee's Designated Federal Officer:* The Board's Designated Federal Officer is Ms. Maria Fried, Response Systems to Adult Sexual Assault Crimes Panel, 1600 Defense Pentagon, Room 3B747, Washington, DC 20301–1600.

Dated: January 7, 2014.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 2014–00251 Filed 1–9–14; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

### Defense Business Board; Notice of Federal Advisory Committee Meeting

**AGENCY:** DoD.

**ACTION:** Meeting notice.

**SUMMARY:** The Department of Defense is publishing this notice to announce the following Federal advisory committee meeting of the Defense Business Board. This meeting is open to the public.

**DATES:** The public meeting of the Defense Business Board (hereafter referred to as ''the Board'') will be held on Thursday, January 23, 2014. The meeting will begin at 11:00 a.m. and end at 12:00 p.m. (Escort required; See guidance in the **SUPPLEMENTARY INFORMATION** section, ''Public's Accessibility to the Meeting.'')

**ADDRESSES:** Room 3D557 in the Pentagon, Washington, DC (Escort required; See guidance in the **SUPPLEMENTARY INFORMATION** section, ''Public's Accessibility to the Meeting.'')

**FOR FURTHER INFORMATION CONTACT:** *Committee's Designated Federal Officer:* The Board's Designated Federal Officer is Phyllis Ferguson, Defense Business Board, 1155 Defense Pentagon, Room 5B1088A, Washington, DC 20301–1155, *phyllis.l.ferguson2.civ@mail.mil,* 703–695–7563. For meeting information please contact Ms. Debora Duffy, Defense Business Board, 1155 Defense Pentagon, Room 5B1088A, Washington, DC 20301–1155, *debora.k.duffy.civ@mail.mil,* (703) 697–2168.

**SUPPLEMENTARY INFORMATION:** This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the Meeting: At this meeting, the Board will deliberate the findings and draft recommendations from *''Implementing Best Practices for Major Business Processes in the Department of Defense''.* The mission of the Board is to examine and advise the Secretary of Defense on overall DoD management and governance. The Board provides independent advice which reflects an outside private sector perspective on proven and effective best business practices that can be applied to DoD.

Availability of Materials for the Meeting: A copy of the agenda and the terms of reference for the Task Group study may be obtained from the Board's Web site at *http://dbb.defense.gov/meetings.* Copies will also be available at the meeting.

Meeting Agenda:

11:00 a.m.–12:00 p.m.—Task Group Outbrief and Board Deliberations on ''Implementing Best Practices for Major Business Processes in the Department of Defense''

Public's Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. Seating is limited and is on a first-come basis. All members of the public who wish to attend the public meeting must contact Ms. Debora Duffy at the number listed in the **FOR FURTHER INFORMATION CONTACT** section no later than 12:00 p.m. on Wednesday, January 15 to register and make arrangements for a Pentagon escort, if necessary. Public attendees requiring escort should arrive at the Pentagon Metro Entrance with sufficient time to complete security screening no later than 10:30 a.m. on January 23. To complete security screening, please come prepared to present two forms of identification and one must be a pictured identification card.

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact Ms. Duffy at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

**Procedures for Providing Public Comments**

Pursuant to 41 CFR 102–3.105(j) and 102–3.140, and section 10(a)(3) of the Federal Advisory Committee Act of 1972, the public or interested organizations may submit written comments to the Board about its mission and topics pertaining to this public meeting.

Written comments should be received by the DFO at least five (5) business days prior to the meeting date so that the comments may be made available to the Board for their consideration prior to the meeting. Written comments should be submitted via email to the address for the DFO given in the **FOR FURTHER INFORMATION CONTACT** section in either Adobe Acrobat or Microsoft Word format. Please note that since the Board operates under the provisions of the Federal Advisory Committee Act, as amended, all submitted comments and public presentations will be treated as public documents and will be made available for public inspection, including, but not limited to, being posted on the Board's Web site.

Due to difficulties finalizing the meeting agenda for the scheduled meeting of January 23, 2014, of the Defense Business Board the requirements of 41 CFR 102–3.150(a) were not met. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

Dated: January 7, 2014.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 2014–00248 Filed 1–9–14; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

### Meeting Invitation to Industry and Comment Period on Draft Edition 3 of Standardization Agreement (STANAG) 4671

**AGENCY:** United States Office of the Secretary of Defense through the United States Department of Defense for North Atlantic Treaty Organization (NATO) STANAG 4671 Custodial Support Team, DOD.

**ACTION:** Notice of meeting and document availability.

**SUMMARY:** The NATO STANAG 4671 Custodial Support Team is inviting industries from NATO countries to review Edition 3 and provide comments and/or concerns prior to finalization and publication for topics of discussion during Industry Day. Interested Industry Day participants may request copy of the draft update to STANAG 4671 (with comment sheet for feedback) by email and copies will be provided within 3 business days of receipt by email only. Upon request from an industry

participant to attend Industry Day a formal invitation will be sent via email prior to February 4, 2014 with details for date, location and access requirements. The objective of the March meetings will be to conduct a technical dialogue on the STANAG 4671. Industry Day discussion topics will be generated based on Industry's feedback as well as specific topics identified by the Custodial Support Team. Comments will be prioritized and addressed in an open forum.

**DATES:** Comments must be submitted no later than January 24, 2014 to Mrs. Sandra A. Greeley at the email address in the **FOR FURTHER INFORMATION CONTACT** section. A tentative meeting date is set for March 25–26, 2014 in Brussels, Belgium.

**ADDRESSES:** A copy of STANAG 4671 and the comment sheet may be obtained by emailing Mrs. Sandra A. Greeley at the email address in the **FOR FURTHER INFORMATION CONTACT** section. The meetings will be held in Brussels, Belgium, the meeting facility location is not yet finalized.

**FOR FURTHER INFORMATION CONTACT:**

Industry Day Meeting Coordinator: Mrs. Sandra A. Greeley, Email: *sandra.a.greeley.ctr@navy.mil,* Telephone: (301) 342–8635.

STANAG 4671 Technical Information and Questions: Mr. Daniel Beck, Email: *daniel.h.beck2.civ@mail.mil,* Telephone: (256) 313–5306.

Dated: January 7, 2014.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 2014–00236 Filed 1–9–14; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

**[Docket ID DoD–2014–OS–0002]**

### Privacy Act of 1974; System of Records

**AGENCY:** Office of the Secretary of Defense, DoD.

**ACTION:** Notice to add a new System of Records.

**SUMMARY:** The Office of the Secretary of Defense proposes to add a new system of records DPR 44 DoD, DoD Postsecondary Education Complaint System (PECS) to its inventory of record systems subject to the Privacy Act of 1974, as amended. The PECS serves as a collaborative environment that permits DoD personnel the ability to track, manage and process submitted complaints in order to meet the requirements of Executive Order 13607, Establishing Principles of Excellence for Educational Institutions Serving Service Members, Veterans, Spouses, and Other Family Members.

**DATES:** This proposed action will be effective on February 10, 2014 unless comments are received which result in a contrary determination. Comments will be accepted on or before February 10, 2014.

**ADDRESSES:** You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

*Instructions:* All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

**FOR FURTHER INFORMATION CONTACT:** Ms. Cindy Allard, Chief, OSD/JS Privacy Office, Freedom of Information Directorate, Washington Headquarters Service, 1155 Defense Pentagon, Washington, DC 20301–1155, or by telephone at (571) 372–0461.

**SUPPLEMENTARY INFORMATION:** The Office of the Secretary of Defense notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or from the Defense Privacy and Civil Liberties Office Web site at *http://dpclo.defense.gov/privacy/SORNs/component/osd/index.html.*

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on December 17, 2013, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: January 6, 2014.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

### DPR 44 DoD

**SYSTEM NAME:**

DoD Postsecondary Education Complaint System (PECS).

**SYSTEM LOCATION:**

Integrated Network Operations and Security Center-East (INOSC–E), 37 Elm Street, Langley AFB, VA 23665–2800.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Uniformed Service Members, spouses, and other family members filing formal complaints pursuant to Executive Order 13607.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Name, complaint case ID, pay grade, street address, city, state, Zip Code, country, phone number, age range, email address, service affiliation (service member, spouse or family member, veteran), service branch, service status, sponsor information (service status, service branch, and pay grade), type of education benefits used, school name, school mailing address, level of study, amount of out-of-pocket tuition or government tuition credit paid (academic year), education center name, education center mailing address, complaint description and resolution, name and contact information of person submitting complaint on behalf of a covered individual.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

E.O. 13607, Establishing Principles of Excellence for Educational Institutions Serving Service Members, Veterans, Spouses, and Other Family Members.

**PURPOSE(S):**

The DoD Postsecondary Education Complaint System (PECS) provides Uniformed Service Members, spouses, and other family members the opportunity to file formal complaints when educational institutions fail to follow the Principles of Excellence outlined in Executive Order 13607. The PECS serves as a collaborative environment that permits DoD personnel the ability to track, manage and process submitted complaints in order to meet the requirements of the executive order.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, as

amended, the records herein may be specifically disclosed outside the Department of Defense as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To the Consumer Sentinel Network (managed by the Federal Trade Commission) for access by the Departments of Veterans Affairs, Education, Justice, and the Consumer Financial Protection Bureau for compliance with E.O. 13607 and potential enforcement efforts.

To the Departments of Veterans Affairs and Education for the purpose of transferring complaints submitted to the DoD, but under the cognizance of one of the above Agencies.

The DoD Blanket Routine Uses published at the beginning of the Office of the Secretary of Defense (OSD) compilation of systems of records notices may apply to this system.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Electronic storage media.

**RETRIEVABILITY:**

Name or complaint case ID.

**SAFEGUARDS:**

Records are maintained on a guarded military installation, in a secure building in a controlled area accessible only to authorized personnel. Physical entry is restricted by the use of cipher locks and passwords and administrative procedures which are changed periodically. The system is designed with access controls, comprehensive intrusion detection, and virus protection. Authentication to access to data is role-based, accessed only through Common Access Card authentication, and restricted to those who require the data in the performance of the official duties and have completed information assurance and privacy training annually. Data is transmitted via Transport Layer Security/Secure Socket Layer encryption to protect session information. Encrypted random tokens are implemented to protect against session hijacking attempts.

**RETENTION AND DISPOSAL:**

Disposition pending (until the National Archives and Records Administration approves retention and disposal schedule, records will be treated as permanent).

**SYSTEM MANAGER(S) AND ADDRESS:**

Military Community & Family Policy, State Liaison & Educational Opportunities Directorate, 4800 Mark Center Drive, Suite 14E08, Alexandria, VA 22350–2300.

**NOTIFICATION PROCEDURE:**

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to OUSD (P&R), Military Community & Family Policy, State Liaison & Educational Opportunities Directorate, 4800 Mark Center Drive, Alexandria, VA 22350–2300.

Request must contain full name and/or Complaint Case ID.

**RECORD ACCESS PROCEDURES:**

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the Office of the Secretary of Defense/Joint Staff Freedom of Information Act Requester Service Center, Washington Headquarters Services/Executive Services Directorate, 4800 Mark Center Drive, Alexandria, VA 22350–3100.

Request must contain full name and/or Complaint Case ID.

**CONTESTING RECORD PROCEDURES:**

The OSD rules for accessing records, and for contesting contents and appealing initial agency determinations are published in OSD Administrative Instruction 81; 32 CFR part 311; or may be obtained from the system manager.

**RECORD SOURCE CATEGORIES:**

Data gathered from the individual or person submitting a complaint on behalf of a covered individual.

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

None.

[FR Doc. 2014–00178 Filed 1–9–14; 8:45 am]

BILLING CODE 5001–06–P

## DEPARTMENT OF DEFENSE

### Office of the Secretary

**[Docket ID DoD–2014–OS–0003]**

### Privacy Act of 1974; Systems of Records

**AGENCY:** National Security Agency/Central Security Service, DoD.

**ACTION:** Notice to alter a System of Records.

**SUMMARY:** The National Security Agency/Central Security Service proposes to alter a system of records, GNSA 03, entitled ''NSA/CSS Office of General Counsel Correspondence, Claims, Complaints, and Litigation Files'' in its existing inventory of records systems subject to the Privacy Act of 1974, as amended. This system is for the research, preparation and documentation of determinations and official responses of the NSA/CSS Office of General Counsel related to inquiries for information, complaints, litigation and official actions of other government agencies and branches.

**DATES:** This proposed action will be effective on February 10, 2014 unless comments are received which result in a contrary determination. Comments will be accepted on or before February 10, 2014.

**ADDRESSES:** You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: http://www.regulations.gov.*

Follow the instructions for submitting comments.

* *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, Suite 02G09, Alexandria, VA 22350–3100.

*Instructions:* All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

**FOR FURTHER INFORMATION CONTACT:** Ms. Kris Grein, National Security Agency/Central Security Service, Freedom of Information Act and Privacy Act Office, 9800 Savage Road, Suite 6248, Ft. George G. Meade, MD 20755–6248 or by phone at (301) 688–6527.

**SUPPLEMENTARY INFORMATION:** The National Security Agency/Central Security Service systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or at *http://dpclo.defense.gov/privacy/SORNs/component/nsa/index.html.*

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on January 2, 2014, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About

Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: January 7, 2014.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

**GNSA 03**

**SYSTEM NAME:**

Correspondence, Cases, Complaints, Visitors, Requests (February 22, 1993, 58 FR 10531)

**CHANGES:**

* * * * *

**SYSTEM NAME:**

Delete entry and replace with ''NSA/CSS Office of General Counsel Correspondence, Claims, Complaints, and Litigation Files.''

**SYSTEM LOCATION:**

Delete entry and replace with ''National Security Agency/Central Security Service, 9800 Savage Road, Ft. George G. Meade, MD 20755–6000.''

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Delete entry and replace with ''Individuals or entities contacting the National Security Agency/Central Security Service (NSA/CSS) Office of General Counsel. Individuals requesting or requiring information relating to NSA/CSS litigation or anticipated NSA/CSS litigation.''

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Delete entry and replace with ''Records collected and maintained include individuals' names, Social Security Numbers (SSN), NSA employee identification numbers and case numbers. Correspondence from individuals include requests, claims, complaints, and administrative appeals. NSA responses, memoranda, notes, emails and supporting documentation relating to individuals' requests, claims, complaints and administrative appeals. Copies of requested records and copies of records that are the subject to requests under administrative appeal. Written material developed during, or in anticipation of, litigation or investigation of inquiries, claims or complaints. Written material developed in response to requests for advice or opinion from an individual. Written material required by law, executive order or regulations related to Equal Employment Opportunity investigations, Inspector General investigations, Judicial Branch subpoenas, orders and related actions.''

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Delete entry and replace with ''National Security Agency Act of 1959; 50 U.S.C. 3605, Disclosure of Agency's organization, function, activities or personnel, (Pub. L. 8636), (formerly 50 U.S.C. 402 note); 50 U.S.C. 831–835, Regulations for employment security, (Pub. L. 88–290); Freedom of Information Act, 5 U.S.C. 552 (2006), amended by Open Government Act of 2007, (Pub. L. 110–175; Privacy Act of 1974, 5 U.S.C. 552a, Records maintained on individuals, (Pub. L. 93–579); Equal Employment Opportunity Act of 1974, (Pub. L. 92–261); Fair Labor Standards Amendment (1974), (Publ. L. 93–259); E.O. 10450, Security Requirements for Government Employment; E.O. 11222, Prescribing Standards of Ethical Conduct for Government Officers and Employees; E.O. 11478, Equal Employment Opportunity in the Federal Government; E.O. 13526, Classified National Security Information and E.O. 9397 (SSN), as amended.''

**PURPOSE:**

Delete entry and replace with ''This system is for the research, preparation and documentation of determinations and official responses of the NSA/CSS Office of General Counsel related to inquiries for information, complaints, litigation and official actions of other government agencies and branches.''

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Delete entry and replace with ''In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, as amended, the records contained in this system may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To the Office of Equal Employment Opportunity as required, reports in summary or statistical form.

To appropriate government departments and agencies and the Judicial Branch where litigation or anticipated civil or criminal litigation is involved or where sensitive national security investigations related to protection of intelligence sources or methods are involved.

To other Federal departments and agencies when necessary and appropriate to coordinate Federal government responses.

To NSA/CSS contractor affiliates when necessary and appropriate for NSA/CSS to carry out the purposes of this system as described above.

The DoD Blanket Routine Uses set forth at the beginning of the NSA/CSS' compilation of system of records notices may apply to this system.''

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Delete entry and replace with ''Paper records and electronic storage media.''

**RETRIEVABILITY:**

Delete entry and replace with ''By individual's name, SSN, NSA employee identification number, case number.''

**SAFEGUARDS:**

Delete entry and replace with ''Buildings are secured by a series of guarded pedestrian gates and checkpoints. Access to facilities is limited to security-cleared personnel and escorted visitors only. Within the limited access facilities are limited access offices. Files are stored in lockable containers and on electronic media made available only to individuals specifically authorized to access. Access to electronic media is controlled by computer accounts and passwords. Specific additional access controls are placed on specific case types. Files related to sensitive investigations by the Equal Employment Opportunity Office, the Inspector General, and the NSA General Counsel are additionally protected pursuant to appropriate statues, executive orders and regulations as well as attorney-client privilege. In some cases records are sealed pursuant to a specific court order or due to the sensitivity of the particular subject matter.''

**RETENTION AND DISPOSAL:**

Delete entry and replace with ''Permanent: Transfer inactive files to NSA Records Center. Transfer to NSA Archives when no longer needed for operations or 30 years old. Transfer to NARA when 40 years old.''

**SYSTEM MANAGER AND ADDRESS:**

Delete entry and replace with ''Office of General Counsel, National Security Agency/Central Security Service, Office of the General Counsel, 9800 Savage Road, Ft. George G. Meade, MD 20755–6278.''

**NOTIFICATION PROCEDURE:**

Delete entry and replace with ''Individuals seeking to determine whether records about themselves are contained in this system should address written inquiries to the National Security Agency/Central Security Service, Freedom of Information Act/Privacy Act Office, 9800 Savage Road, Suite 6248, Ft. George G. Meade, MD 20755–6248.

Written inquiries should contain the requester's full name, mailing address, telephone number and signature.''

**RECORD ACCESS PROCEDURES:**

Delete entry and replace with ''Individuals seeking access to information about themselves contained in this system should address written inquiries to the National Security Agency/Central Security Service, Freedom of Information Act/Privacy Act Office, 9800 Savage Road, Suite 6248, Ft. George G. Meade, MD 20755–6248.

Written inquiries should contain the requester's full name, mailing address, telephone number and signature.''

**CONTESTING RECORD PROCEDURES:**

Delete entry and replace with ''The NSA/CSS rules for contesting contents and appealing initial Agency determinations are published at 32 CFR Part 322 or may be obtained by written request addressed to the National Security Agency/Central Security Service, Freedom of Information Act/Privacy Act Office, 9800 Savage Road, Suite 6248, Ft. George G. Meade, MD 20755–6248.''

**RECORD SOURCE CATEGORIES:**

Delete entry and replace with ''Correspondence to and from individuals and government departments and agencies. Written materials developed in response to requests and queries from individuals and government departments and agencies, claims, complaints, investigations and litigation.''

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

Delete entry and replace with ''Information specifically authorized to be classified under E.O. 13526, as implemented by DoD 5200.1–R, maybe exempt pursuant to 5 U.S.C. 552a(k)(1).

Investigatory material compiled for law enforcement purposes, other than material within the scope of subsection 5 U.S.C. 552a(k)(2). However, if an individual is denied any right, privilege, or benefit for which he would otherwise be entitled by Federal law or for which he would otherwise be eligible, as a result of the maintenance of the information, the individual will be provided access to the information exempt to the extent that disclosure would reveal the identity of a confidential source. **Note:** When claimed, this exemption allows limited protection of investigative reports maintained in a system of records used in personnel or administrative actions.

Records maintained solely for statistical research or program evaluation maintained solely for statistical research or program evaluation purposes and which are not used to make decisions on the rights, benefits, or entitlement of an individual except for census records which may be disclosed under 13 U.S.C. 8, may be exempt pursuant to 5 U.S.C. 552a(k)(4).

Investigatory material compiled solely for the purpose of determining suitability, eligibility or qualifications for federal civilian employment, military service, federal contracts, or access to classified information may be exempt pursuant to 5 U.S.C. 552a(k)(5), but only to the extent that such material would reveal the identity of a confidential source.

An exemption rule for this system has been promulgated according to the requirements of 5 U.S.C. 553(b)(1), (2) and (3), 553(c) and 553(3) and published in 32 CFR Part 322. For additional information contact the system manager.''

[FR Doc. 2014–00216 Filed 1–9–14; 8:45 am]

BILLING CODE 5001–06–P

## DEPARTMENT OF DEFENSE

### Department of the Army; Corps of Engineers

### Notice of Availability of the Draft Environmental Impact Statement (DEIS) for the Installation of a Terminal Groin Structure at the Western End of South Beach, Bald Head Island, Adjacent to the Federal Wilmington Harbor Channel of the Cape Fear River (Brunswick County, North Carolina)

**AGENCY:** Department of the Army, U.S. Army Corps of Engineers, DOD.

**ACTION:** Notice of availability.

**SUMMARY:** The U.S. Army Corps of Engineers (USACE), Wilmington District, Wilmington Regulatory Field Office, has received a request for Department of the Army authorization, pursuant to Section 404 of the Clean Water Act and Section 10 of the Rivers and Harbor Act, from the Village of Bald Head Island (VBHI) to develop and implement a shoreline protection plan that includes the installation of a terminal groin structure on the east side of the Wilmington Harbor Bald Head Shoal Entrance Channel (a federally-maintained navigation channel of the Cape Fear River) at the ''Point'' of Bald Head Island.

**DATES:** A public hearing for the Draft Environmental Impact Statement (DEIS) will be held at the International Longshoreman's Association Hall, located at 211 West 10th Street in Southport, Brunswick County, North Carolina, on February 12, 2014, at 6:00 p.m. Written comments on the DEIS will be received until February 24, 2014.

**ADDRESSES:** Copies of comments and questions regarding scoping of the DEIS may be submitted to: U.S. Army Corps of Engineers (Corps), Wilmington District, Regulatory Division. Attn: File Number SAW–2012–00040, 69 Darlington Avenue, Wilmington, North Carolina 28403.

**FOR FURTHER INFORMATION CONTACT:** Questions about the proposed action and DEIS can be directed to Mr. Ronnie Smith, Wilmington Regulatory Field Office, telephone number: (910) 251–4829. A copy of the DEIS can be found at the following link: *http://www.saw.usace.army.mil/Missions/RegulatoryPermitProgram/PublicNotices.aspx* under the VBHI Terminal Groin Project.

**SUPPLEMENTARY INFORMATION:**

1. *Project Description.* The west end of South Beach, Bald Head Island, Brunswick County, North Carolina, has experienced both chronic and short-term shoreline erosion. This erosion has resulted in direct impacts to nearby beaches and dunes and could potentially impact public infrastructure and homes. This area has been subject to past sand placement activities sponsored by both the VBHI and the Corps. The Corps has placed several million cubic yards of suitable material on this shoreline since 1991 as part of a Federal navigation project. To address its erosion issue, the VBHI desires to implement a long-term beach and dune stabilization strategy to include installation of a single terminal groin at the western end of South Beach. The proposed terminal groin would be expected to perform the following functions: (1) Reduce inlet-directed sand losses from beach fill projects; and (2) stabilize shoreline alignment along the westernmost segment of South Beach in such a manner that alongshore transport rates are reduced. The terminal groin would serve as a ''template'' for fill material placed eastward (of the proposed terminal groin). The proposed groin has been designed as a ''leaky'' structure (*i.e.* semi-permeable) so as to provide for some level of sand transport to West Beach (located northward and downdrift of the proposed groin).

2. *Issues.* There are several potential environmental and public interest issues that are addressed in the DEIS. Additional issues may be identified during the public review process. Issues initially identified as potentially significant include:

a. Potential impacts to marine biological resources (benthic organisms, passageway for fish and other marine life) and Essential Fish Habitat.

b. Potential impacts to threatened and endangered marine mammals, reptiles, birds, fish, and plants.

c. Potential for shoreline changes on West Beach of Bald Head Island and adjacent areas.

d. Potential impacts to navigation, commercial and recreational.

e. Potential impacts to the long-term management of the oceanfront shorelines.

f. Potential effects on regional sand sources and sand management practices.

g. Potential effects of shoreline protection.

h. Potential impacts on public health and safety.

i. Potential impacts to recreational and commercial fishing.

j. Potential impacts to cultural resources.

k. Cumulative impacts of future dredging and nourishment activities.

3. *Alternatives.* Several alternatives are being considered for the proposed project. These alternatives, including the No Action alternative, were further formulated and developed during the scoping process and are considered in the DEIS. A summary of alternatives under consideration are provided below:

- Alternative #1: No-Action (includes component of Status-Quo)
- Alternative #2: Retreat
- Alternative #3: Beach Nourishment/ Disposal With Existing Sand Tube Groinfield To Remain in Place
- Alternative #4: Beach Nourishment/ Beach Disposal and Sand Tube Groinfield Removal
- Alternative #5: Terminal Groin With Beach Nourishment/Beach Disposal (Sand Tube Groinfield Remaining)
- Alternative #6: Terminal Groin With Beach Nourishment/Disposal (Removal of Sand Tube Groinfield)

4. *Scoping Process.* Project Review Team meetings were held to receive comments and assess concerns regarding the appropriate scope and preparation of the DEIS. Federal, state, and local agencies and other interested organizations and persons participated in these Project Review Team meetings.

The Corps is also consulting with the U.S. Fish and Wildlife Service under the Endangered Species Act and the Fish and Wildlife Coordination Act, and with the National Marine Fisheries Service under the Magnuson-Stevens Act and Endangered Species Act. Additionally, the DEIS has assessed potential water quality impacts pursuant to Section 401 of the Clean Water Act, and is being coordinated with North Carolina Division of Coastal Management (NCDCM) to determine the project's consistency with the Coastal Zone Management Act and permittability under State Coastal Management rules. The USACE has worked with the NCDCM through the DEIS process to ensure the process complies with all State Environmental Policy Act (SEPA) requirements. It is the Corps' and NCDCM's intentions to consolidate both National Environmental Policy Act (NEPA) and SEPA processes to eliminate duplications.

5. *Availability of the DEIS.* The DEIS has been published and circulated, and a public hearing will be held February 12, 2014 at the International Longshoreman's Association Center, located at 211 West 10th Street in Southport, Brunswick County, North Carolina at 6 p.m.

Dated: December 30, 2013 .

**Scott McLendon,**

*Chief, Regulatory Division.*

[FR Doc. 2014–00262 Filed 1–9–14; 8:45 am]

BILLING CODE 3720–58–P

## DEPARTMENT OF DEFENSE

### Department of the Navy

**[Docket ID USN–2014–0002]**

### Privacy Act of 1974; System of Records

**AGENCY:** Department of the Navy, DoD.

**ACTION:** Notice to alter a System of Records.

**SUMMARY:** The Department of the Navy proposes to alter the system of records, N01070–13, entitled ''Navy Mobilization Processing System'', in its inventory of record systems subject to the Privacy Act of 1974, as amended. This system will be used to provide end-to-end command visibility and control of integrated augmentation processes and automated work-flow; for requesting manpower requirements, approving requirements, sourcing requirements, and writing orders for requirements; tracking, accounting, data collection, and coordination during activation/deactivation.

**DATES:** This proposed action will be effective on February 10, 2014 unless comments are received which result in a contrary determination. Comments will be accepted on or before February 10, 2014.

**ADDRESSES:** You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

*Instructions:* All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

**FOR FURTHER INFORMATION CONTACT:** Ms. Robin Patterson, Head, PA/FOIA Office (DNS–36), Department of the Navy, 2000 Navy Pentagon, Washington, DC 20350–2000, or by phone at (202) 685–6545.

**SUPPLEMENTARY INFORMATION:** The Department of the Navy's notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or from the Defense Privacy and Civil Liberties Office Web site at *http://dpclo.defense.gov/privacy/SORNs/component/navy/index.html.*

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on December 11, 2013, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: January 6, 2014.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

**N01070–13**

**SYSTEM NAME:**

Navy-Marine Corps Mobilization Processing System (NMCMPS) (April 11, 2007, 72 FR 18215).

**CHANGES:**

* * * * *

**SYSTEM NAME:**

Delete entry and replace with ''Navy Mobilization Processing System.''

**SYSTEM LOCATION:**

Delete entry and replace with ''Primary System Headquarters, Navy Personnel Command, Augmentation Management Division (PERS–46), 5720 Integrity Drive, Millington, TN 38055–4000.

Decentralized Segments—Operational elements of the Department of the Navy. Official mailing addresses are published in the Standard Navy Distribution List that is available as an appendix to the Navy's compilation of system of records notices.''

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Delete entry and replace with ''All Navy active component and reserve component personnel in support of contingency operations and all Navy reserve component personnel in receipt of Active Duty for Special Work orders.''

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Delete entry and replace with ''Name, Social Security Number (SSN), DoD ID number, rate/rank, record of assignment, order request ID, mailing/home/work addresses, home/work/mobile telephone numbers, qualification designation codes; command information to include ultimate duty station's name and address, augmentation type, Boots on Ground (BOG) location name, location code, requirement tracking number, reported begin and end date, and projected end date; Unit Identification Code (UIC), Navy Enlisted Code/Designator, military status, date reported to command, date departed command, training, and military orders.''

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Delete entry and replace with ''5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 5013, Secretary of the Navy; OPNAVINST 3060.7B, Navy Manpower Mobilization/Demobilization Guide (Appendix D); OPNAVINST 1001.24, Individual Augmentation (IA) Policy and Procedures; and E.O. 9397 (SSN), as amended.''

**PURPOSE:**

Delete entry and replace with ''To provide end-to-end command visibility and control of integrated augmentation processes and automated work-flow, for requesting manpower requirements, approving requirements, sourcing requirements, and writing orders for requirements, tracking, accounting, data collection, and coordination during activation/deactivation. This includes the mobilization and demobilization of Reserve Component personnel and the temporary reassignment of Active Component personnel for emergent manpower requirements. It allows administrative, operational, and ad-hoc Task Force based Chain-of-Command duty stations direct access via the web to monitor manpower requests and personnel augmenting their commands.''

* * * * *

**RETRIEVABILITY:**

Delete entry and replace with ''Records are retrieved by Name, SSN, DoD ID number, or order request ID.''

**SAFEGUARDS:**

Delete entry and replace with ''Password controlled system, paper/electronic file, and element access based on predefined need-to-know. Physical access to terminals, terminal rooms, buildings and activities grounds are controlled by locked terminals and rooms, guards, personnel screening and visitor registers. Paper records downloaded from the database are labeled by default with properly in accordance with level of classification and ''For Official Use Only''.''

**RETENTION AND DISPOSAL:**

Delete entry and replace with ''Permanent: Records are submitted to Navy Personnel Command to be entered into the Electronic Military Personnel Records System (EMPRS). Records of retired or former personnel are then transferred to National Personnel Records Center, Military Personnel Records, 9700 Page Avenue, St. Louis, MO 63132–5100, and held for 62 years after retirement or separation from the U.S. Navy. Records are transferred to the National Archives and Records Administration for permanent retention 62 years after separation of service member.''

**SYSTEM MANAGER(S) AND ADDRESS:**

Delete entry and replace with ''Policy Official, Commander, Navy Personnel Command (PERS–4G), 5720 Integrity Drive, Millington, TN 38055–4000.

Commanding Officers, Officers in Charge, and Heads of Department of the Navy activities. Organizational elements of the Department of the Navy. Official mailing addresses are published in the Standard Navy Distribution List that is available as an appendix to the Navy's compilation of system of records notices.

National Personnel Records Center, Military Personnel Records, 9700 Page Avenue, St. Louis, MO 63132–5100, for records of retired or former personnel 62 years after retirement or discharge from the U.S. Navy.''

**NOTIFICATION PROCEDURE:**

Delete entry and replace with ''Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the Bureau of Naval Personnel Online by using *https://www.bol.navy.mil/*.

Inquiries regarding permanent records of all active duty and reserve members (except Individual Ready Reserve (IRR)), former members discharged, deceased, or retired since 1995, should be addressed to the Commander, Navy Personnel Command (PERS–312), 5720 Integrity Drive, Millington, TN 38055–3120.

Inquiries regarding records of former members discharged, deceased, or retired before 1995 should be addressed to the Director, National Personnel Records Center, Military Personnel Records, 9700 Page Avenue, St. Louis, MO 63132–5100 or at Web site *http://www.archives.gov/veterans/military-service-records/index.html* to obtain guidance on how to access records.

This request should contain full name, SSN, and address of the individual concerned and should be signed. The system manager may require an original signature or a notarized signature as a means of proving the identity of the individual requesting access to the records.''

**RECORD ACCESS PROCEDURES:**

Delete entry and replace with ''Individuals seeking to access information about themselves contained in this system should address written inquiries to the Bureau of Naval Personnel Online by using *https://www.bol.navy.mil/*.

Inquiries regarding permanent records of all active duty and reserve members (except Individual Ready Reserve (IRR)), former members discharged, deceased, or retired since 1995, should be addressed to the Commander, Navy Personnel Command (PERS–312), 5720 Integrity Drive, Millington, TN 38055–3120.

Inquiries regarding records of former members discharged, deceased, or retired before 1995 should be addressed to the Director, National Personnel Records Center, Military Personnel Records, 9700 Page Avenue, St. Louis, MO 63132–5100 or at Web site *http://www.archives.gov/veterans/military-service-records/index.html* to obtain guidance on how to access records.

This request should contain full name, SSN, and address of the individual concerned and should be signed. The system manager may require an original signature or a notarized signature as a means of

proving the identity of the individual requesting access to the records.''

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[FR Doc. 2014–00161 Filed 1–9–14; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF EDUCATION

## Applications for New Awards; Personnel Development To Improve Services and Results for Children With Disabilities—Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel

**AGENCY:** Office of Special Education and Rehabilitative Services, Department of Education.

**ACTION:** Notice.

### Overview Information

Personnel Development to Improve Services and Results for Children with Disabilities—Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel.

Notice inviting applications for new awards for fiscal year (FY) 2014.

*Catalog of Federal Domestic Assistance (CFDA) Number:* 84.325D.

**DATES:**

*Applications Available:* January 10, 2014.

*Deadline for Transmittal of Applications:* February 24, 2014.

*Deadline for Intergovernmental Review:* April 25, 2014.

### Full Text of Announcement

### I. Funding Opportunity Description

*Purpose of Program:* The purposes of this program are to (1) help address State-identified needs for personnel preparation in special education, related services, early intervention, and regular education to work with children, including infants and toddlers, with disabilities; and (2) ensure that those personnel have the necessary skills and knowledge, derived from practices that have been determined through scientifically based research and experience, to be successful in serving those children.

*Priorities:* In accordance with 34 CFR 75.105(b)(2)(iv), the absolute priority is from allowable activities specified in the statute (see sections 662 and 681 of the Individuals with Disabilities Education Act (IDEA)).

*Absolute Priority:* For FY 2014 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is: *Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel.*

*Background:*

The purpose of the Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel priority is to support programs that prepare special education, early intervention, and related services personnel at the graduate level who are well-qualified for, and can act effectively in, leadership positions in universities, State educational agencies (SEAs), lead agencies (LAs), local educational agencies (LEAs), early intervention services programs (EIS programs), or schools.

There is a well-documented need for leadership personnel who are prepared at the doctoral and postdoctoral levels to fill faculty and leadership positions in special education, early intervention, and related services (Sindelar & Taylor, 1988; Smith & Lovett, 1987; Smith, Montrosse, Robb, Tyler, & Young, 2011; Smith, Pion, & Tyler, 2004; Smith, Robb, West, & Tyler, 2010; Woods & Snyder, 2009). In the report, *Assessing Trends in Leadership: Special Education's Capacity to Produce a Highly Qualified Workforce,* Smith et al. (2011) stated:

> Although the field has faced a consistent shortage of faculty, the predicted supply/demand imbalance is of historic proportions. To meet projected demand, the nation's doctoral programs will need to produce over six times the current number of SE [special education] doctoral graduates. . . . Unless abated, this shortage will impair the field's capacity to generate new knowledge and produce a sufficient number of SE teacher educators who can in turn produce enough well-prepared teachers to meet the needs of students with disabilities and their families. (p. 38)

Moreover, Smith et al. (2011) report that some special education doctoral programs anticipate ½ to ⅔ of their faculty will retire in the next six years. These leaders teach evidence-based practices to future special education, early intervention, and related services professionals who will work in a variety of educational settings and provide services directly to children and youth with disabilities. These leaders also conduct research to increase the knowledge of effective interventions and services for these children (Smith et al., 2010).

State and local agencies also need leadership personnel who are prepared at the graduate level (i.e., master's, education specialist, and doctoral degrees, depending on State certification requirements) to fill special education and early intervention administrator positions. These administrators supervise and evaluate the implementation of evidence-based instructional programs to make sure that State or local agencies are meeting the needs of children with disabilities. Administrators also ensure that schools and programs meet Federal, State, and local requirements for special education, early intervention, and related services (Lashley & Boscardin, 2003).

Federal support can increase the supply of personnel who have the necessary knowledge and skills to assume leadership positions in special education, early intervention, and related services in universities, SEAs, LAs, LEAs, EIS programs, or schools. Critical competencies for special education, early intervention, and related services personnel vary depending on the type of personnel and the requirements of the preparation program but can include, for example, skills needed for postsecondary instruction, administration, policy development, professional practice, leadership, or research. However, all leadership personnel need to have current knowledge of effective interventions and services that improve outcomes for children with disabilities, including high-need children with disabilities.[1]

*Priority:*

The purpose of the Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel priority is to support pre-existing degree programs that prepare special education, early intervention, and related services personnel at the graduate level who are well-qualified for, and can act effectively in, leadership positions in universities, SEAs, LAs, LEAs, EIS programs, or schools. This priority supports two types of programs:

Type A programs are designed to prepare special education, early intervention, or related services personnel to serve as higher education faculty. Type A programs culminate in a doctoral degree or provide postdoctoral learning opportunities.

**Note:** Preparation programs that lead to clinical doctoral degrees in related services (e.g., a Doctor of Audiology (AuD) degree or Doctor of Physical Therapy (DPT) degree) are not included in this priority. These types of preparation programs are eligible to apply for funding under the Personnel Preparation in

[1] For a definition of ''high-need children with disabilities,'' please see footnote 2.

Special Education, Early Intervention, and Related Services priority (CFDA 84.325K) that the Office of Special Education Programs (OSEP) intends to fund in FY 2014.

Type B programs are designed to prepare special education or early intervention administrators to work in SEAs, LAs, LEAs, EIS programs, or schools. Type B programs prepare personnel for positions such as SEA special education administrators, LEA or regional special education directors, school-based special education directors, including those in youth correctional facilities, preschool coordinators, and early intervention coordinators. Type B programs culminate in a master's, education specialist, or doctoral degree or provide postdoctoral learning opportunities.

**Note:** OSEP intends to fund in FY 2014 at least three high-quality applications proposing Type B programs and may fund applications out of rank order.

**Note:** The preparation of school principals is not included in this priority.

**Note:** Applicants must identify the specific program type, A or B, for which they are applying for funding as part of the competition title on the application cover sheet (SF form 424, item 15). Applicants may not submit the same proposal for more than one program type.

To be considered for funding under the Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel absolute priority, all program applicants must meet the application requirements contained in the priority. All projects funded under the absolute priority also must meet the programmatic and administrative requirements specified in the priority.

The requirements of this priority are as follows:

(a) Demonstrate, in the narrative section of the application under ''Significance of the Project,'' how—

(1) The project addresses national, State, or regional needs for leadership personnel to administer programs or provide, or prepare others to provide, interventions and services that improve outcomes of children with disabilities, ages birth through 21, including high-need children with disabilities.[2] To address this requirement, the applicant must—

(i) Present appropriate and applicable national, State, or regional data demonstrating the need for the leadership personnel the applicant proposes to prepare; and

(ii) Present data on the effectiveness of the graduate program to date in areas such as: The effectiveness of program graduates as educators of teachers, service providers, or administrators, including any results from evaluating the impact of those teachers, service providers, or administrators on the outcomes of children with disabilities; the average amount of time it takes for program graduates to complete the program; the percentage of program graduates finding employment directly related to their preparation; and the professional accomplishments of program graduates (e.g., public service, honors, or publications) that demonstrate their leadership in special education, early intervention, or related services; and

**Note:** Data on the effectiveness of a graduate program should be no older than five years prior to the start date of the project proposed in the application. When reporting percentages, the denominator (i.e., the total number of students) must be provided.

(2) Scholar competencies to be acquired in the program relate to knowledge and skills needed by the leadership personnel the applicant proposes to prepare, including knowledge of technologies designed to provide instruction. To address this requirement, the applicant must—

(i) Identify the competencies needed by leadership personnel in postsecondary instruction, administration, policy development, professional practice, leadership, or research in order to administer programs or provide, or prepare others to provide, interventions and services that improve outcomes of children with disabilities, ages birth through 21, including high-need children with disabilities; and

(ii) Provide the conceptual framework of the leadership preparation program, including any empirical support, that will promote the acquisition of the identified competencies needed by leadership personnel and, where applicable, how these competencies relate to the project's specialized preparation area.

(b) Demonstrate, in the narrative section of the application under ''Quality of the Project Services,'' how—

(1) The project will recruit and support high-quality scholars. The narrative must—

(i) Describe the selection criteria the applicant will use to identify high-quality applicants for admission in the program;

(ii) Describe the recruitment strategies the applicant will use to attract high-quality applicants and any specific recruitment strategies targeting high-quality applicants from traditionally underrepresented groups, including individuals with disabilities; and

(iii) Describe the approach the applicant will use to help all scholars, including individuals with disabilities, complete the program; and

(2) The project is designed to promote the acquisition of the competencies needed by leadership personnel to administer programs or provide, or prepare others to provide, interventions and services that improve outcomes, including college- and career-readiness of children with disabilities. To address this requirement, the applicant must—

(i) Describe how the components of the project, such as coursework, internship or practicum experiences, research requirements, and other opportunities provided to scholars to analyze data, critique research and methodologies, and practice newly acquired knowledge and skills, will enable the scholars to acquire the competencies needed by leadership personnel for postsecondary instruction, administration, policy development, professional practice, leadership, or research in special education, early intervention, or related services;

(ii) Describe how the components of the project are integrated in order to support the acquisition and enhancement of the identified competencies needed by leadership personnel in special education, early intervention, or related services;

(iii) Describe how the components of the project prepare scholars to administer programs or provide, or prepare others to provide, interventions and services that improve outcomes, including college- and career-readiness, of children with disabilities in a variety of settings, including in high-need LEAs,[3] high-poverty schools,[4] low-

[2] For purposes of this priority, ''high-need children with disabilities'' refers to children (ages birth through 21, depending on the State) who are eligible for services under IDEA, and who may be further disadvantaged and at risk of educational failure because they: (1) Are living in poverty, (2) are far below grade level, (3) are at risk of not graduating with a regular high school diploma on time, (4) are homeless, (5) are in foster care, (6) have been incarcerated, (7) are English learners, (8) are pregnant or parenting teenagers, (9) are new immigrants, (10) are migrant, or (11) are not on track to being college- or career-ready by graduation.

[3] For purposes of this priority, the term ''high-need LEA'' means an LEA (a) that serves not fewer than 10,000 children from families with incomes below the poverty line; or (b) for which not less than 20 percent of the children served by the LEA are from families with incomes below the poverty line.

[4] For purposes of this priority, the term ''high-poverty school'' means a school in which at least 50 percent of students are eligible for free or reduced-price lunches under the Richard B. Russell National School Lunch Act or in which at least 50 percent of students are from low-income families as determined using one of the criteria specified under

Continued

performing schools, including persistently lowest-achieving schools,[5] priority schools (in the case of States that have received the Department's approval of a request for ESEA flexibility),[6] and early childhood programs located within the geographical boundaries of a high-need LEA;

(iv) Demonstrate, through a letter of support from the partnering agency, school, or program, a relationship with one or more high-need LEAs; publicly funded preschool programs, including Head Start programs, located within the geographic boundaries of a high-need LEA; or programs serving children eligible for services under Part C or Part B, section 619 of IDEA located within the geographic boundaries of a high-need LEA, that it has agreed to provide scholars with a high-quality internship or practicum experience in a school in a high-need LEA, publicly funded preschool, or early intervention program;

(v) Describe how the project will use resources, as appropriate, available through technical assistance centers, which may include centers funded by the U.S. Department of Education; and

(vi) Describe the approach that faculty members will use to mentor scholars with the goal of helping them acquire competencies needed by leadership personnel and promote career goals in special education, early intervention, or related services.

(c) Demonstrate, in the narrative section of the application under ''Quality of the Project Evaluation,'' how—

(1) The applicant will evaluate the effectiveness of the proposed leadership project. The applicant must describe the outcomes to be measured for both the project and the scholars, particularly the acquisition of scholar competencies and their impact on the services provided by future teachers, service providers, or administrators; the evaluation methodologies to be employed, including proposed instruments, data collection methods, and possible analyses; and the proposed standards or targets for determining effectiveness;

(2) The applicant will collect and use data on current scholars and scholars who graduate from the program to improve the proposed program on an ongoing basis; and

(3) The grantee will report the evaluation results to OSEP in its annual and final performance reports.

(d) Demonstrate, in the narrative under ''Required Project Assurances,'' or appendices as directed, that the following program requirements are met. The applicant must—

(1) Include in the application appendix—

(i) Course syllabi for all coursework in the major and any required coursework for a minor;

(ii) Course syllabi for all research methods, evaluation methods, or data analysis courses required by the degree program and elective research methods, evaluation methods, or data analysis courses that have been completed by more than one student enrolled in the program in the last five years; and

(iii) For new coursework, proposed syllabi;

**Note:** Applicants for Type B programs should provide a syllabus or syllabi for current or proposed courses that provide instruction on or permit practice with research, and the methodological, statistical, and practical considerations in the use of data on early learning outcomes, student achievement, or growth in student achievement to evaluate the effectiveness of early intervention providers, related services providers, teachers, or principals.

(2) Ensure that the proposed number of scholars to be recruited into the program can graduate from the program by the end of the grant's project period. The described scholar recruitment strategies, including recruitment of individuals with disabilities, the program components and their sequence, and proposed budget must be consistent with this project requirement;

(3) Ensure that the project will meet the requirements in 34 CFR 304.23, particularly those related to informing all scholarship recipients of their service obligation commitment. Failure by a grantee to properly meet these requirements is a violation of the grant award that may result in sanctions, including the grantee being liable for returning any misused funds to the department. Specifically, the grantee must prepare, and ensure that each scholarship recipient sign, the following two documents:

(i) A Pre-Scholarship Agreement prior to the scholar receiving a scholarship for an eligible program (Office of Management and Budget (OMB) Control Number 1820–0686); and

(ii) An Exit Certification immediately upon the scholar leaving, completing, or otherwise exiting that program (OMB Control Number 1820–0686);

(4) Ensure that prior approval from the OSEP project officer will be obtained before admitting additional scholars beyond the number of scholars proposed in the application and before transferring a scholar to another preparation program funded by OSEP;

(5) Ensure that the project will meet the statutory requirements in section 662(e) through 662(h) of IDEA;

(6) Ensure that at least 65 percent of the total requested annual budget will be used for scholar support or provide justification in the application narrative for any designation less than 65 percent. Examples of sufficient justification for proposing less than 65 percent of the budget for scholar support include—

(i) A project servicing rural areas that provides long-distance coursework, and requires information technology personnel, adjunct professors, or site-based mentors to operate effectively; and

(ii) A project that expands or adds a new area of emphasis to special education, early intervention, or related services, and includes data on the need for the expansion and information on how these expanded or new areas will be sustained once Federal funding ends;

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section 1113(a)(5) of the Elementary and Secondary Education Act of 1965, as amended (ESEA). For middle and high schools, eligibility may be calculated on the basis of comparable data from feeder schools. Eligibility as a high-poverty school under this definition is determined on the basis of the most currently available data (*www2.ed.gov/legislation/FedRegister/other/2010-4/121510b.html*).

[5] For purposes of this priority, the term ''persistently lowest-achieving schools'' means, as determined by the State—

(a)(1) Any Title I school in improvement, corrective action, or restructuring that—

(i) Is among the lowest-achieving five percent of Title I schools in improvement, corrective action, or restructuring or the lowest-achieving five Title I schools in improvement, corrective action, or restructuring in the State, whichever number of schools is greater; or

(ii) Is a high school that has had a graduation rate as defined in 34 CFR 200.19(b) that is less than 60 percent over a number of years; and

(2) Any secondary school that is eligible for, but does not receive, Title I funds that—

(i) Is among the lowest-achieving five percent of secondary schools or the lowest-achieving five secondary schools in the State that are eligible for, but do not receive, Title I funds, whichever number of schools is greater; or

(ii) Is a high school that has had a graduation rate as defined in 34 CFR 200.19(b) that is less than 60 percent over a number of years.

(b) To identify the persistently lowest-achieving schools, a State must take into account both—

(i) The academic achievement of the ''all students'' group in a school in terms of proficiency on the State's assessments under section 1111(b)(3) of the ESEA in reading/language arts and mathematics combined; and

(ii) The school's lack of progress on those assessments over a number of years in the ''all students'' group.

For the purposes of this priority, the Department considers schools that are identified as Tier I or Tier II schools under the School Improvement Grants Program (see 75 FR 66363) as part of a State's approved FY 2009, FY 2010, FY 2011, or FY 2012 application to be persistently lowest-achieving schools. A list of these Tier I and Tier II schools can be found on the Department's Web site at *www2.ed.gov/programs/sif/index.html*.

[6] For purposes of this priority, the term ''priority school'' means a school that has been identified by the State as a priority school pursuant to the State's approved request for ESEA flexibility.

(7) Ensure that the institution will not require scholars enrolled in the program to work (e.g., as graduate assistants) as a condition of receiving a scholarship, unless the work is specifically related to the acquisition of scholars' competencies and the requirements for completion of their personnel preparation program. This prohibition on work as a condition of receiving a scholarship does not apply to the service obligation requirements in section 662(h) of IDEA;

(8) Ensure that the budget includes attendance of the project director at a three-day project directors' meeting in Washington, DC, during each year of the project. The budget may also provide for the attendance of scholars at the three-day project directors' meeting in Washington, DC;

(9) Ensure that if the project maintains a Web site, relevant information and documents are in a format that meets government or industry-recognized standards for accessibility; and

(10) Ensure that annual data will be submitted on each scholar who receives grant support. Applicants are encouraged to visit the Personnel Development Program Scholar Data Report Web site at: *http://oseppdp.ed.gov* for further information about this data collection requirement. Typically, data collection begins in January of each year, and grantees are notified by email about the data collection period for their grant. This data collection must be submitted electronically by the grantee and does not supplant the annual grant performance report required of each grantee for continuation funding (see 34 CFR 75.590).

*References*


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Sindelar, P. T., & Taylor, C. (1988). Supply and demand for doctoral personnel in special education and communication disorders. *Teacher Education and Special Education, 11,* 162–167.

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Smith, D. D., Pion, G. M., & Tyler, N. C. (2004). Leadership personnel in special education: Can persistent shortages be resolved? In A. M. Sorells, H. J., Rieth & P. T. Sindelar (Eds.), *Critical Issues in Special Education: Access, Diversity, and Accountability* (pp. 258–276). New York: Pearson, Allyn, & Bacon.

Smith, D. D., Robb, S. M., West, J., & Tyler, N. C. (2010). The changing education landscape: How special education leadership preparation can make a difference for teachers and their students with disabilities. *Teacher Education and Special Education, 33*(1), 25–43.

Woods, J., & Snyder, P. (2009). Interdisciplinary doctoral leadership training in early intervention. *Infants & Young Children, 22*(1), 32–34.


*Waiver of Proposed Rulemaking:* Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities and requirements. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priorities in this notice.

**Program Authority:** 20 U.S.C. 1462 and 1481.

*Applicable Regulations:* (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 86, 97, 98, and 99. (b) The Education Department debarment and suspension regulations in 2 CFR part 3485. (c) The regulations for this program in 34 CFR part 304.

**Note:** The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

**Note:** The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

## II. Award Information

*Type of Award:* Discretionary grants.

*Estimated Available Funds:* The Administration has requested $85,799,000 for the Personnel Development to Improve Services and Results for Children with Disabilities program for FY 2014, of which we intend to use an estimated $4,250,000 for this competition. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2015 from the list of unfunded applicants from this competition.

*Estimated Range of Awards:* $225,000–$250,000 per year.

*Estimated Average Size of Awards:* $237,500 per year.

*Maximum Award:* We will reject any application that proposes a budget exceeding $250,000 for a single budget period of 12 months. The Assistant Secretary for Special Education and Rehabilitative Services may change the maximum amount through a notice published in the **Federal Register**.

*Estimated Number of Awards:* 17.

**Note:** The Department is not bound by any estimates in this notice.

*Project Period:* Up to 60 months.

## III. Eligibility Information

1. *Eligible Applicants:* IHEs, private nonprofit organizations.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Other General Requirements:*

(a) Recipients of funding under this program must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Each applicant for, and recipient of, funding under this program must involve individuals with disabilities, or parents of individuals with disabilities ages birth through 26, in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

## IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the Internet or from the Education Publications Center (ED Pubs). To obtain a copy via the Internet, use the following address: *www.ed.gov/fund/grant/apply/grantapps/index.html.* To obtain a copy from ED Pubs, write, fax, or call the following: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794. If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *www.EDPubs.gov* or at its email address: *edpubs@inet.ed.gov.*

If you request an application from ED Pubs, be sure to identify this competition as follows: CFDA number 84.325D.

Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting the person or team listed

under *Accessible Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition. Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit Part III to no more than 50 pages, using the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the *application narrative,* including titles, headings, footnotes, quotations, reference citations, and captions, as well as all text in charts, tables, figures, graphs, and screen shots.
- Use a font that is 12 point or larger.
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) *will not be accepted.*

The page limit and double-spacing requirement does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the *two-page abstract* (follow the guidance provided in the application package for completing the abstract), the table of contents, the list of priority requirements, the resumes, the reference list, the letters of support, or the appendices. However, the page limit and double-spacing requirement does apply to all of Part III, the application narrative, including all text in charts, tables, figures, graphs, and screen shots.

We *will reject your application if you exceed the page limit in the application narrative section;* or if you apply standards other than those specified in the application package.

3. *Submission Dates and Times:*

Applications Available: January 10, 2014. Deadline for Transmittal of Applications: February 24, 2014.

Applications for grants under this competition must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV. 7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice. Deadline for Intergovernmental Review: April 25, 2014.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR Part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this program.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM) (formerly the Central Contractor Registry (CCR)), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow 2–5 weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data entered into the SAM database by an entity. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

**Note:** Once your SAM registration is active, you will need to allow 24 to 48 hours for the information to be available in Grants.gov. and before you can submit an application through Grants.gov.

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov.* To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a SAM.gov Tip Sheet, which you can find at: *http://www2.ed.gov/fund/grant/apply/sam-faqs.html.*

In addition, if you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined at the following Grants.gov Web page: *www.grants.gov/applicants/get_registered.jsp.*

7. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under the Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel competition, CFDA number 84.325D, must be submitted electronically using the Governmentwide Grants.gov Apply site at *www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you

qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for the Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel competition at *www.Grants.gov.* You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.325, not 84.325D).

Please note the following:

• When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.

• Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.

• The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.

• You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov under News and Events on the Department's G5 system home page at *www.G5.gov.*

• You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.

• You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.

• You must upload any narrative sections and all other attachments to your application as files in a PDF (Portable Document) read-only, non-modifiable format. Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF or submit a password-protected file, we will not review that material. Additional, detailed information on how to attach files is in the application instructions.

• Your electronic application must comply with any page-limit requirements described in this notice.

• After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by email. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).

• We may request that you provide us original signatures on forms at a later date.

*Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System:* If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

**Note:** The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

*Exception to Electronic Submission Requirement:* You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

• You do not have access to the Internet; or

• You do not have the capacity to upload large documents to the Grants.gov system; and

• No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevent you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Celia Rosenquist, U.S.

Department of Education, 400 Maryland Avenue SW., room 4070, Potomac Center Plaza (PCP), Washington, DC 20202–2600. FAX: (202) 245–7617.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address:

U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.325D), LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

**Note:** The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address:

U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.325D), 550 12th Street SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

**Note for Mail or Hand Delivery of Paper Applications:** If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

## V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program are from 34 CFR 75.210 and are listed in the application package.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:*

In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The standing panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications. However, if the Department decides to select an equal number of applications in each group for funding, this may result in different cut-off points for fundable applications in each group.

4. *Special Conditions:* Under 34 CFR 74.14 and 80.12, the Secretary may impose special conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 34 CFR parts 74 or 80, as applicable; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

## VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure

information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Performance Measures:* Under the Government Performance and Results Act of 1993 (GPRA), the Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the Personnel Development to Improve Services and Results for Children with Disabilities Program. These measures include: (1) The percentage of Special Education Personnel Development projects that incorporate evidence-based practices into their curriculum; (2) the percentage of scholars completing Special Education Personnel Development-funded programs who are knowledgeable and skilled in evidence-based practices for infants, toddlers, children, and youth with disabilities; (3) the percentage of Special Education Personnel Development-funded scholars who exit preparation programs prior to completion due to poor academic performance; (4) the percentage of Special Education Personnel Development-funded degree/certification recipients who are working in the area(s) for which they were prepared upon program completion; (5) the percentage of Special Education Personnel Development-funded degree/certification recipients who are working in the area(s) for which they were prepared upon program completion and who are fully qualified under IDEA; (6) the percentage of Special Education Personnel Development degree/certification recipients who maintain employment in the area(s) for which they were prepared for three or more years and who are fully qualified under IDEA; and (7) the Federal cost per fully qualified degree/certification recipient.

In addition, the Department will be gathering information on the following outcome measures: (1) The number and percentage of degree/certification recipients who are employed in high-need schools; (2) the number and percentage of degree/certification recipients who are employed in a school for at least three years; and (3) the number and percentage of degree/certification recipients who are rated as effective by their employers.

Grantees may be asked to participate in assessing and providing information on these aspects of program quality.

5. *Continuation Awards:* In making a continuation award, the Secretary may consider, under 34 CFR 75.253, the extent to which a grantee has made ''substantial progress toward meeting the objectives in its approved application.'' This consideration includes the review of a grantee's progress in meeting the targets and projected outcomes in its approved application, and whether the grantee has expended funds in a manner that is consistent with its approved application and budget. In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

## VII. Agency Contact

**FOR FURTHER INFORMATION CONTACT:** Celia Rosenquist, U.S. Department of Education, 400 Maryland Avenue SW., Room 4070, PCP, Washington, DC 20202–2600. Telephone: (202) 245–7373.

If you use a TDD or a TTY, call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

## VIII. Other Information

*Accessible Format:* Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue SW., Room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

*Electronic Access to This Document:* The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: January 7, 2014.

**Michael K. Yudin,**

*Acting Assistant Secretary for Special Education and Rehabilitative Services.*

[FR Doc. 2014–00266 Filed 1–9–14; 8:45 am]

BILLING CODE 4000–01–P

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## DEPARTMENT OF ENERGY

**[OE Docket No. EA–348–B]**

## Application To Export Electric Energy; NextEra Energy Power Marketing, LLC

**AGENCY:** Office of Electricity Delivery and Energy Reliability, DOE.

**ACTION:** Notice of application.

**SUMMARY:** NextEra Energy Power Marketing, LLC (NEPM) has applied to renew its authority to transmit electric energy from the United States to Canada pursuant to section 202(e) of the Federal Power Act.

**DATES:** Comments, protests, or motions to intervene must be submitted on or before February 10, 2014.

**ADDRESSES:** Comments, protests, or motions to intervene should be addressed to: Lamont Jackson, Office of Electricity Delivery and Energy Reliability, Mail Code: OE–20, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585–0350. Because of delays in handling conventional mail, it is recommended that documents be transmitted by overnight mail, by electronic mail to *Lamont.Jackson@hq.doe.gov*, or by facsimile to 202–586–8008.

**FOR FURTHER INFORMATION CONTACT:** Lamont Jackson (Program Office) at 202–586–0808, or by email to *Lamont.Jackson@hq.doe.gov*.

**SUPPLEMENTARY INFORMATION:** Exports of electricity from the United States to a foreign country are regulated by the Department of Energy (DOE) pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b), 7172(f)) and require authorization under section 202(e) of the Federal Power Act (16 U.S.C. 824a(e)).

On February 11, 2009, DOE issued Order No. EA–348 to FPL Energy Power Marketing, Inc. to transmit electric energy from the United States to Canada as a power marketer for a five-year term using existing international transmission facilities. That authority expires on February 11, 2014.

On March 19, 2009, FPL Energy Power Marketing, Inc. notified DOE

that, effective March 12, 2009, it changed its legal name to NextEra Energy Power Marketing, LLC. Accordingly, on March 26, 2009, DOE issued Order No. EA–348–A, in which it amended the original order by changing the name of the authorized exporter to NEPM. All other terms and conditions of Order No. EA–348 remained unchanged.

On December 20, 2013, NEPM filed an application with DOE for renewal of the export authority contained in Order No. EA–348–A for an additional five-year term. Specifically, NEPM states that it seeks renewal, as a power marketer, to export electricity through existing Canadian border facilities.

NEPM states that it does not own, operate, or control any physical assets such as electric generating or transmission facilities, and it does not have a franchised service area. The electric energy that NEPM proposes to export to Canada would be surplus energy purchased from electric utilities and other suppliers within the United States.

The existing international transmission facilities to be utilized by NEPM have previously been authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties.

*Procedural Matters:* Any person desiring to be heard in this proceeding should file a comment or protest to the application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's (FERC) Rules of Practice and Procedures (18 CFR 385.211). Any person desiring to become a party to these proceedings should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214). Five copies of such comments, protests, or motions to intervene should be sent to the address provided above on or before the date listed above.

Comments on the NEPM application to export electric energy to Canada should be clearly marked with OE Docket No. EA–348–B. An additional copy is to be provided directly to both Marty Jo Rogers, Senior Counsel, NextEra Energy Power Marketing, LLC, 601 Travis Street, Suite 1910, Houston, TX 77002, and Gunnar Birgisson, Senior Attorney, NextEra Energy, 801 Pennsylvania Ave. NW., Washington, DC 20004. A final decision will be made on this application after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after a determination is made by DOE that the proposed action will not have an adverse impact on the sufficiency of supply or reliability of the U.S. electric power supply system.

Copies of this application will be made available, upon request, for public inspection and copying at the address provided above, by accessing the program Web site at *http://energy.gov/node/11845*, or by emailing Angela Troy at *Angela.Troy@hq.doe.gov*.

Issued in Washington, DC, on January 6, 2014.

**Brian Mills,**

*Director, Permitting and Siting, Office of Electricity Delivery and Energy Reliability.*

[FR Doc. 2014–00316 Filed 1–9–14; 8:45 am]

BILLING CODE 6450–01–P

## DEPARTMENT OF ENERGY

### Record of Decision and Floodplain Statement of Findings for the Lake Charles Carbon Capture and Sequestration Project

**AGENCY:** Department of Energy.

**ACTION:** Record of Decision.

**SUMMARY:** The U.S. Department of Energy (DOE) announces its decision to provide cost-shared funding to Leucadia Energy, LLC (Leucadia) for its Lake Charles Carbon Capture and Sequestration project (Lake Charles CCS project) under DOE's Industrial Carbon Capture Sequestration (ICCS) Program. DOE prepared an environmental impact statement (EIS) to evaluate the potential environmental impacts associated with DOE's proposed action of providing financial assistance to the Lake Charles CCS project. The EIS evaluated the impacts associated with construction and operation of the proposed project and Leucadia's Gasification Plant, which is a connected action. DOE's proposed action is to provide financial assistance through a cooperative agreement with Leucadia to capture carbon dioxide ($CO_2$) from the Gasification Plant and transport the $CO_2$ via pipelines to the West Hastings oil field, for use in existing, commercial enhanced oil recovery (EOR). The West Hastings research monitoring, verification, and accounting (MVA) program will provide an accurate accounting of approximately 1 million tons of stored $CO_2$.

**ADDRESSES:** The EIS and this Record of Decision (ROD) are available on DOE's Web sites (*www.energy.gov/nepa/*or *www.netl.doe.gov/publications/others/nepa/index.html*). Copies of these documents may also be obtained by contacting Ms. Pierina Fayish, M/S 922–342C, U.S. Department of Energy, National Energy Technology Laboratory, P.O. Box 10940, Pittsburgh, PA 15236; telephone: 412–386–5428; or email: *pierina.fayish@netl.doe.gov.*

**FOR FURTHER INFORMATION CONTACT:** To obtain additional information about the project or the EIS, contact Ms. Pierina Fayish at the address provided above. For general information on DOE's NEPA process, contact Ms. Carol M. Borgstrom, Director, Office of NEPA Policy and Compliance (GC–54), U.S. Department of Energy, 1000 Independence Avenue SW., Washington DC 20585; telephone: 202–586–4600; or toll free at 1–800–472–2756.

**SUPPLEMENTARY INFORMATION:** DOE prepared this ROD pursuant to the National Environmental Policy Act (NEPA) of 1969 (42 United States Code [U.S.C.] 4321 et seq.), and in compliance with the Council on Environmental Quality (CEQ) implementing regulations for NEPA (40 Code of Federal Regulations [CFR] 1500 through 1508), DOE's NEPA implementing procedures (10 CFR Part 1021) and DOE's Compliance with Floodplain and Wetland Environmental Review regulations (10 CFR Part 1022). This ROD is based on DOE's EIS for the Lake Charles CCS Project (DOE/EIS–0464, November 2013) and other program considerations.

#### Purpose and Need for Agency Action

The purpose and need for DOE action is to advance the ICCS program by providing financial assistance to projects that have the best chance of achieving the program's objectives as established by Congress: Demonstrating the next generation of technologies that will capture $CO_2$ from industrial sources and either sequester or beneficially use it. The proposed project was selected under the ICCS program as one of a portfolio of projects that DOE determined were the most appropriate ones to achieve programmatic objectives and meet legislative requirements.

This proposed project would help the ICCS Program meet its congressionally mandated mission of large-scale testing of $CO_2$ sequestration systems. The project would demonstrate the use of advanced technologies to capture $CO_2$ from an industrial source and sequester it as part of an EOR operation. The project would also provide information on the cost and feasibility of deploying sequestration technologies. A successful demonstration of the Rectisol®-based carbon-capture technology with beneficial use of the $CO_2$ at an existing oil field would also generate technical, environmental, and financial data

regarding the design, construction, and operation of a $CO_2$ capture facility, pipeline, and $CO_2$ monitoring at the oil field. These data would be used to evaluate whether these technologies could be effectively implemented at a commercial scale.

**DOE's Proposed Action**

DOE's proposed action is to provide $261.4 million in cost-shared funding through a cooperative agreement with Leucadia for its proposed project. DOE has already provided $13.9 million to Leucadia for preliminary design and related activities. The estimated total cost of the Lake Charles CCS project is $435.6 million.

**Project Description and Location**

The Lake Charles CCS project would result in the construction and operation of a Rectisol®-based facility to capture at least 75 percent of the $CO_2$ from the treated stream which would otherwise be released to the atmosphere from the Gasification Plant. The CCS project includes:

*(1) $CO_2$ Capture and Compression*—Two Lurgi Rectisol® Acid Gas Removal (AGR) units and two compressors would pressurize the $CO_2$ to 2,250 pounds per square inch gauge (psig) for transport and geologic sequestration. The project would be designed to capture approximately 89 percent of the $CO_2$ produced from the Gasification Plant. Over the 30-year expected life, approximately 4.6 million tons of $CO_2$ per year would be captured, on average.

*(2) $CO_2$ Pipeline*—A new pipeline, approximately 16 inches in diameter, would carry the captured $CO_2$ approximately 11.9 miles and connect to the existing Green Pipeline, which extends across Louisiana into Texas.

*(3) Research Monitoring Program*—Denbury Onshore, LLC (Denbury) and the Texas Bureau of Economic Geology (BEG) would jointly implement the West Hastings research monitoring, verification, and accounting (MVA) program aimed at providing an accurate accounting of approximately 1 million tons of stored $CO_2$, and a high level of confidence that the $CO_2$ injected in the oilfield during existing EOR operations will remain permanently sequestered. The West Hastings research MVA activities would supplement Denbury's ongoing commercial monitoring activities and regulatory requirements performed for commercial $CO_2$ EOR and would provide additional information regarding the underground movement and confinement of $CO_2$.

In the context of NEPA, connected actions are actions dependent on the proposed action, as set forth in 40 CFR 1508.25. The Lake Charles CCS project cannot operate without the Gasification Plant, thus construction and operation of the Gasification Plant is a connected action and evaluated in the EIS. The Gasification Plant would convert petroleum coke into syngas, which would be further processed to produce methanol, hydrogen gas, and sulfuric acid, as well as $CO_2$. The Gasification Plant would provide raw syngas containing $CO_2$ to the Lake Charles CCS project, where the $CO_2$ would be separated from the syngas. The Gasification Plant and Lake Charles CCS capture and compression facilities would be located on an approximately 70-acre parcel of land leased from the Lake Charles Harbor and Terminal District (Port of Lake Charles), on the west bank of the Calcasieu River adjacent to Bulk Terminal No. 1, in southern Calcasieu Parish, Louisiana. The Gasification Plant would require new utility linears and pipelines for delivery of materials and transport of products as described in the EIS.

Site preparation activities for the Gasification Plant, including clearing and grading, began in January 2010. Site preparation work to add approximately 12 feet of fill to raise the site elevations above the local 100-year and 500-year base flood elevations also began in November 2010. These activities were authorized under permits issued by the U.S. Army Corps of Engineers (USACE) (Lake Charles Harbor & Terminal District Consent No. DACW29–9–08 [May 30, 2008] and MVN–1998–03311–WY [August 18, 2008]). Construction of the Gasification Plant is expected to begin in the first quarter of 2014 and take approximately 36 months to complete. Peak construction is expected in month 18 and will involve approximately 2,500 workers, of which 900 would be at the Gasification Plant site.

For the purposes of the EIS, DOE assumed that the $CO_2$ capture system would continue to operate for 30 years. Petroleum coke from local refineries is already stored at the Port of Lake Charles and shipped to buyers overseas. The approximately 0.5 million tons per year of petroleum coke needed for the Gasification Plant will come from the port. Another approximately 2.1 million tons per year would come from other ports in the Gulf of Mexico region. During operation of the Gasification Plant, process-related chemicals would be transported to and from the facility by truck, rail, barge or ship.

The Lake Charles CCS Project does not include the commercial operation of the Green Pipeline or the existing EOR operations at the West Hastings oil field. These activities are not connected actions as defined by 40 CFR 1508.25.

**Alternatives**

Congress directed DOE to pursue the ICCS program by providing federal financial assistance to projects owned and controlled by non-federal sponsors. This statutory requirement places DOE in a much more limited role than if it were the owner and operator of these projects. Here, the purpose and need for DOE action is defined by the ICCS program (and its enabling legislation, Public Laws 110–140 and 111–5). As such, the reasonable alternatives available to DOE prior to the selection of this project under the ICCS program were the other projects that met the eligibility requirements of a competitive solicitation. Other applications (and their potential environmental, safety, and health impacts) were considered during the selection process. Pursuant to 10 CFR 1021.216, a publicly-available synopsis of the environmental review and critique developed for the selection process was included in the EIS.

After DOE selects a project for an award, the range of reasonable alternatives becomes the project as proposed by the applicant, any alternatives still under consideration by the applicant, and the no action alternative.

**No Action Alternative**

Under the no action alternative, DOE would not provide cost-shared funding for the proposed Lake Charles CCS project. In the absence of DOE cost-shared funding, Leucadia could reasonably pursue several options. Leucadia could build both the Gasification Plant and the CCS project with funding from other sources and these facilities would include the same features, attributes, and impacts of the proposed project and connected action. Alternatively, Leucadia could choose not to build all or parts of the Gasification Plant and CCS project. For the purpose of making a meaningful comparison between the impacts of DOE providing and withholding financial assistance, DOE assumed that all or part of the Gasification Plant and CCS project would not be completed without DOE funding. Therefore, the following alternatives were identified and analyzed in the EIS:

1. Neither the Gasification Plant nor the Lake Charles CCS project would be built; or

2. The Gasification Plant would be built, but the captured $CO_2$ would be vented to the atmosphere rather than sequestered in an ongoing EOR operation.

The ongoing commercial $CO_2$ EOR operations and the West Hastings research MVA program would continue under each of these no action alternatives. Under these alternatives, the opportunity to capture an average of 4.6 million tons of anthropogenic $CO_2$ per year over the 30 year life of the Gasification Plant for use in EOR would not be realized. These alternatives would not contribute to DOE's goal of advancing the next generation of technologies that capture $CO_2$ from industrial sources for sequestration or beneficial reuse. While the no action alternatives would not satisfy the purpose and need for DOE action, these alternatives were analyzed to allow for comparisons to the impacts of the proposed project as required by 40 CFR 15012.14. The no action alternatives reflect the baseline conditions and serve as benchmarks against which the impacts of the proposed action can be evaluated.

Leucadia has begun preparing the site for construction of the Gasification Plant without DOE funding for other purposes not related to the Lake Charles CCS project. The construction of the Gasification Plant will receive no DOE funding.

**NEPA Process**

DOE published a Notice of Intent (NOI) for this proposed action in the **Federal Register** (FR) on April 29, 2011 (FR Doc. 2011–10448). DOE held public scoping meetings on May 16, 2011, in Pearland, Texas, and May 17, 2011, in Westlake, Louisiana. The public scoping period ended on May 29, 2011, after a 30-day comment period.

DOE prepared a draft EIS identifying and analyzing the potential impacts of the proposed action and no action alternatives. Although DOE funds would only go to the CCS project, DOE determined that the Gasification Plant is a connected action in accordance with 40 CFR 1508.25(a), and its impacts are analyzed in the EIS, as well as DOE's no action alternatives. DOE announced the availability of the draft EIS in a Notice of Availability (NOA) published in the **Federal Register** (FR) by the U.S. Environmental Protection Agency (EPA) on May 10, 2013 (78 FR 28205). DOE published a separate NOA to announce its plans for two public hearings, held in Westlake, Calcasieu Parish, Louisiana, on June 4, 2013, and in Pearland, Brazoria County, Texas on June 5, 2013.

DOE received oral comments on the draft EIS at the public hearings and listened to questions and concerns during informal sessions before the hearings. During the 45-day public comment period, which ended June 25, 2013, DOE received comment letters from several organizations and agencies. Comments included concerns about: (1) The economic benefit of the project and the use of federal funds; (2) the amount of $CO_2$ that would be emitted and captured, and the monitoring of the $CO_2$ throughout the process; (3) the amount and types of wastes generated; (4) the process for selecting projects for DOE funding; (5) the impacts on the ozone non-attainment status of Calcasieu Parish; (6) mitigation measures for construction-related emissions; (7) the loss of forests and impacts on threatened and endangered species; (8) adequacy of the environmental justice analysis; (9) impacts to water resources and wetlands; and (10) safety of chemical use and storage.

DOE considered these comments in preparing the final EIS. DOE distributed the final EIS on November 14, 2013, and EPA published a NOA in the FR on November 22, 2013 (78 FR 70041). DOE received no comments on the final EIS.

**Decision**

DOE has decided to provide Leucadia with $261.4 million in cost-shared funding for its proposed project through a cooperative agreement under DOE's ICCS program.

**Basis of DOE's Decision**

DOE based its decision on the importance of achieving the objectives of the ICCS program and a careful review of the potential environmental impacts presented in the EIS. The proposed project would help DOE meet its congressionally mandated mission of supporting demonstration of the next generation of technologies that capture $CO_2$ from industrial sources for sequestration or beneficial use. The proposed action would also generate technical, environmental, and financial data regarding the design, construction, and operation of a $CO_2$ capture facility, pipeline, and monitoring facilities. The data would contribute to DOE's evaluation of the effective and economic implementation of these technologies at a commercial scale.

This decision incorporates all practicable means to avoid or minimize environmental harm. DOE plans to verify the environmental impacts predicted in the EIS and the implementation of appropriate avoidance and mitigation measures.

**Mitigation**

DOE's decision incorporates measures to avoid and minimize adverse environmental impacts during the design, construction and operation of the project. DOE requires that recipients of financial assistance comply with all applicable federal, state, and local environmental laws, orders, and regulations. During project planning, Leucadia incorporated various minimization measures and anticipated permit requirements into its project. The analyses completed for the EIS assumed that such measures would be implemented. These measures are identified in Chapter 4 of the EIS and hereby incorporated into this ROD as conditions for DOE's financial assistance under the cooperative agreement between DOE and Leucadia. Additional mitigation measures or measures specific to certain impacts or comments received are further discussed below in the section entitled *Potential Environmental Impacts and Mitigation Measures.*

Mitigation measures beyond those typically specified in permit conditions will be addressed in a Mitigation Action Plan (MAP). DOE will prepare the MAP, consistent with 10 CFR 1021.331, to establish how the mitigation measures will be planned, implemented, and monitored. The MAP is an adaptive management tool; therefore mitigation conditions in it would be removed if equivalent conditions are otherwise established by permit, license, or law. Compliance with permit, license or regulatory requirements is not considered mitigation subject to DOE control and therefore are not included in a MAP.

DOE will ensure that requirements in the MAP are met through management of its cooperative agreement with Leucadia, which requires that Leucadia fulfill the monitoring and mitigation measures specified in this ROD. DOE will make copies of the MAP available for inspection online and in appropriate locations for a reasonable time. Copies of the MAP and any annual reports required under it will also be available upon written request.

**Potential Environmental Impacts and Mitigation Measures**

In making its decision, DOE considered the environmental impacts of Leucadia's proposed project, DOE's proposed action, and the no action alternative on potentially affected environmental resource areas. These included: Climate and air quality, including greenhouse gas emissions; geology and soils; surface water, wetlands, and floodplains; groundwater; biological resources; cultural resources; land use; socioeconomics and environmental justice; traffic and transportation; noise; waste management; materials; and human

health and safety. The EIS also considered the impacts of the project in combination with those from other past, present, and reasonably foreseeable future actions. The following sections summarize the potential impacts to the resource areas with mitigation requirements. Detailed information for all resource areas is in the EIS.

**Air Quality**

Construction of the Gasification Plant and the CCS project's $CO_2$ capture and compression facilities would result in short-term, localized increased fugitive dust and vehicle and construction equipment emissions. In response to EPA's comments on the draft EIS, Leucadia will implement additional best management practices (BMPs) and mitigation measures. To control fugitive dust, Leucadia must avoid open storage of dry material, install wind fencing as needed, use water trucks to stabilize surfaces, prevent spillage when hauling material and operating equipment, to the extent possible, and limit the speed of vehicles on site to 15 miles per hour (mph) and earth-moving equipment to 10 mph. To control mobile and stationary source emissions, Leucadia must use remote parking with bus transport to the worksite, maintain and tune engines per manufacturer's specifications to perform at EPA certification levels, prevent tampering with engines, and use new equipment where practicable. Leucadia also must limit idling of heavy equipment; EPA recommends limiting idling to less than 5 minutes.

In assessing potential impacts during operations, DOE evaluated the Lake Charles CCS project and the Gasification Plant as a single facility, because together they make a single source for purposes of air emissions. Leucadia completed air dispersion modeling in support of the initial permit application for criteria pollutants and toxic air pollutants. For all criteria pollutants, maximum modeled concentrations in ambient air due to the proposed facility emissions would not violate federal or Louisiana standards.

A General Conformity analysis is not required for the operations phase as the Gasification Plant, which includes the Lake Charles CCS project $CO_2$ capture and compression facilities, requires a permit under the Prevention of Significant Deterioration program. Under the General Conformity rule, DOE evaluated the impact of construction emissions because Calcasieu Parish has a maintenance plan effective through 2014 for the 8-hour National Ambient Air Quality ozone standard. Total $NO_X$ emissions would increase 1.9 percent and total VOC emissions would increase 0.5 percent above the projected 2014 emission values in Calcasieu Parish. These increases in emissions from construction would not obstruct Calcasieu Parish's efforts to maintain attainment with the ozone standard.

Construction and operation of the $CO_2$ pipeline, and operation of the West Hastings research MVA program would result in short-term, localized increased fugitive dust and vehicle emissions. Denbury has indicated that it will implement BMPs including suppression techniques to minimize dust and operate and maintain vehicles in accordance with manufacturers' recommendations.

**Climate**

Construction of the Gasification Plant and Lake Charles CCS project would generate up to approximately 31,300 tons per year (tpy) of $CO_2$ emissions over the construction period. Operation of the Gasification Plant would result in approximately 5.8 million tpy of new $CO_2$ emissions. According to the terms of the cooperative agreement, Leucadia must design and construct the Lake Charles CCS project with the goal of capturing at least 75 percent of the $CO_2$ from the treated stream, comprising at least 10 percent of $CO_2$ by volume, which would otherwise be emitted to the atmosphere. However, the proposed project is designed to capture approximately 89 percent of the $CO_2$ produced, or approximately 4.6 million tpy, when averaged over 30 years. Additionally, DOE compared the life cycle analysis (LCA) for the proposed project and connected action against the greenhouse gas (GHG) LCA for conventional production methods of the same quantities of methanol (steam reformation of natural gas), hydrogen (pressure swing absorption), and sulfuric acid (combustion of elemental sulfur and catalysis reactions) that would be produced by Leucadia with these facilities. The CCS project captures $CO_2$ and prevents long-distance exportation of petroleum coke, making the Gasification Plant life cycle GHG emissions 56 percent lower than conventional production methods generating the same quantities of methanol.

**Geology and Soils**

Construction and operation of the Gasification Plant and Lake Charles CCS capture and compression facilities would result in negligible impacts to geologic resources. The risk of seismic events is minimal because the area is within the lowest seismic hazard category (Seismic Zone 0). Potential minor impacts to soils during construction of the project pipelines would include disturbance of soils and the potential for increased soil erosion from both wind and water. Construction of the $CO_2$ pipeline would temporarily affect approximately 107 acres of prime farmland. Construction of the water supply and hydrogen pipelines would temporarily affect approximately 111 acres of prime farmland. As the pipelines would be located below the surface, impacts on prime farmland would be minor and temporary. Leucadia must restore surface conditions to their original state and use following construction of the water supply and hydrogen pipelines. Potential soil impacts in all construction areas would be avoided or mitigated as described in a project-specific storm water pollution prevention plan (SWPPP). Operational activities would have negligible impacts on soil, primarily due to disturbance of soils from vehicle traffic and minor spills or leaks from vehicles used during inspection and maintenance activities.

The West Hastings research MVA program would occur in a seismically stable area (Seismic Zone 0). None of the proposed MVA activities would produce vibrations or forces that would result in seismic destabilization, and no geologic hazards exist that would impact the project or that would become more hazardous or be aggravated as a result of those activities. Potential impacts on geologic resources could result from seismic events or subsidence related to $CO_2$ injection; $CO_2$ migration through a permeable zone in the confining unit or through improperly plugged and abandoned wells or unknown wells; or $CO_2$ migration through an existing injection, production, or monitoring well. Denbury has indicated that a well integrity testing program would be conducted and any deficiencies would be corrected prior to use of such wells. $CO_2$ migration from the target geologic units is unlikely, and ongoing monitoring and modeling would provide an accurate accounting of the approximately 1 million tons per year of $CO_2$ stored through the commercial EOR process. Therefore, DOE expects adverse impacts on geologic resources at the West Hastings oil field from the West Hastings research MVA program to be unlikely and negligible to minor due to the nature of the site and the activities being conducted. Furthermore, the research MVA program could have the positive impact of helping to ensure the long-term economic and financial

viability of $CO_2$ capture by confirming storage of $CO_2$ injected during commercial EOR operations.

**Surface Water, Wetlands, and Floodplains**

The quantity of water needed for construction and operation of the Gasification Plant and Lake Charles CCS capture and compression facilities would have negligible impacts on water availability and local water use.

Approximately 26.2 acres of wetlands were permanently impacted during the site preparation for the Gasification Plant and were addressed through off-site mitigation banking. Construction does not conflict with applicable flood management plans or ordinances and would not increase the potential for flooding. Potential surface water and wetland impacts from the construction of the water supply and hydrogen pipelines would occur during crossing of Bayou d'Inde, the Sabine River Canal, and two additional water bodies. Construction of the water supply and hydrogen pipelines could potentially impact 7.1 acres of wetlands, but the final wetland delineation and permitting will be conducted by the U.S. Army Corps of Engineers (USACE). If a water body, wetland, or floodplain is crossed by the water supply and hydrogen pipelines and determined to be a jurisdictional water of the United States and the construction impacts on wetlands exceed applicable thresholds, Leucadia must obtain the necessary USACE permits. If compensatory wetland mitigation becomes necessary under any USACE permit, Leucadia must implement additional mitigation as required and described in the permit(s). Leucadia must use horizontal directional drilling (HDD) where appropriate to minimize the environmental impacts of crossing surface waters.

Activities during the operations period would not result in additional structures in the floodplain, filling of wetlands, or alteration of infiltration rates that would increase volumes downstream.

During construction of the $CO_2$ pipeline potential impacts to surface water quality include increased sediment load, alteration of flow rates and accidental spills of chemicals or lubricants. Denbury has proposed HDD to minimize the environmental impacts of crossing surface waters. In addition, USACE permits must be obtained to cross waters of the United States, including associated wetlands. Approximately 550,100 gallons of water for hydrostatic testing would be obtained from local water bodies or purchased from municipal supplies. No changes in the availability of surface water for current or future uses are anticipated as a result of pipeline construction. Construction of the $CO_2$ pipeline could permanently impact 14.98 acres and temporarily impact 13.23 acres of 100-year floodplain. Due to the narrow width of the permanent right-of-way (ROW), no alteration of infiltration rates are expected and there would be no substantial decrease in the volume of surface water flowing downstream. Normal operation of the $CO_2$ pipeline would not affect surface waters. No impacts on wetlands or floodplains are anticipated from operation of the $CO_2$ pipeline.

The West Hastings Research MVA program would not involve the removal or injection of any materials that would result in changes in surface water availability or runoff or result in significant effluent releases. Recompletion of proposed wells would be outside wetland areas, and Denbury has proposed BMPs to prevent runoff from entering wetlands outside of construction areas. MVA activities would not increase the potential for floods, alter a floodway or floodplain, or otherwise impede or redirect flows.

**Biological Resources**

Construction and operations activities at the Gasification Plant and Lake Charles CCS Capture and Compression facilities are expected to have negligible to moderate impacts on biological resources, which include wildlife, habitat, plant life, threatened and endangered species, and migratory birds. The loss of 70 acres within the 1,740 acres of forested habitat represents 4 percent of the total area. Clearing and filling of the equipment laydown area could remove up to 40 acres of potential adjacent forested emergent wetland habitat. A loss of 40 acres of forest in the equipment laydown and methanol/sulfuric acid storage area represents a 14.5 percent loss within the local 275-acre forested wetland area and 2.3 percent loss within the 1,740-acre forested area of the Bayou ecosystem, which is a part of the Calcasieu estuary. The Port of Lake Charles consulted with the Louisiana Department of Wildlife and Fisheries (LDWF) and Louisiana Natural Heritage Program, regarding construction of the equipment laydown area. The Louisiana Natural Heritage Program indicated that no impacts on rare, threatened, or endangered species or critical habitats are anticipated. Approximately 76 percent of the water supply pipeline route and 99 percent of the hydrogen pipeline route follow existing ROWs. The water supply pipeline and hydrogen pipeline corridor would impact 18.47 and 62.74 acres, respectively, of forest habitat potentially used by the red cockaded woodpecker. The USFWS's Louisiana Ecological Services concurred that the proposed project is not likely to adversely affect resources under the jurisdiction of Endangered Species Act. Prior to construction of the pipelines, Leucadia must contact LDWF to request another database review to identify any new occurrences of nesting areas for migratory birds or colonial water birds. Leucadia must perform site-specific surveys within 2 weeks of project startup, in accordance with LDWF requirements, to determine whether migratory birds or colonial water bird nesting areas are present and the extent of any colonies. Leucadia must further consult with LDWF if active nesting colonies are found within 400 meters of the project site. Operations activities are expected to have negligible impacts to biological resources.

The $CO_2$ pipeline would be located along or within existing utility ROWs to the extent practicable and construction would result in minor impacts to biological resources. Pipeline construction would affect 10.21 acres of forest, 17.65 acres of scrub-shrub, and 2.1 acres of herbaceous grassland habitats. Denbury has indicated that it will obtain necessary federal and state permits, and associated site-specific surveys and mitigation, if necessary, prior to construction. The LDWF recommended that surveys of suitable nesting areas be conducted no more than two weeks before construction begins to determine whether breeding colonies are present. In addition, the USFWS recommended informing on-site personnel of the need to identify colonial wading birds and their nests, and to avoid affecting them during the breeding season. Operations activities are expected to have negligible impacts to biological resources.

Negligible impacts on aquatic ecology, terrestrial vegetation, or wildlife, including threatened and endangered species, are expected as a result of the West Hastings research MVA activities. Affected habitats at these locations have been disturbed by past and ongoing industrial and oil production activities. Operations activities are expected to have negligible impacts to biological resources.

**Cultural Resources**

Construction of the Gasification Plant and Lake Charles CCS Capture and Compression facilities would disturb a portion of one cultural resource site located within the areas of potential

effects (APEs). The Louisiana Site Historic Preservation Officer (SHPO) concurred with the determination that the site was not eligible for listing on the National Register of Historic Places (NRHP) and that no further investigations were necessary. Operation of the plant and facilities would have no impacts on cultural resources or historic properties. DOE initiated consultation with 13 federally recognized Native American tribes in Louisiana, Texas, and other states in accordance with Section 106 of the National Historic Preservation Act of 1966, as amended. The Choctaw Nation of Oklahoma was the only tribe to respond to the consultation letter for the proposed action. It concurred with the finding of no historic properties affected at this time and agreed that the project should move ahead as planned. Leucadia must include a provision in its construction plans for its contractors that require them to immediately notify LCCE if identifiable tribal artifacts or remains are found during construction. If notified of any such discoveries, Leucadia must inform the SHPO and the Choctaw Nation to ensure the artifacts or remains are handled appropriately.

Construction of the CCS $CO_2$ pipeline would destroy one archaeological site. However, the SHPO reviewed the results of the Phase I cultural resources survey within the APE and concluded that the site was not eligible for the NRHP. Construction of the $CO_2$ pipeline also has the potential to result in direct, permanent, negative impacts on the Hardey Family Cemetery. Denbury proposes to avoid the direct impacts by directionally drilling beneath the cemetery to avoid physical disturbance. Cemetery owners have indicated no objection to construction of the proposed pipeline if there are no surface operations and the HDD method is employed to a depth of at least 25 feet below the surface of the cemetery.

Construction and operation of the $CO_2$ pipeline would have minor impacts on cultural resources. Operation of the West Hastings research MVA program would have no impacts on cultural resources because none were identified within the MVA area.

Leucadia, in coordination with DOE, must continue consultation with the SHPO for areas not previously surveyed for cultural resources. This may occur if the currently proposed pipeline route needs to be altered or for other unforeseen areas of ground disturbance not analyzed in the EIS. Leucadia must complete any additional surveys prior to construction in such areas.

**Land Use**

Construction and operation of the Gasification Plant and $CO_2$ Capture and Compression facilities would not conflict with current and future land use plans and/or zoning ordinances of Calcasieu Parish. Impacts on residences would be negligible due to the distance between residential areas and the construction site. Construction of the raw water pipeline would impact a total of 122 acres of land, including 24 acres of permanent ROW and 98 acres of temporary ROW. Construction of the hydrogen pipeline would impact a total of 77 acres of land, including 51 acres of permanent ROW and approximately 26 acres of temporary ROW. To reduce impacts on surrounding land and properties, approximately 76 percent of the water supply pipeline route and 99 percent of the hydrogen pipeline route would follow existing ROWs. Temporary visual impacts would result due to construction and ground disturbance. Impacts on cropland would be temporary, and active cropland would revert to preconstruction use for the full width of the ROWs. Construction would not impact special land uses such as recreation areas, public lands, historic sites, and protected water bodies. Leucadia must use BMPs including dust suppression techniques to control the dust generated by construction. Leucadia must revegetate the pipeline ROWs and adjacent properties to pre-construction conditions and vegetate and maintain new ROW areas. Operation of the Gasification Plant and Lake Charles CCS $CO_2$ Capture and Compression facilities would be compatible with the surrounding industrial properties and would have no or negligible impacts on surrounding land uses. Occasional maintenance of the water supply and hydrogen pipelines may require access to buried portions of the lines. Leucadia would coordinate with property owners to minimize potential disturbances. The ROWs and adjacent properties would be restored to pre-construction conditions and maintained.

Construction of the CCS $CO_2$ pipeline would cause short term impacts on 50.62 acres of temporary ROW and long term impacts to 56.34 acres of permanent ROW. Construction activities would include use of a 12.4 acre site for a warehouse yard and a 6.9-acre site at the pipe storage yard. Construction of the $CO_2$ pipeline would result in the permanent conversion of 8.27 acres of forested land, including 2.98 acres of forested wetland. Small areas of other vegetation (i.e., scrub/shrub, pasture, and grassland) within the construction ROW could be permanently impacted. Following construction, approximately 50.62 acres of land within the temporary ROW would be restored to previous conditions and uses. Active cropland would be allowed to revert to preconstruction use in the full width of the ROW. No special land uses such as recreation areas, public lands, historical sites, or protected water bodies would be impacted by construction activities. Denbury would avoid or minimize adverse impacts on land use by locating the proposed $CO_2$ pipeline within or adjacent to existing utility ROWs with compatible land uses to the extent practicable. Denbury has indicated that it would use BMPs to supplement applicable regulatory requirements in order to minimize impacts on land use during construction. Operation of the $CO_2$ pipeline would require that landowners not construct or place any structures within the permanent ROW. Occasional maintenance may require access to buried portions of the pipeline. Denbury would use BMPs during maintenance to avoid or minimize impacts on adjacent land uses and residences. Operation of the pipeline would have temporary and negligible impacts on surrounding land uses during maintenance. The West Hastings Research MVA activities are consistent with the existing commercial EOR operations and would have negligible impacts on land uses in the immediate and surrounding areas.

**Traffic and Transportation**

A temporary increase in traffic during construction of the Gasification Plant and Lake Charles CCS Capture and Compression facilities is expected from approximately 900 workers accessing the off-site construction parking area and approximately 150 off-site construction vehicles entering the LCCE Gasification site daily during peak construction. No major short or long-term impacts to interstate, multi-lane highway or two lane highway transportation resources are expected to occur, although certain segments of local roadways currently are in degraded conditions. Based on the estimated existing and projected future level of service (LOS) of Ruth Street, the use of this street during peak construction would degrade its LOS. For the offsite construction parking area, Leucadia must operate shuttle buses to reduce traffic congestion on local roadways and may be required to obtain a temporary construction access permit from the Louisiana Department of Transportation and Development (DOTD). To the extent practicable, Leucadia must schedule heavy

equipment deliveries during off peak hours, start work shifts at non-peak hours, stagger arrival times at the off-site construction parking area, request that personnel use roadways with LOS of A, B, or C, and coordinate traffic congestion with Louisiana DOT District 7. Construction of the water supply and hydrogen pipelines may cause short-term, minor traffic delays from large, slow-moving heavy equipment and delivery trucks. Leucadia must ensure adequate notice to landowners and drivers to maintain access to public roads.

During operations, additional traffic from 187 personnel and approximately 127 material deliveries would be negligible compared to the current traffic. The estimated total ship traffic for the Gasification Plant is 12 trips per year or approximately 1.2 percent of the current vessel traffic at the Port of Lake Charles.

A temporary minor increase in traffic during construction of the $CO_2$ pipeline is expected from an average of approximately 100 personnel and 10 trucks accessing the route daily. Denbury has indicated that it would minimize impacts through various measures that ensure adequate notice to landowners and drivers to maintain access to public roads. Periodic maintenance of the ROW would include slow-moving mowers and occasional maintenance vehicles. Impacts on local traffic related to 14 new personnel hired by Denbury to perform the MVA activities, as well as personnel that would conduct temporary site visits, would be negligible.

**Noise**

Sound levels for general construction of the Gasification Plant and Lake Charles CCS Capture and Compression facilities at the closest noise-sensitive, residential receptor are expected to be 58 average-weighted decibels [dBA], which exceeds the 55 dBA EPA guideline. However, a noise study indicated that the current background noise level at the nearest receptor (60 dBA) also exceeds the EPA guideline. As a temporary daytime occurrence, construction noise of this magnitude would likely be imperceptible, and impacts would be negligible. Increased truck traffic during daytime hours would cause a temporary increase in noise at a limited number of residences and the impacts are expected to be negligible. Residences within 500 to 1,000 feet of construction of the water supply and hydrogen pipelines would experience a short-term increase in ambient noise and vibrations from construction activity. Receptors near HDD locations could experience elevated temporary ambient noise levels as high as 78 dBA. Noise minimization measures would be used to reduce levels by approximately 10 dBA. Leucadia must minimize noise levels by limiting construction activities to daylight hours, as practicable, requiring contractors to minimize construction noise and maintain equipment in good working order, and utilizing temporary sound barriers. If necessary, Leucadia must obtain a variance from Calcasieu Parish for operating HDD equipment during evening and weekend hours. Typical sound levels for the equipment to be used during operation of the LCCE Gasification plant and $CO_2$ capture and compression facilities can exceed 120 dBA. Leucadia must implement engineering design and noise minimization measures to limit the levels such that the combination of noise from the plant and existing ambient noise would not exceed 58 dBA at the nearest noise-sensitive receptor during operation.

During the CCS $CO_2$ pipeline construction, noise levels may exceed the EPA guideline of 55 dBA at some residences. HDD activities may need to be conducted in the evening or weekends within 165 feet of a residence or noise sensitive area, which is prohibited by Calcasieu and Cameron Parishes without a variance. Noise minimization measures would be implemented to achieve up to a 10 dBA reduction. As a temporary daytime occurrence, noise from construction of the $CO_2$ pipeline would have short-term, minor impacts on noise receptors. The impacts from traffic noise during construction would be negligible because a majority of the pipeline route traverses rural areas. No noise above ambient levels would be generated by operation of the $CO_2$ pipeline. Noise impacts from equipment and vehicles used during inspection and maintenance activities would be negligible.

Noise produced by equipment during conversion and reworking of wells for the West Hastings Research MVA Program is not expected to exceed the EPA guideline more than 1,000 feet from the equipment. Construction noise of this magnitude would likely be imperceptible, given the industrial setting, and the on-going commercial EOR operations. Therefore, the potential noise from the research MVA well reworking would result in negligible impacts. Traffic noise may increase for additional periodic sampling and monitoring activities, but the increase would not be distinguishable from ambient noise levels and would be negligible.

**Waste Management**

Approximately 2,640 cubic yards of nonhazardous waste and small quantities of hazardous waste would be generated annually during the 3-year construction period of the Gasification Plant and Lake Charles CCS Capture and Compression facilities, or less than 0.0002 percent of the available landfill capacity in Calcasieu Parish. Leucadia must require construction contractors to develop a Waste Management Plan that includes specifications for handling, containment, and disposal of all wastes generated during construction of the Gasification Plant and CCS Capture and Compression facilities. Approximately 65,000 tons (75,000 cubic yards) of nonhazardous waste generated annually during operation represents 0.6 percent of the total landfill capacity in Calcasieu Parish. Approximately 1,500 cubic yards of potentially hazardous waste would be generated annually during operation, or less than 0.03 percent of the capacity of the hazardous waste landfills in Calcasieu Parish. Leucadia must implement a program to reduce, reuse, and recycle waste materials to the extent practicable.

Portions of the CCS $CO_2$ pipeline would be constructed using HDD and a bentonite slurry that would be recycled, spread in upland areas as a soil supplement, if permitted, or removed and disposed of at a local permitted solid waste landfill. Construction and operation would not create hazardous wastes in quantities that would require a RCRA permit. Disposal of nonhazardous and potentially hazardous wastes generated by construction and operation of the proposed $CO_2$ pipeline would have a negligible impact on the capacity or management of hazardous or solid waste services and landfills in the area.

The West Hastings research MVA activities would involve drilling equipment to plug back, recondition, and re-complete existing wells. Research MVA activities could generate waste streams, including drilling mud and produced water during well construction. Produced water and light sediment would be pumped into trucks and hauled off-site by a licensed contractor for disposal. Excess drilling mud would be collected and stabilized in steel tanks and transported off-site to a designated local solid waste landfill. No hazardous waste would be generated as a result of the research MVA activities. Impacts related to the disposal of drill cuttings and treatment of the produced water generated during

the reworking of existing wells would not require the use of unique waste disposal or treatment technologies and would result in negligible impacts on the capacity and management of landfills and disposal facilities in the area.

**Potential Environmental Impacts of the No Action Alternative**

Under no action sub-alternative 1, Leucadia would build neither the Gasification Plant nor the Lake Charles CCS project. The resources necessary for construction would be available for construction of other industrial projects in this area or elsewhere. The Port of Lake Charles would continue to ship pet coke worldwide for use as fuel in power plants. The use of pet coke in conventional power plants would likely emit more air emissions than its use in the Gasification Plant because of the stringent emission requirements imposed on the plant compared to conventional power plants. Environmental conditions would not change. The impacts to the community from noise, traffic, air emissions, and disruption of land use, jobs, and economic development would not occur. The impacts on the environment from air emissions, disruption of wildlife, use of surface water, discharge of wastewater, and loss of wetlands would not occur. Denbury would continue to inject $CO_2$ obtained from geologic sources in its ongoing EOR operations. The Lake Charles CCS project would not fund a research MVA program at the West Hastings oil field. Sub-alternative 1 of the no action alternative would not contribute to the demonstration of the next generation of technologies to capture $CO_2$ from industrial sources.

Under no action sub-alternative 2, Leucadia would build the Gasification Plant and vent the $CO_2$ to the atmosphere. The impacts from the construction and operation of the Gasification Plant would still occur. Leucadia would still capture the $CO_2$ from the syngas using Rectisol®. Leucadia would route the $CO_2$ stream to discharge to the atmosphere under the current air permit issued by LDEQ. Approximately 5.2 million tons of $CO_2$ would be emitted per year from the carbon capture technology that would otherwise be captured. Emissions produced by the construction of the pipeline, and indirect emissions associated with electricity use by the $CO_2$ capture and compression facility, would not occur. No impacts related to construction of the $CO_2$ pipeline would occur. Denbury would continue to inject $CO_2$ obtained from geologic sources in its ongoing EOR operations. The Lake Charles CCS project would not fund a research MVA program at the West Hastings oil field. If the CCS project is not built, the opportunity to capture an average of 4.6 million tons of anthropogenic $CO_2$ per year over the 30 year life of the Gasification Plant for use in EOR would be lost. Sub-alternative 2 would not contribute to DOE's goal of demonstrating the next generation of technologies that capture $CO_2$ emissions from industrial sources.

**Environmentally Preferred Alternative**

From a local perspective, no action sub-alternative 1 is the environmentally preferable alternative because it would result in no changes to existing environmental conditions. However, from a national perspective, DOE's proposed action is the environmentally preferred alternative. Successful operation of the proposed project could facilitate the deployment of advanced technology integrated with an industrial source to capture $CO_2$ that would otherwise be emitted to the atmosphere.

**Floodplain Statement of Findings**

DOE prepared this floodplain statement of findings in accordance with its regulations entitled ''Compliance With Floodplain and Wetland Environmental Review Requirements'' (10 CFR 1022). DOE completed the required floodplain assessment in coordination with development and preparation of the EIS, and incorporated the results and discussion in Sections 3.4, 4.4, and Appendix E of the final EIS.

Based on the FEMA Flood Insurance Map and Rita Recovery Maps, the Gasification Plant and the $CO_2$ Capture and Compression facilities site's Advisory Base Flood Elevation (ABFE) is 10 feet above mean sea level (MSL). The Gasification Plant and Capture and Compression site would be filled to an elevation that is above the ABFE. The 120-acre area, which would include 40 acres for equipment laydown during construction and methanol/sulfuric acid storage during operation, is within the 100-year floodplain of the Calcasieu River. DOE assumes that the site would continue to be filled above the base flood elevation set by FEMA. Given the relative size of the 70-acre site and the 40-acre site compared to the designated floodway of 8 miles along the Calcasieu ship channel and 3,976 acres drainage area, the fill would not result in a measurable increase in the upstream base flood elevation as determined by FEMA, nor have a measurable effect on the performance of the designated floodway. The proposed water and hydrogen pipelines associated with Gasification Plant would be installed below ground within the 100-year floodplain of Bayou d'Inde and Calcasieu River.

The proposed CCS $CO_2$ pipeline route is located in proximity to the floodplains of Bayou d'Inde, the Houston River, and the Calcasieu River, and much of the proposed route is located within 100-year floodplains of the Calcasieu River and its tributaries. The proposed pipeline would be installed below ground, therefore no alteration of infiltration rates and no substantial decrease in the volume of surface water that flows downstream would result.

Approximately one-third of the West Hastings research MVA area, including two proposed well locations, is within the 100-year floodplain of Chigger Creek. However, research MVA activities would not increase the potential for floods, alter a floodway or floodplain, or otherwise impede or redirect flows such that human health, the environment, or personal property could be affected. Activities would be conducted on existing wells and no new construction would occur.

As a result of location requirements, i.e., being adjacent to navigable waters and existing rail, road, and pipeline infrastructure, the proposed project and connected action were found to have no practicable siting alternatives. Based upon DOE's review and the project proponents' coordination with the local floodplain administrator and local USACE District, and adoption of minimization measures, DOE's proposed action would not result in potential harm to or within floodplains.

Issued in Pittsburgh, PA on this 28 day of December 2013.

**Scott M. Klara,**

*Acting Director, National Energy Technology Laboratory.*

[FR Doc. 2014–00299 Filed 1–9–14; 8:45 am]

BILLING CODE 6450–01–P

## ENVIRONMENTAL PROTECTION AGENCY

**[ER–FRL–9012–9]**

## Environmental Impact Statements; Notice of Availability

*Responsible Agency:* Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/compliance/nepa/.*

Weekly receipt of Environmental Impact Statements filed 12/30/2013 through 01/03/2014 pursuant to 40 CFR 1506.9.

**Notice**

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html.*

*EIS No. 20130384, Draft Supplement, USFS, NV,* Ely Westside Rangeland Project, Comment Period Ends: 02/24/2014, Contact: Vernon Keller 775–335–5336

*EIS No. 20140000, Draft EIS, USACE, NC,* Village of Bald Head Island Shoreline Protection Project, Comment Period Ends: 02/24/2014, Contact: Ronnie Smith 910–251–4829

*EIS No. 20140001, Draft EIS, APHIS, 00,* Determinations of Nonregulated Status for 2, 4–D–Resistant Corn and Soybean Varieties, Comment Period Ends: 02/24/2014, Contact: Sid Abel 301–734–6352

Dated: January 7, 2014.

**Cliff Rader,**

*Director, NEPA Compliance Division, Office of Federal Activities.*

[FR Doc. 2014–00214 Filed 1–9–14; 8:45 am]

BILLING CODE 6560–50–P

## FEDERAL HOUSING FINANCE AGENCY

**[No. 2014–N–01]**

## Notice of Annual Adjustment of the Cap on Average Total Assets That Defines Community Financial Institutions

**AGENCY:** Federal Housing Finance Agency.

**ACTION:** Notice.

**SUMMARY:** The Federal Housing Finance Agency (FHFA) has adjusted the cap on average total assets that defines a ''Community Financial Institution'' based on the annual percentage increase in the Consumer Price Index for all urban consumers (CPI–U) as published by the Department of Labor (DOL). These changes took effect on January 1, 2014.

**FOR FURTHER INFORMATION CONTACT:** Nathan D. Wallingford, Division of Federal Home Loan Bank Regulation, (202) 649–3630, *Nathan.Wallingford@fhfa.gov,* or Eric M. Raudenbush, Assistant General Counsel, (202) 649–3084, *Eric.Raudenbush@fhfa.gov,* (not toll-free numbers), Federal Housing Finance Agency, Constitution Center, 400 Seventh Street SW., Washington, DC 20024.

**SUPPLEMENTARY INFORMATION:**

### I. Statutory and Regulatory Background

The Federal Home Loan Bank Act (Bank Act) confers upon insured depository institutions that meet the statutory definition of a ''Community Financial Institution'' (CFI) certain advantages over non-CFI insured depository institutions in qualifying for Federal Home Loan Bank (Bank) membership, and in the purposes for which they may receive long-term advances and the collateral they may pledge to secure advances.[1] Section 2(10)(A) of the Bank Act and § 1263.1 of FHFA's regulations define a CFI as any Bank member the deposits of which are insured by the Federal Deposit Insurance Corporation and that has average total assets below a statutory cap.[2] The Bank Act was amended in 2008 to set the statutory cap at $1 billion and to require the Director of FHFA to adjust the cap annually to reflect the percentage increase in the CPI–U, as published by the DOL, for the prior year.[3] For 2013, FHFA set the CFI asset cap at $1,095,000,000, which reflected a 1.8 percent increase over 2012, based upon the increase in the CPI–U between 2011 and 2012.[4]

### II. The CFI Asset Cap for 2014

As of January 1, 2014, FHFA has increased the CFI asset cap from $1,095,000,000 to $1,108,000,000, which reflects a 1.2 percent increase in the unadjusted CPI–U from November 2012 to November 2013. The new amount was obtained by rounding to the nearest million, as has been the practice for all prior adjustments. Consistent with the practice of other Federal agencies, FHFA bases the annual adjustment to the CFI asset cap on the percentage increase in the CPI–U from November of the year prior to the preceding calendar year to November of the preceding calendar year, because the November figures represent the most recent available data as of January 1st of the current calendar year.

In calculating the CFI asset cap, FHFA uses CPI–U data that have not been seasonally adjusted (*i.e.,* the data have not been adjusted to remove the estimated effect of price changes that normally occur at the same time and in about the same magnitude every year). The DOL encourages use of unadjusted CPI–U data in applying ''escalation'' provisions such as that governing the CFI asset cap, because the factors that are used to seasonally adjust the data are amended annually, and seasonally adjusted data that are published earlier are subject to revision for up to five years following their original release. Unadjusted data are not routinely subject to revision, and previously published unadjusted data are only corrected when significant calculation errors are discovered.

Dated: January 3, 2014.

**Edward J. DeMarco,**

*Acting Director, Federal Housing Finance Agency.*

[FR Doc. 2014–00193 Filed 1–9–14; 8:45 am]

BILLING CODE 8070–01–P

[1] *See* 12 U.S.C. 1424(a), 1430(a).

[2] *See* 12 U.S.C. 1422(10)(A); 12 CFR 1263.1.

[3] *See* 12 U.S.C. 1422(10); 12 CFR 1263.1 (defining the term *CFI asset cap*).

[4] See 78 FR 19262 (Mar. 29, 2013).

## FEDERAL RESERVE SYSTEM

## Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

**AGENCY:** Board of Governors of the Federal Reserve System

**SUMMARY:** *Background.* Notice is hereby given of the final approval of a proposed information collection by the Board of Governors of the Federal Reserve System (Board) under OMB delegated authority, as per 5 CFR 1320.16 (OMB Regulations on Controlling Paperwork Burdens on the Public). Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statements and approved collection of information instruments are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

**FOR FURTHER INFORMATION CONTACT:** Federal Reserve Board Clearance Officer—Cynthia Ayouch—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202–452–3829) Telecommunications Device for the Deaf (TDD) users may contact (202–263–4869), Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503.

*Final approval under OMB delegated authority of the revision, without extension, of the following reports:*

*1. Report title:* Financial Statements for Holding Companies.[1]

*Agency form number:* FR Y–9C.

*OMB control number:* 7100–0128.

*Frequency:* Quarterly.

*Reporters:* Bank holding companies (BHCs), savings and loan holding companies (SLHCs), and securities holding companies (SHCs) (collectively, ''holding companies'' (HCs)).

*Estimated average hours per response:* Non-advanced approaches HCs: 48.84 hours, and advanced approaches HCs: 50.09.

*Estimated annual reporting hours:* 222,770 hours.

*Number of respondents:* 1,140.

*General description of report:* This information collection is mandatory for BHCs (12 U.S.C. 1844(c)(1)(A)). Additionally, 12 U.S.C. 1467a(b)(2)(A) and 1850a(c)(1)(A), respectively, authorize the Federal Reserve to require that SLHCs and supervised SHCs file the FR Y–9C with the Federal Reserve. Confidential treatment is not routinely given to the financial data in this report. However, confidential treatment for the reporting information, in whole or in part, can be requested in accordance with the instructions to the form, pursuant to sections (b)(4), (b)(6), or (b)(8) of FOIA (5 U.S.C. 522(b)(4), (b)(6), and (b)(8)).

*Abstract:* The FR Y–9C consists of standardized financial statements similar to the Federal Financial Institutions Examination Council (FFIEC) Consolidated Reports of Condition and Income (Call Reports) (FFIEC 031 & 041; OMB No. 7100–0036) filed by commercial banks and savings associations. The FR Y–9C collects consolidated data from HCs. The FR Y–9C is filed by top-tier HCs (under certain circumstances, a lower-tier HC may act as the top tier of the organization for purposes of regulatory reporting) with total consolidated assets of $500 million or more. (Under certain circumstances defined in the General Instructions, BHCs under $500 million may be required to file the FR Y–9C.) The Federal Reserve proposed revisions to the FR Y–9C consistent with the regulatory capital rules approved by the Board on July 2, 2013 (revised regulatory capital rules).[2]

*Current Actions:* On August 12, 2013, the Federal Reserve published a notice in the **Federal Register** (78 FR 48871, August 12, 2013) requesting public comment for 60 days on the revision to the FR Y–9C (the proposal). The comment period for this notice expired on October 11, 2013.

The Federal Reserve received two comment letters regarding proposed revisions to the FR Y–9C from one banking organization and one bankers' association. In addition, the Federal Reserve, Federal Deposit Insurance Corporation (FDIC), and Office of the Comptroller of the Currency (OCC) (the agencies) collectively received three comment letters, including the two comment letters mentioned above, on proposed revisions to the Consolidated Reports of Condition and Income (Call Reports) (FFIEC 031 & 041; OMB No. 7100–0036), which parallel proposed revisions to the FR Y–9C and were taken into consideration in finalizing the proposal.[3] The commenters asked for clarification on the applicability and effective dates of the proposed reporting requirements and for additional clarifications and instructions on certain line items.[4]

## Detailed Discussion of Public Comments

### *1. Proposed FR Y–9C, Schedule HC–R*

Under the proposal, in March 2014, the existing and proposed regulatory capital components and ratios portion of Schedule HC–R would be designated Parts I.A and I.B, respectively. Advanced approaches HCs would be required to file Part I.B in March 2014, which includes the reporting revisions consistent with the revised regulatory capital rules. All other HCs, except SLHCs, would file Part I.A, which includes existing data items 1 through 33 of current Schedule HC–R, for the reporting periods in 2014. In March 2015, Part I.A would be removed and Part I.B would be designated Part I; all HCs that are subject to FRY–9C filing requirements would then submit Schedule HC–R, Part I.

As proposed, Part I.B, Regulatory Capital Components and Ratios, would be divided into the following sections: (A) common equity tier 1 capital; (B) common equity tier 1 capital: adjustments and deductions; (C) additional tier 1 capital; (D) tier 2 capital; (E) total assets for the leverage ratio; (F) capital ratios; and (G) capital buffer. A brief description of each of these sections and the corresponding line items is provided below. The Federal Reserve did not receive any comments on the overall structure of the proposed Schedule HC–R, Part I.B and thus the Federal Reserve is proceeding with the overall structure of Part I.B, as proposed.

The Federal Reserve received several questions regarding the effective dates of the proposed FR Y–9C and certain items that apply to advanced approaches institutions only. One commenter asked when an HC subject to the Supervision and Regulation Letter (SR) 01–1 exemption must report the FR Y–9C, including the proposed Schedule HC–R. The Federal Reserve is clarifying in the reporting instructions that, consistent with the revised regulatory capital rules, these institutions are not subject to the consolidated regulatory capital requirements until July 21, 2015.[5] Thus, these institutions will be required to file the FR Y–9C, including the proposed Schedule HC–R, in the first reporting period following that date, which is the September 30, 2015, reporting date.

The same commenter asked when an HC is required to complete items that apply to advanced approaches HCs if the institution becomes subject to the advanced approaches rule but has not begun its parallel run period. The Federal Reserve is clarifying in the general instructions for the proposed Schedule HC–R that an institution must begin reporting certain advanced approaches-related items at the end of the quarter after the quarter in which the institution triggers one of the threshold criteria for applying the

[1] This family of reports also contains the following mandatory reports, which are not being revised: the Parent Company Only Financial Statements for Large Bank Holding Companies (FR Y–9LP), the Financial Statements for Employee Stock Ownership Plan Bank Holding Companies (FR Y–9ES), and the Supplement to the Consolidated Financial Statements for Bank Holding Companies (FR Y–9CS).

[2] On July 2, 2013, the Board approved the revised regulatory capital rules that were proposed on August 30, 2012. On July 9, 2013 the OCC approved the revised regulatory capital rules and the FDIC issued an interim final rule to approve the revised regulatory capital rules. *See* 78 FR 62018 (October 11, 2013) (Board and OCC); 78 FR 55340 (September 10, 2013) (FDIC). *See also* 77 FR 52888, 52909, 52958 (August 30, 2012).

[3] The Federal Reserve expects to publish at a later date a request for comment to revise the risk-weighted assets portion of the FR Y–9C, Schedule HC–R, Part II and add Part II to the FR Y–9SP, Schedule SC–R, consistent with the standardized approach for calculating risk-weighted assets under the revised regulatory capital rules. The revisions to the risk-weighted assets portion of the respective regulatory capital schedules would become effective in the first applicable reporting period in 2015. Therefore, for report dates in 2014, all HC–R respondents will continue to report risk-weighted assets in the portion of Schedule HC–R that contains existing data items 34 through 62 and Memoranda items 1 and 2 of current Schedule HC–R, but this portion of the schedule would be designated Part II and the data items would retain their existing numbers.

[4] In addition, one other commenter on the proposal urged the Federal Reserve to revise the regulatory capital treatment of the allowance for loan and lease losses (ALLL) if the Financial Accounting Standards Board (FASB) changes the accounting standards applicable to ALLL. The Federal Reserve notes that this comment suggests a substantive change to the revised regulatory capital rules and is outside the scope of the proposed changes to the FR Y–9C and the FR Y–9SP.

[5] 78 FR 62018 (October 11, 2013).

advanced approaches rule or elects to use the advanced approaches rule (an opt-in institution). An institution will be deemed to have elected to use the advanced approaches rule on the date that the Federal Reserve receives from the institution a board-approved implementation plan pursuant to section 121(b)(2) of the revised regulatory capital rules. After that date, the institution may no longer apply the accumulated other comprehensive income (AOCI) opt-out election, consistent with section 22(b)(2) of the revised regulatory capital rules, and it becomes immediately subject to the supplementary leverage ratio in section 10(c)(4) and associated transition provisions. The institutions will be required to report all other advanced-approaches related items (i.e., items 30.b, 32.b, 34.b, 35.b, 40.b, column B in items 41 through 44, and item 46.b) only after it completes its parallel run period, consistent with the proposal.

The Federal Reserve received several questions regarding the reporting treatment for items subject to transition provisions in the proposed Schedule HC–R, Part I.B. Specifically, commenters asked for clarification on reporting transition amounts of items subject to regulatory capital adjustments and deductions and reporting disallowed amounts during the transition period. As described below in section 1.B below, transition amounts are to be reported in the Schedule HC–R line item applicable to the particular regulatory capital adjustment or deduction, while the otherwise disallowed portion of each of those items is either risk-weighted or deducted from additional tier 1 capital, depending on the item.

Commenters also asked for clarification of the reporting of the risk-weighted portion of an item subject to deduction in Schedule HC–R. The Federal Reserve is clarifying the instructions for Part I.B of Schedule HC–R that the risk-weighted portion of such items as proposed must be reported in the line item appropriate to the item subject to deduction in Schedule HC–R, Part II, Risk-Weighted Assets. In addition, the Federal Reserve is clarifying that even though certain deductions may be net of associated deferred tax liabilities (DTLs), the risk-weighted portion of those items may not be reduced by the associated DTLs.

For example, for HCs subject to the revised regulatory capital rules on January 1, 2014, the appropriate line item for reporting the risk-weighted portion of mortgage servicing assets (MSAs) that are not deducted from common equity tier 1 capital, for report dates in 2014, is Schedule HC–R, Part II, item 42, ''All other assets.'' The risk-weighted asset portion of MSAs may not be reduced by any associated DTLs. Also, the Federal Reserve proposed that line items in Part II be renumbered in 2015 because, as indicated in the proposal, the risk-weighted assets portion of Schedule HC–R would be revised to incorporate the standardized approach for calculating risk-weighted assets under the revised regulatory capital rules. Line item references in Schedule HC–R, Part II will be updated, as appropriate, in the instructions for 2015 after the revisions to the risk-weighted assets portion of the schedule are finalized.

Two commenters asked whether the proposed deduction of equity investments in financial subsidiaries in Schedule HC–R, Part I.B, line 10(b), should apply to HCs. The Federal Reserve is clarifying the instructions to note that, consistent with the current regulatory capital rules and reporting requirements, the requirement to deduct equity investments in financial subsidiaries does not apply at the consolidated HC level.

One commenter asked about deductions from common equity tier 1 capital and additional tier 1 that must be made to calculate total assets for the leverage ratio. The Federal Reserve is specifying in the reporting instructions the deductions that must be made to calculate total assets for the leverage ratio, as described in section 1.E below.

One commenter asked the Federal Reserve to confirm the effective dates for reporting the capital conservation buffer and the supplementary leverage ratio. The Federal Reserve is confirming that the capital conservation buffer (and any other applicable buffer for advanced approaches institutions) must be reported for report dates after January 1, 2016. Advanced approaches HCs must report the supplementary leverage ratio for report dates after January 1, 2015 (see section 1.F below for further details). The Federal Reserve also is shading out the corresponding cells in the reporting form for Schedule HC–R, Part I.B, to show that institutions should not report these items until they become effective.

A brief description of the proposed revisions and the comments received on specific line items in Schedule HC–R, Part I.B, is provided below.

### A. Proposed Schedule HC–R, Part I.B, Items 1–5: Common Equity Tier 1 Capital

Under the proposal, line items 1 through 5 will collect information regarding the new regulatory capital component, common equity tier 1 capital. The Federal Reserve did not receive any comments on these line items and thus the Federal Reserve is retaining the proposed line items without modification.

### B. Schedule HC–R, Part I.B, Items 6–19: Common Equity Tier 1 Capital: Adjustments and Deductions

Proposed line items 6 through 19 reflect adjustments and deductions to common equity tier 1 capital, as described in section 22 of the revised regulatory capital rules. The Federal Reserve received a number of questions on reporting items subject to transition provisions. Specifically, questions related to items 7 through 10 asked where the transition amounts of the adjustments and deductions covered by these specific items are to be reported. The instructions for proposed Schedule HC–R, Part I.B, explain that during the transition period as proposed, institutions must report the transition amounts of these adjustments and deductions, rather than their fully phased-in amounts, in items 7 through 10. Institutions will not be required to report fully phased-in amounts in items 7 through 10 until the transition period ends.

For example, during the transition period, an institution must report in item 7 the appropriate transition amount of intangible assets (other than goodwill and MSAs), net of associated DTLs, as described in the instructions for that line item. The institution must also risk weight the non-deducted portion of that item at 100 percent and report it in Schedule HC–R, Part II, item 42, ''All other assets.'' As another example, during the transition period, an institution must report in item 8 the appropriate transition amount of deferred tax assets (DTAs) that arise from net operating loss and tax credit carryforwards, net of any related valuation allowances and net of DTLs, calculated as a percentage of the adjustment applied to common equity tier 1 capital. The institution must then report during the transition period the remaining balance of DTAs that arise from net operating loss and tax credit carryforwards, net of any related valuation allowances and net of DTLs, in Schedule HC–R, Part I.B, item 24, ''Additional tier 1 capital deductions.''

A commenter also asked about risk weighting the non-deducted portion of the threshold items (that is, significant investments in the capital of unconsolidated financial institutions in the form of common stock, net of associated DTLs; MSAs net of associated DTLs; and DTAs arising from temporary

differences that could not be realized through net operating loss carrybacks, net of related valuation allowances and net of DTLs). The instructions for proposed Schedule HC–R, Part I.B, will explain that during the transition period the non-deducted portion of these threshold items must be risk weighted at 100 percent in accordance with section 300 of the revised regulatory capital rules and reported in Schedule HC–R, Part II, ''All other assets.'' For report dates after January 1, 2018, the non-deducted portion of the threshold items must be risk-weighted at 250 percent in accordance with section 22 of the revised regulatory capital rules and reported in the appropriate asset category in Schedule HC–R, Part II.

**C. Schedule HC–R, Part I.B, Items 20 Through 25: Additional Tier 1 Capital, and Item 26: Tier 1 Capital**

Proposed line items 20 through 25 pertain to the reporting of additional tier 1 capital elements under section 20 of the revised regulatory capital rules, along with related adjustments for non-qualifying capital instruments subject to phase-out. The Federal Reserve did not receive any comments on these line items and thus the Federal Reserve is retaining the proposed line items without modification.

**D. Schedule HC–R, Part I.B, Items 27 Through 34: Tier 2 Capital, and Item 35: Total Capital**

Proposed line items 27 through 34 pertain to the reporting of tier 2 capital elements under section 20 of the revised regulatory capital rules, along with related adjustments for non-qualifying capital instruments subject to phase-out. The Federal Reserve did not receive any comments on these line items and thus the Federal Reserve is retaining the proposed line items without modification.

**E. Schedule HC–R, Part I.B, Items 36 Through 39: Total Assets for the Leverage Ratio**

Under the proposal, institutions will report data for the calculation of the leverage ratio in items 36 through 39. One commenter asked the Federal Reserve to confirm the deductions from common equity tier 1 capital and additional tier 1 capital that must be made to calculate total assets for the leverage ratio. Specifically, the commenter asked whether the deductions made in Schedule HC–R, Part I.B, items 13 through 15, also must be made for purposes of the leverage ratio. The Federal Reserve is clarifying the reporting instructions for proposed Schedule HC–R, Part I.B, items 37 and 38, to address the commenter's question. The Federal Reserve confirms that the amounts deducted from common equity tier 1 and additional tier 1 capital in Schedule HC–R, Part I.B, that items 6, 7, 8, 10.b, 11, 13 through 17, and 24 must be included in Schedule HC–R, Part I.B, item 37. In addition, any other amounts that are deducted from common equity tier 1 and additional tier 1 capital, such as deductions related to AOCI-adjustments, must be included in Schedule HC–R, Part I.B, item 38.

**F. Schedule HC–R, Part I.B, Item 40: Total Risk-Weighted Assets and Items 41 Through 45: Capital Ratios**

Under the proposal, institutions will report data for the calculation of risk-weighted assets and capital ratios in items 41 through 45. The Federal Reserve received one question on this section of the proposal. Specifically, a commenter asked the Federal Reserve to confirm the effective date of reporting the supplementary leverage ratio in item 45. The Federal Reserve is modifying the Schedule HC–R, Part I.B, reporting form and instructions for proposed item 45 to clarify that this item must be reported for report dates after January 1, 2015.

Under the proposal, for report dates in 2014, HCs that are advanced approaches institutions will continue applying the general risk-based capital rules to calculate their total risk-weighted assets, which will continue to be reported in current item 62 of the risk-weighted assets portion of Schedule HC–R (to be designated Part II of the schedule in March 2014). This total risk-weighted assets amount will then also be reported in item 40.a of Part I.B of Schedule HC–R for report dates in 2014 and will serve as the denominator for the risk-based capital ratios reported in Schedule HC–R, Part I.B, items 41 through 44, column A. Effective March 31, 2015, HCs will be required to apply the standardized approach, described in subpart D of the revised regulatory capital rules, to calculate and report their risk-weighted assets in item 40.a and the risk-based capital ratios in items 41 through 44, column A, of the regulatory capital components and ratios portion of Schedule HC–R.

Advanced approaches HCs will report items 40 through 45 on proposed Schedule HC–R, Part I.B, as follows.

- For report dates in 2014, these institutions will continue applying the general risk-based capital rules to report their total risk-weighted assets in item 40.a, which will serve as the denominator of the ratios reported in items 41 through 44, column A.
- Starting on March 31, 2015, these institutions will apply the standardized approach, described in subpart D of the revised regulatory capital rules, to calculate and report their risk-weighted assets in item 40.a and the regulatory capital ratios in items 41 through 44, column A.
- After they conduct a satisfactory parallel run, these institutions will report their total risk-weighted assets (item 40.b) and regulatory capital ratios (items 41 through 44, column B) using the advanced approaches rule.
- In addition, starting on March 31, 2015, these institutions will report a supplementary leverage ratio in item 45, as described in section 10 of the revised regulatory capital rules.

The Federal Reserve did not receive any comments on the proposed reporting of the regulatory capital ratios by advanced approaches institutions and thus the Federal Reserve is retaining this section of the proposal without modification.

**G. Schedule HC–R, Part I.B, Items 46 Through 48: Capital Buffer**

Under the proposal, an institution's capital conservation buffer and related information will be reported in items 46 through 48. The Federal Reserve received a question asking to confirm the effective date for reporting items 46 through 48. The Federal Reserve is modifying the Schedule HC–R, Part I.B, reporting form and instructions for proposed items 46 through 48 to clarify that these items become effective for report dates after January 1, 2016. Until March 31, 2016, the corresponding cells in the draft reporting form for Schedule HC–R, Part I.B, will be shaded out.

*2. Report Title:* Parent Company Only Financial Statements for Small Holding Companies.

*Agency form number:* FR Y–9SP.

*OMB control number:* 7100–0128.

*Frequency:* Semiannually, as of the last calendar day of June and December.

*Reporters:* BHCs, SLHCs and SHCs with total consolidated assets of less than $500 million (small BHCs, small SLHCs and small SHCs).

*Estimated annual reporting hours:* 49,443.

*Estimated average hours per response:* BHCs: 5.40 hours, SLHCs: 14.20 hours; One-time implementation: 500 hours.

*Number of respondents:* 4,094.

*General description of report:* This information collection is mandatory for BHCs [12 U.S.C. 1844(c)(1)(A).] Additionally, 12 U.S.C. 1467a(b)(2)(A) and 1850a(c)(1)(A), respectively, authorize the Federal Reserve to require that SLHCs and supervised SHCs file the FR Y–9SP with the Federal Reserve.

Confidential treatment is not routinely given to the financial data in this report. However, confidential treatment for the reporting information, in whole or in part, can be requested in accordance with the instructions to the form, pursuant to sections (b)(4), (b)(6), or (b)(8) of the Freedom of Information Act (5 U.S.C. 552(b)(4), (b)(6), and (b)(8)).

*Abstract:* The FR Y–9SP is a parent company only financial statement filed by HCs with total consolidated assets of less than $500 million. This form is a simplified or abbreviated version of the more extensive parent company only financial statement for large HCs (FR Y–9LP). This report is designed to obtain basic balance sheet and income information for the parent company, information on intangible assets, and information on intercompany transactions. The Federal Reserve proposed several revisions to the FR Y–9SP consistent with the regulatory capital rules approved by the Board on July 2, 2013 (revised regulatory capital rules).[6]

*Current Actions:* On August 12, 2013, the Federal Reserve published a notice in the **Federal Register** (78 FR 48871) requesting public comment for 60 days on the revision to the FR Y–9SP. The comment period for this notice expired on October 11, 2013.

The Federal Reserve did not receive any comments specific to the proposed Schedule SC–R on the FR Y–9SP. The Federal Reserve is making corresponding changes to the Schedule SC–R reporting form and instructions consistent with the Schedule HC–R changes described above.

In addition, the Federal Reserve is modifying the name of the proposed ''Schedule SC–R, Regulatory Capital Components and Ratios'' to ''Schedule SC–R, Regulatory Capital, Part I. Regulatory Capital Components and Ratios.'' This modification will be consistent with the Federal Reserve's intent to propose additions to the proposed Schedule SC–R, which will collect information on risk-weighted assets for the regulatory capital ratios and be designated as Part II.

[6] On July 2, 2013, the Board approved the revised regulatory capital rules that were proposed on August 30, 2012. On July 9, 2013 the OCC approved the revised regulatory capital rules and the FDIC issued an interim final rule to approve the revised regulatory capital rules. *See* 78 FR 62018 (October 11, 2013) (Board and OCC); 78 FR 55340 (September 10, 2013) (FDIC). *See also* 77 FR 52888, 52909, 52958 (August 30, 2012).

Board of Governors of the Federal Reserve System, January 7, 2014.

**Robert deV. Frierson,**

*Secretary of the Board.*

[FR Doc. 2014–00227 Filed 1–9–14; 8:45 am]

**BILLING CODE 6210–01–P**

## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than January 24, 2014.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Assistant Vice President) 1000 Peachtree Street NE., Atlanta, Georgia 30309:

1. *John McLanahan, Jr., Athens, Georgia; The McLanahan Children's Irrevocable Trust, Athens, Georgia; Margaret Staton, Atlanta, Georgia; Clarence McLanahan, II, Athens, Georgia; Dorothy Farley, Atlanta, Georgia; John McLanahan, III, Athens, Georgia; and Barrett McLanahan, Athens, Georgia;* to acquire voting shares of First American Bancorp, and thereby indirectly acquire voting shares of First American Bank and Trust Company, both in Athens, Georgia.

B. Federal Reserve Bank of Minneapolis (Jacqueline G. King, Community Affairs Officer) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Mary Kathryn Fleming,* Shorewood, Wisconsin; to acquire voting shares of Headwaters Bancorp, Inc., and thereby indirectly acquire voting shares of Headwaters State Bank, both in Land O' Lakes, Wisconsin.

In addition, Jerry L. Olk, individually and as trustee, Jerry L. Olk Revocable Trust, both of Land O'Lakes, Wisconsin; Thomas L. Olk, and Elise E. Olk, both individually and as trustees, Thomas L. & Elise E. Olk Revocable Trust, all of Stevens Point, Wisconsin; Susan Joanne Olk, individually and as trustee, Susan Joanne Olk Revocable Trust, both of San Francisco, California; R. Joseph Olk Irrevocable Trust, James Fogle, trustee; Hillary Olk Dutcher, all of St. Louis, Missouri; Nathaniel Wood Olk, Chesterfield, Missouri; and Molly Wellborn Olk, Boulder, Colorado; to acquire or retain shares of Headwaters Bancorp., Inc., Land O' Lakes, Wisconsin, and thereby become or remain members of the Olk Family Control Group, which controls 25 percent or more of the shares of Headwaters Bancorp., Inc., Land O' Lakes, Wisconsin.

Board of Governors of the Federal Reserve System, January 6, 2014.

**Michael J. Lewandowski,**

*Associate Secretary of the Board.*

[FR Doc. 2014–00190 Filed 1–9–14; 8:45 am]

**BILLING CODE 6210–01–P**

## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 3, 2014.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Vice President) 33

Liberty Street, New York, New York 10045–0001:

1. *New Investors Bancorp, Inc.,* Short Hills, New Jersey; to become a bank holding company by acquiring 100 percent of the voting shares of Investors Bank, Short Hills, New Jersey.

B. Federal Reserve Bank of St. Louis (Yvonne Sparks, Community Development Officer) P.O. Box 442, St. Louis, Missouri 63166–2034:

1. *Bank of the Ozarks, Inc.,* Little Rock, Arkansas; to acquire 100 percent of the voting shares of Bancshares, Inc., and thereby indirectly acquire Omnibank, N.A., both in Houston, Texas.

C. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Olney Bancshares of Texas, Inc.,* Olney, Texas; to acquire 100 percent of the voting shares of Park Cities Bank, Dallas, Texas.

Board of Governors of the Federal Reserve System, January 6, 2014.

**Michael J. Lewandowski,**

*Associate Secretary of the Board.*

[FR Doc. 2014–00192 Filed 1–9–14; 8:45 am]

BILLING CODE 6210–01–P

## FEDERAL RESERVE SYSTEM

### Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo,* or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 6, 2014.

A. Federal Reserve Bank of Boston (Richard Walker, Community Affairs Officer) 600 Atlantic Avenue, Boston, Massachusetts 02210–2204:

*1. Rockville Financial, Inc.,* Rockville, Connecticut; to acquire 100 percent of the voting shares of United Financial Bancorp, and indirectly acquire United Bank, FSB, both in West Springfield, Massachusetts, and thereby engage in operating a savings association, pursuant to section 225.28(b)(4)(ii).

Board of Governors of the Federal Reserve System, January 7, 2014.

**Michael J. Lewandowski,**

*Associate Secretary of the Board.*

[FR Doc. 2014–00245 Filed 1–9–14; 8:45 am]

BILLING CODE 6210–01–P

## FEDERAL RESERVE SYSTEM

### Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage *de novo,* or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 24, 2014.

A. Federal Reserve Bank of Dallas (E. Ann Worthy, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Strategic Growth Bank Incorporated and Strategic Growth Bancorp Incorporated,* both of El Paso, TX, to acquire up to 23.9 percent of Guardian Mortgage Company, Inc., Richardson, Texas, and thereby engage in extending credit and servicing loans; and contract with a third party in asset management, servicing, and collection of assets, pursuant to sections 225.28(b)(1) and 225.28(b)(2)(vi).

Board of Governors of the Federal Reserve System, January 6, 2014.

**Michael J. Lewandowski,**

*Associate Secretary of the Board.*

[FR Doc. 2014–00191 Filed 1–9–14; 8:45 am]

BILLING CODE 6210–01–P

## GOVERNMENT ACCOUNTABILITY OFFICE

### Health Information Technology Policy Committee Openings

**AGENCY:** Government Accountability Office (GAO).

**ACTION:** Notice on letters of nomination to fill openings.

**SUMMARY:** The American Recovery and Reinvestment Act of 2009 (ARRA) established the Health Information Technology Policy Committee (Health IT Policy Committee) and gave the Comptroller General responsibility for appointing 13 of its 20 members. ARRA requires that: One member should have expertise with improving the health of vulnerable populations and one member should represent information technology vendors. Due to the completion of terms in April 2014 by committee members filing these requirements GAO is accepting nominations of individuals to fill these positions. In addition, ARRA requires that three members should be advocates for patients or consumers and one committee member in this category will be completing their term in April 2014. GAO is also accepting nominations of individuals to fill this position. For these appointments I am announcing the following: Letters of nomination and resumes should be submitted between January 2 and 24, 2014 to ensure adequate opportunity for review and consideration of nominees.

**ADDRESSES:** *GAO: HITCommittee@gao.gov.*

*GAO:* 441 G Street NW., Washington, DC 20548.

**FOR FURTHER INFORMATION CONTACT:** GAO: Office of Public Affairs, (202) 512–4800. 42 U.S.C. 300jj–12.

**Gene L. Dodaro,**

*Comptroller General of the United States.*

[FR Doc. 2013–31482 Filed 1–9–14; 8:45 am]

BILLING CODE 1610–02–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the National Vaccine Advisory Committee

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

**ACTION:** Notice of meeting.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) will hold a meeting. The meeting is open to the public. Pre-registration is required for both public attendance and comment. Individuals who wish to attend the meeting and/or participate in the public comment session should register at *http://www.hhs.gov/nvpo/nvac,* email *nvpo@hhs.gov,* or call 202–690–5566 and provide name, organization, and email address.

**DATES:** The meeting will be held on February 11–12, 2014. The meeting times and agenda will be posted on the NVAC Web site at *http://www.hhs.gov/nvpo/nvac* as soon as they become available.

**ADDRESSES:** U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Room 800, 200 Independence Avenue SW., Washington, DC 20201.

**FOR FURTHER INFORMATION CONTACT:** National Vaccine Program Office, U.S. Department of Health and Human Services, Room 715–H, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. *Phone:* (202) 690–5566; *Fax:* (202) 690–4631; *email: nvpo@hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. 300aa–1), the Secretary of Health and Human Services was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The National Vaccine Advisory Committee was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

The topics to be discussed at the NVAC meeting will include presentations addressing the first annual report of progress on the National Vaccine Plan; adult immunizations, vaccine research, development, and innovation; vaccine financing, access to and supply of vaccines, and a report of the President's Cancer Panel with a focus on HPV vaccination. In addition, NVAC working groups on Human Papillomavirus (HPV) Vaccine and Maternal Immunization will provide updates on the working groups' progress. The meeting agenda will be posted on the NVAC Web site: *http://www.hhs.gov/nvpo/nvac* prior to the meeting.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the National Vaccine Program Office at the address/phone listed above at least one week prior to the meeting. Members of the public will have the opportunity to provide comments at the NVAC meeting during the public comment periods on the agenda. Individuals who would like to submit written statements should email or fax their comments to the National Vaccine Program Office at least five business days prior to the meeting.

Dated: January 6, 2014.

**Bruce Gellin,**

*Director, National Vaccine Program Office, Executive Secretary, National Vaccine Advisory Committee.*

[FR Doc. 2014–00176 Filed 1–9–14; 8:45 am]

BILLING CODE 4150–44–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Agency for Healthcare Research and Quality, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed changes to the currently approved information collection project: ''Medical Expenditure Panel Survey—Insurance Component.'' In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

**DATES:** Comments on this notice must be received by March 11, 2014.

**ADDRESSES:** Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

**FOR FURTHER INFORMATION CONTACT:** Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

**Proposed Project**

**Medical Expenditure Panel Survey—Insurance Component**

Employer-sponsored health insurance is the source of coverage for 85 million current and former workers, plus many of their family members, and is a cornerstone of the U.S. health care system. The Medical Expenditure Panel Survey—Insurance Component (MEPS–IC) measures the extent, cost, and coverage of employer-sponsored health insurance on an annual basis. Statistics are produced at the National, State, and sub-State (metropolitan area) level for private industry. Statistics are also produced for State and Local governments. The MEPS–IC was last approved by OMB on November 21st, 2013 and will expire on November 30th, 2016. The OMB control number for the MEPS–IC is 0935–0110. All of the supporting documents for the current MEPS–IC can be downloaded from OMB's Web site at *http://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201310-0935-001.*

In order to ensure that the MEPS–IC is able to capture important changes in the employer-sponsored health insurance market due to the implementation of the Patient Protection and Affordable Care Act (PPACA), AHRQ researched and proposed revisions to the 2014 survey questionnaires based on the law's provisions. Many of these proposed revisions were related to the implementation of the Small Business Health Options Program (SHOP) exchanges/marketplaces that are available to small employers for purchasing health insurance beginning in 2014.

The proposed revisions were sent to a variety of federal and private stakeholders to obtain their suggestions and comments. These stakeholders included the U.S. Department of Health and Human Services' Assistant

Secretary for Planning and Evaluation (ASPE), the Center for Medicare & Medicaid Services' (CMS) Center for Consumer Information and Insurance Oversight, the CMS Office of the Actuary, the National Center for Health Statistics, the President's Council of Economic Advisors, the Office of Management and Budget, the Bureau of Labor Statistics, the Employee Benefits Security Administration, the Bureau of the Census, and health insurance researchers at various universities and other not-for-profit organizations. These reviewers' comments were invaluable, and are reflected in the questions proposed herein.

In addition to the new questions recommended for 2014, several questions in the 2013 survey are proposed for deletion as part of the 2014 improvements. These deletions are necessary to minimize the burden on survey respondents and are limited to those questions with less analytic value, with poor response rates, or those that are no longer relevant due to changes made under PPACA.

Unlike for previous years' additions to the MEPS–IC questionnaires, the Bureau of the Census—which conducts and processes the survey for AHRQ—was not able to pretest the proposed 2014 questions. Many of the new questions relate to PPACA requirements or options (such as the SHOP marketplaces) which did not exist prior to the deadline for preparation of the 2014 questionnaires, so employers would not yet have made changes to their health insurance coverage that could be researched to help in the development of the new questions.

For all establishment-level MEPS–IC forms, AHRQ proposes to make the following changes. As noted below, some new questions only will be asked of private-sector establishments with certain firm sizes (defined by number of employees) or comparably-sized government units:

Additions:

< = 50 firm size only:

• Did you offer health insurance through a small business (SHOP) exchange or marketplace in your State? Yes/No/Don't Know

All firm sizes, except very large businesses:

• Last year, did your organization offer health insurance as a benefit to its employees at this location? Yes, offered in 2013/No, did not offer in 2013/Don't Know

All firm sizes:

• How many employees reported in Question 2a above worked less than 30 hours per week?

____ employees

Check box: No employees worked less than 30 hours

• Are employees' spouses eligible for health insurance coverage through your organization?

All spouses are eligible/Only spouses not eligible through their own employer/No spouses eligible/Don't Know

Deletions:

• Did your organization offer any health insurance as a benefit to its employees at this location between January 1, 2009 and December 31, 2013? Yes/No

• What was the last year your organization offered health insurance coverage to its employees at this location? Last year offered

• Did your organization offer health insurance to its temporary or seasonal employees at this location in 2014? Yes/No/Organization has no temporary or seasonal employees/Don't Know

For all plan-level MEPS–IC forms, AHRQ proposes to make the following changes. As noted below, some new questions only will be asked of private-sector establishments with certain firm sizes or comparably-sized government units:

Additions:

< = 50 firm size only:

• Health insurance plans are classified into different metal levels or tiers based on their level of benefits and cost-sharing provisions. Which level or tier was this plan in? Bronze/Silver/Gold/Platinum/Don't Know

> 50 firm size only:

• What is the actuarial value of this plan?

The actuarial value is the percentage of medical expenses paid by the plan, rather than out-of-pocket by a covered person.

____ %

Check box: Do not know actuarial value

All firm sizes:

• You reported the total premium for a typical employee for SINGLE coverage. Did this premium vary for individual employees depending on their ages? Yes/No/Don't Know

• Did the amount individual employees contributed toward their single coverage vary by any of these characteristics?

• Participation/achievement in fitness/weight loss program

○ Yes
○ No
○ Don't Know

• Participation/achievement in smoking cessation program

○ Yes
○ No
○ Don't Know

• Participation/achievement in wellness/health monitoring program

○ Yes
○ No
○ Don't Know

• Employee age

○ Yes: go to question below
○ No
○ Don't Know

• Other

○ Yes
○ No
○ Don't Know

• How did individual employees' contributions vary by age? Employer pays same percent of premium, and premiums vary by age/Employer pays the same dollar amount toward premium, and premiums vary by age/Other/Don't Know

• Did the total premium for FAMILY coverage vary depending on the number of family members covered by the plan? Yes/No/Don't Know

• How much and/or what percentage did an enrollee pay out-of-pocket for each type of prescription drug covered?

• Generic

○ $ __ Copay AND/OR __ % Coinsurance

• Preferred Brand Name

○ $ __ Copay AND/OR __ % Coinsurance

• Non-preferred Brand Name

○ $ __ Copay AND/OR __ % Coinsurance

Deletions:

• Did the PREMIUMS for this insurance plan vary by any of these characteristics?

Age/Gender/Wage or salary levels/Smoker/Non-smoker status/Other

• Did the amount an EMPLOYEE CONTRIBUTED toward his/her own coverage vary by any of these employee characteristics? Hours worked/Union status/Wage or salary levels/Occupation/Length of employment/Participation in a fitness/Weight loss program/Participation in a smoking cessation program/Other

• How much and/or what percentage did an enrollee pay out-of-pocket for the lowest tier of prescription drug coverage? $ copayment/% coinsurance

• Could this plan have refused to cover persons with pre-existing medical or health conditions?

Yes/No

• Did this plan have a policy requiring a waiting period before covering pre-existing conditions?

Yes/No

The MEPS Definitions form—MEPS–20(D)—will also be updated with new definitions for terms used in these new questions (and the deletion of terms used only in the deleted questions).

There are no changes to the 2014 MEPS–IC survey estimates of cost and hour burdens due to these proposed question changes. The response rate for the MEPS–IC survey also is not expected to change due to these proposed changes.

The MEPS–IC is conducted pursuant to AHRQ's statutory authority to conduct surveys to collect data on the cost, use and quality of health care, including the types and costs of private health insurance. 42 U.S.C. 299b–2(a).

**Method of Collection**

There are no changes to the current data collection methods.

**Estimated Annual Respondent Burden**

There are no changes to the current burden estimates.

**Estimated Annual Costs to the Federal Government**

There are no changes to the current cost estimates.

**Request for Comments**

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: December 23, 2013.

**Richard Kronick,**

*Director.*

[FR Doc. 2013–31480 Filed 1–9–14; 8:45 am]

**BILLING CODE 4160–90–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[Docket No. CDC–2012–0013]**

### Notice of Availability of the Draft Environmental Impact Statement and Public Hearing

**AGENCY:** Centers for Disease Control and Prevention, HHS.

**ACTION:** Notice of Availability.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), announces the availability of the Roybal Campus 2025 Master Plan Draft Environmental Impact Statement (DEIS) for public review and comment. This notice also announces the date, location and time for the public hearing. The DEIS analyzes the potential impacts associated with the implementation of the 2015–2025 Master Plan (Master Plan) for HHS/CDC's Edward R. Roybal Campus (Roybal Campus) located at 1600 Clifton Road NE., in Atlanta, Georgia. This announcement follows the requirements of the National Environmental Policy Act of 1969 (NEPA) as implemented by the Council on Environmental Quality (CEQ) Regulations (40 CFR Part 1500–1508); and, the Department of Health and Human Services (HHS) General Administration Manual Part 30 Environmental Procedures, dated February 25, 2000.

**DATES:** A public meeting will be held on Wednesday, January 29, 2014 at the CDC Edward R. Roybal Campus, 1600 Clifton Road NE. in Atlanta, Georgia beginning with an ''open house'' at 6:00 p.m. EST. A formal presentation, followed by a public comment period will follow at approximately 7:00 p.m. EST. Written comments must be received on or before Monday, March 3, 2014.

*Deadline for Requests for Special Accommodations:* Persons wishing to participate in the public meeting who need special accommodations should contact George Chandler (*gec2@cdc.gov* or (404) 639–5153) by Wednesday, January 22, 2014.

**ADDRESSES:** Requests for information on the DEIS or for a paper/electronic copy should be directed to: George F. Chandler, Senior Advisor, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop A–22, Atlanta, Georgia 30333. Information may also be requested on the DEIS by electronic mail at *gec2@cdc.gov* or by telephone at (404) 639–5153. The DEIS will be available on the *Federal eRulemaking Portal: http://www.regulations.gov,* identified by Docket No. CDC–2012–0013. Hard copies of the DEIS are also available for review at locations listed in the Availability of the DEIS under **SUPPLEMENTARY INFORMATION.**

You may submit comments identified by Docket No. CDC–2012–0013, by any of the following methods:

*Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

*Mail:* George F. Chandler, Senior Advisor, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop A–22, Atlanta, Georgia 30333

*Instructions:* All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For access to the docket, to read background documents or comments received, go to *http://www.regulations.gov.*

Written and verbal comments on the DEIS will also be accepted during the public meeting scheduled for Wednesday, January 29, 2014, at the CDC Edward R. Roybal Campus, Tom Harkin Global Communications Center (Building 19), Auditorium A, 1600 Clifton Road NE., Atlanta, GA 30333. Please be advised that the meeting is being held in a Federal government building; therefore, Federal security measures are applicable. For additional information please see Roybal Campus Security Guidelines under **SUPPLEMENTARY INFORMATION.**

**FOR FURTHER INFORMATION CONTACT:** George F. Chandler, Senior Advisor, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop A–22, Atlanta, Georgia 30333. Telephone: (404) 639–5153.

**SUPPLEMENTARY INFORMATION:** HHS/CDC has prepared a new long-range Master Plan to guide the future physical development of the Roybal Campus for the planning horizon of 2015 to 2025. The previous 2000–2009 Master Plan has been implemented, and as a result, a new plan is needed in order to ensure that the campus can support HHS/CDC's mission and program requirements through 2025. Mission change and growth resulting from emerging or reemerging infectious diseases, reclassification of pathogens and potential Program staff growth over time are expected to drive increases in laboratory and non-laboratory staff and demand for specialized space. The Master Plan provides an update of

baseline existing conditions and examines the potential growth in agency mission, laboratory and laboratory support space, office space and personnel occupying the Roybal Campus, and identifies a preferred alternative for future development. The preferred alternative was the result of an extensive screening process, which identified and evaluated a range of conceptual development alternatives based on future program needs, campus constraints, and specifically developed selection criteria. Selection criteria included the examination of regional and local planning policy, utility demand, air quality, commute time, transportation system capacity and greenhouse gas effects.

**Alternatives Considered**

HHS/CDC analyzed two alternatives in the DEIS: the Proposed Action and the No Action Alternative. The Proposed Action Alternative consists of HHS/CDC's implementation of the Master Plan preferred alternative. Improvements proposed under the Master Plan preferred alternative include new laboratory construction, existing building renovation, parking expansion, and infrastructure upgrades. Under the Master Plan preferred alternative, the new laboratory building would contain approximately 350,000 to 450,000 gross square feet and would be constructed on an existing surface parking lot located in the eastern portion of the Roybal Campus. In addition to a new laboratory, a new approximately 1,600 space parking deck would be constructed just south of the new laboratory building. Construction of the new parking deck, along with the new laboratory and supporting infrastructure would eliminate an existing surface parking and result in a net increase of approximately 1,200 parking spaces at the Roybal Campus. HHS/CDC anticipates that the construction of the new parking deck would increase the campus parking cap from 3,300 to approximately 4,500 spaces. The employee population at the Roybal Campus is projected to increase by approximately 1,485 new occupants under the Master Plan preferred alternative in 2025.

The No Action Alternative represents continued operation of the existing facilities at the Roybal Campus without any new construction or building additions over the ten-year planning period from 2015 to 2025. However, the employee population at the Roybal Campus is projected to increase by approximately 865 new occupants under the No Action Alternative due to potential background growth of existing Campus programs.

The DEIS evaluates the environmental impacts that may result from the Proposed Action and the No Action Alternative on the natural and built environment. Potential direct, indirect and cumulative impacts of each alternative are evaluated on the following resource categories: socioeconomics, land use, zoning, public policy, community facilities, transportation, air quality, noise, cultural resources, urban design and visual resources, natural resources, utilities, waste, and greenhouse gases and sustainability. The DEIS identifies measures to mitigate potential adverse impacts.

*Availability of the DEIS:* Copies of the DEIS have been distributed to federal, state and local agencies and organizations. The DEIS is also available online on the *Federal eRulemaking Portal: http://www.regulations.gov,* identified by Docket No. CDC–2012–0013. Copies of the DEIS are available at the following locations: Decatur Library, 215 Sycamore Street, Decatur, GA 30030; Toco Hill—Avis G. Williams Library, 1282 McConnell Drive, Decatur, GA 30030; Atlanta—Public Library Ponce de Leon Branch, 980 Ponce de Leon Ave. NE., Atlanta, GA 30306; Atlanta—Public Library—Central Library, One Margaret Mitchell Square, Atlanta, GA 30303; Atlanta—Public Library—Kirkwood Branch, 11 Kirkwood Rd. NE., Atlanta, GA 30317; and, Emory University—Robert W. Woodruff Library, 540 Asbury Cir., Atlanta, GA 30322.

Paper and electronic copies can also be requested as instructed in the **ADDRESSES** section of this notice.

*Public Meeting:* HHS/CDC will hold a public meeting on Wednesday, January 29, 2014 at the HHS/CDC Edward R. Roybal Campus, Tom Harkin Global Communications Center (Building 19), Auditorium A, 1600 Clifton Road NE., Atlanta, GA 30333 to solicit public comments on the DEIS. Comments can be submitted in writing or verbally during the public meeting. The public meeting will consist of an ''Open House'' from 6:00 p.m. EST to approximately 7:00 p.m. EST, followed by a formal presentation and a formal comment period. Comment cards will be available at the Open House for those who wish to submit written comments for the record. Those wishing to make verbal comments will be asked to pre-register during the Open House portion of the public meeting. The formal presentations will begin at approximately 7:00 p.m. EST, at which time HHS/CDC will provide an overview of the NEPA process and the Master Plan proposed improvements and associated environmental impacts. The formal presentations will be followed by a formal public comment period.

A stenographer will record the formal portion of the public meeting. An American Sign Language Interpreter will also be available at both portions of the public hearing. A transcript of the meeting and all comments will be made available to the public and will be posted to the public docket at *www.regulations.gov,* identified by Docket No. CDC–2012–0013.

*Roybal Campus Security Guidelines.* The HHS/CDC Edward R. Roybal Campus is the headquarters of the U.S. Centers for Disease Control and Prevention and is located at 1600 Clifton Road NE., Atlanta, Georgia. The public hearing is being held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, please take into account the need to park and clear security. All visitors must enter the Roybal Campus through the entrance on Clifton Road; the guard force will direct visitors to the designated parking area. Visitors must present government issued photo identification (e.g., a valid Federal identification badge, state driver's license, state non-driver's identification card, or passport). Non-United States citizens must present a valid passport, visa, Permanent Resident Card, or other type of work authorization document. All persons entering the building must pass through a metal detector. Visitors will be issued a visitor's ID badge at the entrance to Building 19 and will be escorted in groups of 5 to 10 persons to the meeting room. All items brought to HHS/CDC are subject to inspection.

Dated: January 6, 2014.

**Tanja Popovic,**

*Deputy Associate Director for Science, Centers for Disease Control and Prevention.*

[FR Doc. 2014–00243 Filed 1–9–14; 8:45 am]

BILLING CODE 4163–18–P

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifiers: CMS–10501]**

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by *February 10, 2014:*

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 or Email: *OIRA_submission@omb.eop.gov*.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*
3. Call the Reports Clearance Office at (410) 786–1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786–1326.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Healthcare Fraud Prevention Partnership (HFPP): Data Sharing and Information Exchange; *Use:* Section 1128C(a)(2) of the Social Security Act (42 U.S.C. 1320a–7c(a)(2)) authorizes the Secretary and the Attorney General to consult with, and arrange for the sharing of data with representatives of health plans to establish a Fraud and Abuse Control Program as specified in Section 1128(C)(a)(1) of the Social Security Act. This is known as the Healthcare Fraud Prevention Partnership (HFPP). It was officially established by a Charter in fall 2012 and signed by HHS Secretary Sibelius and US Attorney General Holder. The HFPP is a joint initiative established by the Department of Health and Human Services (HHS) and Department of Justice (DOJ) to detect and prevent the prevalence of healthcare fraud through data and information-sharing and applying analytic capabilities by the public and private sectors. The HFPP collaboration provides a unique opportunity to transition from traditional ''pay and chase'' approaches for fraud detection and recovery towards a data-driven model for identifying and predicting aberrant activity. A central goal of the HFPP is to identify the optimal way to coordinate nationwide sharing of health care claims information, including aggregating claims and payment information from large public healthcare programs and private insurance payers. In addition to sharing data and information, the HFPP is focused on advancing analytics, training, outreach, education to support anti-fraud efforts and achieving its objectives, primarily through goal-oriented, well-designed fraud studies. *Form Number:* CMS–10501 (OCN: 0938–New); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 75; *Total Annual Responses:* 75; *Total Annual Hours:* 180,000. (For policy questions regarding this collection contact Johnalyn Lyles at 410–786–8410.)

Dated: January 6, 2014.

**Martique Jones,**

*Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2014–00188 Filed 1–9–14; 8:45 am]

**BILLING CODE 4120–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifiers: CMS–102 and 105, and CMS–10209]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by March 11, 2014.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and

recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786–1326.

**SUPPLEMENTARY INFORMATION:**

**Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

**CMS–102 and 105 Clinical Laboratory Improvement Amendments of 1988 (CLIA) Budget Workload Reports and Supporting Regulations**

**CMS–10209 Medicare Advantage Chronic Care Improvement Program (CCIP) and Quality Improvement (QI) Project Reporting Tools**

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

**Information Collections**

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments of 1988 (CLIA) Budget Workload Reports and Supporting Regulations; *Use:* We will use the collected information to determine the amount of Federal reimbursement for surveys conducted. Use of the information includes program evaluation, audit, budget formulation and budget approval. Form CMS–102 is a multi-purpose form designed to capture and record all budget and expenditure data. Form CMS–105 captures the annual projected CLIA workload that the State survey agency will accomplish. Our regional offices also use the information to approve the annual projected CLIA workload. The information is required as part of the section 1864 agreement with the state. *Form Numbers:* CMS–102 and CMS–105 (OCN: 0938–0599); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 50; *Total Annual Responses:* 50; *Total Annual Hours:* 4,500. (For policy questions regarding this collection contact Angela Stancel at 410–786–4876.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Advantage Chronic Care Improvement Program (CCIP) and Quality Improvement (QI) Project Reporting Tools; *Use:* Medicare Advantage Organizations (MAOs) are required to have an ongoing quality improvement (QI) program that meets our requirements and includes at least one chronic care improvement program (CCIP) and one QI Project. Every MAO must have a QI program that monitors and identifies areas where implementing appropriate interventions would improve patient outcomes and patient safety. Information collected using the CCIP and QIP reporting tools is an integral resource for oversight, monitoring, compliance, and auditing activities necessary to ensure high quality value-based health care for Medicare beneficiaries. *Form Number:* CMS–10209 (OCN: 0938–1023); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 1,904; *Total Annual Responses:* 1,904; *Total Annual Hours:* 28,560. (For policy questions regarding this collection contact Ellen Dieujuste at 410–786–2191).

Dated: January 6, 2014.

**Martique Jones,**

*Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2014–00195 Filed 1–9–14; 8:45 am]

BILLING CODE 4120–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–D–1630]**

### Draft Guidance for Industry on Qualification of Exacerbations of Chronic Pulmonary Disease Tool for Measurement of Symptoms of Acute Bacterial Exacerbation of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Qualification of Exacerbations of Chronic Pulmonary Disease Tool for Measurement of Symptoms of Acute Bacterial Exacerbation of Chronic Bronchitis in Patients with Chronic Obstructive Pulmonary Disease.'' This draft guidance provides a statement of qualification for the Exacerbations of Chronic Pulmonary Disease Tool (EXACT) patient-reported outcome instrument and summarizes the concept of interest and context of use (COU) for which the tool is qualified through the Center for Drug Evaluation and Research's (CDER's) drug development tool (DDT) qualification program. Qualification of the EXACT represents a conclusion that, within the stated COU, the instrument can be relied on to have a specific interpretation and application in drug development and regulatory review. This draft guidance is an attachment to the guidance for industry entitled ''Qualification Process for Drug Development Tools.''

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency

considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 10, 2014.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Elektra J. Papadopoulos, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6429, Silver Spring, MD 20993–0002, 301–796–0900.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Qualification of Exacerbations of Chronic Pulmonary Disease Tool for Measurement of Symptoms of Acute Bacterial Exacerbation of Chronic Bronchitis in Patients with Chronic Obstructive Pulmonary Disease.''

In March 2006, FDA issued the ''Critical Path Opportunities Report and List'', in which FDA described six key areas along the critical path to improved therapies and listed specific opportunities for advancement within these topic areas. The report noted that a new product development toolkit containing new scientific and technical methods was needed to improve the efficiency of drug development.

Innovative and improved DDTs can help streamline the drug development process, improve the chances for clinical trial success, and yield more information about a treatment and/or disease. DDTs include, but are not limited to, biomarkers and clinical outcome assessments (COAs). CDER has developed a formal process, the DDT qualification process, to work with developers of these tools to guide them as they refine the tools and rigorously evaluate them for use in the regulatory context. Once qualified, DDTs will be publicly available for use in any drug development program for the qualified COU. COA DDTs are developed and reviewed using this process when they are intended ultimately for use as primary or secondary endpoints in clinical trials designed to provide substantial evidence of treatment benefit. Upon qualification by CDER, a qualification statement is provided describing the concept of interest and COU for which the tool is qualified. This draft guidance describes the qualification statement for the EXACT, a COA DDT.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the qualification of the EXACT COA DDT. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

## III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: January 6, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–00259 Filed 1–9–14; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–D–0136]**

### Draft Guidance for Industry on Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antibacterial drugs for the treatment of community-acquired bacterial pneumonia (CABP). The science of clinical trial design and our understanding of this disease have advanced in recent years, and this draft guidance informs sponsors of our current recommendations for clinical development. FDA is specifically requesting comment on critical areas of scientific interest including the appropriate primary efficacy endpoints, the use of an intent-to-treat (ITT) population for the primary analysis population, and the use of antibacterial therapy by patients before participating in clinical trials. This draft guidance revises the draft guidance of the same name that published March 20, 2009.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 10, 2014.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Sumati Nambiar, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6232, Silver Spring, MD 20993–0002, 301–796–1300; or Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6244, Silver Spring, MD 20993–0002, 301–796–1300.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antibacterial drugs for the treatment of CABP. Issues in CABP clinical trials were discussed at a 2008 workshop cosponsored by FDA and professional societies. Recently, there have been additional discussions about clinical trial design and endpoints for CABP at several meetings of the Anti-Infective Drugs Advisory Committee. As a result of these public discussions, the science of clinical trial design and our understanding of endpoints and approaches to clinical development have advanced.

This revised draft guidance supersedes the draft guidance published in March 2009 and informs sponsors of the changes in our recommendations. Although we acknowledge the challenges in conducting clinical trials of investigational antibacterial drugs in CABP, this revised draft guidance incorporates changes intended to attain a greater degree of balance between the practicability of conducting CABP clinical trials and the trial procedures needed for a scientifically sound and interpretable trial. We are specifically requesting input from the public on these changes for consideration before finalizing the guidance. Specifically, the changes from the 2009 draft guidance include:

- A description of two potential primary efficacy endpoints for CABP clinical trials: (1) Improvement in patient symptoms early in the course of therapy for CABP (at day 3 to day 5) and (2) all-cause mortality.
- A justification for a noninferiority margin based on clinical responses observed early in the course of therapy, as well as a justification for all-cause mortality as a primary efficacy endpoint.
- Suggestions for efficacy analyses based on: (1) An overall ITT population and (2) a microbiological intent-to-treat population consisting of those patients who have a documented bacterial pathogen known to cause CABP.
- An approach for accommodating enrollment of patients who have received prior antibacterial therapy, provided certain constraints are met.

Issuance of this guidance fulfills a portion of the requirements of Title VIII, section 804, of the Food and Drug Administration Safety and Innovation Act (Publ. L. 112–144), which requires FDA to ''review and, as appropriate, revise not fewer than 3 guidance documents per year . . . for the conduct of clinical trials with respect to antibacterial and antifungal drugs. . . .''

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014 and the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

## III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

## IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: January 6, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–00255 Filed 1–9–14; 8:45 am]

BILLING CODE 4160–01–P

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. FDA–1975–N–0355 (Formerly 75N–0185), FDA–1976–N–0272 (Formerly 76N–0056), FDA–1976–N–0344 (Formerly 76N–0057), FDA–1978–N–0701 (Formerly 78N–0070), FDA–1979–N–0224 (Formerly 79N–0169), and FDA–1983–N–0297 (Formerly 83N–0030); DESI 1626, 3265, 12283, and 50213]**

## Drugs for Human Use; Drug Efficacy Study Implementation; Certain Prescription Drugs Offered for Various Indications; Final Resolution of Hearing Requests Under Dockets

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that all outstanding hearing requests pertaining to Docket Nos. FDA–1975–N–0355 (formerly 75N–0185) (DESI 3265); FDA–1976–N–0272 (formerly 76N–0056), FDA–1976–N–0344 (formerly 76N–0057), and FDA–1978–N–0701 (formerly 78N–0070) (DESI 1626); FDA–1979–N–0224 (formerly 79N–0169) (DESI 12283); and FDA–1983–N–0297 (formerly 83N–0030) (DESI 50213) have been withdrawn. Shipment in interstate commerce of any of the products identified in these dockets, or any identical, related, or similar (IRS) product to the products in these dockets, that is not the subject of an approved new drug application (NDA) or abbreviated new drug application (ANDA) (other than an over-the-counter (OTC) product that complies with an applicable OTC monograph) is unlawful as of the effective date of this notice.

**DATES:** *Effective Date:* This notice is effective January 10, 2014.

**ADDRESSES:** All communications in response to this notice should be identified with the appropriate docket number and directed to Sakineh Walther, Division of Prescription Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5242, Silver Spring,

MD 20993–0002, *sakineh.walther@fda.hhs.gov.*

**FOR FURTHER INFORMATION CONTACT:** Sakineh Walther, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5242, Silver Spring, MD 20993–0002, 301–796–3349, *sakineh.walther@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

In a notice published in the **Federal Register** of July 24, 2012 (77 FR 43337) (the July 24, 2012, notice), FDA described the outstanding hearing requests pertaining to, among others, Docket Nos. FDA–1975–N–0355 (formerly 75N–0185) (DESI 3265); FDA–1976–N–0272 (formerly 76N–0056), FDA–1976–N–0344 (formerly 76N–0057), and FDA–1978–N–0701 (formerly 78N–0070) (DESI 1626); FDA–1979–N–0224 (formerly 79N–0169) (DESI 12283); and FDA–1983–N–0297 (formerly 83N–0030) (DESI 50213) established under the Agency's Drug Efficacy Study Implementation (DESI) program. In the July 24, 2012, notice, FDA offered an opportunity for companies with outstanding hearing requests under those dockets to withdraw or affirm their outstanding hearing requests.

### *A. Docket No. FDA–1975–N–0355 (Formerly 75N–0185) (DESI 3265)*

In 1971, FDA published DESI efficacy findings for single-ingredient anticholinergic drugs for oral or injectable use containing dicyclomine hydrochloride (HCl), among other ingredients (36 FR 11754, June 18, 1971). In a notice published on November 11, 1975 (40 FR 52644), FDA determined that the June 18, 1971, **Federal Register** notice should not have included drugs containing certain specified ingredients, including dicyclomine HCl, because the drugs containing those ingredients were not anticholinergic drugs (40 FR 52644 at 52648). Elsewhere in the **Federal Register** of November 11, 1975 (40 FR 52649), FDA published a notice concluding that dicyclomine HCl products, among other products covered by the notice, were less than effective and offering an opportunity for hearing regarding these drugs.

On June 22, 1984, in response to the submission of data, FDA published a followup notice regarding single entity dicyclomine HCl products (49 FR 25681). In that notice, FDA concluded that such products were effective for the treatment of functional bowel/irritable bowel syndrome (irritable colon, spastic colon, and mucous colitis) and established conditions for their marketing and labeling (49 FR 25681 at 25683 and 25684). The Agency also found, however, that the products were lacking substantial evidence of effectiveness for use in the treatment of acute enterocolitis or infant colic (49 FR 25681 at 25684) and offered an opportunity for hearing.

At the time of the July 24, 2012, notice, there was one outstanding hearing request under this docket filed by Merrell-National Laboratories, 110 Amity Rd., Cincinnati, OH 45215, regarding Bentyl Capsules (NDA 7–409), Bentyl Injection (NDA 8–370), Bentyl Syrup (NDA 7–961), and Dactil Tablets (NDA 8–907). FDA believes Sanofi-Aventis U.S. to be the successor-in-interest to Merrell-National Laboratories, but received no response to its attempt to contact Sanofi-Aventis U.S. regarding this hearing request in September 2011. In the July 24, 2012, notice, FDA provided the company an opportunity to affirm or withdraw its hearing request. Requests that were not affirmed within 30 days of that notice were to be deemed by FDA to be withdrawn.

### *B. Docket Nos. FDA–1976–N–0272 (Formerly 76N–0056), FDA–1976–N–0344 (Formerly 76N–0057), and FDA–1978–N–0701 (Formerly 78N–0070) (DESI 1626)*

In 1972, FDA classified certain combination drug products containing a xanthine derivative as lacking substantial evidence of effectiveness for some labeled indications and possibly effective for other labeled indications (37 FR 14895, July 26, 1972). As described in a **Federal Register** notice of February 29, 1984 (49 FR 7454), FDA subsequently handled these products in three groups:

Group 1: Combinations containing 2 grains or less of a xanthine derivative, ephedrine, and 8 milligrams (mg) or less of phenobarbital (Docket No. FDA–1976–N–0344 (formerly 76N–0057));

Group 2: Combinations containing more than 2 grains of xanthine derivative, more than 8 mg of phenobarbital, and/or an ingredient not considered as part of the OTC drug review (Docket No. FDA–1976–N–0272 (formerly 76N–0056)); and

Group 3: Combinations containing theophylline, ephedrine, and hydroxyzine HCl (Docket No. FDA–1978–N–0701 (formerly 78N–0070)).

With respect to the products in Group 2, a notice of opportunity for hearing was published on April 9, 1976 (41 FR 15051). No hearing was requested, and approval of applications for products covered by Docket No. FDA–1976–N–0272 (formerly 76N–0056) (DESI 1626) were withdrawn by notice in the **Federal Register** published October 7, 1977 (42 FR 54620).

With respect to the products in Group 3, FDA granted a hearing in response to requests (49 FR 36443, September 17, 1984). The hearing requests were subsequently withdrawn, and approval of applications for products covered by Docket No. FDA–1078–N–0701 (formerly 78N–0070) (DESI 1626) were withdrawn by notice in the **Federal Register** published July 8, 1998 (63 FR 36923).

With respect to the products in Group 1, in 1976, FDA granted temporary permission for the products to remain on the market because similar products had been marketed OTC in the past and were then undergoing review in the Over-the-Counter Drug Study (41 FR 15053, April 9, 1976). In 1984, FDA amended the April 1976 notice to include its analysis of new information regarding combination products containing a xanthine derivative (49 FR 7454, February 29, 1984). Based on its analysis of the new information, FDA concluded that there is a lack of substantial evidence: (1) That each ingredient contributes to the claimed effect of such combination drug products and (2) that the dosage of each component is such that the combinations are safe and effective for a significant patient population (49 FR 7454). Therefore, FDA proposed in the 1984 notice to withdraw approval of the applications for combination products containing a xanthine derivative and offered an opportunity for hearing regarding its proposal.

At the time of the July 24, 2012, notice, there was one outstanding hearing request under Docket No. FDA–1976–N–0344 (formerly 76N–0057) filed by William P. Poythress & Co, Inc., 16 N. 22nd St., P.O. Box 26946, Richmond, VA 23261, regarding an unidentified product containing a xanthine derivative, ephedrine, and 8 mg or less of phenobarbital. FDA was unable to find current contact information for William P. Poythress & Co, Inc. In the July 24, 2012, notice FDA provided this company an opportunity to withdraw or affirm its hearing request. Requests that were not affirmed within 30 days of that notice were to be deemed by FDA to be withdrawn.

### *C. Docket No. FDA–1979–N–0224 (Formerly 79N–0169) (DESI 12283)*

In 1979, FDA announced its DESI conclusions regarding the effectiveness of chlorthalidone for the treatment of hypertension and certain types of edema (44 FR 54124, September 18, 1979).

Specifically, FDA determined that there was substantial evidence to support the effectiveness of the 25- and 50-mg strengths for use in hypertension and edema, but that there was no longer justification for the 100-mg dosage form of chlorthalidone because of safety concerns at that dosage level (44 FR 54124 at 54126). In the 1979 notice, FDA proposed to withdraw approval of the 100-mg strength and offered an opportunity for hearing regarding its proposal.

At the time of the July 24, 2012, notice, there was one outstanding hearing request under this docket filed by Generics International Division of Apotex, Inc., 2400 North Commerce Pkwy., Suite 400, Weston, FL 33326, regarding chlorthalidone. In the July 24, 2012, notice, FDA provided this company an opportunity to withdraw or affirm its hearing request. Requests that were not affirmed within 30 days of that notice were to be deemed by FDA to be withdrawn.

*D. Docket No. FDA–1983–N–0297 (Formerly 83N–0030) (DESI 50213)*

Under Docket No. FDA–1983–N–0297 (formerly 83N–0030), FDA evaluated the evidence of effectiveness for certain fixed-combination drugs containing antibiotics and sulfonamides and determined that these products lacked substantial evidence of effectiveness (34 FR 6008, April 2, 1969). In the April 1969 **Federal Register** notice, FDA proposed to revoke provisions for certification of these products, and offered interested persons 30 days to submit data concerning the proposal. Data submitted in response to the April 1969 notice did not provide substantial evidence of effectiveness, so FDA amended the antibiotic regulations on June 30, 1970, by revoking provisions for the certification of these drugs (35 FR 10587, June 30, 1970). The order was to become effective in 40 days and allowed 30 days for interested persons to file objections and request a hearing. The time for responding to the June 1970 order was subsequently extended until August 17, 1970 (35 FR 12653, August 8, 1970).

In response to the June 1970 order, Pfizer Inc. submitted data regarding its affected product, Urobiotic 250 Capsules, and requested a hearing. Despite the filing of timely objections, the amendments were inadvertently not stayed, and succeeding codifications of the antibiotic regulations did not explicitly provide for certification of Urobiotic 250 Capsules. However, FDA permitted Pfizer to continue distribution of its product pending resolution of the firm's hearing request. In July 2010, Pfizer voluntarily withdrew its application for Urobiotic (see 75 FR 42455, July 21, 2010).

At the time of the July 24, 2012, notice, there was one outstanding hearing request under this docket filed by Pfizer, Inc., 235 East 42nd St., New York, NY 10017, regarding Urobiotic. As noted in the previous paragraph, the product itself was withdrawn, but FDA attempted to contact the company to verify that it no longer wished to pursue its hearing request. The company did not respond, and in the July 24, 2012, notice, FDA provided this company an opportunity to withdraw or affirm its hearing request. Requests that were not affirmed within 30 days of that notice were to be deemed by FDA to be withdrawn.

## II. Resolution of Hearing Requests Pertaining to Dockets Subject to This Notice

The time period for responding to the July 24, 2012, notice has elapsed, and no companies with outstanding hearing requests pertaining to the dockets listed in this document responded to the notice. Because no outstanding hearing requests relating to these dockets were affirmed in response to the July 24, 2012, notice (or in response to FDA's previous attempts to contact companies with outstanding hearing requests), all of the outstanding hearing requests pertaining to Docket Nos. FDA–1975–N–0355 (formerly 75N–0185) (DESI 3265); FDA–1976–N–0272 (formerly 76N–0056), FDA–1976–N–0344 (formerly 76N–0057), and FDA–1978–N–0701 (formerly 78N–0070) (DESI 1626); FDA–1979–N–0224 (formerly 79N–0169) (DESI 12283); and FDA–1983–N–0297 (formerly 83N–0030) (DESI 50213) are deemed to be withdrawn.

Effective as of the date of this notice, it is unlawful to introduce into interstate commerce any of the products identified in any of the dockets included in this notice, or any IRS product to any product identified in these dockets, that is not the subject of an approved NDA or ANDA. Any person who wishes to determine whether a specific product is covered by this notice should write to the Center for Drug Evaluation and Research (see **ADDRESSES**).

## III. Discontinued Products

Some firms may have previously discontinued manufacturing or distributing products covered by this notice without removing them from the listing of their products under section 510(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(j)). Other firms may discontinue manufacturing or distributing listed products in response to this notice. Firms that wish to notify the Agency of product discontinuation should send a letter identifying the discontinued product(s), including the National Drug Code number(s), and stating that the manufacturing and/or distribution of the product(s) has (have) been discontinued. The letter should be sent electronically to Sakineh Walther (see **ADDRESSES**).

Firms should also electronically update the listing of their products under section 510(j) of the FD&C Act to reflect discontinuation of products covered by this notice. Firms should be aware that, after the effective date of this notice, FDA intends to take enforcement action without further notice against any firm that manufactures or ships in interstate commerce any unapproved product covered by this notice.

Dated: January 6, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–00256 Filed 1–9–14; 8:45 am]

**BILLING CODE 4160–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–1658]**

### Characterizing and Communicating Uncertainty in the Assessment of Benefits and Risks in Drug Regulatory Decision-Making; Public Workshop; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of Public Workshop; request for public comments.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the following workshop convened by the Institute of Medicine (IOM): ''Characterizing and Communicating Uncertainty in the Assessment of Benefits and Risks in Drug Regulatory Decision-Making.'' The purpose of the workshop is twofold: To explore potential approaches to addressing and communicating uncertainty and to identify key considerations on developing, evaluating, and incorporating potential approaches for addressing uncertainty into the assessment of benefits and risks in the human drug review process. The format of the meeting consists of a series of presentations on topics related to uncertainty in the assessment of benefits

and risks, followed by a discussion on those topics with invited panelists and audience members. This workshop satisfies an FDA commitment that is part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V).

**DATES:** The public workshop will be held on February 12, 2014, from 8:30 a.m. to 4:30 p.m. and February 13, 2014, from 8:30 a.m. to 3:30 p.m. Registration to attend the public workshop must be received by January 31, 2014. See the **SUPPLEMENTARY INFORMATION** section for information on how to register for the workshop. Submit either electronic or written comments by March 14, 2014.

**ADDRESSES:** The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, Rm. 1503A, Silver Spring, MD 20993–0002. Entrance for public workshop attendees (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify all comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Sara Eggers, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Rm. 1166, Silver Spring, MD 20993–0002, 301–796–4904, FAX: 301–847–8443, email: *sara.eggers@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144). Title I of FDASIA reauthorizes PDUFA and provides FDA with the user fee resources necessary to maintain an efficient review process for human drug and biological products. The reauthorization of PDUFA includes performance goals and procedures for the Agency that represents FDA's commitments during fiscal years 2013–2017. These commitments are fully described in the document entitled ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017'' (PDUFA Goals Letter), available on FDA's Web site at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf.*

Section X of the PDUFA Goals Letter, entitled ''Enhancing Benefit-Risk Assessment in Regulatory Decision-Making,'' includes development of a plan to further develop and implement a structured approach to benefit-risk assessment in the human drug review process. As part of this enhancement, FDA committed to holding two public workshops on benefit-risk considerations from the regulator's perspective that will begin by the first quarter of fiscal year 2014. The public workshop announced in this notice will fulfill the first of the two workshop commitments.

As part of its commitment, FDA has published the ''Structured Approach to Benefit-Risk Assessment in Drug Regulatory Decision-Making: Draft PDUFA V Implementation Plan,'' available on FDA's Web site at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM329758.pdf.* In this plan, FDA identified as an area of further development the exploration of structured approaches to evaluate and communicate the uncertainty in the assessment of benefits and risks. FDA's human drug regulatory decisions are informed by an extensive body of evidence on the safety and efficacy of a drug product. In many cases, this evidence is subject to uncertainty arising from many sources. One example is the uncertainty in the degree to which premarket clinical trial data translates to the postmarket setting after the drug is approved and used in a much wider patient population. Another example is uncertainty about a potential safety signal that emerges in the postmarket setting, where the basis for the finding comes from multiple evidence sources of varying levels of rigor. Drawing conclusions in the face of uncertainty can be a complex and challenging task. Furthermore, being explicit about the impact of uncertainty on decision-making is an important part of communicating regulatory decisions.

## II. Purpose and Scope of the Workshop

This 2-day public workshop is being convened by IOM. The public workshop will explore more systematic and structured approaches to evaluate and communicate: (1) The sources of uncertainty in the assessment of benefits and risks and (2) their implications on human drug regulatory decisions. Specifically, the workshop will explore potential analytical and communication approaches to addressing and communicating uncertainty and identify key considerations on developing, evaluating, and incorporating potential approaches for addressing uncertainty into the assessment of benefits and risks in the human drug review process. This public workshop will consider the entire drug development life cycle, including premarket drug review and postmarket safety surveillance. The format of the meeting consists of a series of presentations on topics related to uncertainty in the assessment of benefits and risks, followed by a discussion on those topics with invited panelists and audience members.

## III. Attendance and Registration

FDA's Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Persons interested in attending the public workshop must register online by January 31, 2014. To register for the public workshop, please visit FDA's workshop Web site at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm378861.htm.* Early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, the number of participants from each organization may be limited based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the workshop will be based on space availability. If you need special accommodations because of disability, please contact Sara Eggers (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the workshop. More information will be made available on FDA's workshop Web site at least 5 days before the workshop date.

A live Webcast of this workshop will be viewable on FDA's workshop Web site at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm378861.htm* on the day of the workshop. A video recording of the workshop will be available on FDA's workshop Web site approximately 1 week following the workshop. IOM will independently prepare a summary of the workshop, and the summary will be available on FDA's workshop Web site approximately 10 months following the workshop.

## IV. Comments

Regardless of attendance at the public workshop, interested persons may submit either electronic comments or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of

comments. Identify comments with the docket number found in brackets in the heading of this document. To ensure consideration, submit comments by March 14, 2014. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: January 6, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–00258 Filed 1–9–14; 8:45 am]

**BILLING CODE 4160–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–1485]**

### Unapproved and Misbranded Oral and Injectable Drugs Labeled for Prescription Use Containing Codeine Sulfate, Codeine Phosphate, or Dihydrocodeine Bitartrate; Enforcement Action Dates

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing its intention to take enforcement action against unapproved and misbranded oral and injectable drug products labeled for prescription use and containing codeine sulfate, codeine phosphate, or dihydrocodeine bitartrate, and against persons who manufacture or cause the manufacture or distribution of such products in interstate commerce. Prescription drug products containing these ingredients pose serious risks, including the risk of addiction, and some unapproved drug products may lack warnings or other information required in the labeling of approved drug products that is important for safe use. These unapproved drug products compete with approved drug products and thus pose a direct challenge to the drug approval system. This document covers the following unapproved drug products labeled for prescription use: Single-ingredient codeine sulfate oral tablets and solutions, single-ingredient codeine phosphate injection products, fixed-dose combination products containing codeine phosphate, and fixed-dose combination products containing dihydrocodeine bitartrate. A new drug containing codeine sulfate, codeine phosphate, or dihydrocodeine bitartrate requires an approved new drug application (NDA) or abbreviated new drug application (ANDA) to be legally marketed.

**DATES:** This document is effective January 10, 2014. For information about enforcement dates, see the **SUPPLEMENTARY INFORMATION**, section IV.

**ADDRESSES:** All communications in response to this document should be identified with Docket No. FDA–2013–N–1485 and directed to the appropriate office listed in this **ADDRESSES** section:

*Applications under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(b)):* Division of Anesthesia, Analgesia and Addiction Products (for products with analgesic indications) or Division of Pulmonary, Allergy, and Rheumatology Products (for products with antitussive indications), Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD 20993–0002.

*Applications under section 505(j) of the FD&C Act:* Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.

*All other communications:* Astrid Lopez-Goldberg, Office of Unapproved Drugs and Labeling Compliance, Division of Prescription Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5185, Silver Spring, MD 20993–0002.

**FOR FURTHER INFORMATION CONTACT:** Astrid Lopez-Goldberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5185, Silver Spring, MD 20993–0002, 301–796–3485, *Astrid.LopezGoldberg@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

Codeine is an opioid used primarily as an analgesic to relieve pain or as an antitussive to treat coughs. Codeine sulfate and codeine phosphate are different salts of codeine, generally also for analgesic or antitussive use. Dihydrocodeine bitartrate is a chemical derivative of codeine and an opioid pain reliever that produces effects similar to those of codeine.

Side effects are similar among all opioids and include light-headedness, dizziness, drowsiness, headache, fatigue, sedation, sweating, nausea, vomiting, constipation, itching, and skin reactions. Serious adverse effects are respiratory depression, resulting in a slow breathing rate, and decreased blood pressure. Multiple active ingredients (including acetaminophen, aspirin, butalbital, caffeine, carisoprodol, promethazine, or phenylephrine) may be marketed in combination with codeine phosphate or dihydrocodeine bitartrate. Some of these fixed-dose combination products include more than one sedating component.

*Single-ingredient products containing codeine,* such as codeine sulfate oral tablets and solutions, and codeine phosphate injection products, are schedule II narcotics (§ 1308.12 (21 CFR 1308.12)) under the Controlled Substances Act (21 U.S.C. 801 et seq.). Single-ingredient prescription codeine sulfate oral tablets and a single-ingredient prescription codeine sulfate oral solution are approved for the relief of mild to moderately severe pain. On October 13, 2009, the Agency issued four warning letters to companies manufacturing and/or marketing unapproved prescription codeine sulfate oral tablets.[1] However, FDA is aware of at least one unapproved prescription codeine sulfate oral tablet that is still listed with FDA's Drug Registration and Listing System. Although FDA is unaware of any unapproved single-ingredient codeine phosphate injection products on the market at this time, such products were on the market as recently as 2010.

*Fixed dose combination products containing codeine phosphate* are placed on different schedules under the Controlled Substances Act depending on their use:

- Fixed-dose combination products containing codeine, which are generally used as analgesics in pediatric and adult patients, are typically schedule III or schedule V drugs under the Controlled Substances Act depending on the amount of codeine contained in the drug (§§ 1308.13 and 1308.15 (21 CFR 1308.13 and 1308.15)).[2] FDA is aware of a safety concern with an unapproved fixed-dose combination product containing codeine phosphate and acetaminophen that is labeled for analgesic use. We note that this product does not have the Boxed Warning for liver toxicity that would be required if this were an approved product (76 FR 2691, January 14, 2011).

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[1] Available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm238675.htm#codeine_sulfate.*

[2] We note that at dosages exceeding the maximum identified in § 1308.13 these fixed dose combination drug products would be Schedule II.

• Over-The Counter (OTC) Monograph compliant fixed-dose combination products containing codeine (21 CFR 341.14) for use as antitussives are schedule V drugs under the Controlled Substances Act (§ 1308.15). Also in schedule V are prescription fixed-dose combination drug products containing codeine phosphate that are approved to treat coughs in children 6 years old and older. FDA is aware of an unapproved prescription fixed dose combination product containing codeine phosphate that is labeled for antitussive use in children as young as 3 years old.

• Fixed dose combination products containing dihydrocodeine bitartrate are schedule III or schedule V drugs under the Controlled Substances Act, depending on the amount of dihydrocodeine contained in the drug (§§ 1308.13 and 1308.15(c)(2)).[3] There are prescription dihydrocodeine fixed dose combination products that have approval for the relief of moderate to moderately severe pain. FDA is aware of unapproved prescription dihydrocodeine fixed-dose combination products that are labeled as antitussives.

## II. Safety Concerns With Unapproved New Drugs

Because marketed unapproved new drug products have not been through FDA's approval process, there may be safety risks associated with them. Some unapproved drug product labeling omits or modifies safety warnings or other information that is important to ensure safe use, such as drug interactions or potential adverse experiences (e.g., the liver toxicity Boxed Warning discussed in section I of this document). Similarly, as noted in section I, FDA is aware of an unapproved prescription fixed-dose combination product that is inappropriately labeled for children as young as 3 years of age.

Furthermore, some of the products covered in this action include acetaminophen at doses higher than 325 milligrams (mg) in combination with codeine sulfate or dihydrocodeine bitartrate. FDA has taken steps to reduce the risk of acetaminophen-related severe liver injury by limiting the maximum amount of acetaminophen in approved oral prescription products to 325 mg per tablet, capsule, or other dosage unit and revising required warning information (76 FR 2691, January 14, 2011). Severe liver injury can lead to liver failure, liver transplant, and death. Limiting the amount of acetaminophen in oral prescription drug products increases the margin of safety for persons who mistakenly take too many doses or use more than one acetaminophen-containing product at the same time.[4]

Another concern with unapproved prescription fixed-dose combination products containing codeine sulfate or dihydrocodeine bitartrate is that they may include more than one sedating component, which may result in increased sedation or drowsiness. With an unapproved drug product, FDA does not have the opportunity to review the drug product before it is marketed to ensure the combination of ingredients is safe and that the labeling contains adequate dosing information and appropriate warnings and precautions.

Finally, even the expected risks associated with use of drug products containing codeine sulfate, codeine phosphate, or dihydrocodeine bitartrate are potentially greater for unapproved drug products because the quality, safety, and efficacy of unapproved formulations have not been demonstrated to FDA. For example, the ingredients and bioavailability of unapproved prescription drug products have not been submitted for FDA review, nor has FDA had the opportunity to assess the adequacy of their chemistry, manufacturing, and control specifications. Unapproved drug products have unapproved labeling that may not contain appropriate dosing and warning information.

## III. Legal Status of Products Identified in This Document

FDA has reviewed the publicly available scientific literature for unapproved prescription single-ingredient codeine sulfate oral tablets, single-ingredient codeine sulfate oral solutions, single-ingredient codeine phosphate injection products, fixed-dose combination products containing codeine phosphate, and fixed-dose combination products containing dihydrocodeine bitartrate. In no case did FDA find literature sufficient to support a determination that any of these prescription products are generally recognized as safe and effective. Therefore, these prescription drug products are ''new drugs'' within the meaning of section 201(p) of the FD&C Act (21 U.S.C. 321(p)), and they require approved NDAs or ANDAs to be legally marketed.

The unapproved drug products covered by this document are labeled for prescription use. Prescription drugs are defined under section 503(b)(1)(A) of the FD&C Act (21 U.S.C. 353(b)(1)(A)) as drugs that, because of toxicity or other potentially harmful effect, are not safe to use except under the supervision of a practitioner licensed by law to administer such drugs. If an unapproved drug product covered by this document meets the definition of ''prescription drug'' in section 503(b)(1)(A) of the FD&C Act, adequate directions cannot be written for it so that a layman can use the product safely for its intended uses (21 CFR 201.5). Consequently, it is misbranded under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) in that it fails to bear adequate directions for use. An approved prescription drug is exempt from the requirement in section 502(f)(1) of the FD&C Act that it bear adequate directions for use if, among other things, it bears the NDA-approved labeling (21 CFR 201.100(c)(2) and 201.115). Because the unapproved prescription drug products subject to this document do not have approved applications with approved labeling, they fail to qualify for the exemptions to the requirement that they bear ''adequate directions for use,'' and are misbranded under section 502(f)(1) of the FD&C Act.

If a drug covered by this document is labeled as a prescription drug but does not meet the definition of ''prescription drug'' under section 503(b)(1)(A) of the FD&C Act, the drug is misbranded under section 503(b)(4)(B). Additionally, the final OTC drug monograph at part 341 (21 CFR part 341), ''Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Drug Products'' (the final OTC Cold Cough monograph), permits the use of codeine, codeine sulfate, and codeine phosphate as active ingredients for antitussive use, in the amounts and under the conditions specified in the final OTC Cold Cough monograph (see § 341.14). The final OTC Cold Cough monograph is the only monograph that permits OTC use of the active ingredients covered by this document. If a product covered by this document does not meet the definition of ''prescription drug'' under section 503(b)(1)(A) of the FD&C Act, in addition to being misbranded, unless the product was reformulated and labeled to meet all the requirements of the final OTC Cold Cough monograph, the product would still require an approved NDA or ANDA in order to be legally marketed.[5]

[3] We note that at dosages exceeding the maximum identified in § 1308.13 these fixed-dose combination drug products would be Schedule II.

[4] 76 FR 2691; for additional regulatory and safety information concerning acetaminophen, see *http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm239871.htm.*

[5] In addition to any other applicable requirements, firms that manufacture OTC drugs must comply with the labeling requirements at 21 CFR 201.66. Furthermore, States may have

## IV. Notice of Intent To Take Enforcement Action

Although not required to do so by the Administrative Procedure Act, the FD&C Act (or any rules issued under its authority), or for any other legal reason, FDA is providing this notice to persons[6] who are marketing the following unapproved and misbranded drugs labeled for prescription use: Single-ingredient codeine sulfate oral tablets, single-ingredient codeine sulfate oral solutions, single-ingredient codeine phosphate injection products, fixed-dose combination products containing codeine phosphate, and fixed-dose combination products containing dihydrocodeine bitartrate. The Agency intends to take enforcement action against such products and those who manufacture them or cause them to be manufactured or shipped in interstate commerce.

Manufacturing or shipping the drug products covered by this document can result in enforcement action, including seizure, injunction, or other judicial or administrative proceeding. Consistent with policies described in the Agency's guidance entitled ''Marketed Unapproved Drugs—Compliance Policy Guide'' (Marketed Unapproved Drugs CPG) (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070290.pdf*), the Agency does not expect to issue a warning letter or any other further warning to firms marketing drug products covered by this document before taking enforcement action. The Agency also reminds firms that, as stated in the Marketed Unapproved Drugs CPG, any unapproved drug marketed without a required approved application is subject to Agency enforcement action at any time. The issuance of this document does not in any way obligate the Agency to issue similar documents (or any document) in the future regarding marketed unapproved drugs (see Marketed Unapproved Drugs CPG, p. 5).

As described in the Marketed Unapproved Drugs CPG, the Agency may, at its discretion, identify a period of time during which the Agency does not intend to initiate an enforcement action against a currently marketed unapproved drug solely on the grounds that it lacks an approved application under section 505 of the FD&C Act. With respect to drug products covered by this document, the Agency intends to exercise its enforcement discretion for only a limited period of time because there are safety issues with respect to the products covered by this document, and numerous marketed products that have approved applications or comply with an OTC drug final monograph are offered to treat the same or similar indications. Therefore, the Agency intends to implement this document as follows.

For the effective date of this document, see the **DATES** section of this document. Any drug product covered by this document that a company (including a manufacturer or distributor) began marketing after September 19, 2011, is subject to immediate enforcement action. For products covered by this document that a company (including a manufacturer or distributor) began marketing on or before September 19, 2011, FDA intends to take enforcement action against any such product that is not listed with the Agency in full compliance with section 510 of the FD&C Act (21 U.S.C. 360) before January 9, 2014, and is manufactured, shipped, or otherwise introduced or delivered for introduction into interstate commerce by any person on or after January 9, 2014. FDA also intends to take enforcement action against any drug product covered by this document that is listed with FDA in full compliance with section 510 of the FD&C Act but is not being commercially used or sold[7] in the United States before January 9, 2014, and that is manufactured, shipped, or otherwise introduced or delivered for introduction into interstate commerce by any person on or after January 10, 2014.

However, for drug products covered by this document that a company (including a manufacturer or distributor) (1) began marketing in the United States on or before September 19, 2011, (2) are listed with FDA in full compliance with section 510 of the FD&C Act before January 9, 2014 (''currently marketed and listed''), and (3) are manufactured, shipped, or otherwise introduced or delivered for introduction into interstate commerce by any person on or after January 10, 2014, the Agency intends to exercise its enforcement discretion as follows: FDA intends to initiate enforcement action regarding any such currently marketed and listed product that is manufactured on or after February 24, 2014, or that is shipped on or after April 10, 2014. Further, FDA intends to take enforcement action against any person who manufactures or ships such products after these dates. The purpose of these enforcement timeframes is to allow manufacturers and distributors to deplete their current inventory and ensure a smooth transition for consumers. Any person who has submitted or submits an application for a drug product covered by this document, but has not received approval, must comply with this document.

The Agency, however, does not intend to exercise its enforcement discretion as outlined previously if the following apply: (1) A manufacturer or distributor of drug products covered by this document is violating other provisions of the FD&C Act, including, but not limited to, violations related to FDA's current good manufacturing practices, adverse drug event reporting, labeling, or misbranding requirements other than those identified in this document or (2) it appears that a firm, in response to this document, increases its manufacture or interstate shipment of drug products covered by this document above its usual volume during these periods.[8]

Nothing in this document, including FDA's intent to exercise its enforcement discretion, alters any person's liability or obligations in any other enforcement action, or precludes the Agency from initiating or proceeding with enforcement action in connection with any other alleged violation of the FD&C Act, whether or not related to a drug product covered by this document. Similarly, a person who is or becomes enjoined from marketing unapproved or misbranded drugs may not resume marketing of such products based on FDA's exercise of enforcement discretion as described in this document.

Drug manufacturers and distributors should be aware that the Agency is exercising its enforcement discretion as described previously only in regard to drug products covered by this document that are marketed under a National Drug Code (NDC) number listed with the

restrictions on the sale of OTC products that contain codeine.

[6] The term ''person'' includes individuals, partnerships, corporations, and associations (21 U.S.C. 321(e)).

[7] For the purpose of this document, the phrase ''commercially used or sold'' means that the product has been used in a business or activity involving retail or wholesale marketing and/or sale.

[8] If FDA finds it necessary to take enforcement action against a product covered by this document, the Agency may take action relating to all of the defendant's other violations of the FD&C Act at the same time. For example, if a firm continues to manufacture or market a product covered by this document after the applicable enforcement date, to preserve limited agency resources, FDA may at the same time take enforcement action relating to all of the firm's unapproved drugs that require applications (see, e.g., *United States* v. *Sage Pharmaceuticals,* 210 F. 3d 475, 479–480 (5th Cir. 2000) (permitting the Agency to combine all violations of the FD&C Act in one proceeding, rather than taking action against multiple violations of the FD&C Act in ''piecemeal fashion'')).

Agency in full compliance with section 510 of the FD&C Act before January 9, 2014. As previously stated, drug products covered by this document that are currently marketed but not listed with the Agency on the date of this document must, as of the effective date of this document, have approved applications before their shipment in interstate commerce. Moreover, any person or firm that has submitted or submits an application but has yet to receive approval for such products is still responsible for full compliance with this document.

**V. Discontinued Products**

Some firms may have previously discontinued manufacturing or distributing products covered by this document without removing them from the listing of their products under section 510(j) of the FD&C Act. Other firms may discontinue manufacturing or distributing listed products in response to this document. Firms are required to electronically update the listing of their products under section 510(j) of the FD&C Act to reflect discontinuation of unapproved products covered by this document (21 CFR 207.21(b)). Questions on electronic drug listing updates should be sent to: *eDRLS@fda.hhs.gov*. In addition to the required update, firms can also notify the Agency of product discontinuation by sending a letter, signed by the firm's chief executive officer and fully identifying the discontinued product(s), including the product NDC number(s), and stating that the manufacturing and/or distribution of the product(s) has (have) been discontinued. The letter should be sent electronically to Astrid Lopez-Goldberg (see **ADDRESSES**). FDA plans to rely on its existing records, including its drug listing records, the results of any subsequent inspections, or other available information when it targets violations for enforcement action.

**VI. Reformulated Products**

FDA cautions firms against reformulating their products into unapproved new drugs without codeine sulfate, codeine phosphate, or dihydrocodeine bitartrate, and marketing them under the same name or substantially the same name (including a new name that contains the old name) in anticipation of an enforcement action based on this document. As stated in the Marketed Unapproved Drugs CPG, FDA intends to give higher priority to enforcement actions involving unapproved drugs that are reformulated to evade an anticipated FDA enforcement action. In addition, reformulated products marketed under a name previously identified with a different active ingredient have the potential to confuse healthcare practitioners and harm patients.

Dated: January 6, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–00257 Filed 1–9–14; 8:45 am]

**BILLING CODE 4160–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 78 FR 42089–42090 dated July 15, 2013).

This notice reflects organizational changes in the Health Resources and Services Administration. This notice corrects the administrative codes for the Bureau of Clinician Recruitment and Service (RU); the Division of Regional Operations (RU2) and the Office of Business Operations (RU3).

**Chapter RU—Bureau of Clinician Recruitment and Service**

*Section RU–10, Organization*

Delete and replace in its entirety.

The Office of the Associate Administrator (RU) is headed by the Associate Administrator, Bureau of Clinician Recruitment and Service (BCRS), who reports directly to the Administrator, Health Resources and Services Administration. BCRS includes the following components:

(1) Office of the Associate Administrator (RU);

(2) Office of Legal and Compliance (RU1);

(3) Division of Regional Operations (RU2);

(4) Office of Business Operations (RU3);

(5) Division of National Health Service Corps (RU5);

(6) Division of Nursing and Public Health (RU6);

(7) Division of External Affairs (RU7);

(8) Division of Policy and Shortage Designation (RU8); and

(9) Division of Program Operations (RU9).

*Section RU–30, Delegations of Authority*

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon date of signature.

Dated: December 26, 2013.

**Mary K. Wakefield,**

*Administrator.*

[FR Doc. 2014–00221 Filed 1–9–14; 8:45 am]

**BILLING CODE 4165–15–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

### Organization, Function, and Delegations of Authority; Part G; Proposed Functional Statement

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice of change in name of an organizational component.

**SUMMARY:** The Indian Health Service is announcing the name change of the Aberdeen Area Indian Health Service to the Great Plains Area Indian Health Service at the request of Tribes served by the Aberdeen Area Indian Health Service.

**FOR FURTHER INFORMATION CONTACT:** Ms. Mona Galpin, Office of Management Services, Management Policy and Internal Control Staff, 801 Thompson Avenue, TMP Suite 625A, Rockville, MD 20852, Telephone 301–443–2650.

**Section GF–10, Indian Health Service Area Offices—Organization**

An Area Office is a second echelon organization under the direction of an Area Director, who reports to the IHS Director.

Indian Health Service Area Offices of the Indian Health Service in alphabetical order:

- Alaska Area Office (GFB)
- Albuquerque Area Office (GFC)
- Bemidji Area Office (GFE)
- Billings Area Office (GFF)
- California Area Office (GFG)
- Great Plains Area Office (GFA)
- Nashville Area Office (GFH)
- Navajo Area Office (GFJ)
- Oklahoma Area Office (GFK)
- Phoenix Area Office (GFL)
- Portland Area Office (GFM)
- Tucson Area Office (GFN)

Dated: December 6, 2013.

**Yvette Roubideaux,**

*Acting Director, Indian Health Service.*

[FR Doc. 2014–00264 Filed 1–9–14; 8:45 am]

**BILLING CODE 4165–16–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RFAs: PAR12–138 and PAR13–026—NHLBI Systems Biology.

*Date:* February 4–5, 2014.

*Time:* 10:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Ai-Ping Zou, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9497, *zouai@csr.nih.gov.*

*Name of Committee:* Brain Disorders and Clinical Neuroscience Integrated Review Group; Clinical Neuroplasticity and Neurotransmitters Study Section.

*Date:* February 6–7, 2014.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Melrose Hotel, 2430 Pennsylvania Ave. NW., Washington, DC 20037.

*Contact Person:* Suzan Nadi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217B, MSC 7846, Bethesda, MD 20892, 301–435–1259, *nadis@csr.nih.gov.*

*Name of Committee:* Biobehavioral and Behavioral Processes Integrated Review Group; Cognition and Perception Study Section.

*Date:* February 6–7, 2014.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.

*Contact Person:* Dana Jeffrey Plude, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, (301) 435–2309, *pluded@csr.nih.gov.*

*Name of Committee:* Risk, Prevention and Health Behavior Integrated Review Group; Psychosocial Development, Risk and Prevention Study Section.

*Date:* February 6–7, 2014.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Renaissance Mayflower Hotel, 1127 Connecticut Avenue NW., Washington, DC 20036.

*Contact Person:* Anna L Riley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7759, Bethesda, MD 20892, 301–435–2889, *rileyann@csr.nih.gov.*

*Name of Committee:* Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group Clinical and Integrative Diabetes and Obesity Study Section.

*Date:* February 6, 2014.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Nancy Sheard, SCD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6046–E, MSC 7892, Bethesda, MD 20892, 301–408–9901, *sheardn@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS).

Dated: January 6, 2014.

**Carolyn Baum,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2014–00162 Filed 1–9–14; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

### Agency Information Collection Activities: Vessel Entrance or Clearance Statement

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** 30-Day Notice and request for comments; Extension of an existing collection of information: 1651–0019.

**SUMMARY:** U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Vessel Entrance or Clearance Statement (CBP Form 1300). This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (76 FR 39114) on October 29, 2013, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

**DATES:** Written comments should be received on or before February 10, 2014 to be assured of consideration.

**ADDRESSES:** Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, at 202–325–0265.

**SUPPLEMENTARY INFORMATION:** CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3507). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs burden to respondents or record keepers from the collection of information (a

total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

*Title:* Vessel Entrance or Clearance Statement.

*OMB Number:* 1651–0019.

*Form Number:* CBP Form 1300.

*Abstract:* CBP Form 1300, *Vessel Entrance or Clearance Statement,* is used to collect essential commercial vessel data at time of formal entrance and clearance in U.S. ports. The form allows the master to attest to the truthfulness of all CBP forms associated with the manifest package, and collects detailed information on the vessel, cargo, purpose of entrance, certificate numbers and expiration for various certificates. It also serves as a record of fees and tonnage tax payments in order to prevent overpayments. CBP Form 1300 was developed through agreement by the United Nations Intergovernmental Maritime Consultative Organization (IMCO) in conjunction with the United States and various other countries. The form was developed as a single form to replace the numerous other forms used by various countries for the entrance and clearance of vessels. CBP Form 1300 is authorized by 19 U.S.C. 1431, 1433, and 1434, and provided for by 19 CFR 4.7–4.9. This form is accessible at *http://forms.cbp.gov/pdf/CBP_Form_1300.pdf.*

*Current Actions:* CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information being collected.

*Type of Review:* Extension (without change).

*Affected Public:* Businesses.

*Estimated Number of Respondents:* 12,000.

*Estimated Number of Responses per Respondent:* 22.

*Estimated Total Annual Responses:* 264,000.

*Estimated Time per Response:* 30 minutes.

*Estimated Total Annual Burden Hours:* 132,000.

Dated: January 6, 2014.

**Tracey Denning,**

*Agency Clearance Officer, U.S. Customs and Border Protection.*

[FR Doc. 2014–00224 Filed 1–9–14; 8:45 am]

**BILLING CODE 9111–14–P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–5750–N–02]**

### Federal Property Suitable as Facilities To Assist the Homeless

**AGENCY:** Office of the Assistant Secretary for Community Planning and Development, HUD.

**ACTION:** Notice.

**SUMMARY:** This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

**FOR FURTHER INFORMATION CONTACT:** Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7262, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

**SUPPLEMENTARY INFORMATION:** In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: January 2, 2014.

**Mark Johnston,**

*Deputy Assistant Secretary for Special Needs.*

[FR Doc. 2014–00020 Filed 1–9–14; 8:45 am]

**BILLING CODE 4210–67–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[LLWO220000.L10200000.PH0000.00000000]**

### Renewal of Approved Information Collection

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** 60-Day notice and request for comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act, the Bureau of Land Management (BLM) invites public comments on, and plans to request approval to continue, the collection of information from applicants for grazing permits and leases, and from holders of grazing permits and leases. The Office of Management and Budget (OMB) has assigned control number 1004–0041 to this information collection.

**DATES:** Please submit comments on the proposed information collection by March 11, 2014.

**ADDRESSES:** Comments may be submitted by mail, fax, or electronic mail.

Mail: U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW., Room 2134LM, Attention: Jean Sonneman, Washington, DC 20240.

Fax: to Jean Sonneman at 202–245–0050.

Electronic mail: *Jean_Sonneman@blm.gov.*

Please indicate ''Attn: 1004–0041'' regardless of the form of your comments.

**FOR FURTHER INFORMATION CONTACT:** Kimberly Hackett, at 202–912–7216. Persons who use a telecommunication device for the deaf may call the Federal Information Relay Service at 1–800–877–8339, to leave a message for Ms. Hackett.

**SUPPLEMENTARY INFORMATION:** OMB regulations at 5 CFR part 1320, which implement provisions of the Paperwork Reduction Act (44 U.S.C. 3501–3521), require that interested members of the public and affected agencies be given an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d) and 1320.12(a)). This notice identifies an information collection that the BLM plans to submit to the OMB for approval. The Paperwork Reduction Act provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until the OMB approves a collection of information, you are not obligated to respond.

The BLM will request a 3-year term of approval for this information collection activity. Comments are invited on: (1) The need for the collection of information for the performance of the functions of the agency; (2) The accuracy of the agency's burden estimates; (3) Ways to enhance the quality, utility and clarity of the information collection; and (4) Ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany our submission of the information collection requests to OMB.

Before including your address, phone number, email address, or other

personal identifying information in your comment, you should be aware that your entire comment — including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

The following information is provided for the information collection:

*Title:* Authorizing Grazing Use (43 CFR subparts 4110 and 4130)

*Forms:*

- Form 4130–1, Grazing Schedule, Grazing Application;
- Form 4130–1a, Grazing Preference Transfer Application and Preference Application (Base Property Preference Attachment and Assignment);
- Form 4130–1b, Grazing Application Supplemental Information;
- Form 4130–3a, Automated Grazing Application;
- Form 4130–4, Application for Exchange-of-Use Grazing Agreement; and
- Form 4130–5, Actual Grazing Use Report.

*OMB Control Number:* 1004–0041.

*Abstract:* The Taylor Grazing Act (43 U.S.C. 315–315n) and Subchapters III and IV of the Federal Land Policy and Management Act (43 U.S.C. 1731–1753) authorize and require BLM management of domestic livestock grazing on public lands consistent with land use plans, the principles of multiple use and sustained yield, environmental values, economic considerations, and other relevant factors. Compliance with these statutory provisions necessitates collection of information on matters such as permittee and lessee qualifications for a grazing permit or lease, base property used in conjunction with public lands, and the actual use of public lands for domestic livestock grazing.

*Frequency of Collection:* The BLM collects the information on Forms 4130–1, 4130–1a, 4130–1b, and 4130–4 on occasion. The BLM collects the information on Forms 4130–3a and 4130–5 annually. Responses are required in order to obtain or retain a benefit.

*Estimated Number and Description of Respondents:* Any U.S. citizen or validly licensed business may apply for a BLM grazing permit or lease. The BLM administers nearly 18,000 permits and leases for grazing domestic livestock, mostly cattle and sheep, at least part of the year on public lands. Permits and leases generally cover a 10-year period and are renewable if the BLM determines that the terms and conditions of the expiring permit or lease are being met.

*Estimated Reporting and Recordkeeping "Hour" Burden:* 33,810 responses and 7,811 hours annually.

*Estimated Annual Non-Hour Costs:* $30,000.

Estimates of the burdens are itemized below:

| A. Type of response | B. Number of responses | C. Time per response (minutes) | D. Total hours (B × C) |
|---|---|---|---|
| Grazing Schedule—Grazing Application, 43 CFR 4130.1–1, Form 4130–1 | 3,000 | 15 | 750 |
| Grazing Preference Application and Preference Transfer Application (Base Property Preference Attachment and Assignment), 43 CFR 4110.1(c), 4110.2–1(c), and 4110.2–3, Form 4130–1a and related nonform information | 900 | 35 | 525 |
| Grazing Application Supplemental Information, 43 CFR 4110.1 and 4130.7, Form 4130–1b | 900 | 30 | 450 |
| Automated Grazing Application, 43 CFR 4130.4, Form 4130–3a | 14,000 | 10 | 2,333 |
| Application for Exchange-of-Use Grazing Agreement, (43 CFR 4130.6–1), Form 4130–4 | 10 | 18 | 3 |
| Actual Grazing Use Report, 43 CFR 4130.3–2(d), Form 4130–5 | 15,000 | 15 | 3,750 |
| Totals | 33,810 | | 7,811 |

**Jean Sonneman,**

*Information Collection Clearance Officer, Bureau of Land Management.*

[FR Doc. 2014–00196 Filed 1–9–14; 8:45 am]

**BILLING CODE 4310–84–P**

## INTERNATIONAL TRADE COMMISSION

**[Investigation No. 731–TA–1123 (Review)]**

## Steel Wire Garment Hangers From China; Scheduling of an Expedited Five-Year Review Concerning the Antidumping Duty Order on Steel Wire Garment Hangers From China

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission hereby gives notice of the scheduling of an expedited review pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)) (the Act) to determine whether revocation of the antidumping duty order on steel wire garment hangers from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

**DATES:** *Effective Date:* December 20, 2013.

**FOR FURTHER INFORMATION CONTACT:** Stefania Pozzi Porter (202–205–3177), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

**SUPPLEMENTARY INFORMATION:**

*Background.* On December 20, 2013, the Commission determined that the domestic interested party group response to its notice of institution (78 FR 54272, Sept. 3, 2013) of the subject five-year review was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant

conducting a full review.[1] Accordingly, the Commission determined that it would conduct an expedited review pursuant to section 751(c)(3) of the Act.

*Staff report.* A staff report containing information concerning the subject matter of the review will be placed in the nonpublic record on January 17, 2014, and made available to persons on the Administrative Protective Order service list for this review. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission's rules.

*Written submissions.* As provided in section 207.62(d) of the Commission's rules, interested parties that are parties to the review and that have provided individually adequate responses to the notice of institution,[2] and any party other than an interested party to the review may file written comments with the Secretary on what determination the Commission should reach in the review. Comments are due on or before January 23, 2014 and may not contain new factual information. Any person that is neither a party to the five-year review nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the review by January 23, 2014. However, should the Department of Commerce extend the time limit for its completion of the final results of its review, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. Please be aware that the Commission's rules with respect to electronic filing have been amended. The amendments took effect on November 7, 2011. See 76 FR 61937 (Oct. 6, 2011) and the newly revised Commission's Handbook on E-Filing, available on the Commission's Web site at *http://edis.usitc.gov.*

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

**Authority:** This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

Dated: January 6, 2014.

By order of the Commission.

**Lisa R. Barton,**

*Acting Secretary to the Commission.*

[FR Doc. 2014–00209 Filed 1–9–14; 8:45 am]

**BILLING CODE 7020–02–P**

[1] A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's Web site.

[2] The Commission has found the responses submitted by Innovative Fabrication LLP/Indy Hanger, M&B Metal Products Company, Inc., and US Hanger Co., LLC to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

## INTERNATIONAL TRADE COMMISSION

**[Investigation No. 337–TA–871]**

### Investigations: Terminations, Modifications and Rulings: Certain Wireless Communications Base Stations and Components Thereof

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 35) by the presiding administrative law judge (''ALJ'') terminating the investigation in its entirety based on withdrawal of the complaint.

**FOR FURTHER INFORMATION CONTACT:** Clark S. Cheney, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202–205–2661. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

**SUPPLEMENTARY INFORMATION:** The Commission instituted this investigation on March 1, 2013, based on a complaint filed by Adaptix, Inc., of Carrollton, Texas (''Adaptix''). 78 FR 13895 (March 1, 2013). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain wireless communications base stations and components thereof by reason of infringement of U.S. Patent No. 6,870,808. The notice of investigation named Telefonaktiebolaget LM Ericsson, of Stockholm, Sweden, and Ericsson Inc., of Plano, Texas (collectively, ''Ericsson''), as respondents.

On December 3, 2013, Adaptix filed a motion to terminate the investigation in its entirety based on withdrawal of the complaint. Ericsson did not oppose the motion, and the Commission investigative attorney supported the motion.

On December 12, 2013, the ALJ issued an initial determination (Order No. 35) granting the motion. The ALJ noted that Adaptix certified that there are no agreements between the parties concerning the subject matter of the investigation and found that there are no extraordinary circumstances that should prevent Adaptix from withdrawing the complaint. The ALJ also found that terminating the investigation would conserve public and private resources. No petitions for review of the ID have been filed.

The Commission has determined not to review the ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Dated: January 6, 2014.

**Lisa R. Barton,**

*Acting Secretary to the Commission.*

[FR Doc. 2014–00208 Filed 1–9–14; 8:45 am]

**BILLING CODE 7020–02–P**

## DEPARTMENT OF JUSTICE

### Notice of Lodging of Proposed Consent Judgment Under The Resource Conservation and Recovery Act

On December 18, 2013, the Department of Justice lodged a proposed Consent Judgment with the United States District Court for the Eastern District of New York in the lawsuit entitled *United States* v. *County of Suffolk,* Civil Action No. CV–13–7183.

Defendant County of Suffolk (''Suffolk'') has owned and/or operated

at least 68 underground storage tanks (''USTs'') containing gasoline and waste oil throughout Suffolk County. The complaint seeks civil penalties and injunctive relief for Suffolk's violations of Resource Conservation and Recovery Act regulations governing USTs, set forth at 40 CFR Part 280. The complaint also alleges violation of federally enforceable New York State hazardous waste regulations set forth at 6 N.Y.C.R.R. § 372.2(a)(2) governing disposal of spent fluorescent lamps. The Consent Judgment requires Suffolk: (a) to pay a civil penalty of $500,000; (b) to fund a Supplemental Environmental Project in the amount of $1,500,000 to acquire an interest in land, and to manage such land and any associated ecological resources, into perpetuity, to protect and/or enhance groundwater; (c) to maintain compliance with RCRA requirements for all of its underground storage tanks and with NYS regulations in its handling of spent fluorescent lamps; and (d) to submit regular reports to EPA for four years to demonstrate that they are in compliance.

The publication of this notice opens a period for public comment on the Consent Judgment. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *County of Suffolk,* D.J. Ref. No. 90–7–1–09883. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

| *To submit comments:* | *Send them to:* |
|---|---|
| By e-mail ..... | *pubcomment-ees.enrd@usdoj.gov.* |
| By mail ..... | Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611. |

During the public comment period, the Consent Judgment may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the Consent Judgment upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ–ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $15.75 (25 cents per page reproduction cost) payable to the United States Treasury.

**Maureen Katz,**

*Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.*

[FR Doc. 2014–00182 Filed 1–9–14; 8:45 am]

BILLING CODE 4410–15–P

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Importer of Controlled Substances; Notice of Application; Siegfried USA, LLC.

Pursuant to 21 CFR 1301.34 (a), this is notice that on November 19, 2013, Siegfried USA, LLC., 33 Industrial Park Road, Pennsville, New Jersey 08070, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the basic classes of controlled substances:

| Drug | Schedule |
|---|---|
| Opium, raw (9600) ..... | II |
| Poppy Straw Concentrate (9670) | II |

The company plans to import the listed controlled substances to bulk manufacture API'S for distribution to its customer.

Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417 (2007)

As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745, all applicants for registration to import a basic classes of any controlled substances in schedule I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: December 23, 2013.

**Joseph T. Rannazzisi,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

[FR Doc. 2014–00201 Filed 1–9–14; 8:45 am]

BILLING CODE 4410–09–P

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Importer of Controlled Substances, Notice of Application, Myoderm

Pursuant to 21 CFR 1301.34 (a), this is notice that on October 28, 2013, Myoderm, 48 East Main Street, Norristown, Pennsylvania 19401, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the following basic classes of controlled substances:

| Drug | Schedule |
|---|---|
| Amphetamine (1100) ..... | II |
| Lisdexamfetamine (1205) ..... | II |
| Methylphenidate (1724) ..... | II |
| Pentobarbital (2270) ..... | II |
| Nabilone (7379) ..... | II |
| Codeine (9050) ..... | II |
| Oxycodone (9143) ..... | II |
| Hydromorphone (9150) ..... | II |
| Hydrocodone (9193) ..... | II |
| Levomethorphan (9210) ..... | II |
| Meperidine (9230) ..... | II |
| Methadone (9250) ..... | II |
| Methadone intermediate (9254) ... | II |
| Morphine (9300) ..... | II |
| Oxymorphone (9652) ..... | II |
| Fentanyl (9801) ..... | II |

The company plans to import the listed controlled substances in finished dosage form for clinical trials, and research.

The import of the above listed basic classes of controlled substances will be granted only for analytical testing and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form for commercial distribution in the United States.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedules I or II, which fall under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952 (a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43, and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODW), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than February 10, 2014.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745–46, all applicants for registration to import a basic class of any controlled substance in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: December 23, 2013.

**Joseph T. Rannazzisi,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

[FR Doc. 2014–00202 Filed 1–9–14; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Importer of Controlled Substances; Notice of Application; Cody Laboratories, Inc.

Pursuant to 21 CFR 1301.34(a), this is notice that on June 12, 2013, Cody Laboratories Inc., 601 Yellowstone Avenue, Cody, Wyoming 82414–9321, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the following basic classes of controlled substances:

| Drug | Schedule |
|---|---|
| Phenylacetone (8501) | II |
| Poppy Straw Concentrate (9670) | II |
| Tapentadol (9780) | II |

The company plans to import narcotic raw materials for manufacturing and further distribution to its customers. The company is registered with DEA as a manufacturer of several controlled substances that are manufactured from poppy straw concentrate.

The company plans to import an intermediate form of Tapentadol (9780) to bulk manufacture Tapentadol for distribution to its customers.

Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417, (January 25, 2007)

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedules I or II, which fall under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43, and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, **Federal Register** Representative (ODW), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than February 10, 2014.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745–46, all applicants for registration to import a basic class of any controlled substances in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: December 31, 2013.

**Joseph T. Rannazzisi,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

[FR Doc. 2014–00203 Filed 1–9–14; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Importer of Controlled Substances; Notice of Application; Fresenius Kabi USA, LLC.

Pursuant to 21 CFR 1301.34(a), this is notice that on November 2, 2012, Fresenius Kabi USA, LLC., 3159 Stanley Road, Grand Island, New York 14072, made application to the Drug Enforcement Administration (DEA) for registration as an importer of Remifentanil (9739), a basic class of controlled substance listed in schedule II.

The company plans to import this controlled substance for product development and preparation of stability batches.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic class of controlled substance listed in schedules I or II, which fall under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43, and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODW), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than February 10, 2014.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745–46, all applicants for registration to import a basic class of any controlled substance in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: December 31, 2013.

**Joseph T. Rannazzisi,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

[FR Doc. 2014–00197 Filed 1–9–14; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Importer of Controlled Substances; Notice of Registration; Mylan Pharmaceuticals, Inc.

By Notice dated June 18, 2013, and published in the **Federal Register** on July 1, 2013, 78 FR 39336, Mylan Pharmaceuticals, Inc., 3711 Collins Ferry Road, Morgantown, West Virginia 26505, made application to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

| Drug | Schedule |
|---|---|
| Amphetamine (1100) | II |
| Lisdexamfetamine (1205) | II |
| Methylphenidate (1724) | II |
| Pentobarbital (2270) | II |
| Oxycodone (9143) | II |
| Hydromorphone (9150) | II |
| Hydrocodone (9193) | II |
| Levorphanol (9220) | II |
| Morphine (9300) | II |
| Oxymorphone (9652) | II |
| Remifentanil (9739) | II |
| Fentanyl (9801) | II |

The company plans to import the listed controlled substances in finished dosage form (FDF) from foreign sources for analytical testing and clinical trials in which the foreign FDF will be compared to the company's own domestically-manufactured FDF. This analysis is required to allow the company to export domestically-manufactured FDF to foreign markets.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a) and determined that the registration of Mylan Pharmaceuticals, Inc., to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. DEA has investigated Mylan Pharmaceuticals, Inc., to ensure that the company's registration is consistent with the public interest.

The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic classes of controlled substances listed.

Dated: December 31, 2013.

**Joseph T. Rannazzisi,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

[FR Doc. 2014–00206 Filed 1–9–14; 8:45 am]

BILLING CODE 4410–09–P

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Importer of Controlled Substances; Notice of Registration; Fisher Clinical Services, Inc.

By Notice dated September 16, 2013, and published in the **Federal Register** on September 25, 2013, 78 FR 59064, Fisher Clinical Services, Inc., 7554 Schantz Road, Allentown, Pennsylvania 18106, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

| Drug | Schedule |
|---|---|
| Methyphendiate (1724) | II |
| Levorphanol (9220) | II |
| Noroxymorphone (9668) | II |
| Tapentadol (9780) | II |

The company plans to import the listed controlled substances for clinical trials, analytical research and testing.

The import of the above listed basic classes of controlled substances will be granted only for analytical testing and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form for commercial distribution in the United States.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a), and determined that the registration of Fisher Clinical Services, Inc., to import the basic classes of controlled substances is consistent with the public interest, and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. DEA has investigated Fisher Clinical Services, Inc., to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic classes of controlled substances listed.

Dated: December 31, 2013.

**Joseph T. Rannazzisi,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

[FR Doc. 2014–00179 Filed 1–9–14; 8:45 am]

BILLING CODE 4410–09–P

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Manufacturer of Controlled Substances; Notice of Application; Cayman Chemical Company

Pursuant to 21 CFR 1301.33(a), this is notice that on June 27, 2013, Cayman Chemical Company, 1180 East Ellsworth Road, Ann Arbor, Michigan 48108, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

| Drug | Schedule |
|---|---|
| Cathinone (1235) | I |
| Methcathinone (1237) | I |
| 4-Methyl-N-methylcathinone (1248). | I |
| N-Ethylamphetamine (1475) | I |
| N,N-Dimethylamphetamine (1480) | I |
| Aminorex (1585) | I |
| 4-Methylaminorex (cis isomer) (1590). | I |
| Gamma Hydroxybutyric Acid (2010). | I |
| JWH–250 (6250) | I |
| SR–18 also known as RCS–8 (7008). | I |
| XLR11 (7011) | I |
| JWH–019 (7019) | I |
| AKB48 (7048) | I |
| JWH–081 (7081) | I |
| SR–19 also known as RCS–4 (7104). | I |
| 1-Pentyl-3-(1-naphthoyl)indole (7118). | I |
| JWH–122 (7122) | I |
| UR–144 (7144) | I |
| 1-Butyl-3-(1-naphthoyl)indole (7173). | I |
| 1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl) indole (7200) | I |
| AM–2201 (7201) | I |
| JWH–203 (7203) | I |
| Alpha-ethyltryptamine (7249) | I |
| 5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (7297). | I |
| 5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (7298). | I |
| Lysergic acid diethylamide (7315) | I |
| 2,5-Dimethoxy-4-(n)-propylthiophenethylamine (7348). | I |
| Marihuana (7360) | I |
| Tetrahydrocannabinols (7370) | I |
| Mescaline (7381) | I |
| 2C–T–2 (7385) | I |
| 3,4,5-Trimethoxyamphetamine (7390). | I |
| 4-Bromo-2,5-dimethoxyamphetamine (7391). | I |
| 4-Bromo-2,5-dimethoxyphenethylamine (7392). | I |
| 4-Methyl-2,5-dimethoxyamphetamine (7395). | I |

| Drug | Schedule |
|---|---|
| 2,5-Dimethoxyamphetamine (7396). | I |
| JWH–398 (7398) | I |
| 2,5-Dimethoxy-4-ethylamphetamine (7399). | I |
| 3,4-Methylenedioxyamphetamine (7400). | I |
| 5-Methoxy-3,4-methylenedioxyamphetamine (7401). | I |
| N-Hydroxy-3,4-methylenedioxyamphetamine (7402). | I |
| 3,4-Methylenedioxy-N-ethylamphetamine (7404). | I |
| 3,4-Methylenedioxymethamphetamine (7405). | I |
| 4-Methoxyamphetamine (7411) | I |
| 5-Methoxy-N-N-dimethyltryptamine (7431). | I |
| Alpha-methyltryptamine (7432) | I |
| Bufotenine (7433) | I |
| Diethyltryptamine (7434) | I |
| Dimethyltryptamine (7435) | I |
| Psilocybin (7437) | I |
| Psilocyn (7438) | I |
| 5-Methoxy-N,N-diisopropyltryptamine (7439). | I |
| N-Ethyl-1-phenylcyclohexylamine (7455). | I |
| N-Benzylpiperazine (7493) | I |
| 2C–D (7508) | I |
| 2C–E (7509) | I |
| 2C–H (7517) | I |
| 2C–I (7518) | I |
| 2C–C (7519) | I |
| 2C–N (7521) | I |
| 2C–P (7524) | I |
| 2C–T–4 (7532) | I |
| MDPV (7535) | I |
| Methylone (7540) | I |
| AM–694 (7694) | I |
| Desmorphine (9055) | I |
| Dihydromorphine (9145) | I |
| Heroin (9200) | I |
| Morphine-N-oxide (9307) | I |
| Normorphine (9313) | I |
| Tilidine (9750) | I |
| Amphetamine (1100) | II |
| Methamphetamine (1105) | II |
| Lisdexamfetamine (1205) | II |
| Pentobarbital (2270) | II |
| Phencyclidine (7471) | II |
| Phenylacetone (8501) | II |
| Codeine (9050) | II |
| Dihydrocodeine (9120) | II |
| Oxycodone (9143) | II |
| Hydromorphone (9150) | II |
| Hydrocodone (9193) | II |
| Levomethorphan (9210) | II |
| Meperidine (9230) | II |
| Meperidine intermediate-B (9233) | II |
| Methadone (9250) | II |
| Dextropropoxyphene, bulk (non-dosage forms) (9273). | II |
| Morphine (9300) | II |
| Thebaine (9333) | II |
| Oxymorphone (9652) | II |
| Sufentanil (9740) | II |
| Fentanyl (9801) | II |

The company plans to manufacture reference standards for distribution to their research and forensics customers.

In reference to drug code 7360 (Marihuana), the company plans to bulk manufacture cannabidiol as a synthetic intermediate. This controlled substance will be further synthesized to bulk manufacture a synthetic tetrahydrocannabinol (7370). No other activity for this drug code is authorized for this registration.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substances, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODW), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than March 11, 2014.

Dated: December 31, 2013.

**Joseph T. Rannazzisi,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

[FR Doc. 2014–00200 Filed 1–9–14; 8:45 am]

BILLING CODE 4410–09–P

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Manufacturer of Controlled Substances Notice of Application Cody Laboratories, Inc.

Pursuant to 21 CFR 1301.33(a), this is notice that on June 12, 2013, Cody Laboratories, Inc., 601 Yellowstone Avenue, Cody, Wyoming 82414, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

| Drug | Schedule |
|---|---|
| Dihydromorphine (9145) | I |
| Amphetamine (1100) | II |
| Methamphetamine (1105) | II |
| Methylphenidate (1724) | II |
| Amobarbital (2125) | II |
| Pentobarbital (2270) | II |
| Secobarbital (2315) | II |
| 4-Anilino-N-phenethyl-4-piperidine (ANPP) (8333). | II |
| Phenylacetone (8501) | II |
| Cocaine (9041) | II |
| Codeine (9050) | II |
| Dihydrocodeine (9120) | II |
| Oxycodone (9143) | II |
| Hydromorphone (9150) | II |
| Diphenoxylate (9170) | II |
| Ecgonine (9180) | II |
| Hydrocodone (9193) | II |
| Meperidine (9230) | II |
| Methadone (9250) | II |
| Morphine (9300) | II |
| Thebaine (9333) | II |
| Oxymorphone (9652) | II |
| Alfentanil (9737) | II |
| Remifentanil (9739) | II |
| Sufentanil (9740) | II |
| Tapentadol (9780) | II |
| Fentanyl (9801) | II |

The company plans on manufacturing the listed controlled substances in bulk for sale to its customers.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substances, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, **Federal Register** Representative (ODW), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than March 11, 2014.

Dated: December 31, 2013.

**Joseph T. Rannazzisi,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

[FR Doc. 2014–00204 Filed 1–9–14; 8:45 am]

BILLING CODE 4410–09–P

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Manufacturer of Controlled Substances; Notice of Registration; Organix, Inc.

By Notice dated August 20, 2013, and published in the **Federal Register** on August 26, 2013, 78 FR 52801, Organix, Inc., 240 Salem Street, Woburn, Massachusetts 01801, made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

| Drug | Schedule |
|---|---|
| Marihuana (7360) | I |
| Tetrahydrocannabinols (7370) | I |
| Psilocybin (7437) | I |
| Psilocyn (7438) | I |

The company plans to synthesize small quantities of the listed controlled substances to make reference standards which will be distributed to their customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a), and determined that the registration of Organix, Inc., to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time.

DEA has investigated Organix, Inc., to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic class of controlled substance listed.

Dated: December 31, 2013.

**Joseph T. Rannazzisi,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

[FR Doc. 2014–00198 Filed 1–9–14; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Office of Justice Programs

**[OMB Number 1121–0095]**

### Agency Information Collection Activities: Proposed Collection; Comments Requested 2013 National Survey of Indigent Defense Systems

**ACTION:** 60-day notice.

The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics will be submitting 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 collected is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for ''sixty days'' until March 11, 2014. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments especially 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 contact Alexia Cooper, Statistician, Bureau of Justice Statistics, Office of Justice Programs, U.S. Department of Justice, 810 Seventh Street NW., Washington, DC 20531 (phone: 202–302–0582).

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 agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of information collection:* Reinstatement with change of a previously approved collection for which approval has expired

(2) *The title of the Form/Collection:* 2013 National Survey of Indigent Defense Systems

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* OMB Control #1121–0095, Bureau of Justice Statistics, Office of Justice Programs, United States Department of Justice.

(4) *Affected public who will be asked to respond, as well as a brief abstract:* Primary: State and county based indigent defense systems. Staff in state and county based indigent defense systems will be asked to provide information on the following: fiscal resources and expenditures; case-types and caseloads; personnel and compensation; processes for selecting the chief public defender or administrator; procedures for indigence determination; professional development opportunities; use of information technology; standards and guidelines; and boards or commissions. The Bureau of Justice Statistics plans to publish this information in reports and reference it when responding to queries from the U.S. Congress, Executive Office of the President, the U.S. Supreme Court, state officials, international organizations, researchers, students, the media, and others interested in criminal justices statistics.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 1,574 respondents at 3.0 hours each. Respondents have the option to provide responses using either paper or web-based questionnaires. The burden estimate is based on feedback from respondents gathered during pilot testing.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There is an estimated 4,694 annual total burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Avenue, 145 N Street NE., Room 3W–1407B, Washington, DC 20530.

Dated: January 7, 2014.

**Jerri Murray,**

*Department Clearance Officer for PRA, Department of Justice.*

[FR Doc. 2014–00218 Filed 1–9–14; 8:45 am]

**BILLING CODE 4410–18–P**

## DEPARTMENT OF LABOR

### Employment and Training Administration

**[TA–W–82,663]**

### Belden, Inc.; Including On-Site Leased Workers From Adecco Horseheads, New York; Notice of Revised Determination on Reconsideration

The initial investigation, instituted on April 18, 2013, resulted in a negative determination, issued on June 14, 2013, that was based on the Department's finding of no shift in production by Belden, Inc., Horseheads, New York (subject firm) to a foreign country and neither subject firm nor customer imports. The Department's Notice of negative determination was published in the **Federal Register** on July 2, 2013 (78 FR 39776).

Workers of the subject firm are engaged in activity related to the production and assembly of coaxial cable connectors and parts, and are not separately identifiable by article produced. The worker group includes on-site leased workers from Adecco.

During the reconsideration investigation, the Department confirmed previously-submitted information and

received new information which revealed that the subject firm shifted to a foreign country a portion of the production of articles like or directly competitive with the coaxial cable connectors and parts produced at the subject firm.

## Conclusion

After careful review of the additional facts obtained during the reconsideration investigation, I determine that workers of Belden, Inc., Horseheads, New York, who are/were engaged in employment related to the production of coaxial cable connectors and parts, meet the worker group certification criteria under Section 222(a) of the Act, 19 U.S.C. 2272(a). In accordance with Section 223 of the Act, 19 U.S.C. 2273, I make the following certification:

''All workers of Belden, Inc., including on-site leased workers from Adecco, Horseheads, New York, who became totally or partially separated from employment on or after April 16, 2012, through two years from the date of this certification, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.''

Signed in Washington, DC, this 26th day of December, 2013.

**Michael W. Jaffe,**

*Certifying Officer, Office of Trade Adjustment Assistance.*

[FR Doc. 2014–00186 Filed 1–9–14; 8:45 am]

**BILLING CODE 4510–FN–P**

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## DEPARTMENT OF LABOR

### Employment and Training Administration

### Investigations Regarding Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221 (a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221 (a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than January 21, 2014.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than January 21, 2014.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room N–5428, 200 Constitution Avenue NW., Washington, DC 20210.

Signed at Washington, DC, this 23rd day of December 2013.

**Michael W. Jaffe,**

*Certifying Officer, Office of Trade Adjustment Assistance.*

APPENDIX

[21 TAA petitions instituted between 12/9/13 and 12/13/13]

| TA–W | Subject firm (petitioners) | Location | Date of institution | Date of petition |
|---|---|---|---|---|
| 83274 | Eaton's Cooper Power System (Company) | Pewaukee, WI | 12/09/13 | 12/06/13 |
| 83275 | St. Louis Post Dispatch (State/One-Stop) | St. Louis, MO | 12/09/13 | 12/06/13 |
| 83276 | Windsor USA LLC (Company) | Hebron, KY | 12/09/13 | 12/07/13 |
| 83277 | FL Smidth, Inc. (Workers) | Bethlehem, PA | 12/09/13 | 12/07/13 |
| 83278 | Spirit Aerosystems, Inc. (State/One-Stop) | Wichita, KS | 12/09/13 | 12/06/13 |
| 83279 | OneWest Bank (Workers) | Kalamazoo, MI | 12/09/13 | 12/05/13 |
| 83280 | Ocwen Loan Servicing, LLC (Workers) | Fort Washington, PA | 12/09/13 | 12/06/13 |
| 83281 | Weyerhaeuser NR Co. (Technology Center Building) (State/One-Stop). | Federal Way, WA | 12/11/13 | 12/06/13 |
| 83282 | Econolite Control Products, Inc. (Company) | Anaheim, CA | 12/11/13 | 12/10/13 |
| 83283 | IMPCO Technologies, Inc. (Company) | Sterling Heights, MI | 12/11/13 | 12/09/13 |
| 83284 | Navex Global (Formerly ELT, Inc.) (State/One-Stop) | San Francisco, CA | 12/11/13 | 12/04/13 |
| 83285 | Pebble Limited Partnership (State/One-Stop) | Anchorage, AK | 12/12/13 | 12/11/13 |
| 83286 | Yale Sportswear (State/One-Stop) | Federalsburg, MD | 12/12/13 | 12/11/13 |
| 83287 | MOSAIC (State/One-Stop) | Hersey, MI | 12/12/13 | 12/11/13 |
| 83288 | Heinz Frozen Food Company (State/One-Stop) | Ontario, OR | 12/12/13 | 12/11/13 |
| 83289 | Distinctive Industries (State/One-Stop) | Santa Fe Springs, CA | 12/12/13 | 12/11/13 |
| 83290 | Emco USA, LLC (Company) | Zanesville, OH | 12/13/13 | 12/12/13 |
| 83291 | Fabri-Form Company (The) (Workers) | Pekin, IN | 12/13/13 | 12/13/13 |
| 83292 | American Monolythic Ceramics—A Johanson Company (State/One-Stop). | Olean, NY | 12/13/13 | 12/12/13 |
| 83293 | Matric Limited (Company) | Seneca, PA | 12/13/13 | 12/11/13 |
| 83294 | Benteler Automotive (Company) | Grand Rapids, MI | 12/13/13 | 12/11/13 |

[FR Doc. 2014–00184 Filed 1–9–14; 8:45 am]

**BILLING CODE 4510–FN–P**

## DEPARTMENT OF LABOR

### Employment and Training Administration

**[TA–W–82,458; TA–W–82,458A]**

### REC Silicon, Inc.; Including On-Site Leased Workers From Express Employment Professionals; Including Workers Whose Unemployment Insurance (UI) Wages Were Reported Through REC Solar Grade Silicon LLC; Moses Lake, Washington; REC Advanced Silicon Materials, LLC; Including On-Site Leased Workers From Spherion Recruiting and Staffing Silver Bow, Montana; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on March 22, 2013, applicable to workers of REC Silicon, Inc., including on-site leased workers from Express Employment Professionals, and including workers whose unemployment insurance wages are reported through REC Solar Grade Silicon, LLC, Moses Lake, Washington. The Department's notice of determination was published in the **Federal Register** on April 9, 2013 (78 FR 21153).

At the request of a company official, the Department reviewed the certification for workers of the subject firm. The company reported that the workers from REC Advanced Silicon Materials, LLC, including on-site leased workers from Spherion Recruiting and Staffing, Silver Bow, Montana (TA–W–82,458A) have been separated or threatened with separation due to the same conditions that led to certification of the workers at the Moses Lake, Washington facility. Specifically, the worker separations at both facilities are attributable to the acquisition from a foreign country by the firm of articles like or directly competitive with the polysilicon produced by the firm.

Accordingly, the Department is amending the certification to include the workers of REC Advanced Silicon Materials, LLC, including on-site leased workers from Spherion Recruiting and Staffing, Silver Bow, Montana (TA–W–82,458A).

The amended notice applicable to TA–W–82,458 is hereby issued as follows:

''All workers of REC Silicon, Inc., including on-site leased workers from Express Employment Professionals, and including workers whose unemployment insurance wages are reported through REC Solar Grade Silicon, LLC, Moses Lake, Washington (TA–W–82,458) and REC Advanced Silicon Materials, LLC, including on-site leased workers from Spherion Recruiting and Staffing, Silver Bow, Montana (TA–W–82,458A) who became totally or partially separated from employment on or after February 12, 2012 through March 22, 2015, and all workers in the group threatened with total or partial separation from employment on the date of certification through March 22, 2015, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.''

Signed in Washington, DC, this 24th day of December, 2013.

**Michael W. Jaffe**

*Certifying Officer, Office of Trade Adjustment Assistance.*

[FR Doc. 2014–00183 Filed 1–9–14; 8:45 am]

**BILLING CODE 4510–FN–P**

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## 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 by (TA–W) number issued during the period of December 9, 2013 through December 13, 2013.

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Under Section 222(a)(2)(A), the following must be satisfied:

(1) a significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) the sales or production, or both, of such firm have decreased absolutely; and

(3) One of the following must be satisfied:

(A) imports of articles or services like or directly competitive with articles produced or services supplied by such firm have increased;

(B) imports of articles like or directly competitive with articles into which one or more component parts produced by such firm are directly incorporated, have increased;

(C) imports of articles directly incorporating one or more component parts produced outside the United States that are like or directly competitive with imports of articles incorporating one or more component parts produced by such firm have increased;

(D) imports of articles like or directly competitive with articles which are produced directly using services supplied by such firm, have increased; and

(4) the increase in imports contributed importantly to such workers' separation or threat of separation and to the decline in the sales or production of such firm; or

II. Section 222(a)(2)(B) all of the following must be satisfied:

(1) a significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) One of the following must be satisfied:

(A) there has been a shift by the workers' firm to a foreign country in the production of articles or supply of services like or directly competitive with those produced/supplied by the workers' firm;

(B) there has been an acquisition from a foreign country by the workers' firm of articles/services that are like or directly competitive with those produced/supplied by the workers' firm; and

(3) the shift/acquisition contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in public agencies and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) a significant number or proportion of the workers in the public agency have become totally or partially separated, or are threatened to become totally or partially separated;

(2) the public agency has acquired from a foreign country services like or directly competitive with services which are supplied by such agency; and

(3) the acquisition of services contributed importantly to such workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected secondary workers of a firm and a certification issued regarding

eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(c) of the Act must be met.

(1) a significant number or proportion of the workers in the workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) the workers' firm is a Supplier or Downstream Producer to a firm that employed a group of workers who received a certification of eligibility under Section 222(a) of the Act, and such supply or production is related to the article or service that was the basis for such certification; and

(3) either—

(A) the workers' firm is a supplier and the component parts it supplied to the firm described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) a loss of business by the workers' firm with the firm described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in firms identified by the International Trade Commission and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(f) of the Act must be met.

(1) the workers' firm is publicly identified by name by the International Trade Commission as a member of a domestic industry in an investigation resulting in—

(A) an affirmative determination of serious injury or threat thereof under section 202(b)(1);

(B) an affirmative determination of market disruption or threat thereof under section 421(b)(1); or

(C) an affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A));

(2) the petition is filed during the 1-year period beginning on the date on which—

(A) a summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) with respect to the affirmative determination described in paragraph (1)(A) is published in the **Federal Register** under section 202(f)(3); or

(B) notice of an affirmative determination described in subparagraph (1) is published in the **Federal Register**; and

(3) the workers have become totally or partially separated from the workers' firm within—

(A) the 1-year period described in paragraph (2); or

(B) notwithstanding section 223(b)(1), the 1-year period preceding the 1-year period described in paragraph (2).

**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 Section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

| TA–W No. | Subject firm | Location | Impact date |
|---|---|---|---|
| 83,030 | J.R. Simplot, Food Group, BD Employment Solutions, Inc. | Nampa, ID | August 14, 2012. |
| 83,030A | J.R. Simplot, Food Group, BBSI and American Staffing | Heyburn, ID | August 14, 2012. |
| 83,030B | J.R. Simplot, Food Group, BBSI | Aberdeen, ID | August 14, 2012. |
| 83,030C | J.R. Simplot, Food Group, BD Employment Solutions and Gem State Staffing. | Caldwell, ID | August 14, 2012. |
| 83,167 | Flotation Technologies LLC, Manpower and Bonney Staffing | Biddeford, ME | October 23, 2012. |
| 83,234 | Keywell LLC | West Mifflin, PA | November 20, 2012. |

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production or services) of the Trade Act have been met.

| TA–W No. | Subject firm | Location | Impact date |
|---|---|---|---|
| 83,082 | DST Retirement Solutions, LLC | Kansas City, MO | September 13, 2012. |
| 83,090 | IBM Corporation, Global Business Services, Sector Support Specialists Group. | Endicott, NY | September 17, 2012. |
| 83,100 | Oakley Manufacturing, Oakley, Inc., Luxottica, U.S. Holdings Corporation, Alar and Aerotek. | Foothill Ranch, CA | September 19, 2012. |
| 83,146 | Toho Tenax America, Inc., Alternate Staffing, Account Temps and Randstad Staffing. | Rockwood, TN | October 3, 2012. |
| 83,158 | NCR | Bentonville, AR | October 7, 2012. |
| 83,183 | Page 1 Solutions, LLC, Website Development, Search Engine Optimization and Pay Per Click Dept.. | Golden, CO | October 28, 2012. |
| 83,186 | Ruskin Company, Air Distribution Technologies, Inc., Personnel Temporary, Extras Support. | Fairmont, WV | October 30, 2012. |
| 83,192 | Osram Sylvania, Inc. | Wellsboro, PA | October 21, 2012. |
| 83,199 | Northeast Utilities Service Company, Information Technology Division, IBM, Infosys, The Ergonomic Group, etc.. | Berlin, CT | November 5, 2012. |
| 83,210 | KCI USA, Inc., Teksystems, Modis | San Antonio, TX | November 7, 2012. |
| 83,210A | KCI USA, Inc. | Charlotte, NC | November 7, 2012. |
| 83,210B | KCI USA, Inc. | Dillon, MT | November 7, 2012. |
| 83,244 | Inalfa Roof Systems Grand Blanc, Inalfa Roof Systems, Inc., Aerotek and Sentech. | Holly, MI | November 25, 2012. |
| 83,246 | Computershare Inc., Edison Call Center, Express Employment Professionals and Northpointe, etc.. | Edison, NJ | November 26, 2012. |

| TA–W No. | Subject firm | Location | Impact date |
|---|---|---|---|
| 83,247 | AVX Corporation, Kyocera Group Company, IHT Staffing and Huff Consulting. | Myrtle Beach, SC | February 4, 2014. |
| 83,247A | AVX Corporation, Kyocera Group Company | Conway, SC | February 4, 2014. |
| 83,247B | South Coast Networks, Working On-Site at AVX Corporation, Kyocera Group Company. | Myrtle Beach, SC | November 20, 2012. |

The following certifications have been issued. The requirements of Section 222(c) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

| TA–W No. | Subject firm | Location | Impact date |
|---|---|---|---|
| 83,198 | IPS Operations, Hewlett Packard | Sandston, VA | November 4, 2012. |

**Negative Determinations for Worker Adjustment Assistance**

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

The investigation revealed that the criterion under paragraph (a)(1), or (b)(1), or (c)(1) (employment decline or threat of separation) of section 222 has not been met.

| TA–W No. | Subject firm | Location | Impact date |
|---|---|---|---|
| 83,125 | Acushnet Company | New Bedford, MA. | |

The investigation revealed that the criteria under paragraphs (a)(2)(A)(i) (decline in sales or production, or both) and (a)(2)(B) (shift in production or services to a foreign country) of section 222 have not been met.

| TA–W No. | Subject firm | Location | Impact date |
|---|---|---|---|
| 83,195 | Kimball Electronics, Inc., Kimball Electronics Group, Inc., Jasper Division, Spartan Staffing. | Jasper, IN. | |
| 83,221 | State Industries, LLC | Eugene, OR. | |

The investigation revealed that the criteria under paragraphs (a)(2)(A) (increased imports) and (a)(2)(B) (shift in production or services to a foreign country) of section 222 have not been met.

| TA–W No. | Subject firm | Location | Impact date |
|---|---|---|---|
| 83,048 | Goldman Sachs & Company, Operations Division, Asset Staffing, Control Associates/Constantin, etc.. | New York, NY. | |
| 83,102 | Pearl Pressman Liberty Communications Group, Inc. | Philadelphia, PA. | |
| 83,106 | Janesville Acoustics, Jason Incorporated, Nesco LLC | Norwalk, OH. | |

**Determinations Terminating Investigations of Petitions for Worker Adjustment Assistance**

After notice of the petitions was published in the **Federal Register** and on the Department's Web site, as required by Section 221 of the Act (19 U.S.C. 2271), the Department initiated investigations of these petitions.

The following determinations terminating investigations were issued because the petitioning groups of workers are covered by active certifications. Consequently, further investigation in these cases would serve no purpose since the petitioning group of workers cannot be covered by more than one certification at a time.

| TA–W No. | Subject firm | Location | Impact date |
|---|---|---|---|
| 83,239 | Fenton Gift Shops, Inc. | Williamstown, WV. | |

The following determinations terminating investigations were issued because the petitions are the subject of ongoing investigations under petitions filed earlier covering the same petitioners.

| TA–W No. | Subject firm | Location | Impact date |
|---|---|---|---|
| 83,280 | Ocwen Loan Servicing, LLC, Ocwen Financial Corporation | Fort Washington, PA. | |

I hereby certify that the aforementioned determinations were issued during the period of December 9, 2013 through December 13, 2013. These determinations are available on the Department's Web site *tradeact/taa/taa_search_form.cfm* under the searchable listing of determinations or by calling the Office of Trade Adjustment Assistance toll free at 888–365–6822.

Signed at Washington, DC, this 23rd day of December 2013.

**Michael W. Jaffe,**

*Certifying Officer, Office of Trade Adjustment Assistance.*

[FR Doc. 2014–00185 Filed 1–9–14; 8:45 am]

**BILLING CODE 4510–FN–P**

## OFFICE OF MANAGEMENT AND BUDGET

### Fiscal Year (FY) 2013 and (FY) 2014 List of Designated Federal Entities and Federal Entities

**AGENCY:** Office of Management and Budget.

**ACTION:** Notice.

**SUMMARY:** As required by Section 8G of the Inspector General Act of 1978, as amended (IG Act; 5 U.S.C. Appendix), this notice provides the FY 2013 and FY 2014 list of Designated Federal Entities and Federal Entities.

**FOR FURTHER INFORMATION CONTACT:** Mike Wetklow, Office of Management and Budget, Office of Federal Financial Management, New Executive Office Building, Washington, DC 20503, (202) 395–3998.

**SUPPLEMENTARY INFORMATION:** This notice provides the FY 2013 and FY 2014 List of Designated Federal Entities and Federal Entities which, under Section 8G of the IG Act, the Office of Management and Budget (OMB) is required to publish. This list is also posted on the OMB Web site at *http://www.whitehouse.gov/omb.*

The list of the ''Federal Entities'' has been updated to reflect: (1) The re-establishment of the Administrative Conference of the United States in March 2010 (ACUS had not received funding between 1995 and 2009); (2) the establishment of the Financial Stability Oversight Council in Public Law 111–203 (Section 111); (3)the establishment of the Gulf Coast Ecosystem Restoration Council in Public Law 112–141 (Section 1603); and (4) the establishment of the Valles Caldera Trust in Public Law 106–248.

The list of the ''Designated Federal Entities'' has been updated to reflect the amendments in Public Law 111–203 and Public Law 111–259 to Section 8G of the IG Act. With respect to the IG Act's listing of ''designated Federal entities'' in Section 8G(a)(2), Public Law 111–203 added the Bureau of Consumer Financial Protection to the pre-existing listing for ''the Board of Governors of the Federal Reserve System''; and, Public Law 111–259 added the Defense Intelligence Agency, the National Geospatial-Intelligence Agency, the National Reconnaissance Office, and the National Security Agency. In addition, Public Law 111–203 amended Section 8G(a)(4), which is the provision of the IG Act that defines the term ''head of the designated Federal entity.'' As an initial matter, Congress amended the introductory text of Section 8G(a)(4) to state that—in the case of boards and commissions—''the term 'head of the designated Federal entity' means the board or commission of the designated Federal entity.'' As a result of this amendment, Section 8G(a)(4) sets forth three main categories of ''designated Federal entities'' with respect to who is the ''head'' of the entity: the term ''head of the designated Federal entity'' means (1) ''the board or commission of the designated Federal entity''; (2) ''in the event the designated Federal entity does not have a board or commission, any person or persons designated by statute as the head of a designated Federal entity''; and (3) ''if no such designation exists, the chief policymaking officer or board of a designated Federal entity as identified in the list published pursuant to subsection (h)(1) of this section, except that . . .'' In addition, Public Law 111–203 amended Section 8G(a)(4) to include six additional entity-specific exceptions to those general rules; in these exceptions, Congress specifies who is the ''head of the designated Federal entity'' for each of those entities. The pre-existing exceptions—for the National Science Foundation and the United States Postal Service—are found at subparagraphs (A) and (B), and the six added exceptions—for the Federal Labor Relations Authority, the National Archives and Records Administration, the National Credit Union Administration, the National Endowment for the Arts, the National Endowment for the Humanities, and the Peace Corps—are found at subparagraphs (C) through (H).

The list below is divided into two groups: Designated Federal Entities and Federal Entities. Designated Federal Entities are listed in the IG Act, except for those agencies that have ceased to exist or that have been deleted from the list. The Designated Federal Entities are required to establish and maintain Offices of Inspector General to: (1) Conduct and supervise audits and investigations relating to programs and operations; (2) promote economy, efficiency, and effectiveness of, and to prevent and detect fraud and abuse in such programs and operations; and (3) provide a means of keeping the entity head and the Congress fully and currently informed about problems and deficiencies relating to the administration of such programs and operations and the necessity for, and progress of, corrective actions.

Section 8G(a)(1) of the IG Act defines a ''Federal entity'' as: any Government corporation (within the meaning of section 103 (1) of title 5, United States Code), any Government controlled corporation (within the meaning of section 103 (2) of such title), or any other entity in the Executive Branch of the Government, or any independent regulatory agency, but does not include:

(1) An establishment (as defined in section 11(2) of this Act or part of an establishment;

(2) a designated Federal entity [as defined in section 8G(a)(2) of the Act] or part of a designated Federal entity;

(3) the Executive Office of the President;

(4) the Central Intelligence Agency;

(5) the Government Accountability Office; or

(6) any entity in the judicial or legislative branches of the Government, including the Administrative Office of the United States Courts and the Architect of the Capitol and any activities under the direction of the Architect of the Capitol.

Pursuant to section 8(G)(h)(2) of the IG Act, Federal Entities are required to report annually to each House of the Congress and OMB on audit and investigative activities in their organizations.

**Norman Dong,**

*Deputy Controller.*

Herein follows the text of the FY 2013 and FY 2014 List of Designated Federal Entities and Federal Entities.

### FY 2013 and FY 2014 List of Designated Federal Entities and Federal Entities

Section 8G of the IG Act, as amended, requires OMB to publish a list of designated Federal entities and Federal entities and the head of such entities. Designated Federal entities are required to establish Offices of Inspector General. Federal entities are required to report upon annual audit and investigative activities to each House of Congress and the Director of the Office of Management and Budget.

*Designated Federal Entities and Entity Heads*

1. Amtrak (National Railroad Passenger Corporation)—Board
2. Appalachian Regional Commission—Commission
3. The Board of Governors, Federal Reserve System and the Bureau of Consumer Financial Protection—Board
4. Broadcasting Board of Governors—Board
5. Commodity Futures Trading Commission—Commission
6. Consumer Product Safety Commission—Commission
7. Corporation for Public Broadcasting—Board
8. Defense Intelligence Agency—Director
9. Denali Commission—Commission
10. Election Assistance Commission—Commission
11. Equal Employment Opportunity Commission—Commission
12. Farm Credit Administration—Board
13. Federal Communications Commission—Commission
14. Federal Election Commission—Commission
15. Federal Labor Relations Authority—Authority Members
16. Federal Maritime Commission—Commission
17. Federal Trade Commission—Commission
18. Legal Services Corporation—Board
19. National Archives and Records Administration—Archivist of the United States
20. National Credit Union Administration—National Credit Union Administration Board
21. National Endowment for the Arts—National Council on the Arts
22. National Endowment for the Humanities—National Council on the Humanities
23. National Geospatial-Intelligence Agency—Director
24. National Labor Relations Board—Board
25. National Reconnaissance Office—Director
26. National Science Foundation—National Science Board
27. National Security Agency—Director
28. Peace Corps—Director
29. Pension Benefit Guaranty Corporation—Board
30. Postal Regulatory Commission—Commission
31. Securities and Exchange Commission—Commission
32. Smithsonian Institution—Board of Regents
33. United States International Trade Commission—Commission
34. United States Postal Service—Governors of the Postal Service

*Federal Entities and Entity Heads*

1. Administrative Conference of the United States—Chairperson
2. Advisory Council on Historic Preservation—Chairperson
3. African Development Foundation—Chairperson
4. American Battle Monuments Commission—Chairperson
5. Architectural and Transportation Barriers Compliance Board—Chairperson
6. Armed Forces Retirement Home—Chief Operating Officer
7. Barry Goldwater Scholarship and Excellence in Education Foundation—Chairperson
8. Chemical Safety and Hazard Investigation Board—Chairperson
9. Christopher Columbus Fellowship Foundation—Chairperson
10. Commission for the Preservation of America's Heritage Abroad—Chairperson
11. Commission of Fine Arts—Chairperson
12. Commission on Civil Rights—Chairperson
13. Committee for Purchase from People Who Are Blind or Severely Disabled—Chairperson
14. Court of Appeals for Veterans Claims—Chief Judge
15. Court Services and Offender Supervision Agency for DC—Director
16. Defense Nuclear Facilities Safety Board—Chairperson
17. Delta Regional Authority—Federal Co-Chairperson
18. Farm Credit System Insurance Corporation—Chairperson
19. Federal Financial Institutions Examination Council—Chairperson
20. Federal Mediation and Conciliation Service—Director
21. Federal Mine Safety and Health Review Commission—Chairperson
22. Federal Retirement Thrift Investment Board—Executive Director
23. Financial Stability Oversight Council—Chairperson
24. Gulf Coast Ecosystem Restoration—Council—Chairperson
25. Harry S. Truman Scholarship Foundation—Chairperson
26. Institute of American Indian and Alaska Native Culture and Arts Development—Chairperson
27. Institute of Museum and Library Services—Director
28. Inter-American Foundation—Chairperson
29. James Madison Memorial Fellowship Foundation—Chairperson
30. Japan-U.S. Friendship Commission—Chairperson
31. Marine Mammal Commission—Chairperson
32. Merit Systems Protection Board—Chairperson
33. Millennium Challenge Corporation—Chief Executive Officer
34. Morris K. Udall Scholarship and Excellence in National Environmental Policy Foundation—Chairperson
35. National Capital Planning Commission—Chairperson
36. National Council on Disability—Chairperson
37. National Mediation Board—Chairperson
38. National Transportation Safety Board—Chairperson
39. National Veterans Business Development Corporation—Chairperson
40. Neighborhood Reinvestment Corporation—Chairperson
41. Nuclear Waste Technical Review Board—Chairperson
42. Occupational Safety and Health Review Commission—Chairperson
43. Office of the Federal Coordinator for Alaska Natural Gas Transportation Projects—Federal Coordinator
44. Office of Government Ethics—Director
45. Office of Navajo and Hopi Indian Relocation—Chairperson
46. Office of Special Counsel—Special Counsel
47. Overseas Private Investment Corporation—Board
48. Presidio Trust—Chairperson
49. Selective Service System—Director
50. Smithsonian Institution/John F. Kennedy Center for the Performing Arts—Chairperson
51. Smithsonian Institution/National Gallery of Art—President
52. Smithsonian Institution/Woodrow Wilson International Center for Scholars—Director
53. Trade and Development Agency—Director
54. U.S. Holocaust Memorial Museum—Chairperson
55. U.S. Interagency Council on Homelessness—Chairperson
56. U.S. Institute of Peace—Chairperson
57. Valles Caldera Trust—Chairperson
58. Vietnam Education Foundation—Chairperson

[FR Doc. 2014–00210 Filed 1–9–14; 8:45 am]

BILLING CODE P

## NATIONAL SCIENCE FOUNDATION

### Sunshine Act Meeting; National Science Board

The National Science Board's Subcommittee on Facilities (SCF), pursuant to NSF regulations (45 CFR

part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business, as follows:

**DATE & TIME:** Thursday, January 16, 2014, 12:00 p.m.–1:00 p.m. EST.

**SUBJECT MATTER:** SCF members will discuss the forthcoming FY 13 Annual Portfolio Review of Facilities and how it relates to the NSF Facility Plan, which will be presented to the Board in February.

**STATUS:** Open.

This meeting will be held by teleconference. A public listening line will be available. Members of the public must contact the Board Office (call 703–292–7000 or send an email message to *nationalsciencebrd@nsf.gov*) at least 24 hours prior to the teleconference for the public listening number. Please refer to the National Science Board Web site www.nsf.gov/nsb for additional information and schedule updates (time, place, subject matter or status of meeting) which may be found at *http://www.nsf.gov/nsb/notices/*. Point of contact for this meeting is John Veysey at *jveysey@nsf.gov*.

**Ann Bushmiller,**

*Senior Counsel to the National Science Board.*

[FR Doc. 2014–00362 Filed 1–8–14; 11:15 am]

**BILLING CODE 7555–01–P**

## NUCLEAR REGULATORY COMMISSION

**[Docket No. NRC–2013–0280]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. The current OMB clearance expires on May 31, 2014. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* 10 CFR Part 63, ''Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada.''

2. *Current OMB approval number:* 3150–0199.

3. *How often the collection is required:* One time.

4. *Who is required or asked to report:* The State of Nevada, local governments, or affected Indian tribes, or their representatives, requesting consultation with the NRC staff regarding review of the potential high-level waste geologic repository site, or wishing to participate in a license application review for the potential geologic repository.

5. *The number of annual respondents:* 6.

6. *The number of hours needed annually to complete the requirement or request:* 726.

7. *Abstract:* Part 63 of Title 10 of the *Code of Federal Regulations* (10 CFR), requires the State of Nevada, local governments, or affected Indian tribes to submit certain information to the NRC if they request consultation with the NRC staff concerning the review of the potential repository site, or wish to participate in a license application review for the potential repository. Representatives of the State of Nevada, local governments, or affected Indian tribes must submit a statement of their authority to act in such a representative capacity. The information submitted by the State, local governments, and affected Indian tribes is used by the Director of the Office of Nuclear Material Safety and Safeguards as a basis for decisions about the commitment of the NRC staff resources to the consultation and participation efforts.

Submit, by March 11, 2014, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

The public may examine and have copied for a fee publicly-available documents, including the draft supporting statement, at the NRC's Public Document Room, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. The OMB clearance requests are available at the NRC's Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/*. The document will be available on the NRC's home page site for 60 days after the signature date of this notice.

Comments submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. Comments submitted should reference Docket No. NRC–2013–0280. You may submit your comments by any of the following methods: Electronic comments go to *http://www.regulations.gov* and search for Docket No. NRC–2013–0280. Mail comments to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Questions about the information collection requirements may be directed to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6258, or by email to *INFOCOLLECTS.Resource@NRC.GOV.*

Dated at Rockville, Maryland, this 7th day of January 2014.

For the Nuclear Regulatory Commission.

**Tremaine Donnell,**

*NRC Clearance Officer, Office of Information Services.*

[FR Doc. 2014–00261 Filed 1–9–14; 8:45 am]

**BILLING CODE 7590–01–P**

## NUCLEAR REGULATORY COMMISSION

**[NRC–2013–0254]**

### Conceptual Example of a Proposed Risk Management Regulatory Framework Policy Statement

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Conceptual example of a proposed policy statement; extension of comment period and public meeting.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is extending the public comment period on the document entitled, ''White Paper on a Conceptual Example of a Proposed Risk Management Regulatory Framework Policy Statement (the white paper),'' from January 10, 2014, to February 28, 2014. The NRC also plans to hold a public meeting to discuss and receive comments on the white paper.

**DATES:** The public meeting will be held on January 30, 2014. Additional details regarding the meeting are available in Section II, Public Meeting, of this document.

**ADDRESSES:** Please refer to Docket ID NRC–2013–0254 when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this action by the following methods:

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0254. Address questions about NRC dockets to Carol Gallagher; telephone: 301–287–3422; email: *Carol.Gallagher@nrc.gov*. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search*.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*. The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

**FOR FURTHER INFORMATION CONTACT:** Mary Drouin, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–251–7574; email: *Mary.Drouin@nrc.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. Background

On November 25, 2013 (78 FR 70354), the NRC published for public comment a document entitled, ''White Paper on a Conceptual Example of a Proposed Risk Management Regulatory Framework Policy Statement (ADAMS Accession No. ML13273A517).'' The conceptual statement would set forth a possible Commission policy regarding the use of a structured decision-making model that results in risk-informed and performance-based defense-in-depth protections to: Ensure appropriate personnel, barriers, and controls to prevent, contain, and mitigate possible inadvertent exposure to radioactive material according to the hazard present, the relevant scenarios, and the associated uncertainties; and ensure that the risks resulting from the failure of some or all of the established barriers and controls, including human errors, are maintained acceptably low. The white paper is an illustration of the staff's work in progress and is expected to be modified as both internal and external review is solicited and considered.

The public comment period for the white paper would have closed on January 10, 2014, however, the NRC has decided to extend the comment period until February 28, 2014, because it was recognized with the holidays, insufficient time had been given for review and comment.

## II. Public Meeting

The NRC staff plans to hold a public meeting on January 30, 2014. The meeting time and location has not yet been set, however, the final agenda and any meeting materials will be posted no fewer than 10 days prior to the meeting on the NRC's public Web site at *http://meetings.nrc.gov/pmns/mtg*. The purpose of this public meeting is for the NRC staff to answer questions, to provide any clarification to the white paper, and to solicit early stakeholder comments. This meeting will be a Category 3 public meeting and stakeholders wishing to provide a presentation should send a request to Mary Drouin at 301–251–7574 or by email to *Mary.Drouin@nrc.gov*. Presentations must be directly related to providing comments on the white paper (i.e., addressing the questions in the November 25, 2013, **Federal Register** notice). Requests should be sent in as soon as possible; depending on the number of requests, you will be notified if your presentation will be part of the agenda. If you have any questions, contact Mary Drouin at 301–251–7574 or by email to *Mary.Drouin@nrc.gov*.

Dated at Rockville, Maryland, this 6th day of January, 2014.

For the Nuclear Regulatory Commission.

**Patrick Madden,**

*Deputy Director, Division of Risk Analysis, Office of Nuclear Regulatory Research.*

[FR Doc. 2014–00244 Filed 1–9–14; 8:45 am]

BILLING CODE 7590–01–P

## NUCLEAR REGULATORY COMMISSION

**[NRC–2012–0269; Docket Nos. 50–325 and 50–324; License Nos. DPR–71 and DPR–62]**

## Duke Energy Progress, Inc.; Brunswick Steam Electric Plant, Units 1 and 2

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Issuance of Director's decision.

**SUMMARY:** Notice is hereby given that the Director, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission (NRC) has issued a Director's Decision on a petition filed by Mr. David Lochbaum, on behalf of the Union of Concerned Scientists; the North Carolina Waste Awareness & Reduction Network; and the Nuclear Information and Resource Service (hereafter referred to as ''the petitioner'').

**ADDRESSES:** Please refer to Docket ID NRC–2012–0269 when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this action by the following methods:

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0269. Address questions about NRC dockets to Carol Gallagher; telephone: 301–287–3422; email: *Carol.Gallagher@nrc.gov*.

• *NRC's Agencywide Documents Access and Management System (ADAMS*):

You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search*.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*. The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced. The petition, dated July 10, 2012, under ADAMS Accession No. ML12193A123, concerns the operation of the Brunswick Steam Electric Plant, Units 1 and 2 (Brunswick), which are operated by Duke Energy Progress, Inc. (the licensee).

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

**Discussion**

The petitioner requested that the NRC take enforcement action in the form of an Order either modifying the Brunswick operating licenses or requiring the licensee to submit amendment requests for these licenses.

The petitioner requested that the NRC take enforcement action in the form of an Order that would result in a new technical specification (TS) safety limits (SLs) and expand the applicability of numerous TS limiting condition for operations related to spent fuel pool (SFP) storage. As the basis for the request, the petitioner asserted that the changes sought would provide better management of the risk from irradiated fuel stored in the SFPs.

The petitioner had a recorded conference call with the NRC's Office of Nuclear Reactor Regulation's Petition's Review Board on August 15, 2012, to discuss and supplement the petition. The NRC has made the official transcript of the August 15, 2012, conference call publicly available online in the NRC's Library at *http://www.nrc.gov/reading-rm/adams.html* (ADAMS Accession No. ML12234A730).

The NRC sent a copy of the proposed Director's Decision to the petitioner and the licensee for comment on October 23, 2013. The NRC requested the petitioner and the licensee to provide comments within 30 days on any part of the proposed Director's Decision considered erroneous or any issues in the petition that were not addressed. The NRC did not receive any comments.

The Director of the Office of Nuclear Reactor Regulation has denied the request to take enforcement action in the form of an Order either modifying the Brunswick operating licenses or requiring the licensee to submit amendment requests for these licenses, which would result in a new TS SL and expand the applicability of numerous TS limiting conditions of operation (LCOs) related to SFP storage. The NRC staff reviewed the petitioner's requested actions against the regulatory framework that is in place to determine when TS SLs, LCOs, or design features are required, including the Commission's policy statement on TSs. The NRC staff found no basis for taking enforcement action against the licensee based on the petitioner's concerns. The Director's Decision (DD–13–03) under section 2.206 of Title 10 of the *Code of Federal Regulations* (10 CFR), ''Requests for Action under this Subpart,'' explains the reasons for this decision. The complete text is in ADAMS under Accession No. ML13339A590 and is available for inspection at the NRC's PDR. The NRC will file a copy of the Director's Decision with the Secretary of the Commission for the Commission's review in accordance with 10 CFR 2.206.

As provided for by this regulation, the Director's Decision will constitute the final action of the Commission 25 days after the date of the decision unless the Commission, on its own motion, institutes a review of the Director's Decision in that time.

Dated at Rockville, Maryland, this 30 day of December 2013.

For the Nuclear Regulatory Commission.

**Jennifer L. Uhle,**

*Deputy Director for Reactor Safety Programs, Office of Nuclear Reactor Regulation.*

[FR Doc. 2014–00250 Filed 1–9–14; 8:45 am]

**BILLING CODE 7590–01–P**

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## NUCLEAR REGULATORY COMMISSION

**[NRC–2014–0002]**

## Emergency Planning Exemption Requests for Decommissioning Nuclear Power Plants

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Draft interim staff guidance; request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is soliciting public comment on its draft Interim Staff Guidance (ISG) NSIR/DPR–ISG–02, ''Emergency Planning Exemption Requests for Decommissioning Nuclear Power Plants.'' This document would provide guidance for NRC staff to ensure clear and consistent reviews of requests for exemptions from emergency preparedness regulations and license amendments for defueled station emergency plans submitted by nuclear power plant licensees after permanent cessation of plant operations. Nuclear power plants that have ceased operating and are permanently defueled provide less risk of radiological releases than operating nuclear power plants. Licensees of these decommissioning plants have historically submitted exemption requests based on this lower risk. The ISG also could be used by nuclear power plant licensees when drafting these exemption requests.

**DATES:** Submit comments by March 11, 2014. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date.

**ADDRESSES:** You may submit comment by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2014–0002. Address questions about NRC dockets to Carol Gallagher; telephone: 301–287–3422; email: *Carol.Gallagher@nrc.gov*. For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: 3WFN–06–44M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on accessing information and submitting comments, see ''Accessing Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** Michael Wasem, telephone: 301–287–3793, email: *michael.wasem@nrc.gov* or Michael Norris, telephone: 301–287–3754, email: *michael.norris@nrc.gov*. Both of the Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

**SUPPLEMENTARY INFORMATION:**

### I. Accessing Information and Submitting Comments

*A. Accessing Information*

Please refer to Docket ID NRC–2014–0002 when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this action by the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2014–0002.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly-available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*. The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced. In addition, for the convenience of the reader, the

ADAMS accession numbers are provided in a table in the section of this notice entitled, Availability of Documents.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

*B. Submitting Comments*

Please include Docket ID NRC–2014–0002 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at *http://www.regulations.gov* as well as entering the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

## II. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

| Document | ADAMS Accession No./web link/**Federal Register** citation |
|---|---|
| Draft Interim Staff Guidance (ISG) NSIR/DPR–ISG–02, "Emergency Planning Exemption Requests for Decommissioning Nuclear Power Plants". | ADAMS Accession No. ML13304B442. |
| NUREG–1738 "Technical Study of Spent Fuel Pool Accident Risk at Decommissioning Nuclear Power Plants". | ADAMS Accession No. ML010430066. |
| Draft Report, "Consequence Study of a Beyond-Design-Basis Earthquake Affecting the Spent Fuel Pool for a U.S. Mark I Boiling Water Reactor". | ADAMS Accession No. ML13133A132. |
| SECY–00–0145, "Integrated Rulemaking Plan for Nuclear Power Plant Decommissioning". | ADAMS Accession No. ML003721626. |
| NUREG/CR–6451, "A Safety and Regulatory Assessment of Generic BWR and PWR Permanently Shutdown Nuclear Power Plants". | ADAMS Accession No. ML082260098. |
| NUREG–1864, "A Pilot Probabilistic Risk Assessment of a Dry Cask Storage System at a Nuclear Power Plant". | ADAMS Accession No. ML071340012. |
| Memorandum dated August 16, 2002, "Status of Regulatory Exemptions for Decommissioning Plants". | ADAMS Accession No. ML030550706. |
| SECY–97–120, "Rulemaking Plan for Emergency Planning Requirements for Permanently Shutdown Nuclear Power Plant Sites". | *http://www.nrc.gov/reading-rm/doc-collections/commission/secys/1997/secy1997-120/1997-120scy.pdf.* |

## III. Background

Currently, licensees of permanently defueled nuclear power plant sites are required to maintain emergency plans meeting the same requirements as emergency plans for operating nuclear power plants. The NRC recognizes that in the plant's permanently defueled condition, the risk of a radiation release to the public is much less than the risk of a release from an operating plant and the consequences of a release are, in most cases, significantly less than that of an operating reactor. Rulemaking to address these differences, along with security and insurance considerations was considered in the 1990's. The events of September 11, 2001, and the fact that no plants were thought to be entering decommissioning in the immediate future led the NRC to suspend rulemaking activities. Licensees have historically used the exemption process to decrease the burden of maintaining required parts of emergency plans that are no longer necessary to contribute to the safety of workers or the public. This ISG consolidates findings from previous exemption request reviews and informs the justifications for approving exemptions with the results of more recent and complete studies. Use of this ISG should result in consistent and timely reviews of requests for exemption from certain emergency preparedness regulations.

The NRC staff is issuing this notice to solicit public comments on the proposed NSIR/DPR–ISG–02. After the NRC considers any public comments, it will issue a **Federal Register** notice making a determination regarding a final NSIR/DPR–ISG–02.

Dated at Rockville, Maryland, this 23rd day of December, 2013.

For the Nuclear Regulatory Commission.

**Robert Lewis,**

*Director, Division of Preparedness and Response, Office of Nuclear Security and Incident Response.*

[FR Doc. 2014–00249 Filed 1–9–14; 8:45 am]

BILLING CODE 7590–01–P

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## NUCLEAR REGULATORY COMMISSION

**[Docket No. 50–219; NRC–2013–0288]**

## Exelon Generation Company, LLC; License Exemption Request for Oyster Creek Nuclear Generating Station

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Exemption; issuance.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption in response to an October 14, 2013, request from Exelon Generation Company (the licensee) for a one-time exemption from the requirement to participate in the biennial Emergency Preparedness (EP) exercise. The licensee requested to delay conduct of the exercise from October 8, 2013, to March 18, 2014.

**ADDRESSES:** Please refer to Docket ID NRC–2013–0288 when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this document using any of the following methods:

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0288. Address questions about NRC dockets to Carol Gallagher; telephone: 301–287–3422; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER**

**INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

**FOR FURTHER INFORMATION CONTACT:** John G. Lamb, Office of Nuclear Reactor Regulation, Division of Operating Reactor Licensing; telephone: 301–415–3100, email: *John.Lamb@nrc.gov;* U.S. Nuclear Regulatory Commission, Washington DC 20555–0001.

**SUPPLEMENTARY INFORMATION:** The following sections include the text of the exemption in its entirety as issued to Exelon Generation Company, LLC.

## I. Background

The Exelon Generation Company, LLC (the licensee) is the holder of Facility Operating License No. DPR–16, which authorizes operation of the Oyster Creek Nuclear Generating Station (OCNGS). The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the NRC now or hereafter in effect. The facility consists of a boiling-water reactor located in Ocean County, New Jersey.

## II. Request/Action

Title 10 of the *Code of Federal Regulations* (10 CFR), Part 50, Appendix E, Sections IV.F.2.b and IV.F.2.c requires that ''[o]ffsite plans for each site shall be exercised biennially with full participation by each offsite authority having a role under the radiological response plan.'' By letter dated October 14, 2013, and supplemented on December 19, 2013 (ADAMS Accession Nos. ML13288A177 and ML13357A662, respectively), the licensee requested a one-time exemption from this requirement that would allow the licensee to delay conduct of a biennial emergency preparedness (EP) exercise from October 8, 2013, to March 18, 2014. The licensee's request states that the Federal government shutdown various government agencies on October 1, 2013, due to a lapse in funding appropriations. The Federal government shutdown affected the Federal Emergency Management Agency's (FEMA's) and the NRC's capabilities to participate in the OCNGS EP exercise scheduled on October 8, 2013. By letter dated October 3, 2013, FEMA notified the New Jersey Deputy Superintendent Homeland Security, State Police Division Headquarters, that FEMA would not be able to evaluate the OCNGS full participation EP exercise, scheduled for October 8, 2013, because all FEMA travel was cancelled except for life-saving activities.

Based on discussions with FEMA and the New Jersey Office of Emergency Management (NJOEM) representatives, the licensee does not consider it feasible to schedule and perform a full participation biennial exercise prior to the end of calendar year (CY) 2013.

By letter dated October 9, 2013, NJOEM notified the licensee that re-scheduling the OCNGS EP exercise to March 18, 2014, was acceptable. By letter dated October 10, 2013, FEMA sought concurrence from the New Jersey Deputy Superintendent Homeland Security, State Police Division Headquarters, for the new proposed OCNGS full participation EP exercise, scheduled for March 18, 2014. It further provided that it was acceptable for the exercise to be conducted in early 2014.

By letter dated October 14, 2013, the licensee requested a one-time exemption from these requirements to allow a delay for the conduct of the biennial EP exercise from October 8, 2013, to March 18, 2014. The licensee's request states that due to the lapse in government funding appropriations, FEMA and NRC resources were unable to participate in the OCNGS EP exercise scheduled for October 8, 2013.

## III. Discussion

By letter dated December 19, 2013, the licensee stated that the proposed exemption is not a reduction in effectiveness of the OCNGS EP plan. Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR Part 50, Appendix E, when: (1) The exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security; and (2) when special circumstances are present.

*Authorized by Law*

This exemption would allow the Federal government response organizations to accommodate the Federal government shutdown impacts on their resources by postponing the OCNGS EP exercise from the previously scheduled date of October 8, 2013, until March 18, 2014.

As stated above, 10 CFR 50.12 allows the NRC to grant exemptions from the requirements of 10 CFR Part 50, Appendix E. The NRC staff has determined that granting of the licensee's proposed exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. Therefore, the exemption is authorized by law.

*No Undue Risk to Public Health and Safety*

By letter dated December 19, 2013, the licensee stated that the proposed exemption is not a reduction in effectiveness of the OCNGS EP plan, and the NRC staff agrees.

The underlying purpose of 10 CFR Part 50, Appendix E, Sections IV.F.2.b and IV.F.2.c is to ensure that licensees test and maintain interfaces among themselves and affected State and local authorities during the intervals between biennial EP exercises by conducting EP activities and interactions. In order to accommodate the scheduling of full participation exercises, the NRC has allowed licensees to schedule the exercises at any time during the calendar biennium. Conducting the OCNGS full-participation EP exercise by March 18, 2014, rather than CY 2013, places the exercise outside of the required biennium. Since the last biennial EP exercise on September 27, 2011 (onsite and partial offsite demonstration), and June 12, 2012 (offsite demonstration), the licensee has conducted training evolutions supported by NJOEM and local emergency planning zone authorities. Although these drills and training sessions did not exercise all of the proposed rescheduled offsite functions, they do support the licensee's assertion that they have a continuing level of engagement with the State and local authorities to maintain interfaces. During the interim year, the NJOEM and the New Jersey Department of Environmental Protection, Bureau of Nuclear Engineering also successfully exercised the State Radiological Emergency Response Plan and Annex A for Salem/Hope Creek Nuclear Generating Stations on May 22, 2012.

Based on the above, no new accident precursors are created by allowing the

licensee to postpone the biennial exercise from CY 2013 until CY 2014; thus, the probability of postulated accidents is not increased. Also, based on the above, the consequences of postulated accidents are not increased. Therefore, there is no undue risk to public health and safety.

*Consistent With Common Defense and Security*

The proposed exemption would allow rescheduling of the OCNGS biennial EP exercise from the previously scheduled date of October 8, 2013, until March 18, 2014. This change to the EP exercise schedule has no relation to security issues. Therefore, the common defense and security is not impacted by this exemption.

*Special Circumstances*

In order to grant exemptions in accordance with 10 CFR 50.12, special circumstances must be present. Special circumstances per 10 CFR 50.12 that apply to this exemption request are 10 CFR 50.12(a)(2)(ii) and (v). Special circumstances, per 10 CFR 50.12(a)(2)(ii), are present when: ''[a]pplication of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule.'' Sections IV.F.2.b and IV.F.2.c of 10 CFR Part 50, Appendix E require licensees to exercise onsite and offsite plans biennially with full or partial participation by each offsite authority having a role under the plan. The underlying purposes of 10 CFR Part 50, Appendix E, Sections IV.F.2.b and IV.F.2.c are to require licensees to exercise onsite and offsite plans with offsite authority participation to test and maintain interfaces among affected State and local authorities and the licensee. The previous biennial EP exercise was successfully conducted on September 27, 2011, and June 12, 2012. Since this last demonstration, the licensee has conducted 10 onsite training drills/exercises/demonstrations and eight drills/exercises/demonstrations that have involved interface with State and local authorities in 2012 and 2013. The NRC staff considers these measures adequate to test and maintain interfaces with affected State and local authorities during this period, satisfying the underlying purpose of the rule.

Under 10 CFR 50.12(a)(2)(v), special circumstances are present whenever the exemption would provide only temporary relief from the applicable regulation and the licensee or applicant has made good faith efforts to comply with the regulation. The 10 onsite training drills/exercises/demonstrations and eight drills/exercises/demonstrations involving interface with State and local authorities in 2012 and 2013 demonstrate the licensee's good faith effort to comply with the regulations. The requested exemption to postpone the conduct of the biennial EP exercise to March 18, 2014, grants only temporary relief from the applicable regulation. Therefore, since the underlying purpose of 10 CFR Part 50, Appendix E, Sections IV.F.2.b and IV.F.2.c are achieved, the licensee has made a good faith effort to comply with the regulations, and the exemption would grant only temporary relief from the applicable regulation, the special circumstances required by 10 CFR 50.12(a)(2)(ii and v) exist for the granting of an exemption.

## IV. Environmental Considerations

The proposed exemption to postpone the OCNGS EP exercise from October 8, 2013, to March 18, 2014, does not increase the probability of an accident because EP exercises are not initiators of any design-basis event. Additionally, the proposed exemption does not involve any physical changes to plant systems, structures, or components (SSCs), or the manner in which these SSCs are maintained or controlled. Therefore, the proposed exemption does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed exemption does not alter the physical design, safety limits, or safety analysis assumptions associated with the operation of OCNGS. Accordingly, the proposed exemption does not introduce any new accident initiators, nor does it reduce or adversely affect the capabilities of any plant structure or system in the performance of their safety function. Therefore, the proposed exemption does not create the possibility of a new or different kind of accident from any previously evaluated.

The proposed exemption does not impact the assumptions of any design-basis accident, and does not alter assumptions relative to the mitigation of an accident or transient event. Also, the proposed exemption does not involve a significant reduction in a margin of safety.

The NRC staff has determined that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC proposes to determine that the exemption request involves no significant hazards consideration.

The NRC staff determined that the proposed exemption changes the EP exercise from October 8, 2013, to March 18, 2014, involves no significant increase in the amounts, and no significant change in the types, of any effluents that may be released offsite; that there is no significant increase in individual or cumulative occupational radiation exposure; that there is no significant construction impact; and there is no significant increase in the potential for or consequences from a radiological accident.

The NRC staff has further determined that the requirements from which the exemption is sought involve the factors associated with 10 CFR 51.22(c)(25)(vi)(G)—scheduling requirements. Specifically, the proposed exemption changes the EP exercise from October 8, 2013, to March 18, 2014.

Therefore, the criteria specified in 10 CFR 51.22(c)(25)(vi)(G) is satisfied, and accordingly, the exemption meets the eligibility criteria for exclusion set forth in 10 CFR 51.22(c)(25). Pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment is required to be prepared with the issuance of the exemption.

## V. Conclusion

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12, the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also, special circumstances are present. Therefore, the Commission, hereby grants Exelon Generation Company, LLC an exemption from the requirements of 10 CFR Part 50, Appendix E, Sections IV.F.2.b and IV.F.2.c to conduct the OCNGS biennial EP exercise required for 2013, permitting that EP exercise to be conducted in coordination with NRC and OCNGS schedules on March 18, 2014.

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 30th day of December 2013.

For the Nuclear Regulatory Commission.

**Michele G. Evans,**

*Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.*

[FR Doc. 2014–00253 Filed 1–9–14; 8:45 am]

BILLING CODE 7590–01–P

## NUCLEAR REGULATORY COMMISSION

**[NRC–2014–0004]**

## Aging Management of Loss of Coating Integrity for Internal Service Level III (Augmented) Coatings

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Draft license renewal interim staff guidance; request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) requests public comment on the draft License Renewal Interim Staff Guidance (LR–ISG), LR–ISG–2013–01, ''Aging Management of Loss of Coating Integrity for Internal Service Level III (augmented) Coatings.'' The draft LR–ISG proposes to add a new NRC staff-recommended aging management program (AMP), new aging management review (AMR) items, and new age-related definitions in NUREG–1801, Revision 2, ''Generic Aging Lessons Learned (GALL) Report.'' The draft LR–ISG also adds new AMR items and changes to the Final Safety Analysis Supplement program description in NUREG–1800, Revision 2, ''Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants'' (SRP–LR). These changes address new recommendations related to Service Level III (augmented) (a new term) internal coatings in piping, tanks, and heat exchangers.

**DATES:** Submit comments by February 24, 2014. Comments received after this date will be considered, if it is practical to do so, but the NRC staff is able to ensure consideration only for comments received on or before this date.

**ADDRESSES:** You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2014–0004. Address questions about NRC dockets to Carol Gallagher; telephone: 301–287–3422; email: *Carol.Gallagher@nrc.gov*. For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch, Office of Administration, Mail Stop: 3WFN, 06–44M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on accessing information and submitting comments, see ''Accessing Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** William Holston, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–8573; email: *William.Holston@nrc.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Accessing Information and Submitting Comments

*A. Accessing Information*

Please refer to Docket ID NRC–2014–0004 when contacting the NRC about the availability of information regarding this document. You may access publicly available information related to this action by the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2014–0004.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/.html* by selecting ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*. The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced. The draft LR–ISG–2013–01 is available electronically under ADAMS Accession No. ML13262A442. The GALL Report and SRP–LR are available under ADAMS Accession Nos. ML103490041 and ML103490036, respectively.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

*B. Submitting Comments*

Please include Docket ID NRC–2014–0004 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at *http://www.regulations.gov* as well as entering the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

### II. Background

The draft LR–ISG proposes to add a new NRC staff-recommended aging management program, new aging management review items, and new age-related definitions in NUREG–1801, Revision 2, ''Generic Aging Lessons Learned Report.'' The draft LR–ISG also adds new AMR items and changes to the Final Safety Analysis Supplement program description in NUREG–1800, Revision 2, ''Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants.'' These changes address new recommendations related to Service Level III (augmented) internal coatings in piping, tanks, and heat exchangers within the scope of part 54 of Title 10 of the *Code of Federal Regulations* (10 CFR), ''Requirements for Renewal of Operating Licenses for Nuclear Power Plants.''

The NRC issues LR–ISGs to communicate insights and lessons learned and to address emergent issues not covered in license renewal guidance documents, such as the GALL Report and SRP–LR. In this way, the NRC staff and stakeholders may use the guidance in an LR–ISG document before it is incorporated into a formal license renewal guidance document revision. The NRC staff issues LR–ISGs in accordance with the LR–ISG Process, Revision 2 (ADAMS Accession No. ML100920158), for which a notice of availability was published in the **Federal Register** on June 22, 2010 (75 FR 35510).

The NRC staff has developed LR–ISG–2013–01 to address: loss of coating integrity due to blistering, cracking, flaking, peeling, or physical damage of Service Level III (augmented) internal coatings in piping, tanks, and heat exchangers within the scope of 10 CFR Part 54.

## III. Proposed Action

By this action, the NRC is requesting public comments on draft LR–ISG–2013–01. This LR–ISG proposes certain revisions to NRC guidance on implementation of the requirements in 10 CFR Part 54. The NRC staff will make a final determination regarding issuance of the LR–ISG after it considers any public comments received in response to this request.

Dated at Rockville, Maryland, this 6th day of January 2014.

For the Nuclear Regulatory Commission.

**Melanie A. Galloway,**

*Deputy Director, Division of License Renewal, Office of Nuclear Reactor Regulation.*

[FR Doc. 2014–00247 Filed 1–9–14; 8:45 am]

**BILLING CODE 7590–01–P**

## SECURITIES AND EXCHANGE COMMISSION

### Proposed Collection; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

*Extension:*

Form 10, OMB Control No. 3235–0064, SEC File No. 270–051.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the office of Management and Budget (''OMB'') for approval of extensions on the following:

Form 10 (17 CFR 249.210) is used by the Commission to register securities pursuant to Section 12(b) and Section 12(g) (15 U.S.C. 78l(b) and 78l(g)) of the Exchange Act of 1934. Form 10 requires financial and other information about such matters as the registrant's business, properties, identity and remuneration of management, outstanding securities and securities to be registered and financial condition. The information provided by Form 10 is intended to ensure the adequacy of information available to investors about the company. Form 10 takes approximately 215.210 hours per response to prepare and is filed by approximately 238 respondents. We estimated that 25% of the 215.210 hours per response (53.802 hours) is prepared by the company for an annual reporting burden of 12, 805 hours (53.802 hours per response x 238 responses).

Written 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 will have practical utility; (b) the accuracy of the agency's estimate of burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

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.

Please direct your written comment to Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: January 6, 2014.

**Kevin M. O'Neill,**

*Deputy Secretary.*

[FR Doc. 2014–00213 Filed 1–9–14; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

### Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

*Extension:*

Rule 17d–1, OMB Control No. 3235–0562, SEC File No. 270–505.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collections of information summarized below. The Commission plans to submit these existing collections of information to the Office of Management and Budget (''OMB'') for extension and approval.

Section 17(d) (15 U.S.C. 80a–17(d)) of the Investment Company Act of 1940 (15 U.S.C. 80a *et seq.*) (the ''Act'') prohibits first- and second-tier affiliates of a fund, the fund's principal underwriters, and affiliated persons of the fund's principal underwriters, acting as principal, to effect any transaction in which the fund or a company controlled by the fund is a joint or a joint and several participant in contravention of the Commission's rules. Rule 17d–1 (17 CFR 270.17d–1) prohibits an affiliated person of or principal underwriter for any fund (a ''first-tier affiliate''), or any affiliated person of such person or underwriter (a ''second-tier affiliate''), acting as principal, from participating in or effecting any transaction in connection with a joint enterprise or other joint arrangement in which the fund is a participant, unless prior to entering into the enterprise or arrangement ''an application regarding [the transaction] has been filed with the Commission and has been granted by an order.'' In reviewing the proposed affiliated transaction, the rule provides that the Commission will consider whether the proposal is (i) consistent with the provisions, policies, and purposes of the Act, and (ii) on a basis different from or less advantageous than that of other participants in determining whether to grant an exemptive application for a proposed joint enterprise, joint arrangement, or profit-sharing plan.

Rule 17d–1 also contains a number of exceptions to the requirement that a fund must obtain Commission approval prior to entering into joint transactions or arrangements with affiliates. For example, funds do not have to obtain Commission approval for certain employee compensation plans, certain tax-deferred employee benefit plans, certain transactions involving small business investment companies, the receipt of securities or cash by certain affiliates pursuant to a plan of reorganization, certain arrangements regarding liability insurance policies and transactions with ''portfolio affiliates'' (companies that are affiliated with the fund solely as a result of the fund (or an affiliated fund) controlling them or owning more than five percent of their voting securities) so long as certain other affiliated persons of the fund (*e.g.,* the fund's adviser, persons controlling the fund, and persons under common control with the fund) are not parties to the transaction and do not have a ''financial interest'' in a party to the transaction. The rule excludes from the definition of ''financial interest'' any interest that the fund's board of directors (including a majority of the directors who are not interested persons of the fund) finds to be not material, as long as the board records the basis for its finding in their meeting minutes.

Thus, the rule contains two filing and recordkeeping requirements that constitute collections of information. First, rule 17d-1 requires funds that wish to engage in a joint transaction or arrangement with affiliates to meet the procedural requirements for obtaining exemptive relief from the rule's prohibition on joint transactions or arrangements involving first- or second-tier affiliates. Second, rule 17d–1 permits a portfolio affiliate to enter into a joint transaction or arrangement with the fund if a prohibited participant has a financial interest that the fund's board determines is not material and records the basis for this finding in their meeting minutes. These requirements of rule 17d–1 are designed to prevent fund insiders from managing funds for their own benefit, rather than for the benefit of the funds' shareholders.

Based on an analysis of past filings, Commission staff estimates that 13 funds file applications under section 17(d) and rule 17d–1 per year. The staff understands that funds that file an application generally obtain assistance from outside counsel to prepare the application. The cost burden of using outside counsel is discussed below. The Commission staff estimates that each applicant will spend an average of 154 hours to comply with the Commission's applications process. The Commission staff therefore estimates the annual burden hours per year for all funds under rule 17d–1's application process to be 2002 hours at a cost of $726,206.[1] The Commission, therefore, requests authorization to increase the inventory of total burden hours per year for all funds under rule 17d–1 from the current authorized burden of 1232 hours to 2002 hours. The increase is due to an increase in the number of funds that filed applications for exemptions under rule 17d–1.

As noted above, the Commission staff understands that funds that file an application under rule 17d–1 generally use outside counsel to assist in preparing the application. The staff estimates that, on average, funds spend an additional $93,131 for outside legal services in connection with seeking Commission approval of affiliated joint transactions. Thus, the staff estimates that the total annual cost burden imposed by the exemptive application requirements of rule 17d–1 is $1,210,703.[2]

We estimate that funds currently do not rely on the exemption from the term ''financial interest'' with respect to any interest that the fund's board of directors (including a majority of the directors who are not interested persons of the fund) finds to be not material. Accordingly, we estimate that annually there will be no transactions under rule 17d–1 that will result in this aspect of the collection of information.

Based on these calculations, the total annual hour burden is estimated to be 2002 hours and the total annual cost burden is estimated to be $1,024,441.

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act. The estimate is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules. Complying with these collections of information requirement is necessary to obtain the benefit of relying on rule 17d–1. Responses will not be kept confidential. 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.

Written 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 will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Thomas Bayer, Chief Information Officer, Securities and Exchange Commission, C/O Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov*.

Dated: January 6, 2014.

**Kevin M. O'Neill,**

*Deputy Secretary.*

[FR Doc. 2014–00212 Filed 1–9–14; 8:45 am]

BILLING CODE 8011–01–P

[1] The Commission staff estimates that a senior executive, such as the fund's chief compliance officer, will spend an average of 62 hours and a mid-level compliance attorney will spend an average of 92 hours to comply with this collection of information: 62 hours + 92 hours = 154 hours. 13 funds × 154 burden hours = 2002 burden hours. The Commission staff estimate that the chief compliance officer is paid $441 per hour and the compliance attorney is paid $310 per hour. ($441 per hour × 62 hours) + ($310 per hour × 92 hours) = $55,862 per fund. $55,862 × 13 funds = $726,206. The $441 and $310 per hour figures are based on salary information compiled by SIFMA's *Management & Professional Earnings in the Securities Industry, 2012*. The Commission staff has modified SIFMA's information to account for an 1800-hour work year and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead.

[2] The estimate is based on the following calculation: $93,131 × 13 funds = $1,210,703.

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–71236; File No. SR–PHLX–2014–01]**

## Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Clarify That an Extranet Access Fee is Not Charged

January 6, 2014.

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 January 2, 2014, NASDAQ OMX PHLX LLC (''Phlx'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

### I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to clarify that it does not charge an extranet access fee (''Extranet Access Fee'').

The text of the proposed rule change is below. Proposed new language is italicized.

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### NASDAQ OMX PHLX LLC[1] PRICING SCHEDULE

* * * * *

### VIII. NASDAQ OMX PSX FEES

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### Market Data Distributor Fees

(a)–(c) No change.

Extranet Access

*Extranet providers that establish a connection with the Exchange to offer direct access connectivity to market data feeds shall not be assessed a monthly access fee per recipient Customer Premises Equipment (''CPE'') Configuration. For purposes of this rule, the term ''Customer Premises Equipment Configuration'' shall mean any line, circuit, router package, or*

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

*other technical configuration used by an extranet provider to provide a direct access connection to Exchange market data feeds to a recipient's site.*

**Administrative Reports**

No change.

* * * * *

**II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange is proposing to clarify that the Exchange does not charge an Extranet Access Fee, unlike The NASDAQ Stock Market LLC (''NASDAQ'') [3] or NASDAQ OMX BX, Inc. (''BX'') [4].

Specifically, the proposed rule change provides that extranet providers that establish a connection with the Exchange to offer direct access connectivity to market data feeds will not be assessed a monthly access fee per recipient Customer Premises Equipment (''CPE'') Configuration.[5]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [6] in general, and with Section 6(b)(5) of the Act,[7] in particular. The Exchange believes the proposal furthers the objectives of Section 6(b)(5) of the Act [8] in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customer, issuers, brokers and dealers. The Exchange is proposing to add clarifying language that states that extranet providers that establish an extranet connection with the Exchange to access market data feeds from the Exchange will not be subject to an Extranet Access Fee. Accordingly, the Exchange believes that it is consistent with the protection of investors and the public interest to avoid potential market participant confusion that may be caused by the omission of the proposed rule text.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. The proposed rule change clarifies that no fee is being instituted and this applies across all extranet providers and none are [sic] compelled to establish a connection with the Exchange to offer access connectivity to market data feeds.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

Written comments were neither solicited nor received.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [9] and subparagraph (f)(6) of Rule 19b–4 thereunder.[10]

A proposed rule change filed under Rule 19b–4(f)(6) [11] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[12] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. The proposed rule change presents no novel issues. Waiver will allow the Exchange to immediately clarify that it does not charge an extranet access fee, thereby reducing the potential for confusion. For these reasons, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[13]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [14] of the Act to determine whether the proposed rule change should be approved or disapproved.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–PHLX–2014–01 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–PHLX–2014–01. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the

[3] *See* NASDAQ Rule 7025.

[4] *See* BX Rule 7025.

[5] As defined in the proposed rule text, a ''Customer Premises Equipment Configuration'' means any line, circuit, router package, or other technical configuration used by an extranet provider to provide a direct access connection to Exchange market data feeds to a recipient's site.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] *Id.*

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 240.19b–4(f)(6)(iii).

[13] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 15 U.S.C. 78s(b)(2)(B).

submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–PHLX–2014–01, and should be submitted on or before January 31, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

**Kevin M. O'Neill,**

*Deputy Secretary.*

[FR Doc. 2014–00211 Filed 1–9–14; 8:45 am]

**BILLING CODE 8011–01–P**

[15] 17 CFR 200.30–3(a)(12).

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–2013–0174]**

### Qualification of Drivers; Exemption Applications; Vision

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of applications for exemptions; request for comments.

**SUMMARY:** FMCSA announces receipt of applications from 33 individuals for exemption from the vision requirement in the Federal Motor Carrier Safety Regulations. They are unable to meet the vision requirement in one eye for various reasons. The exemptions would enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting the prescribed vision requirement in one eye.

**DATES:** Comments must be received on or before February 10, 2014.

**ADDRESSES:** You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2013–0174 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

*Instructions:* Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

*Docket:* For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

*Privacy Act:* Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the Federal Docket Management System (FDMS) published in the **Federal Register** on January 17, 2008 (73 FR 3316).

**FOR FURTHER INFORMATION CONTACT:** Elaine M. Papp, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:**

#### Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' FMCSA can renew exemptions at the end of each 2-year period. The 33 individuals listed in this notice have each requested such an exemption from the vision requirement in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting an exemption will achieve the required level of safety mandated by statute.

#### Qualifications of Applicants

*Trawn L. Andrews*

Mr. Andrews, age 32, has had amblyopia in his right eye since birth. The visual acuity in his right eye is 20/50, and in his left eye, 20/20. Following an examination in 2013, his optometrist noted, ''I certify that, in my medical opinion, this patient has sufficient vision to operate a commercial motor vehicle.'' Mr. Andrews reported that he has driven straight trucks for 10 years, accumulating 325,000 miles, and tractor-trailer combinations for 10 years, accumulating 325,000 miles. He holds a Class A Commercial Driver's License (CDL) from North Carolina. His driving record for the last 3 years shows one crash, for which he was not cited and to which he did not contribute, and no convictions for moving violations in a CMV.

*Jeffery A. Benoit*

Mr. Benoit, 30, has had amblyopia in his left eye since childhood. The visual acuity in his right eye is 20/15, and in his left eye, 20/150. Following an examination in 2013, his optometrist noted, ''In my optometric opinion, Jeffrey [*sic*] Benoit has sufficient vision to operate a commercial vehicle.'' Mr. Benoit reported that he has driven tractor-trailer combinations for 7 years, accumulating 147,000 miles. He holds a Class A CDL from Vermont. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Norvan D. Brown*

Mr. Brown, 61, has a prosthetic left eye due to a traumatic incident in 2010. The visual acuity in his right eye is 20/20, and in his left eye, no light

perception. Following an examination in 2013, his optometrist noted, ''Mr. Brown is a long time self employed [*sic*] contractor who depends on his CDL for his livelihood. He has vast experience hauling his equipment. I believe with this experience and the positive way he has adapted to his monocular status, he should be granted a CDL or at least given the opportunity to drive with an instructor to further assess his ability.'' Mr. Brown reported that he has driven straight trucks for 44 years, accumulating 1.32 million miles, and tractor-trailer combinations for 40 years, accumulating 600,000 miles. He holds a Class A CDL from Iowa. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Thomas A. Busacca, Jr.*

Mr. Busacca, 48, has had macular atrophy in his left eye since birth. The visual acuity in his right eye is 20/20, and in his left eye, counting fingers. Following an examination in 2013, his optometrist noted, ''I am of the opinion that Mr. Busacca has sufficient vision to operate a commercial vehicle.'' Mr. Busacca reported that he has driven straight trucks for 30 years, accumulating 1.5 million miles, and tractor-trailer combinations for 30 years, accumulating 1.5 million miles. He holds a Class A CDL from Florida. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*James A. Champion*

Mr. Champion, 56, has had anterior ischemic optic neuropathy in his left eye since childhood. The visual acuity in his right eye is 20/20, and in his left eye, 20/100. Following an examination in 2013, his optometrist noted, ''I believe that James has sufficient vision to perform the driving tasks that are required of him while operating a commercial vehicle.'' Mr. Champion reported that he has driven tractor-trailer combinations for 11.5 years, accumulating 747,500 miles. He holds a Class A CDL from Washington. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*James C. Colbert*

Mr. Colbert, 63, has complete loss of vision in his left eye due to a traumatic incident during childhood. The visual acuity in his right eye is 20/20, and in his left eye, no light perception. Following an examination in 2013, his ophthalmologist noted, ''It is my opinion that Mr. Colbert has no ocular disease which should preclude him from obtaining a commercial driver's license. He essentially is a monocular patient, and has been one since childhood. He has apparently adapted quite well to being monocular, and according to him has a 25 year history as a driver for the City of Tallahassee without ever having an accident.'' Mr. Colbert reported that he has driven buses for 23 years, accumulating 3.3 million miles. He holds a Class B CDL from Florida. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Bobby R. Cox*

Mr. Cox, 62, has had a corneal transplant in his left eye since 2001. The visual acuity in his right eye is 20/15, and in his left eye, 20/200. Following an examination in 2013, his optometrist noted, ''Approximately 12 years ago Mr. Cox had a successful corneal transplant in his left eye . . . I feel Mr. Cox is capable of continuing to safely drive a commercial vehicle.'' Mr. Cox reported that he has driven tractor-trailer combinations for 30 years, accumulating 3,000,000 miles. He holds a Class AM CDL from Tennessee. His driving record for the last 3 years shows one crash, for which he was cited, and two convictions for moving violations in a CMV.

*Jackie K. Curlin*

Mr. Curlin, 50, has had angle recession glaucoma in his left eye since 2000. The visual acuity in his right eye is 20/20, and in his left eye, 20/70. Following an examination in 2013, his ophthalmologist noted, ''I do feel that Mr. Curlin has adequate and sufficient vision to drive a commercial vehicle, however, as previously stated, he does have decreased vision in the left eye from the previous trauma. Nothing can be done to improve this vision, but under binocular conditions, I feel he has sufficient vision to operate a commercial vehicle.'' Mr. Curlin reported that he has driven straight trucks for 13 years, accumulating 195,000 miles. He holds a Class DMB CDL from Kentucky. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Justin W. Demarchi*

Mr. Demarchi, 36, has had amblyopia and small angle esotropia in his left eye since childhood. The visual acuity in his right eye is 20/20, and in his left eye, 20/60. Following an examination in 2013, his optometrist noted, ''In my opinion, Justin has sufficient visual acuity, visual fields, and color vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Demarchi reported that he has driven straight trucks for 19 years, accumulating 228,000 miles, and tractor-trailer combinations for 19 years, accumulating 9,500 miles. He holds a Class A CDL from Ohio. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Gary Goostree*

Mr. Goostree, 40, has had a macular scar in his right eye since childhood. The visual acuity in his right eye is 20/400, and in his left eye, 20/15. Following an examination in 2013, his optometrist noted, ''Gary Goostree has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Goostree reported that he has driven straight trucks for 18 years, accumulating 54,000 miles, and tractor-trailer combinations for 18 years, accumulating 54,000. He holds a Class A CDL from Ohio. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Jimmey C. Harris*

Mr. Harris, 61, has had optic atrophy in his right eye since 1999. The visual acuity in his right eye is 20/400, and in his left eye, 20/20. Following an examination in 2013, his optometrist noted, ''In my medical opinion, Mr. Harris has sufficient binocular vision to perform the driving tasks required to operate a commercial vehicle based on the Federal Motor Carrier Safety Regulation (FMCSR) Vision- 49 CFR 391.41(b)(10).'' Mr. Harris reported that he has driven tractor-trailer combinations for 6 years, accumulating 660,000 miles. He holds a Class A CDL from Texas. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*David G. Henry*

Mr. Henry, 50, has had dense amblyopia in his right eye since birth. The visual acuity in his right eye is 20/150, and in his left eye, 20/20. Following an examination in 2013, his ophthalmologist noted, ''In my opinion he should be able to drive commercial vehicle with glasses without difficulty as long as nothing were to hinder his only good eye.'' Mr. Henry reported that he has driven straight trucks for 10 years, accumulating 260,000 miles, and tractor-trailer combinations for 1 year, accumulating 15,000 miles. He holds a Class A CDL from Texas. His driving record for the last 3 years shows no

crashes and no convictions for moving violations in a CMV.

*Rogelio C. Hernandez*

Mr. Hernandez, 46, has had optic pit maculopathy in his right eye since 2008. The visual acuity in his right eye is 20/126, and in his left eye, 20/20. Following an examination in 2013, his ophthalmologist noted, ''In my medical opinion, patient has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Hernandez reported that he has driven straight trucks for 12 years, accumulating 420,000 miles, and tractor-trailer combinations for 12 years, accumulating 420,000 miles. He holds an operator's license from California. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Michael J. Hoskins*

Mr. Hoskins, 53, has a prosthetic right eye due to a traumatic incident in 1993. The visual acuity in his right eye is no light perception, and in his left eye, 20/20. Following an examination in 2013, his optometrist noted that, in his medical opinion, Mr. Hoskins has sufficient vision to operate a commercial motor vehicle. Mr. Hoskins reported that he has driven straight trucks for 35 years, accumulating 183,750 miles, and tractor-trailer combinations for 30 years, accumulating 82,500 miles. He holds a Class A CDL from Kansas. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Zion Irizarry*

Mr. Irizarry, 64, has complete loss of vision in his right eye due to a traumatic incident during childhood. The visual acuity in his right eye is light perception, and in his left eye, 20/20. Following an examination in 2013, his optometrist noted, ''That being said, the patient has sufficient vision in his left eye to perform the driving tasks required for operation of a commercial vehicle.'' Mr. Irizarry reported that he has driven buses for 6 years, accumulating 108,000 miles. He holds a Class C CDL from Nevada. His driving record for the last 3 years shows no crashes and one conviction for a moving violation in a CMV; he failed to obey a traffic control light.

*Mohamed H. Issak*

Mr. Issak, 24, has had amblyopia in his left eye since childhood. The visual acuity in his right eye is 20/20, and in his left eye, 20/60. Following an examination in 2013, his ophthalmologist noted, ''He has had time to adjust to this visual deficiency, thus in my medical opinion, he has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Issak reported that he has driven buses for 3 years, accumulating 58,500 miles. He holds a Class A CDL from Kansas. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Craig B. Jacques*

Mr. Jacques, 62, has had macular degeneration in his right eye since 2008. The visual acuity in his right eye is 20/200, and in his left eye, 20/20. Following an examination in 2013, his ophthalmologist noted, ''As the patient has been functioning well, it is my medical opinion that he has sufficient vision to continue to perform his current driving tasks and operate a commercial vehicle.'' Mr. Jacques reported that he has driven straight trucks for 13 years, accumulating 195,000 miles. He holds an operator's license from New York. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*William D. Jackson*

Mr. Jackson, 58, has had amblyopia in his right eye since childhood. The visual acuity in his right eye is 20/300, and in his left eye, 20/20. Following an examination in 2013, his optometrist noted, ''I verify that William Jackson has sufficient vision to drive commercial vehicles safely.'' Mr. Jackson reported that he has driven straight trucks for 38 years, accumulating 380,000 miles, and tractor-trailer combinations for 33 years, accumulating 792,000 miles. He holds a Class A CDL from Minnesota. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Juan J. Luna*

Mr. Luna, 45, has had amblyopia in his left eye since childhood. The visual acuity in his right eye is 20/20, and in his left eye, 20/200. Following an examination in 2013, his ophthalmologist noted, ''Amblyopia . . . stable . . . good color vision . . . may operate a commercial vehicle.'' Mr. Luna reported that he has driven straight trucks for 5 years, accumulating 150,000 miles, and tractor-trailer combinations for 5 years, accumulating 275,000 miles. He holds a Class A CDL from California. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Robert Mollicone*

Mr. Mollicone, 43, has had a retinal detachment in his left eye since 2000. The visual acuity in his right eye is 20/15, and in his left eye, 20/100. Following an examination in 2013, his optometrist noted, ''I certify that Mr. Mollicone's [*sic*] has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Mollicone reported that he has driven straight trucks for 5 years, accumulating 100,000 miles, and tractor-trailer combinations for 23 years, accumulating 598,000 miles. He holds a Class A CDL from Florida. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Christopher D. Moore*

Mr. Moore, 46, has had amblyopia in his left eye since birth. The visual acuity in his right eye is 20/15, and in his left eye, 20/200. Following an examination in 2013, his optometrist noted, ''Because his poor vision in the left eye has been lifelong, he has compensated well for it and in my opinion it should not affect his ability to perform the driving tasks required to operate a commercial vehicle.'' Mr. Moore reported that he has driven straight trucks for 21 years, accumulating 1.47 million miles. He holds a Class B CDL from North Carolina. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Elmore Nicholson, Jr.*

Mr. Nicholson, 35, has had corneal neovascularization in his left eye since birth. The visual acuity in his right eye is 20/20 and in his left eye, 20/50. Following an examination in 2013, his optometrist noted, ''In my medical opinion he has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Nicholson reported that he has driven tractor-trailer combinations for 8 years, accumulating 832,000 miles. He holds an operator's license from Alabama. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Michael Pace*

Mr. Pace, 47, has a macular scar in his right eye due to a traumatic injury during childhood. The visual acuity in his right eye is 20/80, and in his left eye, 20/20. Following an examination in 2013, his optometrist noted, ''Mr. Pace has binocular visual acuity of 20/20. His right eye uncorrected visual acuity is 20/200 and left eye is 20/20 which meets the documented vision

requirements stating he must have distant binocular acuity of at least 20/40 . . . Based on these findings he should meet all the requirements necessary to operate a commercial vehicle.'' Mr. Pace reported that he has driven straight trucks for 3 years, accumulating 150,000 miles, tractor-trailer combinations for 7 years, accumulating 3.5 million miles, and buses for 3 years, accumulating 45,000. He holds a Class A CDL from Texas. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Ernest S. Parsons, Jr.*

Mr. Parsons, 69, has had strabismic amblyopia in his right eye since birth. The visual acuity in his right eye is 20/100, and in his left eye, 20/20. Following an examination in 2013, his optometrist noted, ''I certify that Mr. Parsons [*sic*] vision is sufficient to perform the driving tasks required to operate a commercial motor vehicle.'' Mr. Parsons reported that he has driven straight trucks for 39 years, accumulating 975,000 miles, tractor-trailer combinations for 25 years, accumulating 750,000 miles. He holds a Class A CDL from New York. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*James C. Paschal, Jr.*

Mr. Paschal, 56, has had a congenital cataract in his left eye since birth. The visual acuity in his right eye is 20/20, and in his left eye, hand motion. Following an examination in 2013, his optometrist noted, ''Mr. Paschal has sufficient vision to operate a commercial vehicle.'' Mr. Paschal reported that he has driven straight trucks for 36 years, accumulating 54,000 miles. He holds an operator's license from Georgia. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Lee E. Perry*

Mr. Perry, 65, has had a macular hole in his left eye since 1993. The visual acuity in his right eye is 20/20, and in his left eye, 20/200. Following an examination in 2013, his ophthalmologist noted, ''In my medical opinion, Mr. Perry has sufficient vision to operate any sort of commercial vehicle and perform all necessary driving tasks.'' Mr. Perry reported that he has driven straight trucks for 1 year, accumulating 19,000 miles, and buses for 13 years, accumulating 338,000 miles. He holds a Class BM CDL from Alabama. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Harold D. Pressley*

Mr. Pressley, 49, has had complete loss of vision in his left eye since birth. The visual acuity in his right eye is 20/15, and in his left eye, no light perception. Following an examination in 2013, his optometrist noted, ''VA OD 20/15 . . . VA OS No Light Perception . . . congenital anomaly since birth due to hx: condition is stable . . . Pt [*sic*] is able to operate a commercial vehicle according to VA's [*sic*].'' Mr. Pressley reported that he has driven straight trucks for 20 years, accumulating 1.5 million miles, buses for 12 years, accumulating 240,000 miles. He holds a Class BM CDL from Texas. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Thomas H. Randall*

Mr. Randall, 52, has had microphthalmia, amblyopia, and aphakia in his right eye since childhood. The visual acuity in his right eye is hand motion, and in his left eye, 20/20. Following an examination in 2013, his optometrist noted, ''Mr. Randall has a longstanding congenital deficiency in his right eye which he is well adapted to and should have no problem operating a commercial vehicle.'' Mr. Randall reported that he has driven straight trucks for 34 years, accumulating 340,000 miles, and buses for 2 years, accumulating 30,000 miles. He holds an operator's license from Minnesota. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*David T. Rueckert*

Mr. Rueckert, 53, has had complete loss of vision in his right eye since birth. The visual acuity in his right eye is no light perception, and in his left eye, 20/20. Following an examination in 2013, his optometrist noted that Mr. Rueckert does not have any visual defect or visual field loss that would affect the safe operation of a commercial motor vehicle. Mr. Rueckert reported that he has driven straight trucks for 26 years, accumulating 780,000 miles. He holds an operator's license from Washington. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Jason C. Sadler*

Mr. Sadler, 34, has had amblyopia in his left eye since birth. The visual acuity in his right eye is 20/40, and in his left eye, 20/200. Following an examination in 2013, his optometrist noted, ''It is my opinion that he has sufficient vision to perform the commercial vehicle driving tasks.'' Mr. Sadler reported that he has driven straight trucks for 11 years, accumulating 1.14 million miles, and tractor-trailer combinations for 11 years, accumulating 1.14 million miles. He holds a Class A CDL from Kentucky. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Robert Schick*

Mr. Schick, 51, has a superior altitudinal defect in his left eye due to a traumatic incident in 1981. The visual acuity in his right eye is 20/20, and in his left eye, 20/200. Following an examination in 2013, his ophthalmologist noted, ''Patient has sufficient vision to drive a commercial vehicle.'' Mr. Schick reported that he has driven straight trucks for 29 years, accumulating 754,000 miles. He holds an operator's license from Pennsylvania. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Michael O. Thomas*

Mr. Thomas, 43, has had amblyopia in his left eye since childhood. The visual acuity in his right eye is 20/20, and in his left eye, 20/200. Following an examination in 2013, his optometrist noted, ''In my opinion, Mr. Thomas has sufficient vision to perform driving tasks required to operate a commercial vehicle.'' Mr. Thomas reported that he has driven straight trucks for 9 years, accumulating 234,000 miles, and tractor-trailer combinations for 9 years, accumulating 234,000 miles. He holds a Class A CDL from North Carolina. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Danielle Wilkins*

Ms. Wilkins, 45, has had aphakia in her right eye since childhood. The visual acuity in her right eye is counting fingers, and in her left eye, 20/20. Following an examination in 2013, her optometrist noted, ''It is found that Danielle has 150 degrees of horizontal vision in her left eye and 150 degrees of horizontal vision in her right eye. In my medical opinion, Danielle has the ability to drive a commercial vehicle.'' Ms. Wilkins reported that she has driven straight trucks for 16 years, accumulating 80,000 miles. She holds an operator's license from California. Her driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

**Request for Comments**

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. The Agency will consider all comments received before the close of business February 10, 2014. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will file comments received after the comment closing date in the public docket, and will consider them to the extent practicable.

In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should monitor the public docket for new material.

**Submitting Comments**

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and in the search box insert the docket number FMCSA–2013–0174 and click the search button. When the new screen appears, click on the blue ''Comment Now!'' button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period and may change this proposed rule based on your comments. FMCSA may issue a final rule at any time after the close of the comment period.

**Viewing Comments and Documents**

To view comments, as well as any documents mentioned in this preamble, To submit your comment online, go to *http://www.regulations.gov* and in the search box insert the docket number FMCSA–2013–0174 and click ''Search.'' Next, click ''Open Docket Folder'' and you will find all documents and comments related to the proposed rulemaking.

Issued On: December 30, 2013.

**Larry W. Minor,**

*Associate Administrator for Policy.*

[FR Doc. 2014–00231 Filed 1–9–14; 8:45 am]

**BILLING CODE 4910–EX–P**

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## DEPARTMENT OF TRANSPORTATION

### Federal Transit Administration

### Notice of Scoping Meetings on Regional Planning Effort To Improve Public Transportation in the Central Wasatch Mountains in Salt Lake and Summit Counties, UT

**AGENCY:** Federal Transit Administration (FTA), DOT.

**ACTION:** Notification of Early Scoping Meeting.

**SUMMARY:** The Federal Transit Administration (FTA) and the Utah Transit Authority (UTA) issue this early scoping notice to advise other agencies and the public that they intend to explore potential alternatives for improving public transportation service to and within the central Wasatch Mountains of Salt Lake County and Summit County, Utah. UTA is conducting this work through formal agreement and partnership with numerous state and local agencies, including Salt Lake County, Summit County, Wasatch Front Regional Council, Salt Lake City, Cottonwood Heights, Sandy City, Park City, Town of Alta, and others. This early scoping process is part of a regional planning effort to examine regional connectivity for the central Wasatch Mountains. This notice invites the public to help frame transportation improvements, while considering the inherent interdependence of watershed protection, wilderness protection, land-use planning, and economic opportunities in the central Wasatch Mountains. This process builds upon prior planning efforts contained in Salt Lake County's ''Wasatch Canyons Tomorrow'' study and ''Mountain Transportation Study'' completed in September 2010 and November 2012, respectively.

The early scoping process is intended to support a future National Environmental Policy Act (NEPA) scoping process, as appropriate.

**DATES:** Two public scoping meetings and one agency scoping meeting, where agencies and the public can learn more about and comment on the proposal, will be held at the following times and locations:

- Public scoping meeting: Tuesday, February 4, 2014, from 4:30 p.m. to 7:30 p.m. at Park City High cafeteria, 1750 Kearns Blvd., Park City, UT
- Public scoping meeting: Wednesday, February 5, 2014, from 4:30 p.m. to 7:30 p.m. at Skyline High School cafeteria, 3251 East 3760 South, Salt Lake City, UT
- Agency scoping meeting: Monday, February 3, 2014, from 10:00 a.m. to 12:00 p.m., Utah Transit Authority, 669 West 200 South, Salt Lake City, UT

At the public and agency scoping meetings, Utah Transit Authority will provide information on the extent of the study area; transportation issues; community and environmental impacts and benefits. Materials will also be available beginning January 21, 2014 on UTA's Web site at *www.rideuta.com* on the ''Wasatch Summit Program'' project tab. Scoping materials will also include project background information and the proposed approaches for moving forward. Written scoping comments are requested by March 7, 2014 and can be sent or emailed to the address below, submitted at a public meeting or sent via the comment form to *www.rideuta.com.*

**ADDRESSES:** Mary DeLoretto, Senior Program Manager, Utah Transit Authority, 669 West 200 South, Salt Lake City, UT 84101; phone: (801) 741–8808; or emailed to *mdeloretto@rideuta.com.*

**FOR FURTHER INFORMATION CONTACT:** Jeffrey Jordan, FTA Environmental Specialist, 12300 West Dakota Avenue, Suite 310, Lakewood, CO 80228; phone: (720) 963–3307; email: *jeffrey.jordan.ctr@dot.gov.*

**SUPPLEMENTARY INFORMATION:**

**Early Scoping**

The early scoping process provides a venue for evaluating the costs, benefits, and preliminary impact identification for a range of transportation alternatives designed to address mobility problems and other locally-identified objectives in the proposed study area. Early scoping for the project will be conducted in accordance with NEPA polices pursuant to the Council on Environmental Quality's regulations and guidance for implementing NEPA, which encourage federal agencies to initiate NEPA early in their planning process, per 40 CFR subsection 1501.2 through 8. The scoping process may begin as soon as there is enough information to describe the proposed alternatives so that the public and relevant agencies can

participate effectively. This process is useful when a proposed action involves a broadly defined corridor or study area with an array of modal and alignment alternatives. This early scoping notice solicits public comments on the planning analysis, including the purpose and need for the project, the range of alternatives, and the environmental, transportation and community impacts and benefits to be considered.

**Utah Transit Authority, Park City Transit and the Regional Transportation System**

Existing conditions: UTA provides 30 minute bus service from the 7200 South and 4500 South TRAX stations to the resorts in the Cottonwood Canyons and once daily bus service between the resorts and downtown Salt Lake City, the University of Utah, and West Valley. This service usually runs from mid-December to mid-April, with no transit service outside the ski season. The *PC–SLC Connect,* a public bus service connecting Park City and Salt Lake City, runs year long, four times a day Monday through Friday with no service on the weekends. There are currently no public transit options between Summit County and the Cottonwood Canyons.

**Transportation Purpose of the Project**

UTA invites comments on the following preliminary statement of the project's purpose and need.

The purpose of the project is to improve regional transportation connectivity and to facilitate safe, convenient, and reliable year-round transportation to destinations within the central Wasatch Mountains from the population bases, recreational destinations, and the regional transit networks in the Salt Lake Valley and Park City/Summit County. The need for the project arises from:

- The need to meet the growing connectivity needs of the central Wasatch Mountains for the region's workers and recreationalists by increasing mobility, access and transportation capacity to and from activity centers in the region, as called for by the Utah Unified Transportation Plan, as well as other plans including related county and city comprehensive transportation plans.
- The need to serve increasing worker and recreational trips between Salt Lake City environs and Wasatch Mountain locations in Salt Lake and Summit Counties. There are diverse recreation opportunities in the central Wasatch Mountains in both Salt Lake and Summit Counties, including hiking, picnicking, camping, rock climbing, bird watching, mountain biking, road biking, fishing, skiing (resort, back country, cross-country), snowshoeing, and ice climbing. The demand for improving the transportation options to access these opportunities continues to grow as documented in the Utah Unified Transportation Plan.
- The need to support source water protection goals. The Central Wasatch Mountains, including Big Cottonwood Canyon, Little Cottonwood Canyon, and Parleys Canyon, are the primary sources of drinking water for more than 400,000 people in the Salt Lake Valley. These municipal watersheds are protected for water supply and water quality purposes pursuant to numerous federal, state, and local laws and plans.
- The need to support land use and forest management plan goals. The central Wasatch Mountains have competing environmental, economic, recreation, and stewardship goals that dictate future regional growth concentrations. The U.S. Forest Service completed a Revised Forest System plan for the Wasatch-Cache National Forest and Record of Decision in 2003, which outlines forest management direction for National Forest Lands in the Wasatch Range and canyons. The Forest Plan direction also addresses some future transportation capabilities.
- The need to improve air quality in the Salt Lake City Valley to maintain Environmental Protection Agency (EPA) standards. The Salt Lake Valley is prone to air quality level exceedences during various time of the year. Determining a way to reduce criteria air pollutant emissions through public transportation improvements and demand management is one goal of Utah Department of Environmental Quality's Clean Utah program to maintain or reduce emissions and thus improve air quality.
- The need to improve road safety conditions in the central Wasatch Mountains due to avalanche hazards, road conditions and emergency response. Due to seasonal weather conditions throughout the central Wasatch Mountains, avalanche hazards are high, and emergency response alternatives are limited.

**Potential Alternatives**

Utah Transit Authority will explore alternative mode, alignment, and design configurations for the central Wasatch Mountains along with active traffic management principles.

There are three main transportation corridors into the central Wasatch Mountains from the Salt Lake Valley: Big Cottonwood Canyon, Little Cottonwood Canyon, and Interstate 80 (Parley's Canyon). Several smaller sub-corridors, or potential minimum operable segments (MOS) with logical termini, were identified in the study area that either connect to one or more of the existing larger corridors. The sub-corridors were identified based on professional evaluation, stakeholder input, and consistency with the Wasatch Front Regional Council Regional Transportation Plan and the Utah Unified Transportation Plan. Specific corridor alternatives that link the existing Wasatch Front regional transit system with the central Wasatch Mountains destinations in Salt Lake and Summit Counties will be developed during the early scoping process.

Alternatives already identified for consideration include:

- The connection from downtown Salt Lake City to the base of Big Cottonwood Canyon
- the connection from downtown Salt Lake City to the base of Little Cottonwood Canyon
- the connection from downtown Salt Lake City to Park City in Summit County via Parley's Canyon
- the base of Big Cottonwood Canyon to the base of Little Cottonwood Canyon
- the base of Big Cottonwood Canyon to Brighton
- the base of Little Cottonwood Canyon to Alta
- Alta to Brighton; and
- Brighton to Park City

**Transportation Modes**

Various transportation modes being considered include:

- Parking and Roadway Improvements
- Bus Service Improvements
- Bus Rapid Transit (BRT)
- Rail Systems
- Aerial Systems
- Active Traffic Management Principles

UTA may also consider other alternatives that arise during the public comment period. The definition of these alternatives for analysis will reflect a range of high and low cost capital improvements. UTA will identify measures for evaluating the relative merits of alternatives, and technical methodologies for generating the information used to support such measures. These measures will typically include disciplines such as travel forecasting; capital, operations and maintenance costs; and corridor-level environmental and land use analyses.

At the end of the early scoping process, a preferred corridor and mode may emerge for further evaluation in a NEPA environmental document (the classification of which is to be

determined). If the preferred mode and corridor involve the potential for significant environmental impacts requiring an Environmental Impact Statement (EIS), and FTA determines that there is a potential for FTA funding, a Notice of Intent to Prepare an EIS will be published in the **Federal Register** and public and agency comment on the scope of the EIS will be invited and considered at that time.

Issued on: January 2, 2014.

**Linda M. Gehrke,**

*Regional Administrator, FTA Region 8.*

[FR Doc. 2014–00230 Filed 1–9–14; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF TRANSPORTATION

### Surface Transportation Board

**[Docket No. FD 35797]**

### Union County Industrial Railroad Company—Operation Exemption—SEDA–COG Joint Rail Authority

Union County Industrial Railroad Company (UCIR), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to operate approximately 4.07 miles of track known as the West Deer Extension Track, from milepost 173.605 to milepost 177.67 in Union County, Pa. (the Line).[1] The Line is currently owned or leased by SEDA–COG Joint Rail Authority, a Pennsylvania Municipal Authority.

The transaction may be consummated on or after January 25, 2014 (30 days after the notice of exemption was filed).

UCIR certifies that its projected annual revenues as a result of this transaction will not exceed those that would qualify it as a Class III rail carrier and will not exceed $5 million.

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than January 17, 2014 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35797, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Richard R. Wilson, Esq., 518 N. Center Street, Suite 1, Ebensburg, PA 15931.

Board decisions and notices are available on our Web site at ''*WWW.STB.DOT.GOV*''.

Decided: January 7, 2014.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

**Raina S. White,**

*Clearance Clerk.*

[FR Doc. 2014–00288 Filed 1–9–14; 8:45 am]

**BILLING CODE 4915–01–P**

[1] Counsel for UCIR has indicated that UCIR promptly will file a copy of the operating agreement that UCIR has entered into with SEDA–COG Joint Rail Authority, a noncarrier. *See Anthony Macrie—Continuance in Control Exemption—N.J. Seashore Lines, Inc.,* FD 35296, slip op. at 3–4 (STB served Aug. 31, 2010).

## DEPARTMENT OF THE TREASURY

### Office of the Comptroller of the Currency

### Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Securities Offering Disclosure Rules

**AGENCY:** Office of the Comptroller of the Currency (OCC), Treasury.

**ACTION:** Notice and request for comment.

**SUMMARY:** The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA).

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning the renewal of an information collection titled, ''Securities Offering Disclosure Rules.'' The OCC is also giving notice that it has sent the rule to OMB for review.

**DATES:** Comments must be submitted on or before February 10, 2014.

**ADDRESSES:** Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0120, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *regs.comments@occ.treas.gov*. You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Additionally, please send a copy of your comments by mail to: OCC Desk Officer, 1557–0120, U.S. Office of Management and Budget, 725 17th Street NW., #10235, Washington, DC 20503, or by email to: *oira_submission@omb.eop.gov*.

**FOR FURTHER INFORMATION CONTACT:** You may request additional information or a copy of the collection and supporting documentation submitted to OMB by contacting: Johnny Vilela or Mary H. Gottlieb, OCC Clearance Officers, (202) 649–5490, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. The OCC is seeking renewal from OMB of the following collection without change.

*Title:* Securities Offering Disclosure Rules.

*OMB Control No.:* 1557–0120.

*Type of Review:* Regular review.

*Description:* Twelve CFR Part 16 and 197 govern the offer and sale of securities by national banks and Federal savings associations. The requirements in those sections enable the OCC to perform its responsibility to ensure that the investing public has information about the condition of the institution, the reasons for raising new capital, and the terms of the offering.

These information collection requirements ensure national bank and Federal savings association compliance with applicable Federal law, promote bank safety and soundness, provide protections for national banks and Federal savings associations, and further public policy interests.

*Affected Public:* Businesses or other for-profit.

*Burden Estimates:*

*Estimated Number of Respondents:* 61.

*Estimated Annual Burden:* 1,310 hours.

*Frequency of Response:* On occasion.

*Comments:* The OCC solicited comment on the collection for 60 days. 78 FR 63310 (October 23, 2013). No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the information collection burden;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: January 3, 2014.

**Stuart E. Feldstein,**

*Director, Legislative and Regulatory Activities Division.*

[FR Doc. 2014–00175 Filed 1–9–14; 8:45 am]

**BILLING CODE 4810–33–P**

## DEPARTMENT OF VETERANS AFFAIRS

**[OMB Control No. 2900–0045]**

## Agency Information Collection (VA Request for Determination of Reasonable Value) Activity Under OMB Review

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

**DATES:** Comments must be submitted on or before February 10, 2014.

**ADDRESSES:** Submit written comments on the collection of information through *www.Regulations.gov* or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0045'' in any correspondence.

**FOR FURTHER INFORMATION CONTACT:** Crystal Rennie, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 632–7492 or email *crystal.rennie@va.gov.* Please refer to ''OMB Control No. 2900–0045.''

**SUPPLEMENTARY INFORMATION:** *Title:* VA Request for Determination of Reasonable Value VA Form 26–1805 and 26–1805–1.

*OMB Control Number:* 2900–0045.

*Type of Review:* Revision of a currently approved collection.

*Abstract:* VA Forms 26–1805 and 26–1805–1 are used to identify properties to be appraised and to make assignments to an appraiser. VA home loans cannot be guaranteed or made unless the nature and conditions of the property is suitable for dwelling purposes is determined; the loan amount to be paid by the veteran for such property for the cost of construction, repairs, or alterations does not exceed the reasonable value; or if the loan is for repair, alteration, or improvements of property, the work substantially protects or improves the basic livability of the property. VA or the lender's participating in the lender appraisal processing program issues a notice of values to notify the veteran and requester of the determination of reasonable value and any conditional requirements.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on September 27, 2013, at pages 59773–59774.

*Affected Public:* Individuals or households.

*Estimated Annual Burden:* 51,400 hours.

*Estimated Average Burden per Respondent:* 12 minutes.

*Frequency of Response:* On occasion.

*Estimated Number of Respondents:* 257,000.

Dated: January 6, 2014.

By direction of the Secretary.

**Crystal Rennie,**

*VA Clearance Officer, Department of Veterans Affairs.*

[FR Doc. 2014–00177 Filed 1–9–14; 8:45 am]

**BILLING CODE 8320–01–P**

# FEDERAL REGISTER

Vol. 79 Friday,

No. 7 January 10, 2014


Part II

## Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 417, 422, et al.

Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Parts 409, 417, 422, 423, and 424**

**[CMS–4159–P]**

**RIN 0938–AR37**

# Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The proposed rule would revise the Medicare Advantage (MA) program (Part C) regulations and prescription drug benefit program (Part D) regulations to implement statutory requirements; strengthen beneficiary protections; exclude plans that perform poorly; improve program efficiencies; and clarify program requirements. The proposed rule also includes several provisions designed to improve payment accuracy.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 7, 2014.

**ADDRESSES:** In commenting, please refer to file code CMS–4159–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4159–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4159–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.) b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Christopher McClintick, (410) 786–4682, Part C issues. Marie Manteuffel, (410) 786–3447, Part D issues. Kristy Nishimoto, (206) 615–2367, Part C and D enrollment and appeals issues. Whitney Johnson, (410) 786–0490, Part C and D payment issues. Clarisse Owens, (410) 786–0880, Part C and D compliance issues. Frank Whelan, (410) 786–1302, Part D improper prescribing issues.

**SUPPLEMENTARY INFORMATION:** *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

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## Acronyms

ADS Automatic Dispensing System
AEP Annual Enrollment Period
AHFS American Hospital Formulary Service
AHFS–DI American Hospital Formulary Service-Drug Information
AHRQ Agency for Health Care Research and Quality
ALJ Administrative Law Judge
ANOC Annual Notice of Change
AO Accrediting Organization
AOR Appointment of Representative
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
BIPA [Medicare, Medicaid, and SCHIP] Benefits Improvement Protection Act of 2000 (Pub. L. 106–554)
BLA Biologics License Application
CAHPS Consumer Assessment Health Providers Survey
CAP Corrective Action Plan
CCIP Chronic Care Improvement Program
CC/MCC Complication/Comorbidity and Major Complication/Comorbidity
CCS Certified Coding Specialist
CDC Centers for Disease Control
CHIP Children's Health Insurance Programs
CMP Civil Money Penalty
CMR Comprehensive Medical Review
CMS Centers for Medicare & Medicaid Services
CMS–HCC CMS Hierarchal Condition Category
CTM Complaints Tracking Module
COB Coordination of Benefits
CORF Comprehensive Outpatient Rehabilitation Facility
CPC Certified Professional Coder
CY Calendar year
DAB Departmental Appeals Board
DEA Drug Enforcement Administration
DIR Direct and Indirect Remuneration
DME Durable Medical Equipment
DMEPOS Durable Medical Equipment, Prosthetic, Orthotics, and Supplies
D–SNPs Dual Eligible SNPs
DOL U.S. Department of Labor
DUM Drug Utilization Management
EAJR Expedited Access to Judicial Review
EGWP Employer Group/Union-Sponsored Waiver Plan
EOB Explanation of Benefits
EOC Evidence of Coverage
ESRD End-Stage Renal Disease
FACA Federal Advisory Committee Act
FDA Food and Drug Administration
FEHBP Federal Employees Health Benefits Plan
FFS Fee-For-Service
FIDE Fully-integrated Dual Eligible
FIDE SNPs Fully-integrated Dual Eligible Special Needs Plans
FMV Fair Market Value
FY Fiscal year
GAO Government Accountability Office
HAC Hospital-Acquired Conditions
HCPP Health Care Prepayment Plans
HEDIS HealthCare Effectiveness Data and Information Set
HHS [U.S. Department of] Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)
HMO Health Maintenance Organization
HOS Health Outcome Survey
HPMS Health Plan Management System
ICEP Initial Coverage Enrollment Period
ICL Initial Coverage Limit
ICR Information Collection Requirement
ID Identification
IRE Independent Review Entity
IRMAA Income-Related Monthly Adjustment Amount
IVC Initial Validation Contractor
LCD Local Coverage Determination
LEP Late Enrollment Penalty
LIS Low Income Subsidy
LPPO Local Preferred Provider Organization
LTC Long Term Care
MA Medicare Advantage
MAAA Member of the American Academy of Actuaries
MA–PD Medicare Advantage-Prescription Drug Plan
MAC Medicare Appeals Council
MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275)
MOC Medicare Options Compare
MOOP Maximum Out-of-Pocket
MPDPF Medicare Prescription Drug Plan Finder
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
MS–DRG Medicare Severity Diagnosis Related Group
MSA Metropolitan Statistical Area
MSAs Medical Savings Accounts
MSP Medicare Secondary Payer
MTM Medication Therapy Management
MTMP Medication Therapy Management Program
NAIC National Association Insurance Commissioners
NCD National Coverage Determination
NCPDP National Council for Prescription Drug Programs
NCQA National Committee for Quality Assurance
NDA New Drug Application
NDC National Drug Code
NGC National Guideline Clearinghouse
NIH National Institutes of Health
NOMNC Notice of Medicare Non-Coverage
NPI National Provider Identifier
OIG Office of Inspector General
OMB Office of Management and Budget
OPM Office of Personnel Management
OTC Over the Counter
Part C Medicare Advantage
Part D Medicare Prescription Drug Benefit Program
PBM Pharmacy Benefit Manager

PDE Prescription Drug Event
PDP Prescription Drug Plan
PFFS Private Fee For Service Plan
POA Present on Admission (Indicator)
POS Point-of-Sale
PPO Preferred Provider Organization
PPS Prospective Payment System
P&T Pharmacy & Therapeutics
QIC Qualified Independent Contractor
QIO Quality Improvement Organization
QRS Quality Review Study
PACE Programs of All Inclusive Care for the Elderly
RADV Risk Adjustment Data Validation
RAPS Risk Adjustment Payment System
RPPO Regional Preferred Provider Organization
SEP Special Enrollment Period
SHIP State Health Insurance Assistance Programs
SNF Skilled Nursing Facility
SNP Special Needs Plan
SPAP State Pharmaceutical Assistance Programs
SSA Social Security Administration
SSI Supplemental Security Income
T&C Terms and Conditions
TPA Third Party Administrator
TrOOP True Out-Of-Pocket
U&C Usual and Customary
UPIN Uniform Provider Identification Number
USP U.S. Pharmacopoeia

## I. Executive Summary

### *A. Purpose*

The purpose of this proposed rule is to make revisions to the Medicare Advantage (MA) program (Part C) and Prescription Drug Benefit Program (Part D) regulations based on our continued experience in the administration of the Part C and Part D programs and to implement certain provisions of the Affordable Care Act. The proposed changes are necessary to—(1) clarify various program participation requirements; (2) make changes to strengthen beneficiary protections; (3) strengthen our ability to identify strong applicants for Part C and Part D program participation and remove consistently poor performers; and (4) make other clarifications and technical changes.

### *B. Summary of the Major Provisions*

1. Eligibility of Enrollment for Individuals Not Lawfully Present in the United States

The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 makes individuals not lawfully present in the United States ineligible to receive federal benefits (such as Medicare), even if they are otherwise entitled to benefits. While we would not pay FFS claims for unlawfully present beneficiaries, MA, and Part D enrollment rules currently do not prevent the payment of capitation rates for these individuals. We are proposing to establish U.S. citizenship and lawful presence as an eligibility requirement for enrollment in MA and Part D plans.

2. Modifying the Agent/Broker Requirements, Specifically Agent/Broker Compensation

The current compensation structure is comprised of a 6-year cycle and is scheduled to end December 31, 2013. MA organizations and PDP sponsors provide an initial compensation payment to independent agents for new enrollees (Year 1), and pay a renewal rate (equal to 50 percent of the initial year compensation) for Years 2 through 6. This structure has proved to be complicated to implement and monitor, and the current structure creates an incentive for agents to move beneficiaries as long as the fair market value (FMV) continues to increase each year. To simplify the administration of these payments and reduce incentives for agents and brokers to encourage beneficiaries to enroll in plans without regard to ensuring plan benefits would meet the beneficiaries' health care needs, we are proposing to revise the existing compensation structure. Under our proposal, MA organizations and PDP sponsors would continue to have the discretion to decide, on an annual basis, whether to pay initial and/or renewal compensation payments to their independent agents. Also, for new enrollments, MA organizations and sponsors could make an initial payment that is no greater than the FMV amount, which we would set annually in our guidance that interprets these regulations. For renewals in Year 2 and subsequent years, the MA organization or sponsor could pay up to 35 percent of the FMV amount for that year. We believe that revising the existing compensation structure to allow MA organizations or Part D sponsors to pay up to 35 percent of the FMV for year 2 and subsequent years is appropriate based on a couple of factors. First, we believe that a 2 tiered payment system (that is, initial and renewal) would be significantly less complicated than a 3-tiered system (that is, initial, 50 percent renewal for years 2 through 6, and 25 percent residual for years 7 and subsequent years), and would reduce administrative burden and confusion for plan sponsors. Second, our analysis determined that 35 percent is the renewal compensation level at which the present value of overall payments under a 2-tiered system would be relatively equal to the present value of overall payments under a 3-tiered system (taking into account the estimated life expectancy for several beneficiary age cohorts). In addition to revising the agent and broker compensation structures, we propose to amend the training and testing requirements as well as setting limits on referral fees for agents and brokers.

3. Drug Categories or Classes of Clinical Concern

This proposed provision would interpret the Affordable Care Act authority to limit protected classes to those for which access to all drugs in a category or class for a typical individual with a disease or condition treated by the drugs in the class is required within 7 days and more specific formulary requirements would not suffice to meet multitude of specific applications of the drugs within the category or class. Instead of mandating coverage of all drug products in a particular class on all Part D formularies, we can save costs by identifying more efficient formulary requirements or other beneficiary protections in most cases.

4. Improving Payment Accuracy

The proposed regulatory provisions would implement the Affordable Care Act requirement that MA organizations and Part D sponsors report and return identified Medicare overpayments. We would adopt the statutory definition of overpayment for both Part C and Part D.

5. Risk Adjustment Data Requirements

The proposed rule would strengthen existing regulations at § 422.310 on MA plan sponsors' accountability for valid risk adjustment data prior to submission.

### *C. Summary of Costs and Benefits*

TABLE 1—SUMMARY OF COSTS AND BENEFITS

| Provision description | Total costs | Transfers |
|---|---|---|
| Changes to Audit and Inspection | We estimate that this change would require an annual cost of $7.95 million (total cost of $39.75 million) for the time and effort for all auditing organizations to perform the program audit. Additionally, we estimate an annual cost of $950,000 (total cost of 4.75 million) for MA organizations or Part D sponsors with audit results that reveal non-compliance to hire an independent auditor to validate that correction has occurred. | |
| Eligibility of enrollment for individuals not lawfully present in the U.S. | N/A | We estimate that this change could save the MA program up to $5 million in 2015, increasing to $8 million in 2019 (total of $32 million over this period), and could save the Part D program (includes the Part D portion of MA-PD plans) up to $5 million in 2015, increasing to $9 million in 2019 (total of $35 million over this period). |
| Modifying the agent/broker requirements, specifically agent/broker compensation. | N/A. | |
| Drug Categories or Classes of Clinical Concern | N/A | We estimate that this change could save the Part D program (includes the Part D portion of MA–PD plans) approximately $30 million in 2016, increasing to $420 million in 2019 (total of $720* million over this period). |
| Improving Payment Accuracy | N/A. | |
| Risk Adjustment Data Requirements | N/A. | |
| Transfer of TrOOP Between Part D Sponsors Due to Enrollment Changes during the Coverage Year. | N/A. | |
| Eligibility of Enrollment for Incarcerated Individuals. | | We estimate that this change could save the MA program up to $27 million in 2015, increasing to $62 million in 2019 (total of $219 million over this period), and could save the Part D program (includes the Part D portion of MA-PD plans) up to $46 million in 2015, increasing to $90 million in 2019 (total of $333 million over this period). |

* Projected savings are based upon full implementation of the criteria and do not reflect that changes for the antipsychotic class of drugs are deferred at this time.

## II. Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) created a new ''Part C'' in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act)) which established what is now known as the Medicare Advantage (MA) program. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), enacted on December 8, 2003, added a new ''Part D'' to the Medicare statute (sections 1860D–1 through 42 of the Act) entitled the Medicare Prescription Drug Benefit Program (PDP), and made significant changes to the existing Part C program, which it named the Medicare Advantage (MA) Program. The MMA directed that important aspects of the Part D program be similar to, and coordinated with, regulations for the MA program. Generally, the provisions enacted in the MMA took effect January 1, 2006. The final rules implementing the MMA for the MA and Part D prescription drug programs appeared in the **Federal Register** on January 28, 2005 (70 FR 4588 through 4741 and 70 FR 4194 through 4585, respectively).

Since the inception of both Parts C and D, we have periodically revised our regulations either to implement statutory directives or to incorporate knowledge obtained through experience with both programs. For instance, on the September 18, 2008 and January 12, 2009 **Federal Register** (73 FR 54226 and 74 FR 1494, respectively), we issued Part C and D regulations to implement provisions in the Medicare Improvement for Patients and Providers Act (MIPPA) (Pub. L. 110–275). We promulgated a separate interim final rule in January 16, 2009 (74 FR 2881) to address MIPPA provisions related to Part D plan formularies. In the final rule that appeared in the April 15, 2010 **Federal Register** (75 FR 19678), we made changes to the Part C and D regulations which strengthened various program participation and exit requirements; strengthened beneficiary protections; ensured that plan offerings to beneficiaries included meaningful differences; improved plan payment rules and processes; improved data collection for oversight and quality assessment; implemented new policies; and clarified existing program policy.

In a final rule that appeared in the April 15, 2011 **Federal Register** (76 FR 21432), we continued our process of implementing improvements in policy consistent with those included in the April 2010 final rule, and also implemented changes to the Part C and Part D programs made by recent legislative changes. The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010, as passed by the Senate on December 24, 2009, and the House on March 21, 2010. The Health Care and Education Reconciliation Act (Pub. L.

111–152), which was enacted on March 30, 2010, modified a number of Medicare provisions in Pub. L. 111–148 and added several new provisions. The Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act (Pub. L. 111–152) are collectively referred to as the Affordable Care Act. The Affordable Care Act included significant reforms to both the private health insurance industry and the Medicare and Medicaid programs. Provisions in the Affordable Care Act concerning the Part C and D programs largely focused on beneficiary protections, MA payments, and simplification of MA and Part D program processes. These provisions affected implementation of our policies regarding beneficiary cost-sharing, assessing bids for meaningful differences, and ensuring that cost-sharing structures in a plan are transparent to beneficiaries and not excessive. In the April 2011 final rule, we revised regulations on a variety of issues based on the Affordable Care Act and our experience in administering the MA and Part D programs. The rule covered areas such as marketing, including agent/broker training; payments to MA organizations based on quality ratings; standards for determining if organizations are fiscally sound; low income subsidy policy under the Part D program; payment rules for non-contract health care providers; extending current network adequacy standards to Medicare medical savings account (MSA) plans that employ a network of providers; establishing limits on out-of-pocket expenses for MA enrollees; and several revisions to the special needs plan requirements, including changes concerning SNP approvals.

In a final rule that appeared in the April 12, 2012 **Federal Register** (77 FR 22072 through 22175), we made several changes to the Part C and Part D programs required by statute, including the Affordable Care Act, as well as made improvements to both programs through modifications reflecting experience we have obtained administering the Part C and Part D programs. Key provisions of that final rule implemented changes closing the Part D coverage gap, or ''donut hole,'' for Medicare beneficiaries who do not already receive low-income subsidies from us by establishing the Medicare Coverage Gap Discount Program. We also included provisions providing new benefit flexibility for fully-integrated dual eligible special needs plans, clarifying coverage of durable medical equipment, and combatting possible fraudulent activity by requiring Part D sponsors to include an active and valid prescriber National Provider Identifier on prescription drug event records.

## III. Provisions of the Proposed Regulations

### *A. Clarifying Various Program Participation Requirements*

1. Closing Cost Contract Plans to New Enrollment (§ 422.2 and § 422.503(b)(5))

In implementing the original Part C requirements in our June 26, 1998 final rule, entitled, ''Medicare Program; Establishment of the Medicare+Choice Program'' (63 FR 34968 through 35116), we established a requirement in 42 CFR 422.501(b)(4) that an ''entity seeking to contract as [an Medicare Advantage (MA)] organization must not accept new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer [an MA] plan.'' We stated our reasons for the policy, specifying in the preamble of the interim final rule that, ''[o]ur reason for establishing this rule is to eliminate the potential for an organization to encourage higher-cost enrollees to enroll under its cost contract while healthy enrollees are enrolled in its risk-based [MA] plan. This [final] rule is consistent with our long-standing policy that entities not have both a risk and cost contract under section 1876 [of the Act] in the same area.'' (63 FR 35014 through 35015).

This provision was recodified at 42 CFR 422.503(b)(5) in regulations implementing the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, but the requirement, as well as the rationale for the requirement, remained intact.

Since this requirement only precludes ''the entity'' contracting as an MA organization from having a cost contract open to new enrollment, the prohibition does not apply to another separate legal entity owned by the same parent organization, such that two legal entities owned by the same parent could offer a competing cost contract and MA plan. We do not believe that this result is consistent with the original intent of the prohibition because it permits legal entities that are related to each other under a common parent organization to offer a cost contract and MA plan in the same service area, creating the same potential for the entities to move higher risk enrollees from one plan to another in order to take advantage of the differing Medicare payment rules for the two plan types or for other reasons that are not related to the enrollees' best interests.

To ensure that our original intent is realized and to eliminate the potential for organizations to move enrollees from one of their plans to another based on financial or some other interest, we propose to revise paragraph § 422.503(b)(5) so that an, ''entity seeking to contract as an MA organization must [n]ot accept, or share a corporate parent organization with an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.''

In making the proposed revision to paragraph § 422.503(b), we also propose to add the definition of ''parent organization'' to § 422.2 of the MA program definitions. We would specify that, ''Parent organization means a legal entity that owns one or more other subsidiary legal entities.'' We are requesting comments on whether a parent organization with less than a 100-percent interest in a subsidiary legal entity should trigger the prohibition we propose with the amendment at § 422.503(b)(5). Although the MA program regulations do not currently define the term ''parent organization,'' our proposed definition is consistent with the way the term is currently used in the context of the MA program, for example, when assessing an organization's business structure.

2. Two Year Limitation on Submitting a New Bid in an Area Where an MA Has Been Required To Terminate a Low Enrollment MA Plan (§ 422.504(a)(19))

Under § 422.506(b)(1)(iv), we must non-renew an MA plan that does not have a sufficient number of enrollees to establish that it is a viable independent plan option. We have currently interpreted the standard of whether the MA plan has a ''sufficient number of enrollees to establish that it is a viable independent plan option'' as meaning that the MA plan has fewer than 500 enrollees for non-SNPs and fewer than 100 enrollees for SNPs over a specified time period of 3 years. As we determine adjustments are appropriate, we will revisit this interpretation as part of annual plan guidance. In cases in which an MA plan has been non-renewed on this basis, it would defeat the intent and purpose of this rule if the MA organization could simply submit a new bid for the next year in the same area for the same type of plan that failed to attract enrollment over a number of years. Indeed, the problem addressed in § 422.506(b)(1)(iv) would be exacerbated, as the new plan would start out with no MA enrollees.

In section 3209 of the Affordable Care Act, the Congress added a new section

1854(a)(5)(C)(1) of the Act that clarified that CMS is not ''require[d] . . . to accept any or every bid submitted by an MA organization. . . .'' Section 1856(b)(1) of the Act further provides authority for CMS to establish MA standards by regulation, and section 1857(e)(1) of the Act also provides authority to impose contract requirements that CMS finds ''necessary and appropriate.'' Under the foregoing authority, we propose to revise § 422.504(a) to add a new contract requirement that stipulates that the Medicare Advantage Organization (MA organization) agrees not to submit a new bid of the same type of plan that has been non-renewed under § 422.506(b)(1)(iv) in the same service area as the non-renewed plan for 2 years after such a non-renewal.

We believe this requirement will enhance our ongoing efforts to ensure that MA organization offerings in a service area present beneficiaries with viable plans that are responsive to their needs.

3. Authority To Impose Intermediate Sanctions and Civil Money Penalties (§ 422.752, § 423.752, § 422.760 and § 423.760)

Section 1857(a) of the Social Security Act (the Act) provides the Secretary with the authority to enter into contracts with MA organizations, and section 1860D–12(b)(1) of the Act provides the Secretary with the authority to enter into contracts with Part D sponsors. Section 1857(g)(1) of the Act provides a list of contract violations for which the potential enforcement response under section 1857(g)(2) of the Act is the imposition of intermediate sanctions (sanctions) and/or civil money penalties (CMPs). Section 1860D–12(b)(3)(E) of the Act applies these provisions to Part D contracts. We codified this authority in the June 28, 2000 final rule with comment period entitled, ''Medicare Program; Medicare+Choice Program (65 FR 40170) for Part C, and the January 28, 2005 final rule entitled, ''Medicare Program; Medicare Prescription Drug Benefit'' (70 FR 4194) for Part D. The authority was codified at § 422.752 (Part C) and § 423.752 (Part D). We are proposing two changes to our existing authority to impose sanctions and CMPs.

First, section 6408 of the Affordable Care Act (Pub. L. 111–148) provided the Secretary with new authorities to impose sanctions or CMPs for violations of the Part C and D marketing and enrollment requirements. Section 6408 amended 1857(g)(1) of the Act by adding new sections (H) through (K). These provisions provide CMS with the authority to impose intermediate sanctions on an organization that enrolls an individual without prior consent (except in certain limited circumstances) or transfers an individual to a new plan without prior consent. They also specifically make it a contract violation to violate the Part C and D marketing requirements, and specify that it is a violation of the sponsor's Part C or D agreement with CMS for the sponsoring organization to employ or contract with any individual or entity who engages in the conduct described in paragraphs (A) through (J) of 1857(g)(1) of the Act.

We are proposing to revise our regulations to codify the aforementioned authorities at § 422.752 (Part C) and § 423.752 (Part D), following the statutory language with little modification.

Second, we are proposing changes to the regulations intended to clarify CMS' authority to impose CMPs for the violations contained in section 1857(g)(1) of the Act and corresponding regulations at § 422.752 (Part C) and § 423.752 (Part D). Existing regulations provide the government with authority to impose CMPs for the listed violations. The existing regulations, however, designate the Office of Inspector General (OIG) as the sole government agency with the authority to impose CMPs for the violations contained in § 422.752 and § 423.752. We are proposing to revise the language of these provisions to clarify that either CMS or the OIG may impose CMPs for the violations listed at § 422.752(a) and § 423.752(a), except § 422.752(a)(5) and § 423.752(a)(5). Only the OIG will continue to have the authority to impose CMPs for the violations at § 422.752(a)(5) and § 423.752(a)(5), regarding the misrepresentation and/or falsification of information furnished to CMS, an individual or other entity. CMS or the OIG will impose the CMPs in accordance with the amounts specified in section 1857(g)(2) of the Act and § 422.760 and § 423.760 of the corresponding regulations.

We are proposing to revise the existing regulations at § 422.752, § 423.752, § 422.760, and § 423.760 to effectuate this change.

4. Contract Termination Notification Requirements and Contract Termination Basis (§ 422.510 and § 423.509)

Sections 1857(c) and 1860D–12(b)(3)(B) of the Act provide us with the authority to terminate a Part C or D sponsoring organization's contract at any time if we make a determination that the contracting organization is substantially failing to meet contract requirements and expectations. Sections 1857(h)(1)(B) and 1860D–12(b)(3)(F) of the Act provide us with the procedures necessary to facilitate the termination of contracts held between CMS and MA organizations and Part D sponsors, respectively. The Part C contract termination authorities and procedures were codified into regulations in the June 29, 2000 final rule entitled, ''Medicare Program; Medicare+Choice Program'' (65 FR 40170) at § 422.510. Likewise, the Part D authorities and procedures were codified into regulations in the January 28, 2005 final rule entitled, ''Medicare Program; Medicare Prescription Drug Benefit'' (70 FR 4194) at § 423.509.

We are proposing three revisions to our existing regulations that relate to contract termination. First, we are proposing clarification of the scope of our authority to terminate Part C and D contracts under § 422.510(a) and § 423.509(a). Section 1857(c)(2) of the Act provides us with authority to terminate a Part C or D contract if we make a determination that the organization—

- Has failed substantially to carry out the contract;
- Is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part; or
- No longer substantially meets the applicable conditions of this part.

Existing regulations at § 422.510 and § 423.509 reiterate the three bases for termination set forth in the statute, however, over time CMS has also included in regulation a number of specific violations within the scope of our statutory authority, that is, violations which meet the standard established by the statute. In the June 26, 1998 proposed rule (63 FR 34968, at 35018), we stated that ''[i]n addition to repeating the above statutory language, we are implementing this language by identifying specific circumstances that we believe constitute examples of [an MA] organization substantially failing to carry out either its contract, or carrying out its contract in a manner that is inconsistent with the effective and efficient administration.''

However, we have come to believe over time that the inclusion of our broad statutory authorities in the regulations, along with the more specific violations, has the potential to lead to confusion regarding the scope of our termination authority. Terminating a contract is the strongest action that CMS may take in response to an MA organization or Part D sponsor's noncompliance. It is imperative that both CMS and affected organization understand the standard

we apply when CMS has made a determination to end the contractual relationship. Therefore, we are proposing to modify the language at § 422.510(a) and § 423.509(a) to clarify our contract termination authority by separating the statutory bases from the examples. To effectuate this change we will need to renumber the lists of bases contained in § 422.510(a) and § 423.509. Because there are cross references using the current numbering scheme, we are also proposing to make several corresponding reference changes to reflect the renumbering of this section throughout parts 422 and 423. We believe that by making these changes, we will improve the clarity of this regulation.

Second, we are proposing revisions to our contract termination notification procedures contained at § 422.510(b)(1) and § 423.509(b)(1). Current regulations state that if CMS decides to terminate a Part C or D sponsoring organization's contract, we must notify the MA organization/Part D sponsor in writing 90 days before the intended date of the termination. We believe that the 90-day timeframe is not in the best interest of Medicare beneficiaries, in light of the fact that CMS terminates contracts in circumstances where an organization is significantly out of compliance with Part C and D requirements. We also think that the 90-day timeframe is unnecessarily long given the existing procedural protections and appeal rights provided for MA organizations and Part D sponsors.

The authorizing statute for Part C, at section 1857(h)(1)(B) of the Act (applicable to Part D pursuant to section 1860D–12(b)(3)(F) of the Act), states that the Secretary must provide reasonable notice and opportunity for hearing regarding the termination (including the right to appeal the initial determination); during this hearing process, the termination is effectively stayed pursuant to § 422.664 and § 423.652. Therefore, we believe that a 45-day timeframe better balances the need to provide contracting organizations with reasonable notice of the impending contract termination with the interests of the Medicare beneficiaries who are enrolled in a plan that is deficient enough in its adherence to Part C and/or D requirements that contract termination is necessary. We also propose to make necessary cross-reference changes in parts 422 and 423 at § 422.644(c)(1) and § 423.642(c)(1).

Additionally, in an effort to respond to changes in the media and information technology landscape, we are proposing a slight modification to the termination notification provision for the general public at § 422.510(b)(1)(iii) and § 423.509(b)(1)(iii) by proposing that contracting organizations now release a press statement to news media serving the affected community or county and posting the press statement prominently on the organization's Web site instead of publishing the notice in applicable newspapers.

Third, we are proposing minor revisions to the wording of our regulations at § 422.510 and § 423.509 to reflect the authorizing language contained in sections 1857(c)(2) and 1860D–12 of the Act. Specifically, we are proposing to replace the word ''fails'' with ''failed'' in the applicable provisions of § 422.510 and § 423.509. In current regulations both of the terms failed and fails are used when describing contract violations that may be the basis for a contract termination. We would like for this list to read consistently, therefore, we are proposing to revise the language as such. The purpose of this change is merely to ensure that consistent language is used throughout § 422.510 and § 423.509 and in no way changes the meaning or policy encompassed in these provisions.

5. Reducing the Burden of the Compliance Program Training Requirements (§ 422.503(b)(4)(vi)(C) and § 423.504(b)(4)(vi)(C))

Section 1857(a) of the Act provides the Secretary with the authority to enter into contracts with MA Organizations, and section 1860D–12(b)(1) of the Act provides the Secretary with the authority to enter into contracts with Part D sponsors. Sections 1860D–12(b)(3)(D)(i) and 1857(e)(1) of the Act, specify that these contracts shall contain other terms and conditions that the Secretary may find necessary and appropriate. When we implemented the Part C program, we determined that all Part C contracts (and subsequently Part D contracts) would require that the Part C or D organization has the necessary administrative and management arrangements to have an effective compliance program, as reflected in § 422.503(b)(4)(vi) and § 423.504(b)(4)(iv).

In the December 5, 2007 **Federal Register**, we published the ''Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals and Intermediate Sanctions Process'' final rule (72 FR 68700). In that final rule, we established that compliance plans for sponsoring organizations must include training and education and effective lines of communication between the compliance officer and the sponsoring organization's employees, managers, and directors as well as their first-tier, downstream and related entities (FDRs). We reiterated the importance of this requirement in the October 22, 2009 proposed rule entitled, ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (74 FR 53634).

In the 2009 proposed rule, entitled, ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs,'' we addressed concerns about the burden on FDRs such as pharmacies, hospitals and physicians as a result of this requirement, given the likelihood that many of these entities and individuals contract with multiple contracting organizations. We were concerned that these FDRs would potentially have to participate in (largely duplicative) training for each organization with whom they contract. We requested public comments on how best to ensure that the training requirement continues to be met while not overly burdening the contracting organization or its FDRs. In response, we received numerous comments suggesting that CMS develop its own web-based trainings to lessen this burden on sponsors and FDRs (75 FR 19678 at 19688).

In response to these requests, we have created the CMS Standardized General Compliance Program Training and Education Module. Until now, we have offered this as an optional training. In this rule, we propose to require that all contracting organizations accept a certificate of completion of the CMS training as satisfaction of this general compliance program training requirement. We anticipate that this proposal will greatly reduce the burden on various sectors of the industry, including, but not limited to, insurance providers, hospitals, suppliers, pharmacists, and physicians.

Under this proposed change, Part D sponsors and Part C organizations would not be permitted to develop or implement sponsor specific training or provide supplemental training materials to fulfill the general compliance program training requirement; only CMS training would suffice.

We understand that sponsors often include sponsor specific information (such as compliance officer's contact information, compliance reporting processes and expectations, hotline number or email address for compliance questions, Web site information for accessing the sponsor's compliance policies and procedures) in the training materials provided to the FDRs and will need an appropriate mechanism for

conveying this information given that the training vehicle will no longer be available. To address this issue, a sponsor may choose to include such information in the contract held between the sponsor and the FDR. Alternatively, we would allow each sponsor to develop a one page information sheet containing this material, to be distributed by the sponsor to each of its FDRs. We seek comments concerning this portion of our proposal and suggestions on other options we could implement to accomplish the desired outcome.

We are proposing to modify the regulation text by adding a new § 422.503(b)(vi)(C)(3) and § 423.504(b)(vi)(C)(4) to permit only this CMS training for satisfaction of the requirement to train FDRs.

6. Changes to Audit and Inspection Authority (§ 422.503(d)(2) and § 423.504(d)(2))

Sections 1857(d)(2)(A) and 1860D–12(b)(3)(C) of the Act specify that each contract under these sections must state that CMS has the right to audit and inspect the facilities and records of each organization. We are proposing three changes to our audit and inspection authority. First, under section 6408 of the Affordable Care Act new authority was provided to the Secretary that now requires that each contract provide the right to ''timely'': (1) Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the contract; (2) inspect or otherwise evaluate the facilities of the organization when there is reasonable evidence of some need for such inspection; and (3) audit and inspect any books, contracts, and records of the organization 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.

Therefore, we are proposing to revise both § 422.503(d)(2) and § 423.504(d)(2) to reflect this change. Specifically, we are proposing to insert the word ''timely'' at the end of both of the introductory paragraphs for § 422.503(d)(2) and § 423.504(d)(2).

Second, we are proposing to add authority that will allow CMS to require MA organizations and Part D sponsors to hire an independent auditor to perform full or partial program audits to determine compliance with CMS requirements.

MA organizations and Part D sponsors must adhere to CMS requirements to properly administer Part C and Part D benefits. These requirements are contained in statute, regulations and in the Part C and Part D sponsor agreements themselves. CMS needs assurance that MA organizations and Part D sponsors are substantially adhering to Part C and/or D requirements, and that Medicare beneficiaries are receiving the benefits to which they are entitled. To determine the extent of MA organization and Part D sponsor compliance with program requirements, CMS uses a variety of oversight and monitoring tools including CMS-conducted program audits.

CMS conducts a program audit by examining core operational areas and functions and determining the sponsors' level of compliance with these Part C and Part D program requirements. CMS may audit any program requirement, but in recent years we have focused on Part C and Part D coverage decisions, appeals, grievances, compliance program effectiveness, and formulary administration. CMS reviews a number of targeted samples to evaluate MA organizations and Part D sponsors' processes and systems. Targeting samples is an efficient way to highlight deficiencies and ensure that they are quickly and successfully remediated. The process is primarily designed to be educational for the MA organization and/or Part D sponsor as it expands the sponsor's understanding of CMS' expectations, and how program requirements are to be applied. It also identifies areas of risk or actual non-compliance so sponsors can quickly correct the deficiency. This understanding allows the MA organization and/or Part D sponsor to develop and implement a robust internal auditing and monitoring program to identify deficiencies before they reach a level of substantial non-compliance in the future. An effective monitoring program should result in early detection of system and process failures and should lead to problems being fixed quickly and steps being implemented to prevent future failures.

Organizations that are chosen for audit fall into at least one of the five following categories: High Star rated plans; sponsors with a Low Performing Icon (LPI); high risk plans (based on a data driven risk assessment); sponsors not audited in last 3 years, and CMS Regional or Central Office referrals. Annually, CMS conducts a risk assessment to determine which high-risk organizations to audit. Many of the program audits currently being conducted are with organizations whose contract performance or data indicators demonstrate the potential risk of failing to perform core program functions that, if not complied with, may result in potential beneficiary harm. These audits are a useful tool to help identify systemic deficiencies and failures in meeting CMS requirements and they help to promote compliance with those requirements. While these types of audits are necessary because these organizations pose the most risk, not all organizations are receiving the benefit of having an independent audit of their organization on a regular basis.

CMS is constrained in the number of program audits we can conduct each year, due to limited resources. Currently, CMS has close to 300 parent organizations that perform MA and/or Part D functions. CMS is only able to audit approximately 30 parent organizations per year; or roughly 10 percent of all MA organizations and/or Part D sponsors. CMS believes that MA organizations and/or Part D sponsors, their enrollees, and the Medicare program all benefit from a regular cycle of independent auditing. Therefore, we are proposing to revise our regulations to allow CMS to require MA organizations and/or Part D sponsors to hire an independent auditor to conduct regularly scheduled program audits in accordance with CMS specifications.

We currently make all of our program audit protocols available to MA organizations and/or Part D sponsors through our Web site. Pursuant to the proposed new regulatory provision, CMS would notify the MA organization and/or Part D sponsor that it has been selected to perform a full or partial program audit. The MA organization and/or Part D sponsor would then be required to engage an independent auditor to perform a full or partial program audit as directed by CMS using the CMS published protocols, methodologies, and methods of evaluation. At the conclusion of the audit, at the direction of the MA organization and/or Part D sponsor, the independent auditor will provide a draft copy of its findings to CMS and the MA organization and/or Part D sponsor. Once the MA organization and/or Part D sponsor has had an opportunity to rebut any findings, the independent auditor will provide its final report of findings to CMS and the MA organization and/or Part D sponsor. CMS anticipates that additional instruction will be necessary to interpret and implement this audit requirement of a complete and full independent review. Therefore, we intend to develop and release sub regulatory guidance to address, among other things, language and specifications which should be included in the contract between the sponsoring

organization and the independent auditor conducting the audit. The proposed authority will allow CMS to better evaluate MA organizations' and Part D plan sponsor's performance. With the proposed approach, each MA organization and/or Part D sponsor will be required to undergo an independent program audit at least every 3 years. Under this proposal, more organizations will be audited each year, which will provide CMS with substantially more data to evaluate program-wide performance, improve industry performance and protect beneficiaries enrolled in the Medicare Advantage and Prescription Drug Benefit programs. This will enhance CMS's oversight and provide us with information that enables us to focus our time and resources in the areas most needed to ensure compliance with Part C and Part D program requirements.

CMS will continue to perform program audits in limited scenarios, such as when indicated by a risk analysis; and will perform limited ''look back'' audits to ensure the integrity of the independent audit process proposed here. The latter audits will focus on reviewing the program audit findings that we receive from the independent auditors engaged by the Part C and Part D organizations, to ensure that the independent auditor conducted the audit in accordance with CMS specifications. We think that this additional authority will significantly strengthen the Medicare Parts C and D audit and oversight program.

Therefore, we are proposing to add language to § 422.503(d)(2) and § 423.504(d)(2) that will allow us to require a MA organization or Part D sponsor to hire an independent auditor, working in accordance with CMS specifications, to perform program audits to determine compliance with CMS requirements and provide to CMS an attestation affirming that the audit has been completed as required.

Third and finally, we are proposing to revise our regulations to specifically permit CMS to require MA organizations or Part D sponsors with audit results that reveal non-compliance with CMS requirements to hire an independent auditor to validate that correction has occurred. We may invoke this authority regardless of whether an independent auditor or CMS conducted the program audit that identified the programmatic deficiencies.

When program audits are conducted, non-compliance with CMS requirements is often found. When CMS finds these deficiencies, it notifies the MA organization or Part D sponsor of its non-compliance and requires correction. We do not close out audits until we have validated that correction has occurred. While we firmly believe in the value of such validation, these efforts are also limited by resources. In order to assist us in making the determination that the deficiencies found during the audit have been corrected and are not likely to recur, we need to have greater flexibilities in performing validation activities. Therefore, we are proposing that we may require a MA organization or Part D sponsor to hire an independent auditor to provide us with additional information to determine if the deficiencies found during the course of the audit have actually been corrected and are not likely to recur. The independent auditor would be hired by the MA organization and/or Part D sponsor and work in accordance with our specifications in order to provide accurate and reliable information to CMS.

CMS often relies on self-disclosed information from the MA organization or Part D sponsor, CMS and plan data; in the alternative, we must attempt to engage in a process to independently verify that deficiencies have been corrected. Given the nature and extent of some compliance deficiencies and the level of skill and experience required to conduct an exhaustive verification of correction, we have concluded that an independent auditor hired by the MA organization or Part D sponsor would be beneficial for both the organization and CMS.

This proposal is also consistent with our regulatory authority at 42 CFR 422.756 and 423.756 which permits us to require a sanctioned organization to hire an independent auditor to help us determine if a sanction should be lifted. Program experience has demonstrated other situations when the expertise of an independent auditor would be helpful in determining correction. For example, an independent auditor who specializes in complex information technology systems and who has specialized knowledge of how those systems interact with each other, in order to be compliant with our requirements, may be helpful in ensuring timely and successful correction of complex claims processing deficiencies. This is one example of a situation where we may require the MA organization or Part D sponsor to hire an independent auditor in order to assist in making the determination that the deficiencies found during the program audit have been corrected.

Therefore, we are proposing to add language to § 422.503(d)(2) and § 423.504(d)(2) that will allow us to require that a sponsoring organization hire an independent auditor, working in accordance with CMS specifications, to provide us with additional information to determine if the deficiencies that were found during a program audit have been corrected.

7. Procedures for Imposing Intermediate Sanctions and Civil Money Penalties Under Parts C and D (§ 422.756 and § 423.756)

Sections 1857(g) and 1860D–12(b)(3)(E) of the Act provide the Secretary the ability to impose intermediate sanctions on MA organizations and PDP sponsors. Intermediate sanctions consist of suspension of enrollment, suspension of marketing and suspension of payment. Current regulations governing intermediate sanctions are contained in subparts O of part 422 and part 423. Sections 422.756 and 423.756 provide specific procedures for imposing intermediate sanctions, and include provisions which address the duration of the sanction and the standard that we apply when determining if a sanction should be lifted. As specified in the Act and regulations, when intermediate sanctions are imposed on sponsoring organizations, the sanctions remain in place until we are satisfied that the basis for the sanction determination has been corrected and is not likely to recur.

Because sanctions remain in place until the deficiencies have been corrected and we are assured that they are not likely to recur, we are unable to fully test the contracting organization's compliance with certain requirements until the sanction is lifted. Therefore, in the October 2009 proposed rule, entitled ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (74 FR 54634), we proposed a rule, later finalized in the April 15, 2010 ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (75 FR 19678), that allows us to require a plan under a marketing and/or enrollment sanction to engage in a test period of marketing or accepting enrollments or both for a limited period of time. As we explained in that proposed rule, the purpose of the test period is to assist us in making a determination as to whether the deficiencies that are the bases for the intermediate sanctions have been corrected and are not likely to recur. The test period provides us with the opportunity to observe a sanctioned plan's ability to enroll or market to Medicare beneficiaries prior to lifting

the sanction. Since finalizing that rule in April 2010 (75 FR 19678), we have further considered its utility as a result of compliance issues that we have encountered over the past 2 years. We are proposing two modifications to this existing rule. First, we are proposing to expand the potential applicability of the test period requirement to all types of all intermediate sanctions. The existing regulation would only allow CMS to require this test period in instances where CMS has imposed a marketing and/or enrollment sanction. However, the type of intermediate sanction imposed is not necessarily related to the particular violations that form the basis for the sanction. Therefore, we are proposing to modify the existing rule to clarify that CMS may require a test period for a sponsoring organization that has had any of the three types of intermediate sanctions imposed: marketing, enrollment and/or payment.

We also want to clarify that our ability to require this test period is not limited to sanctions stemming from marketing or enrollment violations. In the preamble language for the October 2009 proposed rule, (74 FR 54634), we stated that ''[t]he basis for this proposal is that we have found that there is often not a satisfactory way to determine if marketing and/or enrollment problems have been corrected while a sanction is in place and no such activities are permitted.'' Upon reflection, we are concerned that this statement may have given the impression that the test period would only be used in instances where the underlying bases for the sanction are marketing and/or enrollment deficiencies. Therefore, we are clarifying here that the purpose of the test period is to assist us in making a determination as to whether the deficiencies that are the bases for the intermediate sanction have been corrected and are not likely to recur. The aforementioned deficiencies may be in any operational area, and are not limited or restricted to enrollment and/or marketing deficiencies.

Second, we are proposing to clarify the enrollment parameters for Part D contracting organizations that are under the benchmark and would normally participate in the annual and monthly auto enrollment process for beneficiaries who receive a low income subsidy (LIS) during a test period. During a test period, sanctioned Part D plans may not be allowed to receive or process these types of enrollments.

LIS beneficiaries are a vulnerable population who are particularly sensitive to financial instability. It is critical that Part D sponsors correctly identify a beneficiary's LIS status. Our goal when enrolling this particular population is to ensure that these vulnerable beneficiaries are best able to access their drugs and services in the manner to which they are entitled under the Part D program. We believe that if we allow auto-enrollments into a plan that has recently demonstrated substantial non-compliance with our regulations as evidenced by the imposition of an intermediate sanction, these vulnerable beneficiaries may experience difficulties in accessing prescription drugs. Therefore, we are proposing to make clear that we may determine that a sanctioned plan is not available to receive automatically assigned beneficiaries for the entire duration or a portion of the testing period.

We are proposing to modify the regulation text at § 422.756 and § 423.756 to reflect these changes.

8. Timely Access to Mail Order Services (§ 423.120)

Section 1860D 12(b)(3) of the Act authorizes the Secretary to include contract terms for Part D sponsors, not inconsistent with the Part C and D statutes, as necessary and appropriate. Section 423.120(a)(3) specifies that a Part D sponsor's contracted network may include non-retail pharmacies, including mail order pharmacies, so long as the network access requirements are met. Part D plans are increasingly entering into contracts with mail order pharmacies to offer beneficiaries an alternative way to fill prescriptions under the Part D benefit, often at much lower cost sharing than is available at network retail pharmacies. While mail order pharmacies make up a relatively small percentage of total prescriptions filled under the Part D program, we are committed to ensuring consistent and reliable beneficiary access to medications, regardless of what type of pharmacy fills the prescriptions.

Section 1860D–4 of the Act describes the various beneficiary protections in place in the Part D program. It is the industry standard in retail and institutional pharmacies to fill almost all prescriptions on the same day the prescription is presented. We have established a 24 hour fulfillment standard for home infusion drugs covered under Part D (§ 423.120(a)(4)(iv)). For mail order pharmacies, the industry standard for delivery times appears to range from 7 to 10 business days from the date the prescription was received, and Part D sponsors' marketing materials often specify this time frame to beneficiaries. Beneficiaries generally choose to fill prescriptions through a mail order pharmacy, for lower cost sharing, when it is feasible to wait 7 to 10 days to receive their medications. However, if this time frame is disrupted, beneficiaries may experience gaps in therapy.

We are aware of a specific instance in which significant incentives (for example, zero cost sharing) caused increased demand for mail order prescriptions sufficient to disrupt the delivery time frame, and we are concerned about the adverse effect such incentives might have on beneficiaries. When issues with filling a prescription arise in a retail setting, the beneficiary often is notified of the problem in real time, or within hours of discovery. When issues arise in a mail order setting, the delays in finding, communicating, and making the appropriate contacts to resolve the problem may add days onto the ultimate delivery date, resulting in a potentially more significant concern for mail order beneficiaries if these delays result in gaps in therapy. For this reason, we believe it is necessary and appropriate to establish fulfillment requirements for mail order pharmacies as well as home delivery services offered by retail pharmacies, to set consistent expectations for beneficiary access to drugs in this growing segment. Many beneficiaries may be very well served by this type of pharmacy access, but only if they can rely upon efficient processing and turnaround times. Mail order pharmacies contracted by Part D sponsors can reasonably be expected to meet minimum performance standards for order fulfillment, including convenient order turnaround times, as a beneficiary protection and as a component of providing good customer service. Clearly stating in beneficiary materials the expected turnaround time for delivery allows the beneficiary to better control when they need to reorder to ensure no gaps in medication supply. Clarity in expected turnaround times also can prevent needing to address customer inquiries into the status of a pending order, setting parameters for when an order is or is not delayed and what options become available at that point. We believe that established companies that have been providing these services for years have generally been meeting these standards in practice already, and that the proposed turnaround times are in line with current practices followed by mail order pharmacies today. Establishing mail order fulfillment requirements as a contract term would require plan sponsors to require that all pharmacies in its network meet the same minimum

level of service. This would underscore the importance of consistent and reliable access to medications, protecting beneficiaries from inconsistent or unreliable practices that may otherwise jeopardize timely access to prescriptions.

Therefore, we are proposing to amend § 423.120(a)(3) to specify mail order fulfillment requirements in line with what we have observed in other markets: 5 business days (from when the pharmacy receives the prescription order to when it is shipped) for those prescriptions requiring intervention beyond filling (such as clarifying illegible orders, resolving third party rejections, and coordinating with multiple providers as part of drug utilization management); and 3 business days (from when the pharmacy receives the prescription order to when it is shipped) for those prescriptions not requiring intervention. We recognize that some prescription orders may require clarification or additional steps to be taken by the provider or beneficiary that will extend beyond the proposed period of 5 days. We believe that such cases represent a minority of mail order prescriptions, and as such we would anticipate that more than 99 percent of all mail order prescriptions processed are filled in compliance with either the 3- or 5-day standard. We believe our proposed standards are in alignment with fulfillment requirements already in place in the market and as such do not create a new burden or new standard for mail order pharmacies to meet. We are soliciting comments not only on the proposed time frames, but also on whether there are instances (in addition to those discussed previously) in which the proposed 5-day time frame should apply.

We additionally are soliciting comments on whether we should establish additional requirements for beneficiary materials relating to mail order services, such as: clear definitions of processing time and delivery time; how to access customer support; how to submit a complaint via 1 800 MEDICARE; and beneficiary options for accessing medications when a delivery is lost or delayed.

We also welcome comments on any other requirements we should consider for mail order or other home delivery options. For example, also potentially affecting consistent access to medication is the use of mail order to fill initial prescriptions of new drugs or to fill 30-day supplies of chronically used medications. The need to order a refill early, allowing sufficient time for processing and delivery, can result in refill too soon edits based upon retail 30 day standards. Resolving inappropriate or inapplicable edits increases burden on the beneficiary and the mail order pharmacy and essentially creates a disincentive for beneficiaries who are planning ahead and attempting to order early enough to ensure un-interrupted supplies of chronic medications. In general, we believe that filling initial prescriptions or routine 30-day supplies at mail order is not good practice. We recognize that there may be a small minority of beneficiaries who successfully depend solely upon mail order or other home delivery options for access to prescription drugs due to particular circumstances of geography or mobility. We have no reason to discourage their continued use of these services. However, due to the difficulties reported to CMS with consistently and effectively filling short time frame supplies through mail order, we do not believe that Medicare beneficiaries in general should be incentivized through lower cost sharing to utilize mail order pharmacies for initial prescriptions or 30-day supplies.

9. Collections of Premiums and Cost Sharing (§ 423.294)

Since the beginning of the Part D program, when asked whether Part D sponsors could waive premiums and cost sharing we have responded that reducing or waiving either of these amounts would be inconsistent with the approved bid. The bid requirements, specified in section 1860D–11(e)(2)((C) of the Act, state the bid must reasonably and equitably reflect the revenue requirements of the expected population for the benefits provided under the plan. Waiving or reducing the cost sharing and/or premiums that are reflected in the approved bid would indicate that the plan bid was overstated and the amounts were not necessary for the provision of coverage. However, recently we have received reports of sponsors reducing or waiving cost-sharing and/or premiums. As a result, we propose to codify requirements for sponsor collection of cost sharing and premiums in regulation.

In addition to violating the bid requirements, as we noted in the preamble of the October 22, 2009 proposed rule entitled, ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (74 FR 54690), waiving cost sharing or premiums also violates the uniform benefit requirements because doing so results in the plan's not providing the same coverage to all eligible beneficiaries within its service area. Section 1860D–2(a) of the Act defines qualified prescription drug coverage to mean access to standard or actuarially equivalent prescription drug coverage and access to negotiated prices (in accordance with section 1860D–2(d) of the Act). Thus, a Part D sponsor must offer its plan to all eligible beneficiaries residing in the plan's service area. We further interpret section 1860D–2(a) of the Act as requiring the provision of uniform premium and benefits and have codified these requirements in our regulations at § 423.104(b).

Once CMS has approved a sponsor's Part D benefit package, it cannot be varied for some or all of the plan's Part D enrollees. Thus, sponsors must commit to providing the level of benefits described in the sponsor's benefit package and cannot waive or reduce cost sharing, as that would violate the uniform benefit provisions set forth in § 423.104(b). This is true regardless of whether the Part D sponsor waives the copayment directly or indirectly through an affiliate, and regardless of whether such a waiver is prohibited by other laws. Some Part D sponsors are related to pharmacies through common ownership or control, and we note that an exception to the anti-kickback statute, set forth in section 1128B(b)(3)(G) of the Act, permits a pharmacy to waive cost sharing (that is, coinsurance and deductibles) imposed under Part D, if the conditions described in clauses (i) through (iii) of section 1128A(i)(6)(A) of the Act are met. These conditions include that the waiver is not advertised (through media outlets, telemarketing or otherwise) and is not routine, and the cost sharing is waived after a good faith determination that the individual is in financial need [1] or reasonable efforts to collect the cost sharing have failed. This exception may protect from sanctions under the anti-kickback statute the waiver of cost sharing by pharmacies owned by Part D sponsors. However, as noted in the proposed rule, entitled ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (74 FR 54690), sponsor failure to collect or attempt to collect cost sharing at the time the service is provided or to bill cost sharing to the appropriate party (either a beneficiary or another payer) after the fact, is a violation of the uniform benefit provisions set forth in the current regulation at § 423.104(b). The fact that cost sharing is waived by a pharmacy

[1] Under section 1128B(b)(3)(G) of the Act, an individual determination of financial need is not required for Part D beneficiaries eligible for the low-income subsidy under section 1860D–14 of the Act.

that is related to a Part D sponsor by common ownership, rather than the Part D sponsor itself, and that it may be protected from sanctions under the anti-kickback statute, does not relieve the Part D sponsor of responsibility for this violation of the uniform benefit provisions. If a pharmacy is unrelated to a Part D sponsor and waives cost sharing under the conditions previously described, the pharmacy is making an independent business decision to which the Part D sponsor is indifferent. However, if an affiliated pharmacy waives cost sharing for a beneficiary enrolled in the sponsor's Part D plan, the sponsor is not indifferent because the cost-sharing waiver is more likely to be a strategic decision by the sponsoring organization to move market share to the related-party pharmacy and increase profits to the sponsor. Thus, the sponsor is altering the level of cost sharing in the approved bid in violation of the uniform benefit provisions in § 423.104(b). To clarify this for all parties, we propose to codify the prohibition of the waiver or reduction of premiums and cost sharing by adding a new section at § 423.294. We propose to specify that Part D sponsors either directly, or indirectly through related party pharmacies, as defined in regulation at § 423.501, are prohibited from reducing or waiving collection of premiums and cost sharing. In contrast, a pharmacy affiliated with one Part D sponsor may waive Part D cost sharing for beneficiaries enrolled Part D plans offered by other sponsors without violating the uniform benefit provisions.

Additionally, we have become aware that the regulations in Part 423 do not address Part D sponsor requirements for refunding incorrect collections of premiums and cost sharing or for retroactively collecting underpayments of cost sharing. Therefore, we also propose to codify requirements at § 423.294 that mirror the language at § 422.270. We propose to apply the timeframe in § 423.466(a) to these refunds and recoveries. In other words, whenever a sponsor receives information that necessitates a retroactive refund of incorrect collections of premiums and/or cost sharing or collection of underpayments of cost sharing, the sponsor would be required to issue refunds or recovery notices within 45 days. For incorrect collections, we propose to duplicate the language at § 422.270 with one exception. That is, in the absence of authority to do so, we are not proposing to reduce Part D sponsor premiums for failure to refund amounts incorrectly collected from Part D enrollees. Instead, we propose that sponsors that fail to meet these requirements may receive compliance notices from CMS or, depending on the significance of the non-compliance, be the subject of an intermediate sanction (for example, suspension of marketing and enrollment activities) pursuant to Part 423, Subpart O.

10. Enrollment Eligibility for Individuals Not Lawfully Present in the United States (§ 417.2, § 417.420, § 417.422, § 417.460, § 422.1, § 422.50, § 422.74, § 423.1, § 423.30, and § 423.44)

a. Basic Enrollment Requirements

Sections 226 and 226A of the Act establish the conditions for Medicare Part A entitlement for individuals who have attained age 65, are disabled or have end-stage renal disease (ESRD), and are entitled to monthly Social Security benefits under section 202 of the Act. Individuals entitled to Part A under these sections do not have to pay premiums for such coverage, and they may, but are not required to, enroll in Medicare Part B. Section 1818 of the Act establishes the conditions for Medicare enrollment for individuals who are not entitled to monthly Social Security benefits under section 202 of the Act. Individuals covered under section 1818 of the Act must meet citizenship or alien status requirements, in addition to other requirements, in order to enroll in Part B. Individuals must have Part B in order to purchase Part A hospital insurance.

Sections 1851(a)(3)(B), 1860D–1(a)(3)(A), and 1876(a)(1)(A) of the Act outline the eligibility requirements to enroll in MA (Part C), Medicare prescription drug coverage (Part D), and Medicare cost plans. Under all options, individuals must have active Medicare coverage. Specifically, to enroll in MA, an individual must be entitled to benefits under Part A and be enrolled in Part B; to enroll in Part D, an individual must be entitled to Part A and/or enrolled in Part B; to enroll in a Medicare cost plan, an individual must be enrolled in Part B (Part A entitlement is not required).

b. Medicare Eligibility and Lawful Presence

Section 401 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), amended by section 5561 of the BBA, mandates that qualified aliens not lawfully present in the United States are not eligible to receive any federal benefit. This is outlined in 8 U.S.C. 1611 (Aliens who are not qualified aliens ineligible for federal public benefits) and 8 U.S.C. 1641 (Definitions). The definition of qualified alien is codified in 8 CFR 1.3 (Lawfully present aliens for purposes of applying for Social Security benefits).

The aforementioned provisions affect eligibility to receive benefits that would otherwise be payable under provisions in the Act. For example, aliens meeting certain criteria are able to earn qualified credits towards Social Security retirement benefits as outlined in 8 U.S.C. 1631 (Federal attribution of sponsor's income and resources to alien) and 8 U.S.C. 1645 (Qualifying quarters). Such individuals may earn the total number of qualified credits to be eligible under the Act to receive retirement benefits under sections 226 and 226A of the Act. However, should such individuals be unlawfully present in the United States under the previously mentioned PRWORA provisions, they are not eligible to receive the Social Security benefits they have earned for as long as they remain unlawfully present. At such time as they are lawfully present in the United States, or live outside the United States, they would again become eligible to receive Social Security payments.

Similarly, when aliens become eligible for Medicare based on age or disability under the terms of the Act, they would also automatically be entitled to premium free Part A benefits and be eligible to enroll in Part B during a valid enrollment period. Furthermore, aliens receiving Social Security retirement benefits 4 months prior to turning 65, or are in their 21st month of receiving Social Security disability benefits, would, under the terms of the Act, also automatically be enrolled into both Part A and Part B consistent with section 1837 of the Act and the enrollment process outlined in § 407.17. Again, however, under PRWORA, these individuals are not eligible to receive payment of Medicare benefits for so long as they are unlawfully present in the United States. Only upon becoming lawfully present would they become eligible to receive the Medicare benefits to which they would otherwise be entitled by paying into Social Security for the requisite number of quarters or paying premiums.

We note that current regulations at § 406.28 and § 407.27 outline the reasons for loss of premium Part A and Part B enrollment, and do not include the absence of lawful presence or citizenship as a reason for loss of entitlement. Individuals who are entitled to Part A and enrolled in Part B based on eligibility of Social Security benefits currently may be enrolled in

Medicare even if they are not lawfully present in the United States.

When PRWORA was enacted, the Act was not amended to include the additional eligibility criteria for entitlement to either Social Security benefits or for Medicare Part A entitlement, nor were new provisions put into place regarding termination of entitlement or establishment of a special enrollment period to account for situations in which individuals reestablished lawful presence. As a result, individuals who meet the current statutory eligibility criteria have been reflected in CMS records as entitled to both Social Security benefits and Medicare coverage.

c. Alignment of MA, Part D, and Cost Plan Eligibility With Fee-For-Service (FFS) Payment Exclusion Policy

In order to implement 8 U.S.C. 1611 and ensure that individuals who are present in the United States unlawfully do not receive benefits, the Social Security Administration (SSA) established internal policies and procedures to suspend Social Security benefits during periods for which individuals are unlawfully present in the United States. Because Medicare entitlement flows from entitlement to Social Security retirement and disability benefits, Medicare also has implemented this provision through a payment exclusion process.

Under Medicare's payment exclusion process, data on lawful presence is transmitted to CMS from the Department of Homeland Security via regular data exchanges from SSA. Once the data is received by us, the lawful presence status is noted on an individual's record and is retained in the FFS claims processing systems. As a result, we deny payment of both Part A and Part B claims for non-citizens where lawful presence is not established on their record, and do so until individuals regain their lawful presence status. Although payment is being denied for claims, individuals who are ''fully insured'' per section 226 of the Act, maintain Part A entitlement and remain enrolled in Part B on CMS records as long as premiums are paid. Similarly, individuals who are enrolled in premium Part A and/or Part B, maintain their enrollment status as long as premiums are paid.

Although CMS implementation of the lawful presence criteria in the FFS program achieved the intent of PRWORA by preventing FFS payments for services rendered to individuals who are not lawfully present, this policy was not adopted in regulations for Part A and Part B eligibility in 42 CFR parts 406 and 407 or addressed in regulations or subregulatory guidance for MA, Part D, and Medicare cost plans. Thus, individuals who are not lawfully present, but are nevertheless shown on CMS records to be entitled to Medicare Part A and/or enrolled in Part B, have been able to enroll in MA, Part D, and Medicare cost plans and obtain Medicare coverage for which they should not be eligible under 8 U.S.C. 1611. By permitting these MA, Part D and cost plan enrollments to remain in place, we are allowing improper payments to be made to plans on behalf of these individuals, which in turn impacts the Medicare Trust Funds. In addition, MA organizations, PDP sponsors and cost plans are making benefit payments under the Medicare program on behalf of these enrollees that are similarly prohibited under PRWORA.

Therefore, we are proposing to align eligibility for enrollment in MA, Part D, and cost plans (and resulting Medicare payments to plans and by plans that violate PRWORA) with the FFS payment exclusion policy to ensure that Medicare is only paying for services rendered to individuals who are eligible to receive them. These steps are consistent with recommendations made by the Office of Inspector General in its January 2013 report (A–07–12–01116) regarding the need for CMS to maintain adequate controls to prevent and detect improper payments for Medicare services rendered to unlawfully present beneficiaries. Accordingly, we are proposing to revise the regulations to establish U.S. citizenship and lawful presence as eligibility requirements for enrollment in MA, Part D, and cost plans. Further, we propose that individuals who are not lawfully present in the United States would be involuntarily disenrolled from MA, Part D, and cost plans, based on the date on which they lose their lawful presence status. Disenrollments would be effective the first of the month following the loss of eligibility, and the disenrollment process would follow that currently set forth in the regulations when an individual is no longer eligible to be enrolled in a plan.

These regulatory changes would prevent an individual from enrolling in a plan and/or remaining enrolled in a plan if they are not lawfully present in the United States. Affected individuals will retain their Medicare entitlement and remain enrolled in FFS, as long as premiums continue to be paid, but MA, Part D and cost plan payments would be denied for time periods during which the individuals are not lawfully present in the United States. We must ensure that in administering the Medicare program, all programs are compliant with 8 U.S.C. 161l. Specifically, we are proposing the following to address the eligibility and disenrollment of individuals not lawfully present in the United States:

- Sections 417.420, 417.422, 422.50, and 423.30 would be amended to add lawful presence or United States citizenship as eligibility criteria for enrollment in a cost, MA, or Part D plan, respectively.
- Sections 417.460, 422.74, and 423.44 would be amended to require the involuntarily disenrollment of individuals from cost, MA or Part D plans when they lose lawful presence status.

Conforming changes would be made to § 417.2, § 422.1, and § 423.1 to outline the authority for the aforementioned requirements, in 8 U.S.C. 1611 (Aliens who are not qualified aliens ineligible for Federal public benefits).

11. Part D Notice of Changes (§ 423.128(g))

Section 1860D 4(a) of the Act requires Part D sponsors to disclose to beneficiaries information about their Part D drug plans in standardized form. The Act further directs Part D sponsors to include, as appropriate, information that MA organizations must disclose under section 1852(c)(1) of the Act, which includes a detailed description of benefits. (In guidance, we refer to the document containing this information and delivered to beneficiaries as the Evidence of Coverage (EOC).) To make informed decisions, enrollees need to understand how their benefits, including premiums and cost sharing, would change from one year to the next, should they reenroll in the same plan. (In guidance, we refer to the documents containing this information and delivered to beneficiaries as the Annual Notice of Change (ANOC).) And enrollees also need to be aware of changes that may take place during the course of the year as well. Part D regulations currently do not include language found in the Part C regulations at § 422.111(d) requiring notice of changes to the plan to be provided to CMS for review pursuant to procedures for marketing material review and to all enrollees at least 15 days prior to the annual coordinated election period. Given that guidance applicable to both programs discusses notice of changes, we propose to require, for Part D, delivery of an ANOC.

Specifically, we propose to adopt in Part D, with modifications, the language contained in § 422.111(d). As is the case with the Medicare Advantage

regulation, proposed § 423.128(g) would require that Part D sponsors submit their changes to us under the procedures contained in subpart V of part 423, and, for those changes taking effect on January 1, provide a notice of changes to all enrollees 15 days before the beginning of the annual election period. While part 422 requires a minimum of 30 days' notice before the effective date for all other changes, proposed § 423.128 would not impose that standard, but rather would state that Part D sponsors remain subject to all other notice requirements specified elsewhere in the Part D regulations. Our proposal reflects a programmatic difference between Parts C and D: Under Part D it is not unusual for access to drugs listed on a plan's formulary to change during the course of a year. Changes can include changes to formulary status, tier placement, and utilization management or other restrictions. It is vital that beneficiaries currently taking a drug receive timely notice before such changes take place in order that they can decide whether to, for instance, change drugs or request an exception to cover the drug. Accordingly, our regulations currently specify when sponsors must provide notice of these kinds of changes. Our proposal to require the delivery of an ANOC is not intended to disrupt or change those existing notice requirements.

We would also like to take this opportunity to comment on the particular importance for Part D sponsors to provide notice in the ANOC of any changes they are making that will affect the amount of cost sharing which enrollees must pay for each drug belonging to a specific tier. As has been articulated in guidance, we continue to expect that sponsors will provide notice of such changes to all enrollees, including enrollees moved to a consolidated plan. Generally, sponsors compare numbers for the same plan from one year to the next in the ANOC. However, comparing numbers for the same plan would not benefit individuals moved from one plan to another. For instance, when a sponsor crosswalks members from a non-renewing plan to a consolidated renewal plan from one year to the next, cost sharing may change at the drug-tier level. For example, an enrollee who previously had zero cost sharing for all covered Part D drugs within the preferred generic tier may find that the consolidated plan now requires copays for drugs in that tier depending on how many months' supplies he or she orders, and whether he or she obtains those drugs at a retail level pharmacy or through mail order. We continue to expect that enrollees will receive ANOCs that clearly compare the non-renewed and consolidated plans' copayments or coinsurance for all drugs within each tier.

12. Separating the Evidence of Coverage (EOC) From the Annual Notice of Change (ANOC) (§ 422.111(a)(3) and § 423.128(a)(3))

As provided in sections 1852(c)(1) and 1860D–4(a) of the Act, MA organizations and Part D sponsors must disclose detailed information about the plans they offer to their enrollees. This detailed information is specified in section 1852(c)(1) of the Act and § 422.111(b) and § 423.128(b) of the Part C and Part D program regulations, respectively.

Under § 422.111(a)(3), we require MA plans to disclose a detailed plan description to each enrollee ''at the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.'' A similar rule for Part D sponsors is found at § 423.128(a)(3). The content of the annual plan description is provided in paragraph (b) of the respective regulations. This is commonly referred to as the EOC. In addition, under § 422.111(d), we require MA organizations to notify all enrollees ''at least 15 days before the beginning of the Annual Coordinated Election Period'' of any changes that will take effect on January 1 of the next plan year. This notification is commonly referred to as the ANOC. Although our Part D guidance calls for Part D sponsors to provide an ANOC, there currently is not a regulatory requirement that they do so. Therefore, in the previous section of this proposed rule, we have proposed to codify such a requirement.

Prior to the 2009 contract year, these regulations required the provision of the EOC at the time of enrollment and at least annually thereafter but did not specify a deadline for the annual provision of the EOC. We permitted MA organizations and Part D sponsors to provide the EOC as late as January 31 of the applicable contract year. Therefore, prior to the annual coordinated election period (AEP) for the 2009 contract year, MA organizations and Part D sponsors may have provided the EOC and ANOC at different times. In the final rule entitled, ''Medicare Program, Medicare Advantage and Prescription Drug Programs; Final Marketing Provisions'' (73 FR 54220 and 54222), we required MA organizations to send the EOC at the same time as the ANOC (that is, 15 days before the AEP), with the result that the EOC was sent about 4 months earlier. Our rationale for this requirement was to provide beneficiaries with comprehensive information prior to the AEP. In addition, the consolidated mailing reduced the number of mailings to enrollees and eliminated duplicative information. However, we have found through consumer testing that beneficiaries receive multiple documents from their plans and CMS during the AEP that address similar topics, which at times beneficiaries find confusing or overwhelming. The ANOC, which is much shorter than the EOC, is intended to convey all of the information essential to a beneficiary's decision to remain enrolled in the plan or choose another plan during the AEP. Research based on the consumer testing suggests that participants were more likely to review the ANOC if it was not included with the EOC. For example, when asked about the utility of each document, many participants stated that they would read the ANOC as soon as they received it, and use it more often than a combined ANOC/EOC because the combined document is too much to worry about, too wordy, and/or too difficult to find information in compared to just the ANOC.

We have also found that sending the EOC months earlier has led to some unintended consequences. Specifically, the earlier deadline shortens the production time and affects the MA organization's or Part D sponsor's ability to produce an EOC that provides accurate benefit information in accordance with CMS required timeframes, which results in plans sending and beneficiaries receiving additional mailings containing errata sheets. We have reviewed plan ANOC/EOC documents for errors and found that, of the total number errors found, EOCs contain significantly more errors (86 percent) than the ANOCs (14 percent), which leads us to believe that allowing plans to have additional time to prepare EOCs would allow them to produce EOCs with fewer errors. Additionally, resources are wasted when beneficiaries are sent a combined ANOC and EOC, but ultimately decide to enroll in a different plan, and have no need for the EOC.

In order to help current members make timely and informed decisions about plan choices for the next year while ensuring that they continue to receive all the post-enrollment information necessary in a timely manner, we believe it would be more effective for them to receive an ANOC before the AEP, and then receive the EOC from the plan he or she chooses for

the next year after enrollment is effective. Therefore, we propose to require MA organizations and Part D sponsors to ensure that their current members receive the ANOC 15 days prior to the AEP, and receive the EOC no later than December 31st, for the contract year taking effect the following January 1st. To accomplish this, we propose to amend § 422.111(a)(3) and § 423.128(c)(3) to remove the current deadline and insert ''by December 31 for the following contract year.'' The deadline established by § 422.111(d)(2) for provision of the ANOC would continue to be 15 days prior to the beginning of the AEP. In addition, as mentioned previously, we are proposing to amend § 423.128 to require Part D sponsors to provide a separate ANOC and to adjust the time frames for delivery accordingly.

13. Agent/Broker Compensation Requirements (§ 422.2274 and § 423.2274)

Section 103(b)(1)(B) of MIPPA revised the Act to charge the Secretary with establishing guidelines to ''ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the MA plan that is intended to best meet their health care needs.'' Section 103(b)(2) of MIPPA revised the Act to apply these same guidelines to Part D sponsors. Our program experience indicates that some agents may encourage beneficiaries to enroll in plans that offer higher commissions without regard to whether plan benefits meet the beneficiaries' health needs. In recognition that agents and brokers play a significant role in providing guidance and advice to beneficiaries and are in a unique position to influence beneficiary choice, we had proposed, prior to the enactment of MIPPA, a rule to regulate agent and broker compensation. To implement the MIPAA provisions and relying in part on comments in response to our previously proposed rule, we adopted an interim final rule on September 18, 2008, entitled ''Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Final Marketing Provisions'' (73 FR 54208, at 54226), which, among other things, established the current compensation structure for agents and brokers in connection with Parts C and D. That rule remains significantly in place at § 422.2274 and § 423.2274, and our experience since then indicates that revision of the compensation requirements is appropriate to ensure that we continue to meet our statutory mandate.

The current compensation structure is comprised of a 6-year compensation cycle that began in contract year 2009. MA organizations and Part D sponsors were to provide an initial compensation payment to independent agents for new enrollees (year 1) and pay a renewal rate (equal to 50 percent of the initial year compensation) to independent agents for years 2 through 6. These rates were to be adjusted annually based on changes to the MA payment rates or Part D parameters as established by CMS. We later amended the regulations to allow MA organizations and Part D sponsors to compensate independent agents and brokers annually using an amount at or below the fair market value. (See the final rule with comment period entitled, ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes'' (77 FR 22072) published in the April 12, 2012 **Federal Register**.)

The 6-year cycle is scheduled to end at the end of CY 2013, on December 31, 2013. The first year, 2009, was considered to be the first renewal year, effectively making 2009 the second full year of compensation. Because our regulations were silent regarding compensation amounts for Year 7 and beyond, we stated in our Final Call Letter for Contract Year 2014, issued on April 1, 2013, that MA organizations and Part D sponsors could, at their discretion, pay agents and brokers the renewal amount for Year 7 and beyond. However, this subregulatory guidance was intended to be a temporary measure, pending changes to our regulations.

Under the current structure MA organizations and Part D sponsors pay an initial rate for the first year, and then a renewal payment of 50 percent of the initial compensation paid to the agent for years 2 through 6. This structure has proven to be complicated to implement and monitor as it requires the MA organization or Part D sponsor to track the compensation paid for every enrollee's initial enrollment, and calculate the renewal rate based on that initial payment. For example, assume that the same agent enrolls three beneficiaries; one in each of the 2012, 2013, and 2014 contract years. Beneficiary A is a new, initial enrollee in MA plan XYZ for CY2012. Assume that the fair market value (FMV) cut-off amount for agent services for CY 2012 is $400. Plan XYZ has decided that its initial compensation will be equal to the full FMV, resulting in a payment to the agent of $400. Beneficiary B is a new, initial enrollee in MA plan XYZ for CY2013. In CY2013, assume the FMV has increased to $420. Plan XYZ has again decided that its initial compensation will be equal to the full FMV for Beneficiary B, resulting in a payment to the agent of $420. Also in CY2013, Plan XYZ is required to pay a renewal amount of 50 percent of initial enrollment to the agent for Beneficiary A. Since the initial payment for Beneficiary A was $400, Plan XYZ will pay a renewal amount of $200. Beneficiary C is a new, initial enrollee in MA plan XYZ for CY2014. In CY2014, assume the FMV value has again increased to $430. The Plan's initial compensation is, again, equal to the full FMV. Plan XYZ's payments to the agent would be as follows: $430 for Beneficiary C (new, initial), $210 for Beneficiary B (renewal, 50 percent of the initial payment of the CY2013 FMV of $420), and $200 for Beneficiary A (50 percent of the initial payment of the CY2012 FMV of $400). Thus, Plan XYZ has to know, at any given time, the amount of the initial compensation for each plan year—going back as far as 2009—in which the member enrolled in order to pay the correct compensation amount to the agent. Moreover, MA organizations and Part D sponsors must first review CMS' reports to determine whether an initial or renewal payment should be made, and then combine that information with the FMV, or, if applicable, the plan's compensation set at less than the FMV, for each plan year to ensure the correct payments are made to agents. When these simple examples are multiplied by tens or thousands of members, the complexity and challenges associated with implementing the current compensation requirements becomes clear.

In addition to its complexity, we are concerned that the current structure creates an incentive for agents and brokers to move enrollees from a plan of one parent organization to a plan of another parent organization, even for like plan type changes. Currently, in these cases, the new parent organization would pay the agent 50 percent of the current initial rate of the new parent organization; not 50 percent of the original initial rate paid by the other parent organization. Thus, in cases where the FMV has increased, or the other parent organization pays a higher commission, the incentive exists for the agent to move beneficiaries from one parent organization to another. (See § 422.2274(a)(3) and § 423.2274(a)(3)). So, in the example provided previously, if Beneficiary A switched to Plan ABC for CY2014, Plan ABC would pay the same agent $215 (50 percent of the 2014 initial rate of $430), instead of the $200 renewal payment the agent would have received if Beneficiary A remained in

Plan XYZ. Although the mere $15 increase in the payment to the agent may not appear to be much of an incentive to move one enrollee, an agent would receive considerably more income by moving tens of enrollees to another plan.

Since 2008, we have received inquiries from MA organizations and Part D sponsors regarding the correct calculation of agent/broker compensation, and found it necessary to take compliance actions against MA organizations and Part D sponsors for failure to comply with the compensation requirements. To the extent that there is confusion about the exact levels or timing of compensation required, there could be an un-level playing field for MA organizations and Part D sponsors operating in the same geographic area. In addition, CMS' audit findings and monitoring efforts have shown that MA organizations and Part D sponsors are having difficulty correctly administering the compensation requirements. Therefore, we believe that simpler agent/broker compensation regulations that are easier to understand will better ensure that plan payments are correct and establish a level playing field that will further limit incentives for agents and brokers to move enrollees for financial gain.

We are proposing to revise the existing compensation structure for agents and brokers so that, for new enrollments, MA organizations and Part D sponsors could make an initial payment that is no greater than the FMV amount for renewals in Year 2 and beyond, the MA organization or Part D sponsor could pay up to 35 percent of the FMV amount for the renewal year, resulting in the renewal year payment changing each year if the MA organization or Part D sponsor chooses to pay 35 percent of the current FMV (that is, the renewal year FMV threshold). As we do now, we would interpret the FMV threshold in our annual guidance to MA organizations and Part D sponsors. This flexibility would enable MA organizations and Part D sponsors to better react to changes in the marketplace and adjust their compensation structures accordingly.

Under the proposed compensation structure, the calculations would be simpler than those required under the current rule, as shown in the following example:

Assume again that Beneficiary A is a new, initial enrollee in MA plan XYZ for CY2015. Assume the FMV for CY 2015 is $400. Plan XYZ has decided to pay the full FMV, resulting in a payment to the agent of $400. In CY2016, assume the FMV is $420. Again, Plan XYZ has decided to pay the maximum FMV for initial enrollments, so it pays the agent $420 for Beneficiary B, who is an initial enrollee. Plan XYZ has also decided to pay the maximum renewal payment (35 percent of the FMV), resulting in a payment of $147 ($420 x .35) to the agent for Beneficiary A. Thus, Plan XYZ's payments to its agents are based on the FMV for the contract year in question, regardless of when the beneficiary enrolled in the plan. That is, when making the renewal payment, Plan XYZ doesn't have to determine what the FMV was in the initial year, but only looks to the FMV for the current year and pays the chosen percentage up to the maximum 35 percent of the FMV established by CMS.

In order to implement these changes in the identical Part C and Part D regulations at, § 422.2274 and § 423.2274, we first propose to designate the definition of ''compensation'' as paragraph (a)(1) and to restate the fair market value limit on compensation for the initial year as paragraph (b)(1)(i). Second, we propose to combine the current (a)(1)(i)(B), which addresses payments for renewals, and (a)(1)(iii), which addresses the length of time that renewals should be paid, and designate the revisions as a new (b)(1)(ii). Thus, the new paragraph (b)(1)(ii) would state that plans may pay up to 35 percent of the current FMV and that renewal payments may be made for the second year of enrollment and beyond.

In addition, we propose to modify paragraph (a)(3) to remove the 6-year cap on the compensation cycle. Currently, paragraph (a)(3) refers to policies that are replaced with a like plan during the first year or the subsequent 5 renewal years. Since we are proposing to eliminate the 6-year cycle, our revised paragraph (b)(2) deletes the reference to the initial year and the 5 renewal years. By tying renewal compensation to the FMV for the renewal year, rather than the initial year of enrollment, our proposal reduces the financial incentives for an agent or broker to encourage Medicare beneficiaries to change plans, especially from one parent organization to another parent organization. As with the current regulation, we propose in paragraph (b)(2)(iii) that a change in enrollment to a new plan type be payable under the same rules that apply to an initial enrollment, regardless of whether the change is to an unlike plan type in the same parent organization or an unlike plan type in another parent organization. Note that, as with the current rule, our proposal only addresses compensation paid to independent agents and does not address compensation payable by an MA organization or Part D sponsor to its employees that perform services similar to agents and brokers.

For our proposed regulations, we considered several different alternatives, including prohibiting compensation payments entirely beyond year 6, permitting MA organizations and Part D sponsors to pay a residual payment for year 7 and subsequent years, and permitting existing renewal payments to continue. We also evaluated different renewal amounts, including a 50 percent renewal payment for years 2 through 6 with a continuing 25 percent residual payment for years 7 and beyond. The evaluation took into account different ages for an initial enrollment, as well as the life expectancy of beneficiaries. In the analysis, a continual renewal payment of 35 percent was similar in payout to the combination of a 50 percent payment for years 2 through 6 and a residual payment of 25 percent for year 7 and beyond. We believe that revising the existing compensation structure to allow MA organizations or Part D sponsors to pay up to 35 percent of the FMV for year 2 and beyond is appropriate based on a couple of factors. First, we believe that a two-tiered payment system (that is, initial and renewal) would be significantly less complicated than a three-tiered system (that is, initial, 50 percent renewal for years 2 through 6, and 25 percent residual for years 7 and beyond), and would reduce administrative burden and confusion for plan sponsors. Second, our analysis determined that 35 percent is the renewal compensation level at which the present value of overall payments under a two-tiered system would be relatively equal to the present value of overall payments under a three-tiered system (taking into account the estimated mortality rates for several beneficiary age cohorts). This analysis is based on the existing commission structure basing renewal commissions on the starting year initial commission amount and not the current year FMV amount. We welcome comments on both the amount of the renewal payment as well as the proposed indefinite time frame.

Current regulations at § 422.2274(a)(4) and § 423.2274(a)(4) address the timing of plan payments, as well as recovery of payments when a beneficiary disenrolls from a plan. Specifically, (a)(4) states that compensation may only be paid for the beneficiary's months of enrollment during the year (January through December). We propose to revise (a)(4) to define more clearly a plan year for

purposes of compensation. The annual compensation amount covers January 1 through December 31 of each year. We have learned that some plans have been paying compensation based on an annual cycle, rather than a calendar year cycle. We have taken appropriate compliance actions in those instances where we have evidence that an MA organization or Part D sponsor is paying compensation incorrectly, and issued sub-regulatory guidance on August 14, 2013 reminding organizations and sponsors that compensation is to be paid based on a calendar year cycle. Along the same lines, we propose to revise the language at § 422.2274(a)(4) to clarify that the payment made to an agent must be for January 1 through December 31 of the year and may not cross calendar years. For example, a renewal payment cannot be made for the period of November 1, 2013 through October 31, 2014. Rather, the renewal payment must cover January 1, 2013through December 31, 2013.

Currently, the regulation text at § 422.2274(a)(4) (i) permit payments to be made at one time or in installments and at any time. CMS proposes to change the timing of payments to require that payments may not be made until January 1 of the compensation year, and must be paid in full by December 31 of the compensation year. CMS believes this proposal is appropriate given the ability of beneficiaries to change plans during the annual coordinated election period (AEP), which runs from October 15 through December 7. That is, beneficiaries can choose a new plan during the AEP, and then revise that choice as many times as they desire during the AEP; the last enrollment choice made is the one that becomes effective on January 1 of the following year. Under CMS' current requirements, each MA organization or Part D sponsor would have to recoup compensation, if already paid, for every beneficiary that initially enrolled in their plan but later decided to enroll in a different parent organization prior to January 1. Under the proposed rule, MA organizations and Part D sponsors would not be allowed to pay compensation until the beginning of the calendar year, when the final AEP enrollment becomes effective. Thus, the proposed rule would simplify MA organizations' and sponsors' compensation processes and enable them to make more accurate payments. We welcome comments on this proposal.

Current regulations at § 422.2274(4)(ii)(A) and § 423.2274(4)(ii)(A) require MA organizations and Part D sponsors to recover compensation paid to agents when a beneficiary disenrolls from a plan within the first three months of enrollment. However, in sub-regulatory guidance, we have recognized several circumstances (for example, death of the beneficiary, the beneficiary moves out of the service area, the beneficiary becomes eligible to receive LIS, or the beneficiary loses Medicaid benefits) in which plans should not recover compensation even though the beneficiary was enrolled in the plan for less than 3 months. In circumstances such as these, since the disenrollment decision could not be based on agent or broker behavior, we believe it to be appropriate for the agent to receive the compensation associated with the months that beneficiary was a member of the plan. While the plan would not recover the compensation for those months, it would recover any compensation paid for the months after the disenrollment. Therefore, CMS is proposing to combine paragraphs (a)(4)(ii)(A) and (a)(4)(ii)(B) into a revised paragraph (b)(3)(iii),which would include new text to clarify that plans should recover compensation for only the months that the beneficiary is not enrolled, unless the disenrollment took place within the first 3 months. Under our proposal, we would require disenrollments that are the result of agent or broker behavior to trigger recoupment of any compensation that has been paid for that period. In cases where disenrollment took place within the first 3 months and the disenrollment did not result from or could not have resulted from an agent's behavior, we would not require that compensation be recovered under our proposal. We would provide more specific information in sub-regulatory guidance, and welcome comments regarding possible examples to include in that guidance.

CMS also proposes here, in § 422.2274(h) and § 423.2274(h) to codify existing sub-regulatory guidance regarding referral (finder's) fees. CMS released a memorandum on October 19, 2011 addressing excessive referral fees, noting that referral fees should not exceed $100. CMS has long been concerned that some MA organizations or Part D sponsors can offer the entire amount of compensation an agent or broker receives through only a referral, while others must combine any compensation for referrals with other agent marketing activities while meeting the same total cap on compensation, thereby creating an un-level playing field within the marketplace and a clear financial incentive for the referring agent to steer beneficiaries to MA organizations or Part D sponsors that offer the higher amount, without regard to whether plan benefits meet the beneficiaries' health care needs. Therefore, we are proposing to limit the amount that can be paid as a referral fee to independent, captive, and employed agents and brokers, regardless of who completes the enrollment, to a reasonable amount specified by CMS, which is currently, for CY 2013, and CY 2014, $100. Furthermore, note that, under § 422.2274(a) and § 423.2274(a), CMS requires that referral fees paid to independent agents and brokers must be part of total compensation not to exceed the FMV for that calendar year.

14. Drug Categories or Classes of Clinical Concern and Exceptions (§ 423.120(b)(2)(v) and (vi))

Section 3307 of the Affordable Care Act amended section 1860D–4(b)(3)(G) of the Act by replacing the specific criteria established under MIPPA in 2008 to identify categories or classes of Part D drugs for which all Part D drugs therein shall be included on Part D sponsor formularies. The specified criteria were replaced with the requirement that the Secretary establish criteria through notice and comment rulemaking to identify drug categories or classes of clinical concern. In addition, section 3307 of the Affordable Care Act requires the Secretary to engage in rulemaking to establish any exceptions that permit a Part D sponsor to exclude from its formulary a particular Part D drug (or otherwise limit access to such drug through utilization management or prior authorization restrictions) within the drug categories or classes that meet the criteria established by the Secretary. The Affordable Care Act amendments to section 1860D–4(b)(3)(G) of the Act specified that until such time as the Secretary establishes the criteria to identify drug categories or classes of clinical concern through rulemaking, the following categories or classes shall be identified as categories or classes of clinical concern: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection. We now propose to implement the Affordable Care Act requirements set forth in section 1860D–4(b)(3)(G) of the Act by revising § 423.120(b)(2)(v) and (vi) as follows: (1) the criteria the Secretary will use to identify drug categories or classes of clinical concern; and (2) the exceptions that permit Part D sponsors to exclude certain Part D drugs from within an identified drug category or class from

their formularies (or otherwise limit access to such drugs, including through utilization management or prior authorization restrictions). We also propose to specify drug categories or classes that would meet the proposed criteria and explain the process we used for making these determinations.

a. Categories or Classes of Clinical Concern

In 2005, well before the passage of MIPPA, and before the start date of the Part D program, we directed Part D sponsors through guidance to include on their formularies all or substantially all drugs in six categories or classes (antidepressants; antipsychotics; anticonvulsants; immunosuppressants for transplant rejection; antiretrovirals; and antineoplastics). Our authority for this policy arises from section 1860D–11(e)(2)(D)(i) of the Act, which requires that in order to approve a plan, we must not find 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. We refer to this as our ''non-discrimination'' policy. This statutory directive helped to ensure a smooth transition of the approximately 6 million Medicare-Medicaid beneficiaries who were converting from Medicaid drug coverage to Medicare drug coverage at the start of the Part D program. Under the existing circumstances, any formularies that did not have all or substantially all drugs in these categories or classes potentially would have been discriminatory for the Medicare-Medicaid beneficiary population because state Medicaid program formularies were generally open compared to the Part D formularies that we were anticipating prior to the beginning of the Part D program. Thus, it stood to reason that Medicare-Medicaid beneficiaries and many of their providers were largely unaccustomed to drug utilization management techniques. That is, for the most part they had little experience dealing with the rejection of a drug claim at the point of sale because the drug was either not on formulary, or another drug needed to be tried first, or because more information was required to determine whether the drug could be covered under the plan. Moreover, since the majority of the Medicare-Medicaid beneficiaries did not make a decision to elect their new plan, but were instead auto-enrolled, these individuals may not have understood whether their current medications would continue to be covered under their new Medicare plan. Since the Part D program would be administered by private plans with extensive experience managing prescription drug costs through tighter formularies and a variety of utilization management techniques, we anticipated the need for a learning curve and delays in negotiating appeals processes that might endanger the beneficiaries who needed access to drugs in these particular categories or classes. In order to mitigate the risks and complications associated with an interruption of therapy for vulnerable beneficiaries, who would be trying to navigate a new drug benefit when they attempted to fill or refill their first prescriptions under the Part D program on or after January 1, 2006, we created the special requirements for coverage of the six drug classes. However, the circumstances that existed when this policy was originally implemented have changed dramatically in the more than seven years the program has been in operation. CMS, Part D sponsors, our partners who assist beneficiaries with making enrollment choices, and particularly our Medicare-Medicaid beneficiaries and their advocates have had a great deal of experience working with Part D plans since 2005.

Section 176 of MIPPA added a new section 1860D–4(b)(3)(G)(i) to the Act requiring, effective with plan year 2010, that the Secretary identify certain categories or classes of drugs that meet two statutory specifications: (1) Restricted access to the drugs in the category or class would have major or life-threatening clinical consequences for individuals who have a disease or condition treated by drugs in such category or class; and (2) There is a significant need for such individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects of the drugs within a category or class, such as drugs used in the treatment of cancer. In addition, MIPPA provided the Secretary with the discretion to establish exceptions permitting Part D sponsors to exclude from their formularies, or to otherwise limit access to (including utilization management or prior authorization restrictions), certain Part D drugs in the protected categories or classes.

In the January 16, 2009 **Federal Register** (74 FR 2881), we published an interim final rule with comment period (IFC) entitled, ''MIPPA Drug Formulary and Protected Classes Policies.'' This rule revised the regulations governing the Medicare Part D formularies to reflect the MIPPA requirements. We codified at § 423.120(b)(2)(v) the MIPPA provision requiring the inclusion of all Part D drugs in categories or classes that we identified as meeting the two conditions set forth in section 1860D–4(b)(3)(G)(i) of the Act. Given the limited timeframe then available for establishing and implementing a process to identify such drug categories or classes due to formulary submission deadlines, we maintained the existing six drug categories and classes of clinical concern for 2010 with the intention to propose and finalize a new process through rulemaking that would be used to identify drug categories or classes that met the MIPPA criteria for CY2011. After receiving comments in response to the January 16, 2009 IFC, entitled, ''Medicare Advantage and Prescription Drug Programs MIPPA Drug Formulary Protected Classes Policies'' that persuaded us that the further interpretative rulemaking was necessary, we published a notice of proposed rulemaking (NPRM) on October 22, 2009, entitled, ''Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (74 FR 54634) to further refine the MIPPA criteria and establish a process that met MIPPA requirements. However, between the issuance of the October 22, 2009 proposed rule and the April 15, 2010 final rule (75 FR 19766), the Affordable Care Act was enacted. Section 3307 of the Affordable Care Act amended section 1860D–4(b)(3)(G) of the Act to specify that the existing drug categories or classes of clinical concern would remain so until such time as the Secretary establishes new criteria to identify drug categories or classes of clinical concern under section 1860D–4(b)(3)(G) of the Act through notice and comment rulemaking.

We are concerned that requiring essentially open coverage of certain categories and classes of drugs presents both financial disadvantages and patient welfare concerns for the Part D program as a result of increased drug prices and overutilization. The principal disadvantage is that an open coverage policy substantially limits Part D sponsors' ability to negotiate price concessions in exchange for formulary placement of drugs in these categories or classes. Since the beginning of the Part D program we have heard from stakeholders that this policy—frequently referred to as the ''protected classes'' policy—significantly reduces any leverage the sponsor has in price negotiations and results in higher Part D costs. A report by the OIG in March 2011 documented similar assertions from selected Part D sponsors, including assertions that ''they received either no or minimal rebates for the drugs in these

six classes,'' that ''there is little incentive for drug manufacturers to offer rebates for these six classes of drugs because they do not need to compete for formulary placement,'' and that ''if [a rebate] is provided, it's probably at a lower percentage than [the rebate for the drugs] that had some competition.'' (HHS Office of Inspector General, ''Concerns with Rebates in the Medicare Part D Program'', March 2011, OEI–02–08–00050)

We are aware of other analyses that support these findings. A 2008 study conducted by the actuarial and consulting firm Milliman found that the six protected drug classes disproportionately accounted for between 16.8 percent and 33.2 percent of total drug spend among sponsors surveyed (Kipp RA, Ko C). (See ''Potential cost impacts resulting from CMS guidance on 'Special Protections for Six Protected Drug Classifications' and Section 176 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (PL 110–275)'' available at: *http://amcp.org/WorkArea/DownloadAsset.aspx?id=9279*). Milliman reported that the Part D program administrators (plan sponsors and PBMs) commented that the protected status of these drug classes limited plan sponsors' ability to effectively negotiate lower costs with manufacturers since it is known that these drugs must be included on the formulary. The Milliman report estimated that affected drug costs were on average 10 percent higher than they would be in the absence of the protected class policy and that this represented $511 million per year in excess costs to beneficiaries and the Part D program. We note that numerous brand drug patents expire between now and 2015 which might reduce future cost projections. Another 2008 study from the National Bureau of Economic Research (NBER) suggested that while Medicare Part D led to a substantial decline in average pharmaceutical prices, Medicare-intensive drugs in protected classes did not experience price declines as did their counterparts not in protected classes and may have actually experienced price increases (Duggan M, Morton FS. 2010. ''The Effect of Medicare Part D on Pharmaceutical Prices and Utilization,'' American Economic Review, American Economic Association, vol. 100(1), pages 590–607). Plan sponsors can still negotiate with manufacturers for preferred or non-preferred tier placement of protected class drugs, but CMS does not have any information on the justification for the relative magnitude of these rebates. However, it can reasonably be anticipated that such rebates would vary widely for individual manufacturers and sponsors, and anecdotal evidence would suggest the leverage these options provide sponsors may be minimal when compared to leverage available in connection with an initial decision regarding formulary inclusion, especially since tier placement has no impact on statutory LIS cost sharing levels. Consequently, we would predict future savings for both beneficiaries and the Part D program from both increased price competition as newly approved drugs come onto the market and more immediate savings if plans were able to remove some currently covered agents from their formularies.

In addition to our concerns about increased Part D costs resulting from higher drug prices, we are also concerned that the policy potentially facilitates the overutilization of drugs within the protected classes. By limiting the ability of Part D sponsors to implement utilization management tools (for example, prior authorization or step therapy requirements) for an entire category or class, we also limit their ability to prevent the misuse or abuse of drugs that are not medically necessary. Not only can this increase Part D costs, but inappropriate use can also lead to adverse effects that can harm the beneficiary and require medical treatment that would otherwise not have been necessary. We believe the profitability of products not subject to normal price negotiations as the result of protected class status is a strong incentive for the promotion of overutilization, particularly off-label overutilization, of some of these drugs.

Given the findings in these reports and our expertise with the Part D program, we believe it is appropriate to revisit our original policy for the six drug categories and classes of clinical concern—particularly to assess whether it remains appropriate to require this additional level of protection for these categories or classes of drugs in order to ensure that Part D plans offer nondiscriminatory benefit designs and sufficient beneficiary access to medically necessary therapies. In considering the balance among beneficiary access, quality assurance, cost containment, and patient welfare in light of our existing beneficiary protections, we believe that drug categories and classes should be subject to normal formulary and price competition unless we cannot ensure clinically appropriate access (and thus non-discriminatory benefit design) to our Medicare beneficiaries in any less anticompetitive way than requiring the inclusion on all Part D formularies of all drugs in that category or class. Moreover, we believe that our consideration of how to implement section 3307 of the Affordable Care Act must take into account both the purpose of the Part D benefit and the context in which it is offered. Part D does not typically involve access to medications on an emergency basis. In cases where an emergency may arise, the Part D program has some protections to address this—for example, our long term care emergency first fill requirement requires plans to cover an emergency supply of non-formulary Part D drugs for long term care residents as part of their transition process. Moreover, the Part D benefit must be considered in light of the fact that urgently needed and emergency care is generally covered by Medicare Parts A and B.

To that end, we believe that criteria for identifying drug categories and classes of clinical concern should identify only those drug categories or classes for which access cannot be adequately ensured by beneficiary protections that otherwise apply. Consequently, as we take this opportunity to propose to codify criteria for identifying categories or classes of drugs that are of clinical concern, we believe that the requirements of section 3307 of the Affordable Care Act should be implemented taking into consideration the other protections available to beneficiaries. Otherwise, section 3307 of the Affordable Care Act would establish duplicative, and thus unnecessary, protections that would serve only to increase Part D costs—without any added benefit and with the possibility of added harm from misuse. Therefore, in considering whether additional protections continue to be needed under this section, we need to take the other beneficiary access protections into account. There are five such protections and these are formulary transparency, formulary requirements, reassignment formulary coverage notices, transition supplies and notices, and the coverage determination and appeals processes.

The first protection is our requirement for full transparency to beneficiaries. Sponsors are required to provide comprehensive formulary drug listings to the public through their own Web sites and printed materials, as well as to CMS for access through the online automated drug plan comparison tool, the Medicare Plan Finder (Plan Finder). Beneficiaries or their representatives can complete a personalized search on

Plan Finder to locate and select a Part D plan that covers their drugs. With our more than 7 years of experience with the Part D program, we are not aware of any Part D drug that is not included on at least one Part D formulary. Thus, beneficiaries who review plan formularies can select plans that cover all of their current medications.

The second type of protection is the Part D formulary requirements. Our annual formulary review and approval process includes extensive checks to ensure adequate representation of all necessary Part D drug categories or classes for the Medicare population and includes the following:

- Discrimination Review (§ 423.272(b)(2)). Formularies are reviewed to ensure inclusion of drug categories and classes that are used to treat all disease states. CMS evaluates the sufficiency of a Part D sponsor's formulary drug categories and classes in conjunction with the plan's formulary drug list to ensure that the formulary provides access to an acceptable range of Part D drug choices.
- Two Drugs Requirement (§ 423.120(b)(2)(i)). Each submitted formulary is reviewed for the inclusion of at least two distinct drugs from each of the submitted categories and classes, except as provided in § 423.120(b)(2)(ii).
- Formulary Tier Review (Medicare Prescription Drug Benefit Manual, Chapter 6, 30.2.7). The tiering structure of each formulary is reviewed to ensure that each category and class has at least one drug in a preferred tier.
- Common Medicare Drugs Review (§ 423.120(b)(2)(iii)). Formularies are reviewed for inclusion of the drugs or drug classes that are most commonly utilized by the Medicare population. We use prior years' data to identify the drugs or drug classes with the highest utilization in Medicare Part D, and use these drugs and drug classes as the basis for our review in this area. We also review formularies for the alternative dosage forms of the drugs that are most commonly utilized by the long-term care (LTC) population.
- Treatment Guidelines Review (§ 423.120(b)(2)(iii)). The World Health Organization (WHO) defines a standard treatment guideline as a systematically developed statement designed to assist practitioners and patients in making decisions about appropriate health care for specific clinical circumstances (available at *http://www.who.int/medicines/technical_briefing/tbs/10-PG_Standard-Treatment-Guidelines_final-08.pdf*). We analyze formularies to determine whether appropriate access is afforded to drugs or drug classes included in widely accepted treatment guidelines. In general, although sponsors have some flexibility in determining the classification system they will use to identify categories or classes of drugs, if a treatment guideline speaks to a specific category or class of drugs, we look for representation from that drug category or class of drugs on the formulary. Moreover, if the treatment guidelines address specific drugs, we would expand this requirement to review formularies for those specific drugs, and not just the drug category or class to which they belong.
- Common Home Infusion Drugs (§ 423.120(a)(4)). We review formularies for the drugs most commonly utilized in the home infusion setting in order to help facilitate rapid access to these drugs for beneficiaries.
- Vaccines Review (§ 423.100). Each formulary submission is reviewed to ensure the formulary includes Part D vaccines.
- Insulin Supplies Review (§ 423.100). Formularies are reviewed for the supplies associated with the administration of insulin: insulin syringes, alcohol swabs, and gauze pads.
- Specialty Tier Review (§ 423.578(a)(7)). For formularies using a specialty tier, we perform an extensive review of the composition of each tier. We apply a standard outlined in the annual Call Letter to determine whether drugs placed in specialty tiers meet the relevant cost criteria.
- Quantity Limits Outlier Review (§ 423.153(b)). All formulary submissions are compared to analyze the use of quantity limit (QL) edits. Formularies that are outliers with respect to the application of QL edits are asked to remove edits or provide a reasonable justification for the applicable QL.
- Quantity Limits Amount Review (§ 423.153(b)). QL restrictions are reviewed for appropriateness. The standard for the review is generally based on the Food and Drug Administration (FDA)-approved maximum doses, when such dose limits are identified in the label.
- Restricted Access Review (§ 423.153(b)). Formularies are reviewed for use of Prior Authorization (PA) and Step Therapy (ST) edits across drug categories and classes. We decline to approve utilization management (UM) for entire drug classes, other than those considered to be best practices, for example, for erythropoietin stimulating agents (ESAs).
- Step Therapy Criteria Review (§ 423.153(b)). The ST requirements are reviewed to ensure that the algorithms are consistent with best practices.
- Prior Authorization Outlier Review (§ 423.153(b)). All formulary submissions are compared to analyze the use of PA edits. Formularies that are outliers with respect to the application of PA edits are asked to remove edits or provide a reasonable justification for such PA edits.
- Prior Authorization Criteria Review (§ 423.153(b)). We then review the criteria for focused drugs requiring PA on the initial formulary submissions. We look to existing best practices, including prerequisite drugs, current industry standards and appropriate treatment guidelines, to check that the Part D plans' use of PA is consistent with such practices. Submitted criteria are also compared to compendia and FDA-approved label indications.
- Mid-year formulary change restrictions (§ 423.120(b)(5)); Chapter 6 of the Medicare Prescription Drug Benefit Manual, 30.3.3). Except when the Food and Drug Administration deems a Part D drug unsafe or a manufacturer removes a Part D drug from the market, a Part D sponsor may not remove a covered Part D drug from its formulary, or make any adverse change in preferred or tiered cost-sharing status of a covered Part D drug, between the beginning of the annual coordinated election period described in section § 423.38(b) and 60 days after the beginning of the contract year associated with the annual coordinated election period. However, prescription drug therapies are constantly evolving, and new drug availability, medical knowledge, and opportunities for improving safety and quality in prescription drug use at a lower cost will inevitably occur over the course of the year. As recognized in regulation, these new developments may require formulary changes during the year in order to provide high-quality, affordable prescription drug coverage. To address such developments our negative formulary change policy requires that beneficiaries retain ''grandfathered'' coverage for the remainder of the coverage year if we permit an adverse change in the formulary status of any drug without a generic equivalent. Thus, in summary, our formulary rules both ensure that all Part D formularies contain sufficient drugs to treat all disease states in the Medicare population and protect beneficiaries from significant changes in formularies during the course of a coverage year.

The third type of beneficiary protection is the annual notice to reassigned enrollees required under section 3305 of the Affordable Care Act. Effective January 1, 2011, we provide LIS individuals who are reassigned to

another Part D plan with information on the differences under the new plan formulary, as well as information on the beneficiary's grievance and appeal rights in the new plan. Thus, any individual who has his or her plan selection decision made through our reassignment process (in order to maintain access to a $0 premium) receives detailed coverage status information for each drug for which he or she filled a prescription between January and August of the previous year. With regard to the new plan, this notice describes for each drug whether it is on the formulary, whether the brand or generic version is covered, and whether or not utilization management tools may be applied. Moreover, the notice also provides a list of other plans that are available to the beneficiary to enroll in with no premium if they would prefer not to remain in the plan where they were reassigned. We send notices after the individual's reassignment and in time to allow for another voluntary plan selection effective January 1. Thus, any reassigned LIS individual receives advance notice of any change in formulary coverage of their medications in plenty of time to work with their prescribers if they wish to remain in the new plan, or to select a different Part D plan.

The fourth type of beneficiary protection is our unique transition supply and notice requirements. A Part D sponsor must provide for an appropriate transition process for Part D drugs that are not on its formulary with respect to: (1) The transition of new enrollees into prescription drug plans following the annual coordinated election period; (2) the transition of newly eligible Medicare beneficiaries from other coverage; (3) the transition of individuals who switch from one plan to another after the start of the contract year; and (4) in some cases, current enrollees affected by formulary changes from one contract year to the next (see § 423.120(b)(3); Chapter 6 of the Medicare Prescription Drug Benefit Manual, 30.4). Within the first 90 days of a beneficiary's enrollment in a new plan, plans must provide a temporary fill when the beneficiary requests a refill of a non-formulary drug (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules). Since certain enrollees may join a plan at any time during the year, this requirement applies beginning on an enrollee's first effective date of coverage, regardless of whether this is within the first 90 days of the contract year.

A successful transition process is contingent not only upon providing the transitional drug supply, but also upon informing affected enrollees, their caregivers, and their providers about the beneficiary's options for ensuring that his or her medical needs are safely accommodated within a Part D sponsor's formulary. For this reason, when providing a temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules), sponsors must provide enrollees and their providers with written notice within 3 business days after adjudication of the temporary fill that they are receiving a transition supply of a non-formulary Part D drug and that they must take action. The temporary fill and notice provides beneficiaries with a reasonable amount of time during which they and their providers can address the issue (by requesting a formulary exception or transitioning to a formulary drug) and prevents them from having to abruptly change or go without their medication (see Transition notice requirements (to beneficiaries and providers) [§ 423.120(b)(3)(iv and v); Chapter 6 of the Medicare Prescription Drug Benefit Manual, 30.4.10]). Thus all beneficiaries and their prescribers have advance notice of any issue with continued coverage of a previously initiated therapy and sufficient time to resolve those issues without any lapse in appropriate therapy. The preceding formulary review and transition requirements are described in Chapter 6 of the Medicare Prescription Drug Benefit Manual (located at *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf*).

The fifth beneficiary protection we take into account is the requirement for a robust coverage determination and appeal process, including the right of an enrollee or his or her prescriber to request an exception to the plan's utilization management criteria, tiered cost-sharing structure, or formulary. Part D plan sponsors are required to issue a coverage decision and notify the enrollee (and the prescriber, as appropriate) in writing in accordance with strict regulatory timeframes. A plan must grant a tiering or formulary exception (for example, provide coverage for a non-formulary drug or an exception to the UM criteria) when it determines that the requested drug is medically necessary, consistent with the prescriber's supporting statement indicating that preferred alternatives(s) would not be as effective and/or would have adverse effects. We have established by regulation both an expedited adjudication timeframe if the plan or prescriber believes that applying the standard timeframe may jeopardize the enrollee's health, and a requirement that plans must issue all coverage decisions as expeditiously as the enrollee's health condition requires. Any initial coverage request that the plan expects to deny based on a lack of medical necessity must be reviewed by a physician. If the Part D sponsor makes an adverse coverage determination, the required written notice must explain the specific reason(s) for the denial and include a description of the enrollee's right to a standard or expedited redetermination by the plan, and the rest of the five-level appeals process, including the right to request independent review. We require plans to conduct all redeterminations (first level appeals) using a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare criteria, if the initial denial was based on a lack of medical necessity. If a plan fails to make a coverage decision and notify the enrollee within the required timeframe, the request must be forwarded to the independent review entity to be adjudicated.

Moreover, while we do not treat a claim transaction as a coverage determination, we do require Part D sponsors to arrange with network pharmacies to provide enrollees with a written copy of the Office of Management and Budget (OMB)-approved standardized pharmacy notice (''Notice of Denial of Medicare Prescription Drug Coverage,'' CMS–10146) when the enrollee's prescription cannot be filled under the Part D benefit and the issue cannot be resolved at the POS. The notice instructs the enrollee on how to contact his or her plan and explains the enrollee's right to request a coverage determination. Thus, all beneficiaries immediately receive clear concise instructions on how to pursue their appeal rights whenever a prescription cannot be filled. For additional information on the coverage determination, appeals and grievance process, including information about the pharmacy notice, see 42 CFR Part 423, subparts M and U, and Chapter 18 of the Medicare Prescription Drug Benefit Manual.

As the preceding discussion demonstrates, we have implemented extensive beneficiary protections in the

form of formulary review checks, reassignment formulary coverage notices, drug therapy transition policies and notices for both new enrollees and continuously enrolled members experiencing changes in formulary benefits between coverage years, and robust exceptions and appeals processes that generally will assure appropriate access without having to guarantee formulary placement. Additionally, the formulary exceptions and appeals requirements facilitate obtaining any medically necessary Part D drug that is not on the formulary or that is otherwise subject to utilization management requirements. Taken together, we believe these requirements are comprehensive enough that additional access safeguards are needed only in those situations where a Part D beneficiary's clinical needs cannot be more efficiently met.

b. Criteria Necessary To Identify Categories and Classes of Clinical Concern

In developing our proposed criteria to identify drug classes of clinical concern, we considered all of the existing beneficiary protections described previously in section III.A.14.a. of this proposed rule, particularly our coverage determination and appeals process, which requires plans and other adjudicators to make all coverage decisions as expeditiously as the enrollee's health condition requires. Given our existing protections, we believe clinical concern would arise only if access to drugs within a category or class for the typical individual who is initiating therapy must be obtained in less than 7 days because the coverage determination and appeals process generally does not provide for independent review and determination, when necessary, within such timeframe. We believe this would be the case only when failure to initiate the therapy within that time period would be likely to lead to hospitalization, incapacity, disability or death as a result of the exacerbation of the disease or condition to be treated. We do not believe it is necessary to require all Part D drugs within a drug category or class to be included on the formulary if access within 7 days is likely sufficient to allow for initiation of therapy without putting beneficiaries at risk of hospitalization, incapacity, disability, or death. In other words, we believe that inconvenience associated with a delay that is unlikely to pose these serious consequences for the typical individual initiating a new therapy does not warrant requiring all Part D drugs from within the category or class to be included on the formulary because in such an instance, the beneficiary would have other protections to ensure that he or she has appropriate access to the drug. Moreover, we do not believe it is necessary to require all Part D drugs within a drug category or class to be included on the formulary when, for a typical individual who already is taking the drug, interruption in existing drug therapy might have adverse health consequences. Specifically, we believe that existing protections such as the Part D formulary change restrictions (for example, prohibition on midyear implementation of new PA, ST, or QL restrictions on existing therapies) and the transition requirements under § 423.120, which provide for temporary fills and require beneficiary notification of the need to request a coverage determination (including an exception or prior authorization approval) for future fills ensure sufficient protection for beneficiaries who may face an interruption in their ongoing therapies as a result of a change in their plan or formulary. Thus, our transition and negative formulary change requirements afford strong protections to individuals with ongoing therapy. However, this is in contrast to individuals who are initiating therapy. These individuals do not get an initial fill to try a medication while they petition for an exception, and thus the transition protections do not apply. Finally, we note that when we refer to a beneficiary's having ''access'' to a drug within 7 days, we mean that the beneficiary must need to ingest or otherwise use or consume the drug within that time period in order to avoid the adverse consequences. Thus, ''access'' means administration, which may include self-administration, of drugs. To illustrate this last point, initiation of therapy with drugs used to treat HIV/AIDS generally should not be delayed because initiation of therapy has rapid effects on viral load. Conversely, a minor delay with the initiation of therapy with HMG-CoA reductase inhibitors (also known as ''statins'') for patients with hyperlipidemia, even when transitioning among medications in the category or class in response to lipid profiles, liver or kidney function, or adverse events, is not as critical because it usually takes several weeks to detect measurable effects on serum lipid concentrations.

Thus, for all of these reasons, we propose to specify at § 423.120(b)(2)(v)(A) a first criterion under section 1860D–4(b)(1)(G)(ii)(II) of the Act as follows: In the case of a typical beneficiary who has a disease or condition treated by drugs in the following category or class, hospitalization, persistent or significant incapacity or disability, or death likely will result if initial administration (including self-administration) of a drug in the category or class does not occur within 7 days of the date the prescription for the drug was presented to the pharmacy to be filled. By typical beneficiary, we mean, for a given disease or condition, an individual who has the average clinical presentation of the relevant disease or condition.

While this first criterion would establish the critical need to promptly initiate drug therapy with a drug from an identified drug category or class, we believe that, standing alone, it may be overly inclusive and, as such, would fail to appropriately balance the need for beneficiary protection with the need to allow plans to take appropriate steps to control costs and overutilization. If the drug category or class consists of many similar drugs that are often considered to be therapeutically interchangeable with one another when initiating drug therapy, a requirement to include on the formulary all drugs in that category or class would undermine the important place that formularies, due to their ability to control costs, hold within the Part D program without providing any additional beneficiary protection. According to the Academy of Managed Care Pharmacy (AMCP), therapeutic interchange is the practice of replacing, with the prescribing provider's approval, a prescription medication originally prescribed for a patient with a chemically different medication; medications used in therapeutic interchange programs are expected to produce similar levels of clinical effectiveness and sound medical outcomes, based on available scientific evidence. Moreover, in the absence of any specific treatment guidelines to the contrary, inclusion of all drugs in that category or class would be unnecessary. For example, some drugs in the nitrate class of drugs likely would meet our first proposed criterion, but because there are many therapeutically interchangeable options among nitrates, it is not necessary to require that all nitrate products be included on every Part D formulary. Indeed, under our current formulary treatment guideline reviews, while we require that sublingual nitroglycerin be included on all formularies because beneficiaries often need it on an urgent basis, we do not require inclusion of *all* other nitrates (for example, isosorbide dinitrate, isosorbide mononitrate, and transdermal nitroglycerin) because these dosage

forms are long-acting and typically are not needed on an urgent basis. (However, current treatment guidelines require the inclusion of isosorbide dinitrate for congestive heart failure.) Similarly, the typical diabetic patient who needs insulin could reasonably be anticipated to require two insulin products as part of his or her treatment regimen: Specifically, one shorter-acting, and one longer-acting insulin. Among the insulins, there are four sub-classes: Rapid acting, short acting, intermediate acting, and long acting. Within each of the sub-classes, there are alternatives from which to choose. In accordance with treatment guidelines, in most cases a patient's regimen is comprised of one selection from either the rapid acting or short acting sub-classes, and one selection from either the intermediate acting or long acting sub-classes. While the beneficiary would require access to multiple drugs within the class (insulins), which at times could certainly be considered urgent enough to risk dire consequences as discussed in the first criterion, they would not need access to all of the options within that class because there are many alternative products on the market within those sub-classes that are largely therapeutically interchangeable, and any one of these products will generally meet the patient's needs. Thus, our formulary checks for insulin require some products in each sub-class to ensure that access through each plan is clinically appropriate.

These examples illustrate the principle that it is both feasible and appropriate to permit plan sponsors to develop formularies that exclude certain products when adequate access to an appropriate alternative is assured by way of our existing formulary requirements and review process. Moreover, the transition and coverage determination and appeal processes are available in those situations when a non-formulary drug is medically necessary for a specific individual.

For these reasons, we believe it is important to include a second criterion that must be met in order for us to consider a drug category or class to be one of clinical concern for the purposes of section 3307 of the Affordable Care Act. Specifically, we believe a drug category or class would be of clinical concern if CMS cannot establish that a formulary that includes fewer than all Part D drugs from within that category or class would include sufficient drugs needed to treat the diseases or conditions generally treated by such drugs. In other words, CMS cannot reasonably establish more specific CMS formulary requirements because there are too many potential drug-and-disease-specific scenarios that require specific drugs from within a category or class, even within sub-classes. This would be the case when the different drugs within a category or class are uniquely associated with specific clinical applications because of the unique effects of such drugs or the variable nature of the disease or condition treated by such drugs. For example, a cancer patient whose clinical picture is rapidly changing must immediately initiate very specific changes in antineoplastic therapy when the new disease target is identified. While perhaps possible, it would not be practical to establish a multitude of more class-specific formulary requirements for every current or future combination or sequence of such drugs simply to possibly exclude a few drugs. Thus, we propose to add § 423.120(b)(2)(v)(B) specifying a second criterion to identify a clinical concern as follows: More specific CMS formulary requirements will not suffice to meet the universe of clinical drug-and-disease-specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.

In summary, we propose to modify § 423.120(b)(2)(v) to require that (unless an exception applies) all Part D drugs within a drug category or class be included on the formulary if a the drug category or class of drugs for a typical individual with a disease or condition treated by the drugs in the category or class meets both of the following criteria (as determined by CMS):

- Hospitalization, persistent or significant disability or incapacity, or death likely will result if initial administration (including self-administration) of a drug in the category or class does not occur within 7 days of the date the prescription for the drug was presented to the pharmacy to be filled; and
- More specific CMS formulary requirements will not suffice to meet the universe of clinical drug-and-disease-specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.

c. Exceptions

Section 1860D–4(b)(3)(G)(i)(II) of the Act provides us with the authority to establish exceptions to the requirement that a Part D sponsor must include all Part D drugs on its formulary in the drug categories or classes identified by us as drug categories or classes of clinical concern under section1860D–4(b)(3)(G)(ii)(I) of the Act. Despite the narrow scope of applicability defined by the proposed criteria, we believe it is necessary to identify exceptions to help ensure Part D coverage is limited to Part D drugs, minimize duplicative protections within a drug category or class of clinical concern, and assure beneficiary safety while curbing potential abuse and misuse as a result of the added protection.

First, we propose to retain § 423.120(b)(2)(vi)(A) as currently codified. This provision makes an exception for drug products that are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' also known as the Orange Book). Thus, two drug products that are determined to be therapeutic equivalents by the FDA and identified in the FDA's Orange Book are considered to be the same Part D ''drug'' solely for purposes of this requirement, and sponsors would not be required to include all therapeutic equivalents on their formularies. Rather, the inclusion of one such drug product would satisfy the formulary requirement with respect to all therapeutically equivalent products.

We also propose to amend and renumber (as paragraph (F)) existing § 423.120(b)(2)(vi)(B) to make an exception for point-of-sale utilization management safety edits that are based on maximum daily doses and black-box warnings specified on the FDA-approved label, potential drug interactions, or duplication of therapy. In fact, we believe that this exception is consistent with the requirement under section 1860D–4(c)(1)(B) of the Act that requires Part D sponsors to have in place quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use. As noted previously, although we believe that section 3307 of the Affordable Care Act is intended to provide additional beneficiary protections, we also believe that it would be imprudent to interpret these protections in such a way that they interfere with existing protections intended to promote safety and efficacy. We believe that it is appropriate for Part D sponsors to establish edits for safety and that our policies should not interfere with basic drug utilization management edits that sponsors apply at point of sale to ensure that adverse events do not occur. For example, we

would expect that a claim for a 90 days supply of Atripla® for 180 tablets, when the drug is only approved for use once a day, would trigger a point-of-sale safety edit. Such edits must be consistent with FDA labeling to ensure that they are based on scientific evidence and medical standards of practice. However, the use of safety edits should not create a significant opening for plans to establish restrictive policies, because safety edits need to conform to FDA labeling.

Next, we propose to add new language at § 423.120(b)(2)(vi)(B) to make an exception for drug products that are almost always covered under Medicare Parts A or B. In order to minimize confusion about the scope of the protections under section 3307 of the Affordable Care Act, we specify that the formulary requirements set forth in section 1860D–4(b)(3)(G)(i) of the Act do not apply to drugs almost always covered by Medicare Part A or B. We do not currently require, and would not require under the authority of section 3307 of the Affordable Care Act, the inclusion of drugs that have been historically paid for under Part B (for example, ''incident to'' drugs supplied and administered by physicians during a patient visit and paid for under Part B). Given the fact that these drugs are generally covered under Medicare Part B and are not required under our existing policy, we believe their absence from plan formularies would not disrupt access. We further believe that requiring the inclusion of these drugs on the formulary would lead to beneficiary confusion. For these reasons, we are proposing to exclude drug products almost always covered under Medicare Part A or B.

We also propose to add an exception at § 423.120(b)(2)(vi)(G) to permit prior authorization for purposes of determining whether a drug is a Part D drug being used for a medically-accepted indication as defined in section 1860D–2(e)(4) of the Act or to verify a drug is not covered under Medicare Parts A or B as prescribed and dispensed or administered. Coverage under Part D is not available for drugs that are not used for a medically-accepted indication, and section 3307 of the Affordable Care Act does not change any Part D coverage rules. Moreover, we believe that this exception, like the exception for Medicare Part A or B drugs described in proposed paragraph (B), would not cause disruption because it merely reflects existing limits on Part D coverage.

Thus, we also propose that prior authorization in the drug categories or classes of clinical concern is appropriate when used to confirm the presence of a medically-accepted indication or that coverage is not available under Medicare Parts A or B as prescribed and dispensed or administered. Prior authorization requirements to determine medically-accepted indications should be limited to those drugs for which it is reasonably foreseeable that use for non-medically-accepted indications are likely to occur. For example, when only narrow indications are supported (for example, pain medications indicated only for cancer pain, supported by the FDA label or compendia), we would expect Part D sponsors to use prior authorizations to ensure that such agents are being used for the narrowly-supported indications only. Similarly, sponsors must apply prior authorizations for Medicare Parts A/B versus D determinations in a manner consistent how those determinations are made in all other categories or classes (that is, based upon likelihood of coverage under Medicare Part A or B), and thus, we would not expect to see a disproportionate amount of prior authorization requirements for the categories or classes of clinical concern compared to other formulary categories or classes. We expect that the plan sponsor's medical director is involved in establishment and oversight of plan policies related to prior authorization requirements. As with all PA requirements, these would require CMS review and approval. Consistent with current guidance, in Parts A or B versus D situations, CMS expects Part D sponsors will work aggressively to eliminate any interruptions of current therapy.

In addition, we propose to amend § 423.120(b)(2)(vi)(C) to make an exception for Part D compounds. As noted in previous rulemaking, Part D only covers those ingredients in a compound that independently meet the definition of a Part D drug (see § 423.120(d)). Since the Part D compound as a whole is not FDA approved, we do not believe that such compounded products reasonably can be classified as being included in a specific category or class that meets the criteria proposed in new § 423.120(2)(v)(A). Currently, Part D compounds that include ingredients that fall within a protected category or class are not required to be included on formularies, and we do not interpret section 3307 of the Affordable Care Act as requiring their inclusion now. Thus, we believe their continued absence from plan formularies would not disrupt access.

We also propose to add § 423.120(b)(2)(vi)(D) to make an exception for drugs (other than antiretrovirals) that are FDA approved and that are fixed-combination dosage form prescription drug products as defined in 21 CFR 300.50, that contain at least one Part D drug in the category or class of clinical concern. Because all drugs in the category or class of clinical concern would be on the formulary as single entity products, we do not believe it is necessary, in most cases, to require inclusion of the fixed dose combination or co-packaged products. However, we would propose to carve out from this exception fixed dose combinations and co-packaged antiretrovirals, as discussed in FDA guidance found here: *http://www.fda.gov/downloads/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/ucm079742.pdf*) because avoiding excessive pill burden and simplifying dosage regimens is of utmost importance with this class of drugs. This is because the risk associated with non-adherence when beneficiaries have to take the single-entity products has far more severe consequences, such as viral resistance, than in most other instances, where occasional non-adherence does not present such dire complications. Consequently, although we believe this exception is generally appropriate for the categories and classes of clinical concern that receive added protections under section 3307 of the Affordable Care Act, we propose that it not be available for antiretrovirals. This means that, under our proposed criteria, which, as discussed further in the following paragraphs, apply to antiretrovirals, all Part D formularies would need to include not only all single-entity antiretrovirals, but also all FDA-approved fixed-dose combination and co-packaged antiretrovirals.

Additionally, consistent with current guidance, we propose an exception at § 423.120(b)(2)(vi)(E) for certain types of Part D drugs, including multi-source brands of the identical molecular structure, extended-release products when the immediate-release product is included, products that have the same active ingredient or moiety, and dosage forms that do not provide a unique route of administration (for example, tablets and capsules versus tablets and transdermal products). Although such products may contribute to improvements in beneficiary adherence to their medication regimens, other interventions such as Medication Therapy Management Programs and special compliance packaging can also improve adherence. Therefore, the added costs of required formulary inclusion of such products may not

provide added value since they do not provide a clinically different therapeutic alternative. Such products currently are not required to be included on formularies, and we do not interpret section 3307 of the Affordable Care Act as requiring their inclusion now. Thus, we do not believe this exception would disrupt access.

Finally, we considered proposing an exception at § 423.120(b)(2)(vi)(H), to allow Part D sponsors to implement prior authorization, including PA used to implement step therapy requirements, to convert beneficiaries to preferred alternatives within these drug categories or classes for enrollees who are initiating therapy (new starts). This is consistent with current guidance that Part D sponsors may not implement prior authorization, including PA used to implement step therapy requirements that are intended to steer beneficiaries to preferred alternatives within these drug categories or classes for enrollees who are currently taking a drug, unless they are trying to establish appropriate coverage under Parts A, B, or D. This prohibition applies to those beneficiaries already enrolled in the plan, as well as to new enrollees who were actively taking drugs in any of the drug categories or classes of clinical concern prior to enrollment in the plan. If a sponsor cannot determine at the point of sale that an enrollee is not currently taking a drug (for example, new enrollee filling a prescription for the first time), the sponsor treats such enrollee as currently taking the drug. Additionally, step therapy and prior authorization for HIV/AIDS drugs are generally not employed in widely-used best-practice formulary models and are not permitted under the current policy. Although this has been our policy since the start of the Part D program, and we are not aware of any problems with it to date, we recognize that this raises the potential for a delay in access to initial therapy to occur and could be in conflict with our first proposed criterion. However, we must balance this with incentives for efficient formularies and do not want to eliminate a tool that may be useful for Part D sponsors. Consequently, we solicit comment on the continued need and utility of this policy and whether it should be included in the exceptions at 423.120(b)(2)(vi). These exceptions would supersede any previous guidance relative to PAs and UM for the categories and classes of clinical concern.

d. Analysis and Identification of the Categories or Classes of Clinical Concern

We convened a consensus panel of CMS pharmacists and the Chief Medical Officer for the Center for Medicare to identify which drug categories or classes met our proposed criteria for clinical concern. The panel was supported by a contractor that performed background research and provided specific information on Part D utilization by drug category or class and associated widely-accepted treatment guidelines for each drug category or class, when available. The panel reviewed all Part D drugs with utilization in 2012 using the American Hospital Formulary Service (AHFS)–6 classification system. We chose the AHFS–6 classification system as a framework because it provided us with a tool to logically, and in stepwise fashion, apply the criteria to all Part D drugs. A detailed synopsis of the panel's findings is posted at *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_FormularyGuidance.html*. The consensus panel determined that of the current six drug categories or classes of clinical concern, three (anticonvulsants, antineoplastics, and antiretrovirals) meet both of the proposed criteria, and three do not (antidepressants, antipsychotics, immunosuppressants). The panel also determined that while other drug categories and classes met one of the criteria, no other drug categories or classes met both criteria.

With respect to the first criterion, the panel concluded that initiation of therapy with drugs from the antiretroviral, antineoplastic, and anticonvulsant categories and classes for the typical individual prescribed these drugs in a Part D setting generally cannot be delayed for 7 days because of the risk of hospitalization, incapacity, disability, or death. For antiretrovirals, the risk associated with the failure to immediately initiate recommended concurrent therapies could significantly increase the risk of developing drug resistance and the potential for re-exacerbation of the disease. For antineoplastics, prompt initiation of therapy is also critical. Given that the antineoplastic drug therapy often is but one part of a complex cancer treatment protocol that includes non-drug therapies, such as radiation or surgery, initiation of the antineoplastic drug therapy is usually integrated with the entire treatment protocol. Thus, delaying initiation of antineoplastic drugs can delay a beneficiary's entire course of treatment. For anticonvulsants, the risk of seizure associated with a delay in drug therapy for 7 days can lead to hospitalization and significant incapacity.

With respect to the second criterion, the panel concluded that the antiretroviral, antineoplastic and anticonvulsant categories and classes meet the criterion because different drugs within those categories and classes are used in so many patient-, drug-, or disease-specific clinical applications that an alternative formulary requirement is not feasible. For antiretrovirals, the panel based this conclusion on the number of multiple drug combinations and adjunctive therapies involved, frequency with which recommended drug protocols change, and the role that changing drug resistance plays in determining the selection of among the different antiretroviral drugs. The need to adjust specific combination antiretroviral therapy in real time is complex and must consider, among other things, viral sensitivity to the drugs, drug interactions, pregnancy status (if applicable), and potentially the patient's pharmacogenomic profile of the cytochrome P450 system. Similarly, for antineoplastic drug therapies, the panel based its conclusion on the diversity of treatment protocols, the specificity of such treatment protocols, including the role that specific genetic variations can play in the selection of the appropriate drug therapy, and the frequency with which disease-specific treatment protocols recognized in the official Part D compendia change and get updated. A cancer patient whose clinical picture is rapidly changing must immediately initiate very specific changes in antineoplastic therapy when the new disease target is identified. Finally, for anticonvulsants the panel concluded that the class met the criterion based on the number of unique types of seizures, the multiple drug combinations indicated for them, and the potential for altered drug effects based on drug-drug interactions that occur via the cytochrome P450 system. For all three of the classes (anticonvulsants, antineoplastics, and antiretrovirals), the panel concluded that CMS would be unable to address them more efficiently through formulary requirements that would allow for some restrictions at this time based upon the number and specificity of the different treatment protocols.

After a detailed analysis of existing therapies and widely-accepted treatment guidelines, the panel concluded that immunosuppressants for transplant rejection, antidepressants, and antipsychotics do not meet both of

the proposed criteria and thus would not be eligible for the additional protections intended by section 3307 of the Affordable Care Act.

With respect to immunosuppressants for transplant rejection, the panel concluded that the first criterion was met. Due to the immune system's ability to mount progressively faster and stronger attacks against a beneficiary's new organ, and to maintain a memory relative to those attacks, initiation of therapy in a Part D setting generally cannot be delayed for up to 7 days because of the risk of hospitalization, incapacity, disability, or death, and thus meets the first criterion. Because widely-accepted treatment guidelines recommend sub-classes of drugs rather than specific, individual drugs, the panel did not believe that every drug product should be required for inclusion on Part D sponsors' formularies. Moreover, relative to the reasonably small number of transplant options available to beneficiaries (for example, stem cell, liver, lung, kidney, pancreas, heart and intestine), the consistency and specificity of treatment guidelines, and the amount of therapeutic drug monitoring required for these drugs, provide us with sufficient clinical information necessary to establish additional, specific formulary requirements without needing to continue to identify it as a drug category or class of clinical concern.

For antidepressants, the panel concluded that a 7-day delay in initiation of therapy would generally not put the typical individual at risk of hospitalization, incapacity, disability or death, and thus did not meet the first criterion. The panel also concluded that antidepressants did not meet the second criterion. This determination was based upon the similarities of drugs within sub-classes and the lack of unique effects for distinguishing individual drug products when initiating drug therapy for the typical individual in a Part D setting. For example, for a patient initiating antidepressant therapy for depression, when the treatment guidelines indicate that a drug within the selective serotonin reuptake inhibitor (SSRI) sub-class of antidepressants should be used, there are multiple options from which to choose, such as fluoxetine, paroxetine, sertraline, citalopram, and escitalopram. While treatment guidelines may indicate the choice of an SSRI over the tri-cyclic antidepressant (TCA) or serotonin-norepinephrine reuptake inhibitor (SNRI) sub-classes, assuming a patient is dosed correctly, they generally do not advocate a preference of one SSRI drug over another for initiation of therapy, nor do they provide a hierarchical inventory for these drugs' place in therapy relative to each other. In fact, the American Psychiatric Association's 2010 treatment guideline (available at *http://www.guideline.gov/content.aspx?id=24158*) states that ''the effectiveness of antidepressant medications is generally comparable between classes and within classes of medications.''

With respect to antipsychotics, many of these take weeks to reach their full effect (steady state). In addition, with regard to the Medicare population, particularly in long term care settings, current treatment guidelines indicate that the use of antipsychotics in the elderly is, in many cases, unwarranted and in others, possibly dangerous. However, due to the potential that, untreated, beneficiaries with active psychotic symptoms may be dangerous to themselves or others, the panel concluded that a 7-day delay in initiation of therapy met the threshold to put a typical individual with psychotic symptoms at risk of hospitalization, incapacity, disability or death, and thus met the first criterion.

However, the panel concluded that antipsychotics did not have unique effects that distinguished one drug from another for the purposes of choosing the appropriate drug to initiate therapy. For example, for a patient initiating antipsychotic therapy for schizophrenia or schizoaffective, or schizophreniform disorder, when the treatment guidelines may indicate that a drug within the second generation (atypical) antipsychotic sub-class should be used, there are multiple options from which to choose such as aripiprazole, risperidone, olanzapine, quetiapine, ziprasidone, and clozapine. While the treatment guidelines may indicate the choice of a second generation antipsychotic over the neuroleptics or first generation antipsychotic sub-classes, assuming a patient is dosed correctly, they generally do not advocate a preference of one atypical antipsychotic over another for initiation of therapy, nor do they provide a hierarchical inventory for these drugs' place in therapy relative to each other. Moreover, the 2009 update to the American Psychiatric Association's treatment guideline for the management of patients with schizophrenia (available at *http://psychiatryonline.org/data/Books/prac/Schizophrenia_Guideline%20Watch.pdf*) states ''the distinction between first- and second-generation antipsychotics appears to have limited clinical utility.'' Thus the panel concluded that these agents are considered to be generally therapeutically interchangeable when initiating therapy, and based on treatment guidelines, our formulary requirements could efficiently ensure appropriate access to antipsychotics without requiring inclusion on the formulary of every drug in the class.

In addition to any cost savings that would result from the proposed change for the antipsychotic drug class, it is important to emphasize that the change also would provide Part D sponsors with an improved capability to address widespread inappropriate overuse of antipsychotic drugs through better utilization management. A recent study published in Psychiatric Services analyzing 2009 claims data from private insurance claims found that 58 percent of individuals prescribed psychotropic medication in 2009 had no psychiatric diagnosis during the year (*Psychiatric Services 2013;* doi: 10.1176/appi.ps.201200557). Moreover, on September 20, 2013, the American Psychiatric Association released a ''list of specific uses of antipsychotic medications that are common, but potentially unnecessary and sometimes harmful'', including a recommendation not to prescribe these drugs ''as a first-line intervention to treat behavioral and psychological symptoms of dementia'' (*http://www.psychiatry.org/choosingwisely*). CMS has been particularly concerned with unnecessary use of antipsychotic drugs in nursing homes, which might be exacerbated by our current policy, which significantly limits Part D sponsors' options for ensuring appropriate use of these drugs. While this change in formulary requirements generally would not impede appropriate access to antipsychotic drug therapy for the mentally ill given the other formulary protections discussed previously, it would allow Part D sponsors to better align utilization management with CMS efforts to prevent inappropriate use of these drugs and the potential harmful effects associated with such inappropriate use.

While proposing to remove the previous level of formulary coverage from these particular classes, it is worth noting that the requirement to include on plan formularies all drugs in certain categories and classes is unique to the Part D program. We are not aware of any other U.S. government programs (such as the Veteran's Administration (VA), Tricare, the Federal Employees Health Benefits Program (FEBHP), and, most recently, the Affordable Care Act Essential Health Benefits (EHB) Benchmark Plans), or commercial private health plans having a similar

requirement. Similar to the Part D program, these plans also operate in the outpatient setting where access to medications is not typically needed on an emergency basis. Even though Part D formularies are more restrictive than Federal Employees Health Benefits Plans (FEHBP) and EHB plans, when CMS compared Part D formulary requirements with those of the VA National and Department of Defense (DoD) Basic Core formularies, out of 26 distinct antidepressant drugs required on all Part D formularies, the VA included 17, and the DoD included 10. Similarly, out of 19 distinct antipsychotic drugs required on all Part D formularies, the VA included 15, and the DoD included 2.

Supporting this analysis that our formulary checks could efficiently require adequate access to the antidepressant and antipsychotic drug categories and classes without requiring that every drug be included on all Part D formularies, we compared a Part D formulary to other formularies. We took an approved CY 2014 formulary containing the average number of RxNorm Concept Unique Identifiers (RxCUIs). This formulary includes the following: 23 generic (ANDA) antidepressant drugs, 7 brand (NDA) antidepressant drugs, 18 generic antipsychotic drugs, and 9 brand antipsychotic drugs. We then reviewed the drugs comprising the aforementioned list against our formulary review requirements standards for treatment guidelines, common Medicare drugs, and the discrimination review. We found that the formulary could have passed these checks with 9 generic antidepressant drugs, and 6 generic antipsychotic drugs. No brands were necessary to meet the formulary review requirements. Thus, this formulary includes an excess of 16 brand drugs and 26 generic drugs within these two classes of medications.

While the immunosuppressant, antidepressant and antipsychotic classes all fail to meet the second criterion, we are deferring any change in formulary requirements for the antipsychotic class at this time and will continue to require all drugs from within this class to be on Part D formularies in 2015, subject to the exceptions that get finalized in § 423.120(b)(2)(vi). Section 1860D–4(b)(3)(G)(I) of the Act requires that the Secretary identify classes and categories of clinical concern ''as appropriate,'' using criteria specified in notice and comment rulemaking. We interpret this provision as permitting us to postpone applying our proposed criteria to antipsychotics at this time, and as we are not applying the criteria to antipsychotics at this time, we believe it is appropriate to continue to treat antipsychotics as a class of clinical concern, in light of section 1860D–4(b)(3)(G)(iv) of the Act, because we wish to make certain we have not overlooked a need for any transitional considerations. This is because the risks associated with untreated psychotic illness, as differentiated from the broad category of mental illness, have the potential to be so severe. Therefore, although we previously explained why we do not believe the antipsychotic drug class would meet the new proposed criteria, at this time, we are proposing not to subject the antipsychotic class to the new criteria and therefore are proposing not to change the current requirement that all drugs from within this class must be included on all formularies, except as permitted under our proposed exceptions.

In general, our existing beneficiary protections should suffice to ensure appropriate access to antipsychotic drug therapies. However, we are not changing the requirement for antipsychotics at this time because we need to determine if additional transitional consideration is necessary for any individuals taking these medications. While we are not convinced that our existing transition requirements are insufficient, we seek comment on whether there are additional considerations for transitioning some patients taking these drugs to alternative drug therapies and if so, why our current requirements are not adequate. In addition, we seek comments on what specific patient population(s) or individual patient characteristics would require such additional transition protections and how such population(s) can be consistently identified. Conversely, we also seek comments on whether it might be in the best interest of beneficiaries to have their existing antipsychotic therapies reevaluated through utilization management, given our concern with the inappropriate use of these drugs especially in nursing homes and the limited clinical utility of distinctions among agents in this class of drugs. If so, we would also appreciate comments on whether the benefits of such a periodic reevaluation that would arise from routine utilization management might outweigh other transitional risks. While we do not believe the risks associated with illnesses treated by antidepressants are as severe as those treated by antipsychotics, we are also seeking comment on whether any transitional policies specific to antidepressants would be appropriate.

We are concerned about overutilization and inappropriate prescribing of antipsychotic medications in individuals with dementia for whom these medications may be prescribed as a mechanism for behavioral control; persons for whom antipsychotics are being used as sleeping aids or anxiolytics; and children who have not been diagnosed with a disorder for which an antipsychotic medication has been FDA-approved. Our concerns about overutilization are not aimed at individuals with a current mental illness or those who are or have recently or previously been stabilized on antipsychotic medications. We do not want to limit access to effective medications, or to limit a return to those effective medications for adults with a psychotic illness who need them. Finally, we seek comment on the timing necessary to address any additional transitional considerations, and remove the temporary protections for antipsychotics, if necessary.

Therefore, the initial drug categories and classes of clinical concern that meet the proposed criteria for coverage year 2015 are anticonvulsants, antiretrovirals, and antineoplastics. In addition, the antipsychotic drug class will continue to be treated as a class of clinical concern in 2015 and until CMS determines that it is appropriate to apply the criteria with respect to the antipsychotics. These categories and classes will be read narrowly and are not inclusive of every related drug product that an individual who has a disease treated by one of these categories or classes of drugs would need to take. For example, conjugated or esterified estrogens used for the palliative treatment of carcinoma of the prostate or metastatic breast cancer are not considered antineoplastics and would not be included in the antineoplastic class of clinical concern. We will provide more detailed guidance on the specific formulary checks that will be in place relative to antidepressant and immunosuppressant categories and classes of drugs at a later date. Additionally, we plan to work with stakeholders to provide outreach to beneficiaries around the proposed modification of the categories and classes of drugs of clinical concern that receive additional protections under section 3307 of the Affordable Care Act so that beneficiaries can select the most appropriate drug plan for their needs based on drug choice as well as cost. Finally, CMS plans to periodically review the drug categories and classes

as the clinical landscape changes to determine whether these classes continue to meet both criteria and/or if other categories/classes meet both criteria. We would propose any changes to the categories and classes of clinical concern through a public notice and comment process such as the annual Call Letter.

15. Medication Therapy Management Program (MTM) Under Part D (§ 423.153(d))

Section 1860D–4(c)(2) of the Act, provides that Part D sponsors, in offering Medication Therapy Management (MTM) programs, must target individuals who: (1) Have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure); (2) are taking multiple covered Part D drugs; and (3) are identified as likely to incur annual costs for covered Part D drugs that exceed a level specified by the Secretary. At the start of the Part D program, we believed that 25 percent of enrollees would qualify for MTM services. However, analysis revealed that MTM program enrollment was well below that level. In the 2010 Call Letter and subsequent regulation, we modified the criteria to reduce the variability in eligibility and level of service and to improve access to MTM services, again targeting 25 percent of enrollees. Despite these changes, MTM program participation remains very low. Moreover, additional evidence that the program improves quality and generates medical savings supports the idea that more than 25 percent of enrollees will benefit from MTM services.

Section 1860D–4(c)(2)(C) of the Act, as implemented in § 423.153(d)(vii), specifies that sponsors shall offer a minimum level of MTM services to targeted beneficiaries to increase adherence to prescription medications or other goals deemed necessary by the Secretary. Additionally, section 1860D–4(c)(2)(E [2]) of the Act, as implemented in § 423.153(d)(1)(v), provides that Part D sponsors must automatically enroll targeted beneficiaries in the MTM program, allowing beneficiaries the option to opt out. Under that authority, we also issued sub-regulatory guidance (found at *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter7.pdf*) and an annual memo with MTM Program Guidance and Submission instructions notifying Part D sponsors that we expect them to promote continuity of care by performing an end-of-year analysis that identifies current MTM program participants who will continue to meet the eligibility criteria for the next program year for the same plan. We indicated that this targeting could be done to auto-enroll beneficiaries in the plan's MTM program early in the next program year in order to provide MTM interventions with less interruption. Although beneficiaries who are new to Part D or who may have changed plans may be captured during the quarterly, or more frequent, targeting throughout the year, there is a time lag at the start of the year before these beneficiaries can be enrolled in MTM. This concern is particularly relevant for LIS enrollees who may have been reassigned to a new Part D plan if their existing plan terminated or no longer qualified as a benchmark plan. Moreover, we believe that there are other special populations of beneficiaries for whom simply increasing the frequency of targeting will not adequately address barriers they face to receiving MTM services. There are also situations in which a beneficiary is unable to accept the offer to participate in a CMR, but offering to perform the CMR with the beneficiary's prescriber, caregiver, or other authorized individual, as provided at § 423.153(d)(1)(vii)(B)(2), may not be effectively addressed by the sponsor. For example, sponsors may not effectively take steps to identify the beneficiary's authorized representative or coordinate with the beneficiary's LTC facility when appropriate. Consequently, to improve access to this beneficial service, we are exploring new ways to improve access to MTM services for Part D enrollees.

Although we initially estimated that 25 percent of the Part D eligible population would meet the three criteria for MTM services at the start of the Part D program, we provided minimal detail on how sponsors should implement the criteria. For example, we did not initially provide in regulation any detail on the number of chronic diseases or covered Part D drugs, or an annual cost threshold that would be required to establish a beneficiary's eligibility for MTM services, although we established an annual cost threshold of $4,000 in subregulatory guidance. We did this to allow maximum flexibility for the industry to develop best practices in the provision of MTM services.

After an analysis of common practices revealed wide ranges in eligibility and the levels of services provided, we announced in the 2010 Call Letter (available at *http://www.cms.gov/PrescriptionDrugCovContra/Downloads/2010CallLetter.pdf*) that the MTM requirements would be revised beginning in 2010 to provide greater consistency among the MTM programs and to raise the level of MTM interventions offered to positively impact medication use by Medicare Part D beneficiaries. We clarified that in defining multiple chronic diseases, sponsors could not require more than three chronic diseases as the minimum number of chronic diseases and that sponsors must target at least four of seven core chronic diseases (hypertension, heart failure, diabetes, dyslipidemia, respiratory disease (such as asthma, chronic obstructive pulmonary disease (COPD), or chronic lung disorders), bone disease—arthritis (such as osteoporosis, osteoarthritis, or rheumatoid arthritis), and mental health (such as depression, schizophrenia, bipolar disorder, or chronic and disabling disorders)). We further clarified that in defining multiple Part D drugs, sponsors could not require more than eight Part D drugs as the minimum number of multiple covered Part D drugs. We also lowered the cost threshold to $3,000 and instructed sponsors to adjust their targeting criteria accordingly. These requirements were subsequently codified in the regulations at § 423.153(d)(1) and (2).

Despite the expanded criteria, we continue to see restrictive criteria, such as plan sponsors specifying a narrow list of chronic diseases or Part D drugs coupled with requiring a higher minimum number of covered drugs (for example, eight drugs versus two) for eligibility. As a result, access to MTM services remains very low with MTM program eligibility rates at less than 8 percent in 2011. Even more concerning, there may be racial disparities in meeting the eligibility criteria. In the 2012 Call Letter (available at *http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2012.pdf*), we reviewed a 2010 study published in *Health Services Research* (HSR) by Wang and colleagues (Wang, et al. 2010. ''Disparity Implications of Medicare Eligibility Criteria for Medication Therapy Management Services.'' *Health Services Research.* 45 (4): 1061–1082.). This study was based on data from the Medical Expenditure Panel Survey (MEPS) collected prior to the implementation of the Part D program and used the original 2006 and the revised 2010 MTM eligibility thresholds. The study suggested that Hispanic and African American beneficiaries could be less likely to meet MTM eligibility criteria where utilization was a criterion for program

[2] Two subparts (E) have been enacted in section 1860D–4(c)(2). Here, we refer to the first one.

participation. The study findings had important implications for the Part D program because utilization based upon drug costs is a critical part of MTM eligibility. In 2012, Wang and colleagues repeated the study (Wang, et al. 2012. ''Historical trend of disparity implications of Medicare MTM eligibility criteria.'' *Research in Social and Administrative Pharmacy (2012):* 1–12) using 2007–2008 data along with both the 2006 and 2010 MTM eligibility thresholds. They found that disparity patterns did not change from the first study. Their findings that ''racial and ethnic disparities in meeting the MTM eligibility criteria may not decrease over time unless the eligibility criteria are changed'' have led us to conclude that the current MTM eligibility criteria are overly restrictive.

A 2011 report from the United States Public Health Service (PHS) Pharmacist Professional Advisory Committee (PharmPAC report) (available at *http://www.usphs.gov/corpslinks/pharmacy/sc_comms_sg_report.aspx*) supports the conclusion that the current eligibility criteria are restricting access to MTM services. The PharmPAC report, which was based on the experiences of PHS clinical pharmacists who attempted to provide services to Part D beneficiaries, indicated that the Part D MTM eligibility criteria, and variability in the application of these criteria among Part D sponsors, constituted a policy constraint which limited patient participation in the program, despite the 2010 enhancements. The authors of the PharmPAC report expressed concern that, at the time, the criteria permitted sponsors to define eligibility parameters. The PharmPAC report went on to say that as a result of the overly restrictive targeting criteria, patients who may need MTM services but did not meet the plan's criteria were not able to participate, unless the plan offered MTM services to a wider group than the targeted population.

Further supporting this conclusion, a recent study conducted in conjunction with the Center for Medicare and Medicaid Innovation called Medication Therapy Management in Chronically Ill Population: Final Report (August 2013) (''CMMI MTM study'') (available at *http://innovation.cms.gov/Data-and-Reports/index.html*) explored the variations in MTM eligibility criteria. This CMMI MTM study identified patients with equivalent MTM eligibility characteristics who were in different plans with different eligibility criteria. The enrollees were ineligible for MTM in their own plan, but would have been eligible for MTM if they were enrolled in another plan which targets a particular chronic disease that is not targeted for MTM services by their own plan or which targets beneficiaries for MTM services based on a lower number of chronic diseases or Part D drugs for eligibility. We are concerned with such variability, especially in cases where a beneficiary meets the minimum number of chronic diseases for eligibility, but may not qualify for MTM because his or her chronic condition is not targeted by the plan, he or she does not take enough medications for the plan's program (even though medication management issues are present), or because high utilization of lower cost generics places prescription drug costs for the beneficiary below the cost threshold. Restrictive application of MTM eligibility criteria may limit MTM enrollment to beneficiaries with spending well above the $3,000 threshold, and the CMMI MTM study indicates that drug spending for MTM enrollees varied from $4,452 to $7,477. The CMMI MTM study's final report was published in August, 2013 and is available at: *http://innovation.cms.gov/Files/reports/MTM-FINAL-Report.pdf*.

As discussed in the 2014 Call Letter (available at *http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcements2014.pdf*), the CMMI MTM study found that MTM programs effectively targeted high risk individuals who had problems with their drug-therapy regimens and had high rates of hospital and emergency room visits before enrollment as well as those that experienced a recent visit to the hospital or emergency room. The study also found that individuals with diabetes, CHF, and COPD who were enrolled in MTM programs—particularly those who received annual comprehensive medication reviews (CMRs)—experienced significant improvements in drug therapy outcomes when compared to beneficiaries who did not receive any MTM services, thus supporting the hypothesis that the annual CMR may be one of the more crucial elements of MTM. Significant cost savings associated with all-cause hospitalizations at the overall PDP and MA–PD levels were found, which may be due to MTM's comprehensive, rather than disease specific approach. This research supports statements in a recent Congressional Budget Office report that programs and services that manage the prescription drug benefit well or improve prescription drug use might result in medical savings (Congressional Budget Office, Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services, November 2012, available at *http://www.cbo.gov/publication/43741*).

Consistent with the findings of this research, we believe that the CMS-established eligibility criteria should be considered as the threshold for MTM eligibility, but not the driver of interventions by the plan. However, because plans target beneficiaries with specific diseases for MTM services, some plans, in turn, have designed interventions only focused on these diseases, in contrast to a more comprehensive approach to improving medication management and adherence. For example, one plan targeted beneficiaries with CHF and diabetes and designed interventions for these conditions. Beneficiaries who also had COPD qualified for MTM services, but the plan did not address their COPD medication issues, a practice that is inconsistent with the intent of comprehensive MTM. Nonetheless, the best-performing plans were able to improve medication adherence and quality of prescribing while maintaining or reducing overall health care costs (including drug costs), despite the costs associated with delivering a high number of CMRs. Moreover, the study's findings suggested that other conditions associated with cardiovascular disease, such as acute myocardial infarction (AMI), stroke, and vascular disorders, in addition to those already targeted under the eligibility criteria adopted in 2010, disproportionately appeared among the top cost savers.

Overall, the CMMI MTM study identified practices that typified high-performing MTM programs, including three that concern beneficiary targeting. They are:

- Establishing proactive and persistent CMR recruitment efforts;
- Targeting and aggressively recruiting patients to complete a CMR based on information on medical events such as a recent hospital discharge in addition to scanning for the usual MTM eligibility criteria; and
- Coordinating care by utilizing trusted community relationships, including networks of community pharmacists, to recruit MTM eligible candidates, and utilizing existing working relationships between MTM providers (pharmacists) and prescribers to make recommendations and discuss identified problems for patients.

Potential additional requirements, related to the first and third practices, are discussed elsewhere in this proposed rule. However, the second practice leads us to reconsider our current MTM targeting requirements. We believe that the results of the aforementioned studies indicate the

necessity to reduce variability in eligibility criteria among plans and as a result improve access to MTM services.

a. Multiple Chronic Diseases

The statute identifies targeted beneficiaries as those Part D beneficiaries who have multiple chronic diseases such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure. We previously interpreted this language to allow sponsors to define ''multiple chronic diseases'' with three chronic diseases being the maximum number a plan sponsor may require for targeted enrollment. Further, sponsors are allowed to target beneficiaries with select chronic diseases, but must include at least five of the nine core chronic diseases in their criteria. This list of core chronic diseases, as updated in the 2013 Call Letter (available at *http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads//Announcement2013.pdf*), includes hypertension, congestive heart failure, diabetes, dyslipidemia, respiratory disease, bone disease—arthritis, mental health, Alzheimer's disease, and end stage renal disease. We propose to revise our interpretation of ''multiple chronic diseases'' to require that sponsors must target enrollees having two or more chronic diseases for MTM services. We believe this is a reasonable interpretation of the statute because ''multiple'' is commonly understood to mean more than one.

In addition, we believe that the statute specifically named the diseases that are most prevalent within the Medicare Part D beneficiary population and that present a likelihood of having medication use issues that impact therapeutic outcomes. Therefore, we propose to require that at least one of the chronic diseases that a beneficiary has in order to satisfy the eligibility criteria must be one of the list of core chronic diseases. This list has been updated since 2010 to encompass common targeting practices among plan sponsors and diseases prevalent among beneficiaries. We also believe that this interpretation is consistent with other literature concerning the relative risk of the combination of multiple disease states and medications and ensures that Medicare Part D beneficiaries with prevalent health conditions receive access to MTM. In addition, to be more consistent with the findings of the CMMI MTM study and the current drug hierarchical condition categories (RxHCCs) used in the Part D risk adjuster, we propose to redefine the core diseases by combining hypertension and congestive heart failure under the umbrella of ''cardiovascular disease,'' which would also encompass congestive heart failure, acute myocardial infarction, cerebral hemorrhage and effects of stroke, vascular disease, specified heart arrhythmias, and hypertensive heart disease. The list of core chronic diseases would thus become cardiovascular disease, diabetes, dyslipidemia, respiratory disease, bone disease—arthritis, mental health, Alzheimer's disease, and end stage renal disease. However, in future rulemaking, we may consider further revising the regulation to establish standards by which these core chronic diseases are selected, and therefore establish the list of core chronic diseases annually in subregulatory guidance based on those factors. We solicit comment on what specific patient population(s) or individual patient characteristics should be considered in establishing such standards.

b. Multiple Part D Drugs

The statute identifies targeted beneficiaries as those Part D beneficiaries who are taking multiple covered Part D drugs. Although we initially had no requirements in this area, as early as contract year 2006, we asked plan sponsors to report to us the number of covered Part D drugs that a beneficiary must have filled to meet their targeting criteria for MTM, and if applicable, to list the type of Part D drugs that would apply. While still allowing a great deal of flexibility in the design of MTM programs, for contract year 2007 forward, we requested more detailed information in this area in MTM Program Submission materials for a March 15, 2006 User Group Call which were distributed through HPMS. We asked plan sponsors to identify the number of covered Part D drugs that a beneficiary must have filled to meet their criteria for MTM programs, and to provide information on the type of covered Part D drugs that would apply. Specifically, we asked if any Part D drug would apply, only chronic/maintenance drugs, only disease-specific drugs related to chronic diseases, or if specific Part D drug classes would apply (and what those drug classes were), or what other types of categories the plan sponsor intended to use. For coverage year 2013, we consolidated this list of types of covered Part D drugs that could apply and no longer specifically collected information on disease-specific drugs related to chronic diseases. (MTM Program Submission Process Guidance for CY 2013 is available at: *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Memo-Contract-Year-2013-Medication-Therapy-Management-MTM-Program-Submission-v041012.pdf*)

Because our analyses continued to reveal such wide ranges in eligibility under this criterion, we issued guidance in 2009, which we subsequently codified in our April 2010 final rule entitled, ''Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (75 FR 19678), to establish specific requirements regarding the minimum number of covered Part D drugs that plan sponsors should consider in order to satisfy the statutory requirement. Specifically, we instructed that Part D sponsors should define ''multiple'' for purposes of satisfying this requirement as no more than eight Part D covered drugs. (75 FR 19772) Although we tried to maintain maximum flexibility for plan sponsors by permitting this broad range, the authors of the PharmPAC report specifically cite the options available to plan sponsors in determining enrollee eligibility criteria for multiple Part D drugs as a limitation of the MTM programs required under Part D. We now believe that allowing plans this flexibility has contributed to beneficiary confusion, decreased access to MTM services, and even led to racial disparities in access to services.

We propose to revise our interpretation of ''multiple Part D drugs'' to require that sponsors must target enrollees taking two or more Part D covered drugs for MTM services. While we are expanding this criterion, we are also proposing to restrict the flexibility previously available to sponsors by requiring that they consider any Part D covered drug. Literature supports the idea that patients with multiple diseases and taking at least two drugs are more likely to have drug therapy problems.

The importance of MTM services for patients taking two or more medications was demonstrated in a 2007 evaluation which validated the Risk Based Relative Value Scale (RBRVS) for MTM Services by Isetts and colleagues on behalf of the state of Minnesota (available at *http://www.dhs.state.mn.us/main/groups/business_partners/documents/pub/dhs16_140283.pdf*). This study shows that when a patient has a single indication treated by at least two medications, there is likely to be at least one drug therapy problem. When the patient moves to two indications, he or she is more likely to be treated by at least three to five medications, and will likely have at least two drug therapy problems. It should be noted that this

evaluation considered not only prescription drugs, but also over the counter medications and dietary supplements.

TABLE 2—PHARMACEUTICAL CARE RBRVS *—AT A GLIMPSE

| Level ** | Number of medical indications | Number of medications | Number of drug therapy problems (DTP) |
|---|---|---|---|
| Level 1 | At least 1 | At least 1 | None observed. |
| Level 1 | At least 1 | At least 2 | 1 DTP. |
| Level 2 | At least 2 | At least 3–5 | 2 DTPs. |
| Level 3 | At least 3 | At least 6–8 | 3 DTPs. |
| Level 4 | 4 or more | 9 or more | 4 or more DTPs. |

* Summarized from the Minnesota DHS Web site Program Guide for Delivery of Medication Therapy Management Services (MTMS).
** The level of care reported is the lowest of patient needs met by all criteria in each level.

Section 3503 of the Affordable Care Act establishes a program under the Public Health Service Act under which the Secretary is authorized to provide grants or contracts to eligible entities to implement MTM services and provides that MTM programs shall target individuals who take four or more prescribed medications, including over-the-counter (OTC) medications and dietary supplements, and take any high-risk medications. Although this provision does not directly pertain to the Part D program, we believe that an examination of the criteria used to target individuals under that provision is helpful in considering what changes could be made to improve the effectiveness of MTM programs offered under Part D. Unlike section 3503 of the Affordable Care Act, which expressly requires that services be targeted based on the use of either prescription or non-prescription drugs, the Part D statute expressly requires that Part D plans target beneficiaries taking multiple covered Part D drugs for MTM services. OTC medications or dietary supplements are not covered Part D drugs, and we cannot require Part D sponsors to consider them in targeting beneficiaries for MTM services. Nevertheless, as evidenced by the RBRVS approach discussed previously, we believe that these OTC medications and supplements may contribute to drug therapy problems. Therefore, we believe that it is reasonable to propose that ''multiple Part D drugs'' should be construed to mean two or more Part D drugs in order to ensure that beneficiaries that are at risk of drug therapy problems, including problems associated with taking multiple prescription medications in conjunction with over-the-counter medications, are appropriately targeted for MTM services. A literature review (Hajjar ER, Cafiero AC, Hanlon JT. Polypharmacy in elderly patients. *Am J Geriatric Pharmacother.* 2007; 5:345–351) cited a study that found that almost 90 percent of elderly, rural community-dwelling patients took one or more OTC products and almost 50 percent took two to four. Another study of noninstitutionalized patients found that 47 to 59 percent of older patients took a vitamin or mineral and 11 to 14 percent took herbal supplements. The review found that polypharmacy among the elderly may be increasing. (Stoehr GP, Ganguli M, Seaberg EC, et al. Over the counter medication use in an older rural community: The MOVIES Project. *J Am Geriatr Soc.* 1997; 45:158–165). Therefore, it is reasonable to conclude that the Part D MTM population with multiple chronic diseases would also be taking OTC medications. Furthermore, we expect that sponsors will perform outreach to beneficiaries to acquire additional information regarding OTC medication use by their enrollees, consistent with our current guidance for CMRs, which explains that the medication review as part of the CMR should include prescriptions, OTC medications, herbal therapies, and dietary supplements (available at *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Memo-Contract-Year-2013-Medication-Therapy-Management-MTM-Program-Submission-v041012.pdf*).

Although we are proposing this option, we also considered alternatives such as duplication of the section 3503 of the Affordable Care Act criteria for four or more prescribed medications which could include OTC medications and dietary supplements, provided the beneficiary was taking at least 2 covered Part D drugs. However, we recognized that Part D sponsors would not have the ability to assess an enrollee's use of OTC medications or dietary supplements in order to determine MTM eligibility despite the RBRVS approach which suggests that beneficiaries may still experience drug therapy problems when they have only one chronic disease but take at least two medications, which could include OTC medications or dietary supplements. As a result, we solicit comments on alternative definitions for ''multiple Part D drugs,'' including what minimum number of medications is appropriate for MTM targeting.

c. Annual Cost Threshold

The Congress did not impose any specific requirements with respect to the cost threshold at the time the MTM criteria were passed in to law, nor has it addressed this threshold in any of the subsequent amendments to section 1860D–4(c)(2) of the Act. When we first established the requirements regarding MTM programs, we recognized that cost alone was not the best indicator of those that could benefit most from MTM. Indeed, in our January 2005 final rule entitled, ''Medicare Prescription Drug Benefit'' (70 FR 4282), we stated that cost might not be the best proxy for identifying patients that could benefit most from MTM. Nevertheless, in an attempt to identify a manageable population at the start of the program, we believed that individuals with the highest costs were more likely to be suffering from more chronic conditions and taking more Part D medications. Therefore, we believed that setting a cost threshold that would limit MTM programs to the individuals with the highest costs would increase the likelihood that MTM services would be provided to those individuals that could benefit most (because those individuals were likely to be at greater risk for improper medication use and adverse drug events). Thus, although it was set in subregulatory guidance, we established the initial $4000 cost threshold at the inception of the Part D program.

As discussed in our April 2010 final rule entitled, ''Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs'' (75 FR 19776), following an analysis of plan reported data, we found

that only 10 percent of beneficiaries enrolled in a Part D plan with an approved MTM program were eligible for MTM services in 2006 and only 13.1 percent were eligible for MTM services in 2007. In 2008, we conducted an analysis of beneficiary drug costs using Prescription Drug Event (PDE) data from contract years 2006 and 2007 obtained from the Integrated Data Repository (IDR) system. As part of this analysis, the total gross drug cost and number of beneficiaries that incurred annual drug costs (below) or (greater or equal to) the $4000 cost threshold was determined. The average number of PDEs and average costs per beneficiary were also calculated. Further analysis examined cost breakouts in $500 increments to determine the distribution of beneficiaries, as well as the number of fills, and gross drug cost for beneficiaries with annual drug costs in each of these categories. We determined that close to 25 percent of Part D enrolled beneficiaries with drug utilization (beneficiaries with at least one PDE during the study period) during 2006 and 2007 had annual gross drug costs of at least $3,000. Therefore, we lowered the cost threshold to $3,000 in the 2010 Call Letter. Based upon our analysis of the more recent data in 2010, we concluded that this threshold would ensure that approximately 25 percent of the beneficiaries using the Part D benefit would receive MTM services, and we codified the $3,000 threshold, as updated annually by the annual percentage increase in the average per capita aggregate expenditures for Part D drugs for Part D eligible individuals under § 423.104(d)(5)(iv) in the April 2010 final rule entitled, ''Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs'' (75 FR 19818). The threshold is currently $3,144 in 2013.

However, the use of lower cost generics has been increasing since the Part D program began, so the application of this threshold may exclude many beneficiaries who are in need of MTM services. We believe this increase in the use of lower cost generics may contribute to low MTM program enrollment rates which currently hover around 8 percent, and may also be a driver in racial disparity in MTM program enrollment. Additionally, prior work, including the RBRVS approach described previously, assigns relative risk of needing MTM services using the number of indications that an individual has and the number of medications that he or she is taking, but does not address a cost threshold. Consequently, we are concerned that there are a number of beneficiaries who need MTM, but are not currently eligible because they do not meet the current cost threshold of $3,144, despite the increased likelihood of having drug therapy problems as a result of having multiple chronic diseases and taking multiple medications. Moreover, the current cost threshold may have the unintended consequence of causing beneficiaries to no longer qualify for MTM services in the next plan year (whether remaining in the same plan or enrolling into a new plan) if they fall below the cost threshold as a result of their enrollment in plans that employ cost avoidant strategies, such as aggressive use of generics, or in MTM programs that center on therapeutic interchange.

Consistent with our proposal that sponsors must target enrollees taking two or more Part D covered drugs for MTM services and taking into account that one or more of these Part D drugs are likely to be generics, we propose setting the annual amount in Part D drug costs at an amount that represents the intersection of multiple conditions and multiple drugs. Based on an analysis of PDE data, the average cost of a generic prescription is $25.85. Because a very small percentage of prescriptions are for more than 30 days, we assume that this amount is the average cost for a 30-day generic prescription. Thus, the annual total drug cost for a beneficiary filling two generic prescriptions is $620.40. Accordingly, consistent with our proposal to determine a cost threshold that is commensurate with the drug spending of beneficiaries that meet the first two criteria regarding multiple conditions and use of multiple covered Part D drugs, we would set the cost threshold at $620, which is the approximate cost of filling two generic prescriptions. We propose to revise this number periodically to reflect more up-to-date information regarding the drug spending of beneficiaries that have two or more chronic conditions and use two covered Part D drugs. We remind sponsors that the drug costs used to determine if the total annual cost of a beneficiary's covered Part D drugs is likely to equal or exceed the specified annual cost threshold for MTM program eligibility includes the ingredient cost, dispensing fee, sales tax, and vaccine administration fee, if applicable. Because the statute requires that plans target beneficiaries who ''are identified as likely to incur annual costs for covered Part D drugs that exceed a level specified by the Secretary,'' we encourage sponsors, as most do now, to project annual costs for a beneficiary based on costs from the preceding month or quarter.

We took a number of factors into consideration in deciding to propose lowering the annual threshold to a level commensurate with the drug spending of beneficiaries with multiple chronic diseases taking two covered Part D drugs. Doing so promotes consistency among Part D plans relative to the three eligibility criteria set forth in the statute by factoring multiple conditions and multiple Part D drugs into how the cost threshold is set. We know now that patients with multiple conditions and taking multiple drugs have a higher probability of having at least two drug therapy problems and could benefit from MTM. More beneficiaries are using lower cost generic alternatives and no longer meet the current cost threshold, which is over $3,000, and studies have found that the current cost threshold may promote racial disparities in MTM eligibility.

Based on an analysis of 2011 PDE data and 2011 RxHCCs from the Risk Adjustment system, approximately 60 percent of Part D enrollees have two or more chronic diseases were taking two or more Part D drugs and incurred drug costs greater than or equal to $500. We found that 50 percent of Part D enrollees have two or more chronic diseases, were taking two or more Part D drugs, and had drug costs of greater than or equal to $1000. Therefore, we estimate that approximately 55 percent of Part D beneficiaries will be eligible for MTM based on the proposed criteria (two or more chronic diseases, two or more Part D drugs, and likely to incur $620 in annual Part D drug costs).

The CMMI MTM study found that high-performing MTM programs not only improved drug therapy outcomes but also maintained or lowered rates of hospitalizations, ER visits, and associated costs. Therefore, more of the Part D population can benefit from MTM services and these programs can potentially positively impact the Medicare program as a whole through improved medication use and lower healthcare costs. As a result of this, we no longer believe that it is appropriate to target only 25 percent of the Part D populations, and only those beneficiaries with high drug costs. This is consistent with our view in our January 2005 final rule where we stated that we believe that MTM must evolve and become a cornerstone of the Medicare Prescription Drug Benefit. We also intend that the Medicare Prescription Drug Benefit will serve as a model for achieving quality

improvement in prescription drug therapy.

Although we are proposing to set the annual threshold at a level that is commensurate with the drug spending of beneficiaries with two or more chronic diseases that use two covered Part D drugs, we considered other alternatives. For example, we considered setting the threshold at $900 or $1200, which roughly coincide with cost thresholds achieved by taking three or four generic drugs. We solicit comment, based on industry and MTM provider experience, on where this threshold might be alternatively set.

Although we are proposing to broaden MTM eligibility, we also believe there are special populations of beneficiaries for whom broader targeting criteria will not adequately address barriers they may face to receiving MTM services. The CMMI MTM study found that effective MTM programs establish proactive and persistent CMR recruitment efforts. These programs also utilize trusted community relationships, including networks of community pharmacists, to recruit MTM eligible candidates as well as existing working relationships between MTM providers (pharmacists) and prescribers to make recommendations and discuss identified problems for patients. Trusted community relationships are an important tool that can be leveraged to reduce disparities in access to MTM services, and other health disparities in general, faced by some special populations of beneficiaries.

For example, LIS-enrollees are a diverse group and are more likely than other Medicare enrollees to have a high burden of disability and chronic disease, to have limited English proficiency, and to belong to a racial or ethnic minority group. Although LIS-eligibility is not a perfect indicator for the social determinants of health faced by those with limited English proficiency or belonging to racial or ethnic minorities, it is true that those with limited English proficiency, and those belonging to racial and ethnic minorities are more likely than other Medicare enrollees to be poor. Because this financial status is frequently compounded by a variety of barriers to accessing health insurance and care, these beneficiaries generally have a higher burden of disability and chronic disease. As discussed previously, the use of utilization-based criteria to target at-risk individuals who may not, as a result of cultural norms or preferences, be high utilizers of health care services is particularly troubling. This comes in spite of evidence in treatment guidelines which suggests that they may need targeted outreach. Such criteria may also miss other high-risk individuals who use multiple low-cost generic drugs that present a safety risk without reaching a cost threshold. More of these beneficiaries will be eligible for MTM services due to the revised criteria that we are proposing in this rule. However, there are currently no requirements under our regulations that Part D plans ensure that beneficiaries in these special populations receive focused outreach or engagement to increase their participation in MTM.

Chronic disease and disability are common in the LIS population. More than 80 percent of Part D enrollees who had spending high enough to reach catastrophic coverage were LIS enrollees. Additionally, the reassignment process can present additional challenges for LIS enrollees such as new formularies, requirements for prior authorizations, step therapy, or quantity limits, processes for exceptions, appeals, and grievances, and contacting their plan. This makes it more challenging for LIS enrollees to maintain access to their drugs. Further, pharmacists at the point of sale frequently spend a great deal of time with and on behalf of these enrollees as they face formulary changes. This, in turn often generates high levels of frustration for the enrollee, as he or she waits for the pharmacist to resolve the issues, as well as for the pharmacist, as the effort required to assist the customer approaches the level of service furnished in MTM, but remains uncompensated.

Challenges faced by LIS enrollees in the Part D program are exacerbated for those with limited English proficiency or who belong to a racial or ethnic minority. For example, translators and multi-language inserts currently required may not be adequate to address the cumulative effects of race and ethnicity, lower levels of education, and poverty that are frequently associated with individuals with limited English proficiency. Moreover, messages conveyed by such approaches may not be consistent with an individual's underlying cultural beliefs and attitudes about medicine and therapy.

Another example involves the Indian Health Service, which is staffed by many health care providers in the United States Public Health Service and bears primary responsibility for caring for American Indians and Alaska Natives. The Indian Health Service is comprised of facilities operated by the Indian Health Service, tribes or tribal organizations pursuant to the Indian Self-Determination and Education Assistance Act, and urban Indian organizations pursuant to title V of the Indian Health Care Improvement Act. When the majority of American Indians and Alaska Natives live outside reservation land, where most IHS/tribal facilities are located, barriers in access to care are seen in both rural and urban landscapes, where there is limited availability of providers or limited offering of services, respectively. Transportation to IHS/tribal facilities may be a barrier and, the PharmPAC report also indicates that the patient-perceived benefit of paying monthly premiums, in light of 100 percent coverage of health care expenses for eligible patients, may also reduce participation in MTM services. The PharmPAC report goes on to state that the Public Health Service Pharmacy program has apprehension about contracting with Part D plans offering MTM programs because limited compensation by Part D plans for MTM services is not cost-effective to implement on a national scale.

We believe that the difficulties faced by special populations of beneficiaries represent important opportunities for robust MTM services that, when associated with early completion of CMRs, will help beneficiaries navigate the reassignment process, better reward pharmacists for the level of effort needed to serve these beneficiaries, and provide another option for sponsors to manage high cost beneficiaries. We have previously discussed the impact of one-to-one counseling by State Health Insurance Assistance Programs, and a growing body of evidence indicates that the person-to-person aspect of MTM (including through the use of telehealth technologies) has the potential to yield multiple benefits that warrant more effective outreach by sponsors to LIS beneficiaries and those with limited English proficiency or who belong to a racial or ethnic minority. As we see with the proportion of LIS-eligible-but-unenrolled beneficiaries who have to apply to qualify for subsidies, generalized attempts at outreach are not sufficient to increase enrollment. Because of the wide variety in social determinants that contribute to barriers in access to coverage and care, individualized approaches to target populations such as LIS-eligible, limited English proficiency, racial and ethnic minorities, including American Indians and Alaska Natives, within the larger MTM-eligible population will likely require a multi-faceted approach. Thus, the opt-out method of enrolling targeted beneficiaries into MTM at § 423.153(d)(1)(v) may only partly

address the increased barriers to care faced by this group.

We are concerned that such social determinants contribute to persistently low MTM enrollment and participation despite attempts to broaden the criteria. As we have gained more experience with the MTM programs, we have become concerned with the number of simplistic, generalized strategies that have been implemented for delivering MTM services. We believe that Part D sponsors' strategies for outreach and service provision cannot be ''one size fits all'' and must be appropriately geared to social and demographic subpopulations within the overall targeted population in order to be effective. As discussed previously, the CMMI MTM study identified that high-performing MTM programs engage in multi-pronged, persistent efforts to recruit Medicare beneficiaries to CMRs and often use effective and diverse communication modalities such as person-to-person interactions, phone calls, or community contacts (through networks of trusted community pharmacists), if needed. Moreover, as illustrated in the example of the Indian Health Service, this may also include negotiating rates more acceptable to MTM providers that beneficiaries perceive as more accessible and trustworthy.

Consequently, we are interpreting section 1860D–4(c)(2)(D) of the Act, which requires plans to have in place a process to assess medication use of individuals who are at-risk but not enrolled in MTM, to require Part D sponsors to establish effective strategies that ensure access to MTM services for all eligible beneficiaries. The statutory requirement to assess the medication use of at risk beneficiaries should encompass the requirement that plan sponsors better address barriers in access to MTM services and improve participation rates, particularly at the start of enrollment in the plan, faced by those with limited English proficiency, those who belong to racial and ethnic minorities, or who are LIS enrollees. Without being prescriptive about what strategies must be employed, we are proposing that sponsors develop an effective strategy to ensure access to services for all MTM-eligible beneficiaries, including those who have disabilities or who have limited English proficiency. Specifically, we propose to revise § 423.153(d)(1)(v) to include the requirement that a Part D sponsor must ''have an outreach strategy designed to effectively engage all at-risk beneficiaries enrolled in the plan.''

Sponsors have previously commented to us that they have difficulty reaching many individuals in these special populations because of inconsistent or incorrect contact information. While this certainly presents an added challenge, plan sponsors could, for example, analyze fill data, and partner with pharmacies they know that a particular beneficiary or populations of beneficiaries frequent. Incorporating the pharmacies that targeted individuals utilize into the MTM program may be a particularly effective strategy for successful outreach that will lead to enrollment in MTM programs that is more broadly representative of the breadth of demographic segments in the targeted population. We believe that current plan reporting requirements, along with other CMS data sources, will be sufficient for us to evaluate the impact of such strategies. We solicit stakeholder comment on other important strategies that might prove successful in improving access to MTM services which could be considered at a later time. This proposed rule may be of interest to, and affect, American Indians/Alaska Natives. Therefore, we plan to consult with Tribes during the comment period and prior to publishing a final rule. We also intend to monitor best practices as sponsors implement more effective strategies and may consider imposing additional requirements in future rulemaking.

In summary, we are proposing revisions to the MTM eligibility criteria to target beneficiaries who have two or more chronic conditions, with at least one being a core chronic disease, who are taking two or more covered Part D drugs, and who have annual Part D drug costs commensurate with the drug spending of beneficiaries with two or more chronic diseases that use two covered Part D drugs. By decreasing the number of chronic diseases and medications and lowering the cost threshold for MTM eligibility, we anticipate that more beneficiaries will have access to MTM services which have been shown to improve drug therapy outcomes and decrease healthcare costs. We believe that these changes will simplify the MTM criteria and minimize beneficiary confusion when choosing or transitioning between plans. We believe these changes will also reduce disparities within the Part D beneficiary population and allow more beneficiaries with drug therapy problems to receive MTM. Additionally, broadened criteria, when paired with more effective strategies for outreach and access to MTM services, will more appropriately reach those individuals in need of these services. We remind sponsors that these proposed changes represent the minimum requirements, and that they may target additional beneficiaries. Effective MTM programs strengthen the Part D program and improve its overall value and, we note, our 5-star plans have consistently made significant investments in MTM.

16. Business Continuity for MA Organizations and Part D Sponsors (§ 422.504(o) and § 423.505(p))

A variety of events ranging from power outages to disasters and warnings of disasters can disrupt normal business operations, and when these events occur it is important to ensure beneficiary access to health care services and drugs. Sections 1852(d) and 1860D–4(b) of the Act, respectively applicable to Parts C and D, establish access to services and covered Part D drugs as a core beneficiary protection. After Hurricane Sandy it became apparent that a few entities, particularly those with operational centers and/or information technology (IT) resources physically located in the affected areas, did not have consistent continuity plans or back-up systems and processes to ensure ongoing coordinated deployment of critical staff to alternate locations.

Sections 1857(e)(1) and 1860D–12(b)(3)(D) of the Act authorize the Secretary to adopt additional contract terms for, respectively, MA organizations and Part D sponsors, including section 1876 cost contracts and Program for the All-Inclusive Care for the Elderly (PACE) organizations that provide qualified prescription drug coverage, that are not inconsistent with Parts C and D, respectively, of Title XVIII of the Act, when the Secretary finds it necessary and appropriate. Hereafter, all proposed requirements described in this section as applicable to Part D sponsors, also apply to section 1876 cost contract and PACE organizations that provide qualified prescription drug coverage. While a limited number of beneficiaries were affected by problems on the part of a small number of entities as a result of Hurricane Sandy, the goal of consistent disaster response remains: All MA organizations and Part D sponsors must limit the beneficiary impact of unavoidable disruptions and must ensure rapid restoration of operations. Accordingly, we propose to add contract provisions to require that MA organizations and Part D sponsors develop and maintain business continuity plans in order to better anticipate the types of disruptions that could occur and then implement policies and procedures to reduce interference with business operations. We believe this is appropriate to ensure

that Medicare beneficiaries have access to the care and coverage contemplated by the statute.

The proposed provision would, in § 422.504(o)(1) and § 423.505(p)(1), require that every MA organization and Part D sponsor develop, maintain, and implement a business continuity plan that meets certain minimum standards. In § 422.504(o)(1)(i) and § 423.505(p)(1)(i), we propose that the business continuity plan must assess risks posed to critical business operations by disasters and other disruptions to business as usual, be they natural, human, or environmental. Proposed § 422.504(o)(1)(ii) and § 423.505(p)(1)(ii) would impose a requirement that the business continuity plan contain a mitigation strategy to lessen hazards, identify essential functions, and prioritize the order in which functions are restored to normal operations; proposed paragraphs (1)(iii) through (v) contain other minimum requirements for the business continuity plan, discussed in more detail in the following paragraphs. In paragraphs (o)(2) of § 422.504 and (p)(2) of § 423.505, we propose essential functions that must be restored within 24 hours of a failure, disaster, emergency, or other disruption.

In paragraph (1)(ii) of § 422.504(o) and § 423.505(p), we would require MA organizations and Part D sponsors to mitigate those risks through a variety of strategies, specifically, by: (A) Identifying events (triggers) that would activate the business continuity plan; (B) developing plans to maintain the availability and, as applicable, the confidentiality of hard copy and electronic essential records, including a disaster recovery plan for IT and beneficiary communication systems; (C) establishing a chain of command, which would ensure that employees know the rules of succession; (D) creating a communications plan that includes emergency capabilities and means to communicate with employees and third parties; (E) establishing procedures to address management of space and transfer of employee functions; and (F) establishing a restoration plan with procedures to transition back to normal operations. Finally, we also propose, at (1)(ii)(G) in § 422.504(o) and § 423.505(p), that the business continuity plan comply with all applicable federal, state, and local laws. In light of the nature of the records an MA organization and Part D sponsor would have in its possession, we propose to emphasize continuing compliance with the contingency plan requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rule (45 CFR Parts 160 and 164, Subparts A and C) by including a cross-reference to those requirements in paragraph (1)(ii)(B)(*2*). These areas of responsibility are essential to continuing the business operations that allow beneficiaries to access health care services and covered Part D drugs.

To better ensure that a business continuity plan works as a practical matter, we next propose in § 422.504(o)(1)(iii) and (iv) and § 423.505(p)(1)(iii) and (iv) to require that on an annual basis, each MA organization and Part D sponsor test and revise the plan as necessary, and train employees on their responsibilities under the plan. Sections 422.504(o)(1)(v) and 423.505(p)(1)(v) would require that MA organizations and Part D sponsors keep records of their business continuity plans that would be available to CMS upon request.

We do not believe the broad list of areas that we propose be covered by business continuity plans are new to MA organizations and Part D sponsors. Rather, these topics typically appear in standard business continuity plans. And we are also building on some requirements that already exist under federal and state laws. For instance, with respect to electronic protected health information, health plans have long had to comply with the contingency plan requirements found in the HIPAA Security Rule. Indeed, our goal is to provide a list broad enough to align with the business contingency plans that we believe most, if not the vast majority, of MA organizations and Part D sponsors already have in place.

In contrast to the aforementioned list of broad content requirements, we believe the need to protect beneficiary access requires a prescriptive approach for some functions. In paragraphs (o)(2) and (p)(2), as part of the proposal that essential functions must be restored within 24 hours of failure (whether due to disaster, emergency, or other disruption), we identify what we believe are the minimum essential functions for each MA plan and Part D plan: Benefit authorization, if authorization requirements have not been waived, and claims adjudication and processing; an exceptions and appeals process; and call center operations. Given the mandate of the Act to ensure beneficiary access to health care and covered Part D drugs and the inability of many beneficiaries to pay for services or drugs without the Medicare benefit, we believe that the operations listed in the proposed regulations are the most essential operations because they directly support the provision of Part C and D benefits. They ensure immediate electronic communication on the availability and extent of Part C and D benefits and also provide support that makes it more likely that Medicare benefits will be appropriately and timely provided (for example, by providing telephone assistance to beneficiaries with questions on how to obtain benefits and maintaining a forum in which beneficiaries can challenge benefit denials). Without real time provision of Medicare benefits, beneficiaries might not pay for the entire cost of the services or drugs and therefore go without necessary treatment.

We believe the operations listed here are the essential operations which must be restored in a rapid time frame. We intend our proposed deadline of 24 hours to be the outside limit and would expect MA organizations and Part D sponsors to restore operation of essential functions as soon as possible but not later than 24 hours after they fail or otherwise stop functioning as usual. The clock would begin running in cases of total failure (for example, a computer or telecommunications system crashes or stops working after disruption of the power supply) and also when significant problems occur (for example, a central database is corrupted).

The need to ensure correct claims adjudication and benefit administration of health care services and drugs is no less acute during emergencies. A disaster or other disruption in one part of the country may disable computer systems that service areas across the country that have not otherwise been disrupted. Beneficiaries in those unaffected areas who were denied health care or drug benefits (that is, access to drugs or reimbursement for claims paid out of pocket) before the disruption took place should not be denied the right to immediately challenge those denials or to learn timely the resolution of earlier challenges. As proposed, § 422.504(o)(2)(i) and § 423.505(p)(2)(i) identify benefit authorization (if authorization requirements have not been waived) and claim adjudication and processing as essential functions which must be operational within 24 hours. We intend that this proposed regulation would require restoration of those operations for services rendered at a hospital, clinic or provider office or at the point of sale for Part D covered drugs. This function is essential for both Medicare Advantage and Part D plans.

In addition, we also propose standards specific to Part D sponsors in § 423.505(p)(2)(ii) and (iii) to ensure that a beneficiary who presents at a

pharmacy with an appropriate prescription for a covered Part D drug during a disruption will be more likely to walk away with the drug in hand. The first three prongs under proposed § 423.505(p)(2) would classify as essential the following functions: (i) Authorization, adjudication and processing of pharmacy claims at the point of sale; (ii) administration and tracking of enrollee's drug benefits in real time, including automated coordination of benefits with other payers; and (iii) provision of pharmacy technical assistance. These essential tasks entail numerous sub-functions. For instance, Part D sponsors would need to restore within the 24 hour return to operations (RTO) all computer and other systems that meet all privacy and security requirements in order to communicate to pharmacies information about topics including: Coverage under Part D and the specific plan; cost-sharing and deductibles; any restrictions such as prior authorization, step therapy, or quantity limit edits; and coordination of benefits from other insurers and any low income subsidies. Additionally, the sponsor would need to undertake a concurrent drug utilization review (DUR) to address, for instance, safety issues, as well as restore its pharmacy help desk to provide prompt answers to any questions pharmacies might have. (For more detail on some of these functions and sub-functions, as related to Part D, please see the preamble to section III. A. 17 of this proposed rule entitled, ''Requirement for Applicants or their Contracted First Tier, Downstream, or Related Entities to Have Experience in the Part D Program Providing Key Part D Functions''.)

Proposed § 422.504(o)(2)(ii) and § 423.505(p)(2)(iv) would classify as an essential operation an enrollee exceptions and appeals process including coverage determinations. Under this provision, within 24 hours of failure, MA organizations and Part D sponsors would need to restore all IT and workforce support necessary to maintain the ''safety net'' that ensures beneficiaries the right to appeal or to seek a formulary exception.

Finally, for both MA organizations and Part D sponsors, we propose that the operation of the call center be an essential function which must be restored within 24 hours. By classifying operation of the call center as essential, proposed § 422.504(o)(2)(iii) and § 423.505(p)(2)(v) would ensure that beneficiaries can receive the information necessary to find out where they need to go to access benefits and learn about any special rules that might apply (for example, whether pre-authorization requirements are waived or beneficiaries can obtain benefits at out-of-network providers or pharmacies) by requiring MA organizations and Part D sponsors to restore operation of call center services within 24 hours. Enabling a beneficiary who has just been denied Part D coverage at his or her usual pharmacy to call immediately and speak to a customer service representative while still standing in that pharmacy can ensure that he or she obtains drugs appropriately covered by his or her Part D plan before returning home or moving to a safer area.

Furthermore, because it may be difficult during a disaster to get to a provider's office or a pharmacy, we believe it is also important that benefit authorization, claims adjudication, and call center operations be restored within 24 hours after failure. While our proposed provision would require MA organizations and Part D sponsors to coordinate their workforce, facilities, and IT and other systems support to meet the 24 hour RTO, we believe that the vast majority of MA organizations and Part D sponsors already meet, or if not, would be able to meet this requirement with their current resources, based upon our knowledge of the industry and as evidenced by the lack of widespread problems with MAO and Part D operations that resulted after recent natural disasters in different parts of the country. MA organizations and Part D sponsors would not be required to take any prescribed actions (for example, there is no requirement for redundant systems located at certain distances apart). Rather, the 24 hour RTO would allow MA organizations and Part D sponsors the flexibility to continue to seek their own disaster preparedness solutions (for instance, vendor sites or functions spread across facilities).

Our goal in proposing a contractual requirement for business continuity plans is to ensure beneficiary access to health care services and Part D drugs during disasters and other interruptions to regular business operations. We view prior planning as essential to achieving this goal. We specifically solicit comments regarding which functions should be identified as essential operations and the 24-hour timeframe for RTO and would appreciate any information unique to the role of MA organizations and Part D sponsors.

17. Requirement for Applicants or Their Contracted First Tier, Downstream, or Related Entities To Have Experience in the Part D Program Providing Key Part D Functions (§ 423.504(b))

Since its establishment in 2006, the Medicare Part D program has matured into a generally stable, well functioning program, and the Part D sponsors (as well as their first tier, downstream, and related entities (FDRs)) with which CMS contracts have developed vast expertise in the operational complexities of the program. While we will continue to fine tune the program through rulemaking, guidance, and additional oversight procedures, we believe the program has largely entered a mature stage. Despite this progress, we still find ourselves spending a disproportionate amount of resources and attention on the operations of new Part D sponsors where neither the new sponsor nor its supporting FDRs have experience with Part D. In an environment where there is an abundance of Part D industry expertise, we are committed to establishing an approach to contracting with new Part D sponsors that ensures that they take advantage of that expertise and experience in the development of their Part D program operations.

To address this problem, pursuant to our authority at section 1860D 12(b)(3)(D) of the Act to adopt additional contract terms, not inconsistent with the Part C and D statutes, that are necessary and appropriate to administer the Part D program, we are proposing to adopt provisions that would require any entity seeking to contract as a Part D plan sponsor (as a stand alone prescription drug plan sponsor or as a Medicare Advantage organization offering Part D benefits) to have arrangements in place such that either the applicant or one of its contracted FDRs has one full benefit year serving as a Part D plan sponsor, or at least one full benefit year of experience performing key Part D functions for another Part D plan sponsor. The applicant or a contracted FDR will be required to have obtained that experience within the two years preceding the Part D sponsor qualification application submission. Under this proposal, the experience requirement would be met by an entity seeking to contract as a Part D plan sponsor if its parent or another subsidiary of that parent already holds a Part D sponsor contract that has been in effect for at least one year at the time of the application submission.

Of course, all applicants and their FDRs were new to the Part D program

in 2006, so we necessarily went forward with partners that may have had significant drug benefit administration experience, but no experience with the unique features of Part D. In 2014, there will be approximately 310 parent organizations that own 578 legal entities offering 881 contracts for Part D. In addition, more than 300 organizations (including Part D sponsors and their FDRs) perform key Part D functions on behalf of the Part D sponsors. Given this large number of organizations with Part D experience available to serve beneficiaries, we believe it is in the Part D program's best interest to be more discriminating about the entities with which we partner to deliver the Part D benefit.

New, inexperienced entities may be more likely to fail in all or some key Part D functions, causing harm to beneficiaries and requiring us to devote significant resources providing technical support to the new Part D sponsor in order to protect the Medicare beneficiaries enrolled in the sponsor's plan(s). Given the wealth of available Part D expertise that now exists, it is justifiable for us to require that new applicants to the program bring with them Part D experience so that we can better protect Part D enrollees and minimize unnecessary expenditures of resources by us in correcting avoidable problems.

We have determined that prior experience offering drug benefits in the commercial insurance or Medicaid markets is no longer a sufficient substitute for experience operating the Part D benefit. The Medicare drug benefit is fundamentally different from other drug benefits, with unique and operationally complex provisions, including transition fill requirements, protected class medication formulary requirements, low income subsidy administration, Part A and B versus Part D coverage determinations, requirements related to the tracking of true out of pocket costs, and requirements related to the coordination of benefits with other payers in real time. When neither a Part D sponsor, nor its FDRs providing key Part D functions, has any experience delivering Part D benefits, the consequences can be disastrous for beneficiaries and highly disruptive for the program and CMS. In a recent plan year, we placed a new PDP sponsor, where neither it nor its FDR had PDP experience, under an immediate enrollment and marketing sanction just months after the organization began its PDP operations. The sponsor had experienced widespread failures across all of the most important PDP operational areas and was unable to fix its problems without hiring additional staff and contractors with PDP experience. In this case, among other deficiencies, this sponsor had inappropriately rejected drug claims at the point of sale; failed to properly process coverage determinations (that is, requests for drug coverage or payment and reimbursement); denied enrollees the chance to appeal rejected claims and failed to ensure that denied coverage determinations were reviewed by an independent third party; and failed to process enrollment and disenrollment requests, or failed to properly process enrollment transactions. In short, the PDP sponsor was not providing the PDP benefit to its members. This became obvious when the rate at which we received beneficiary complaints about the sponsor for the first 4 months of operation was more than 225 percent higher than the average rate at which we received complaints about all other PDP sponsors for the same period. We were forced to dedicate significant resources and personnel to addressing the sponsor's systemic failures.

We believe that these failures would not occur, or would be less catastrophic, if either the Part D sponsor or its supporting FDRs have had experience actually performing key Part D functions. When both the new sponsor and its FDRs lack experience in Part D, there is no source of Part D expertise associated with the operation of a Medicare contract that could be counted on not only to establish and maintain systems that would ensure the effective delivery of the drug benefit, but also to identify emerging operational problems and promptly develop and implement necessary corrective action plans. Thus, we have found that the marriage of Part D novices under a single contract has proven to be a particularly risky and disruptive combination.

At the heart of the Part D benefit is the sponsor's ability to process claims for prescription drugs in real time because, unlike health benefits, where claims payment normally follows the delivery of services, pharmacies require confirmation of claims payment at point of sale either from an insurer or payment from the individual. While there are many operational functions that must run smoothly for a Part D plan to be successful (for example, pharmacy network development/maintenance, enrollment processing, prescription drug discount negotiation, and provision of customer service), we are proposing to require Part D experience in only three critical areas in which beneficiaries are particularly vulnerable should the sponsor demonstrate significant non compliance. We believe limiting our new requirement proposal to just three targeted areas offers a balanced approach which protects beneficiaries while at the same time provides needed flexibility to new sponsors to structure their business arrangements to address the dozens of other Part D functions. The three areas for which we are proposing to require prior experience in Part D at the time of application to become a new Part D sponsor are

- (1) Authorization, adjudication and processing of pharmacy claims at the point of sale;
- (2) Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers; and
- (3) Operation of an enrollee appeals and grievance process.

It is in these three areas where—in our view, based on our experience with Part D enrollee health is placed at the most significant risk by Part D sponsor compliance failures. Further, our audit work has indicated that these are the operational areas where sponsors are most likely to have significant failures that require immediate corrective action. While other areas, like enrollment processing, also present risks of direct beneficiary harm, our experience has shown that organizations usually can overcome enrollment problems in a manner that minimizes direct beneficiary harm fairly quickly. Also, our audit findings have shown far fewer serious problems in the enrollment area compared to the three selected areas (see *http://www.cms.gov/Medicare/ComplianceandAudits/PartCandPartDComplianceandAudits/Downloads/2012PartCPartDProgramAuditAnnualReport.pdf*).

Authorization, adjudication and processing of pharmacy claims at the point of sale are the most basic features of the Part D program, allowing Part D plan enrollees to have their prescriptions filled at the pharmacy counter. When presented with a prescription by a beneficiary, the pharmacy communicates electronically with the Part D sponsor to determine eligibility, coverage, and cost sharing for the item according to the formulary and benefit structure of the plan in which the beneficiary is enrolled. Aspects of eligibility and coverage unique to Part D include eligibility for the Low Income Subsidy and transition benefits. Assuming that the sponsor informs the pharmacy that the prescribed drug is covered under the beneficiary's plan, the pharmacy charges the beneficiary the appropriate cost share or deductible amount, as determined by the plan

sponsor. The Part D sponsor also uses the online, real time system to conduct concurrent drug utilization review (DUR), a process through which pharmacists receive a message warning of potential safety issues given the drug requested and the patient's drug history. If any of the cost sharing information is incorrect, or if the claim fails to adjudicate electronically for any reason, the beneficiary may be forced to pay out of his own pocket costs that are not his responsibility or leave the pharmacy without his prescription drugs. If concurrent DUR is not performed correctly, the beneficiary's health and safety is at risk.

Administration and tracking of enrollees' drug benefits in real time refers to a Part D sponsor correctly adjudicating the formulary it had submitted to CMS and that had been approved by CMS, along with accurately tracking an enrollee's drug spend within the Part D benefit, and coordinating benefits in real time with other payers. Sponsors must insure that the drug dispensed meets the definition of a covered Part D drug, including a medically accepted indication that is not otherwise covered under Part A or B of Medicare. Sponsors must also insure that any approved prior authorization, step therapy, and quantity limit edits are processed consistent with those approved by us, so that drugs are not denied inappropriately at the point of sale. Sponsors are also required to insure that enrollees are charged correct cost sharing, as amounts vary depending on the drug's tier placement, the enrollee's drug spend to date, contributions from other payers, and other factors such as whether the beneficiary receives a low income subsidy. Critically, compliance also includes correct application of our transition requirements, which is a beneficiary protection that is unique to Part D, and ensures beneficiaries facing a situation where their drugs are not on the plan's formulary have access to a temporary fill of the prescription, giving beneficiaries time to switch to another drug or seek a formulary exception. Failures in this area can have significant negative health consequences for enrollees because they are likely to be denied access to Part D drugs or face incorrect charges at the point of sale.

The third key function we selected as part of the experience requirement is operation of an enrollee appeals process (including coverage determinations). A sponsor's appeals operations serve as a ''safety net'' for improper benefits administration. Medicare enrollees have the right to contact their sponsor to make a complaint about the denial of coverage for drugs or services to which the enrollee believes he or she is entitled. Generally, sponsors are required to classify and process complaints about coverage for drugs or payment as a request for a coverage determination or appeal. Improper processing of a coverage determination denies an enrollee their due process and appeal rights and may delay an enrollee's access to medically necessary, even life sustaining services or drugs. There are different decision making timeframes for the review of coverage determinations and appeals. We have a beneficiary protection in place that requires plans to forward coverage determinations and redeterminations to an Independent Review Entity (IRE) when the plan has missed the applicable adjudication timeframe. If the plan sponsor reverses its initial adverse coverage determination or the IRE reverses the plan sponsor's adverse decision, the plan sponsor must correctly authorize or provide the benefit under dispute within the timeframes set forth in regulation. If the plan sponsor does not effectuate the decision timely and correctly, this can result in delays to an enrollee's access to medically necessary or even life sustaining drugs. Thus, the appeals process is a vital beneficiary protection that serves as the beneficiary's safety net when something goes wrong with claims adjudication or benefit administration, and once again, directly affects a beneficiary's access to prescription drugs.

Under our proposal, multiple separate organizations could together combine their experience to meet the prior qualification requirements for the three key Part D functions. That is, no one single entity would need to have prior experience in all three areas. Rather, the requirement would be for the Part D applicant in combination with its FDRs, if any, to have Part D experience covering the three key functions.

We believe there will be minimal impact on the prescription drug benefit administration market stemming from our proposal, particularly since large numbers of experienced organizations currently perform this Part D work. Fifty nine entities currently perform authorization, adjudication and processing of pharmacy claims at the point of sale; 66 entities perform administration and tracking of enrollees' drug benefits in real time; and 203 entities operate an enrollee appeals and grievance process. The ready availability of entities that would meet the criteria we establish here is demonstrated by the fact that the vast majority of new Part D sponsors each year choose to contract with experienced Part D FDRs. For example, as of late May 2013, there are 21 new organizations (at the parent level) with active Part D contract qualification applications for 2014, and each applicant has contracted with an FDR having at least one year of recent Part D experience. Some of the applicants for 2014 that attempted to apply with inexperienced entities performing the selected key functions withdrew their applications upon learning that they contained significant deficiencies.

Our proposal also does not prohibit additional organizations from gaining Part D experience in the selected key functional areas. Should an organization wish to become a new Part D FDR for one or more of the key functions, this ''novice'' entity could provide the service for just one of the hundreds of existing Part D sponsors. After a period of one year, the novice entity would then be qualified to provide its services to existing Part D sponsors as well as partner with new Part D applicants. We are comfortable with this scenario because during the novice entity's first year gaining Part D experience the existing Part D sponsor would apply its knowledge of how to oversee its FDRs, have institutional knowledge of the functional area, understand the complexity of the program, and know the risks of failing to implement the program successfully.

In the somewhat the opposite scenario, a new Part D sponsor contracting with experienced FDRs will have the opportunity to gain its experience in the key Part D functions by working closely with its FDRs, developing in house expertise, and providing oversight. After a period of one or more years, if desired, the Part D sponsor itself could conceivably take responsibility for carrying out one or more of the key Part D functions. We fully believe that our proposed approach allows for new organizations to develop Part D expertise, yet minimizes the significant risk to beneficiaries that would be caused by the types of widespread failures we have seen in the selected key Part D functions performed by inexperienced entities.

While our proposal does not require the Part D experience to be current at the time of an application to become a Part D sponsor, we are proposing that the experience be recent (that is, within the past 2 years) and have lasted for at least one full benefit year. As stated previously, the Part D program is complex, and program policies evolve each year, requiring organizations working in Part D to adapt and adjust

their operations. We believe that any experience older than 2 years would be out of date and would not represent experience with the current state of the Part D program. As for our proposed requirement that the experience be for at least a term of one full benefit year, this approach is appropriate because operating the benefit involves cyclical activities, some of which take place only one time per year, and thus an organization can only gain full experience by operating its Part D functional area for an entire benefit year.

We intend to implement this proposal through our existing Part D contract qualification application process, and we have proposed to amend § 423.504(b) accordingly. Today, at the time of application, an entity seeking a Part D sponsor contract must provide evidence that it has contractual arrangements in place for any key Part D function that the applicant itself will not be performing. For the three key functions identified under this proposal, new application procedures will require the applicant to submit evidence that the entity to perform such functions (whether itself or an FDR) has provided the same function for another Part D sponsor within the past 2 years, for at least one full benefit year. Applicants with existing Part D contracts or whose parents or other subsidiaries of the same parent hold Part D contracts will not be required to submit evidence of their Part D experience.

18. Requirement for Applicants for Stand-Alone Part D Plan Sponsor Contracts To Be Actively Engaged in the Business of the Administration of Health Insurance Benefits (§ 423.504(b)(9))

The Medicare prescription drug benefit program has matured into a generally stable, well-functioning program, and the Part D sponsors with which CMS contracts have developed vast expertise in the operational complexities of the program. The market for stand-alone Part D Prescription Drug Plans (PDPs) has also matured significantly since the program's inception and what was once a novel product is now available to residents of every state from multiple sponsors who offer several plan options. Over the same period, we have noticed that the Part D program has in some cases attracted sponsors wishing to offer stand-alone PDPs who have no prior experience in the delivery of health or prescription drug insurance benefits, often to the detriment of the Part D program and the Medicare beneficiaries who elect plans offered by these sponsors. We are committed to establishing an approach to contracting with organizations new to the stand-alone PDP program that ensures that their first experience in the health insurance and health benefits market is not as the sponsor of a stand-alone PDP.

To address this problem, we are proposing, pursuant to our authority at section 1860D–12(b)(3)(D) of the Act to adopt additional contract terms that are necessary and appropriate to administer the Part D program, regulatory provisions that would require any entity seeking to contract as a stand-alone PDP sponsor, to have either actively provided health insurance or health benefits coverage for 2 continuous years immediately prior to submitting a contract qualification application, or provided certain prescription drug benefit management services to a company providing health insurance or health benefits coverage for 5 continuous years immediately prior to submitting an application. This requirement would not apply to an entity seeking to contract as the sponsor of a stand-alone PDP if its parent or another subsidiary of itself or its parent possesses the requisite experience.

This proposal may appear similar to the immediately-preceding proposal (section III.A.17) of this proposed rule requiring, at § 423.504(b)(8), that new Part D sponsors engage first tier, downstream, and related entities with prior Part D experience. However, the proposed change we are discussing in this section, which we propose to codify at § 423.504(b)(8), would apply only to entities seeking to contract as a Part D sponsor of a stand-alone PDP, whereas the proposed requirement at § 423.504(b)(8) would apply to all new Part D sponsors, including those seeking to contract as Medicare Advantage organizations offering Part D through an MA–PD plan. We are proposing both requirements because the problems encountered by new PDP sponsors with no experience in the health insurance market are distinct from those encountered by new PDP sponsors and MA organizations who use PBMs with no experience in the Part D market. New PDPs with no prior health insurance or health benefits experience have demonstrated significant problems even when using experienced PBMs.

The Part D program has matured to the point where beneficiaries in every state now have access to several options for basic and enhanced stand-alone Part D coverage. In 2013, there is an average of 15 enhanced stand-alone plans and 16 basic plans per PDP Region and no region had fewer than 23 plans from which beneficiaries may choose. These numbers are consistent with the quantity of available PDPs in recent benefit years and are well above the minimum of two plans per region required by section 1860D–(a)(1) of the Act. Also, a total of 57 parent organizations that own 72 legal entities hold 75 Part D contracts for stand-alone PDPs, numbers that indicate that CMS has kept the PDP marketplace open to a significant number of entities that compete to serve beneficiaries.

Among the patterns we have identified during our implementation and administration of the Part D program is the extent to which the program has attracted organizations with no experience in the delivery of health or prescription drug benefits prior to their entry into the Part D program. These organizations often have experience in other lines of business, such as information technology, or are formed by investment groups with no other health care business for the sole or primary purpose of entering the Part D market. The Part D program is effectively used by these organizations as a means to finance their first (and often only) foray into the health insurance or health benefits industry. It appears to CMS that these sponsors view the Part D program as simply another line of business to which they can profitably apply their information management expertise, especially if they believe they can sell these new contracts to a larger participant at a substantial profit after several years. While relatively few sponsors fit this profile each year, they have caused disproportionate problems for beneficiaries and CMS, as described in the following paragraphs. The proper administration of the Part D benefit involves much more than claims adjudication. Our interaction with these novice sponsors leads us to believe that they underestimate the value of clinical expertise in administering Part D benefits, particularly in conducting effective coverage determination and appeals processes. Also, we believe they often do not recognize the critical role that relationships, particularly those among beneficiaries, physicians, pharmacists, other health care professionals, and insurers, play in the successful delivery of a healthcare or prescription drug benefit. Yet, the stakes involved in administering a Part D plan are likely higher than those associated with any other line of business in the novice sponsor's portfolio. Operational failures in Part D can cause improper denials at the pharmacy counter of beneficiaries' valid claims for prescriptions or improper denial of

appeals, leading to interruptions in their therapies, which can have life-threatening implications. In short, we have found that these types of applicants have been unable to administer a Part D benefit.

The compliance record of PDP sponsors with no healthcare-related experience confirms our assessment of the risks they pose to the Part D program. Time and again, these sponsors fail our past Medicare contract performance and audit tests or receive low quality scores (that is, star ratings) because they lack the ability to administer even the most basic elements of a health or drug benefit program, let alone one as complex as Medicare Part D. For example, we recently sanctioned a new stand-alone PDP sponsor (a situation we describe in section III.A.17 of this rulemaking where we propose to establish the requirement that all new Part D sponsors engage subcontractors with Part D experience). The sponsor had no recent experience providing or administering health benefits. It only began offering healthcare-related benefits when it became a Part D plan sponsor. We believe the sponsor's inexperience administering health insurance and health benefits, as well as its apparent reliance on Medicare as its sole source of revenue, compounded the problems it experienced, as the sponsor was unable to independently and expeditiously identify and resolve problems with benefits administration.

Another, more dramatic case, involved a CMS decision in 2010 to immediately terminate a PDP sponsor's contract under urgent circumstances in which beneficiaries were being significantly harmed. Prior to contracting with CMS, the PDP sponsor involved had no experience providing or administering health insurance or health benefits coverage. We terminated the sponsor's contract when an audit (prompted by urgent complaints from providers) revealed that the sponsor's compliance failures resulted in improperly denied access to Part D drugs and put the health of enrollees in the sponsor's PDP at imminent and serious risk. Numerous compliance failures resulted in beneficiaries being denied drugs that they were entitled to, including those needed to treat HIV, cancer, and seizures, or receiving delayed access to these drugs, sometimes after being required to undergo medically unnecessary and invasive procedures. The problems were so egregious and widespread that we were compelled to terminate the contract less than a month after we were first alerted to the problems and less than a week after an onsite audit of the sponsor. This termination created massive disruption for beneficiaries and to the program and required significant resources from CMS to resolve. As discussed previously, we believe that these failures would not have occurred, or would not have been as catastrophic, if the sponsors had prior, recent experience providing health insurance, health benefits coverage, or key services related to health benefits coverage.

When the sponsor is a novice not only to Medicare Part D, but also to virtually every aspect of health benefits administration, there is no assurance that the entity will be able to administer or oversee the most basic elements of health benefits coverage, such as processing claims, administering a coverage determination and appeals process, enrolling beneficiaries, or administering the benefit as approved. Its systems and procedures for doing so are by definition new and unproven. We do not believe that health care is a commodity that can be reduced to a programmable data set, or that administering the Part D benefit involves little more than having the right software package. To entrust inexperienced applicants with responsibility for correctly operating a program for which even experienced health insurers have had to develop new expertise has proven to be unacceptably risky. Part D sponsors are charged with both ensuring that beneficiaries get the drugs they need and applying clinically appropriate utilization management protocols to control costs and protect beneficiary safety. In this capacity, they have a role in clinical decision making that is usually reserved for physicians and health care providers with years of academic training and clinical practice. Permitting an organization with prior experience limited to, for example, developing payroll software, to design and broker individuals' access to prescription drugs for potentially life-threatening conditions is an unacceptable mismatch between a set of tasks and the expertise applied to it.

We propose that new applicants have two years of experience providing health insurance or health benefits coverage (that is, operating as risk-bearing entities licensed in the states where they offer benefits) prior to applying as stand-alone Part D Sponsors because we believe that this provides sufficient time to demonstrate the applicant's ability to operate a health plan. A risk-bearing entity with significant problems administering health benefits would be unlikely to remain in good standing with its licensing authority for two years. While a longer record of successful operations would likely provide better evidence of the organization's competence, we are also sensitive to the need to promote innovation and competition that can come from new PDP sponsors. We believe that requiring two years of experience as a risk bearing entity offering health insurance or health benefits coverage ensures that new sponsors of stand-alone PDPs have minimal experience operating a health benefits program without unduly limiting new entrants to the marketplace.

We recognize that a number of PBMs and Third Party Administrators with experience administering prescription drug benefits have entered the stand-alone PDP market and have adapted to providing the Part D benefit despite their lack of previous experience as health insurers. We believe this success is the result, at least in part, of their substantial experience operating key functions that form the core of PDP benefits on behalf of insurers. This experience is not sufficient in and of itself to administering a Part D plan, but it is certainly necessary. Therefore, we are proposing elsewhere in this proposed rule that organizations applying to contract as stand-alone PDP sponsors that do not have experience as a risk-bearing entity providing health insurance or health benefits coverage would, in the alternative, be eligible to hold a PDP contract if they had experience performing services on behalf of an insurer in the delivery of benefits in any health insurance market in the three key areas indicated in this section III.A.17 of this proposed rule. The three areas that we are proposing as meeting the experience requirements are: (1) Adjudication and processing of pharmacy claims at the point of sale; (2) administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers; and (3) operation of an enrollee appeals and grievance process. Our reasons for selecting these three areas as meeting the experience requirements are described in more detail in the section of this rulemaking notice relating to the proposed requirement at § 423.504(b)(8) that new Part D sponsors employ experienced FDRs for these functions.

We are proposing that entities without two years of experience as a risk bearing entity offering health insurance or health benefits coverage have five continuous years' experience providing services in the three key areas listed previously. We are proposing a longer experience requirement for these entities because entities offering these services face fewer barriers to entry in

the marketplace and are not as tightly regulated as risk bearing entities. An entity seeking to become a risk bearing entity must qualify for a state license, which requires the entity to demonstrate on a continuous basis that it meets extensive financial, capitalization, and administrative requirements. By contrast, an entity seeking to become a PBM or Third Party administrator faces little or no regulatory oversight for the services it offers. The investment required to start a PBM or Third Party Administrator may be significantly lower than that required of risk bearing entities operating health insurance programs. While a PBM that performs poorly may lose contracts, it is unlikely to be subject to regulatory action that would become part of the publicly available record that CMS could use to evaluate its application to operate a stand-alone PDP. However, we do believe that over a longer period of time, a PBM or Third Party Administrator's poor reputation would become known among participants in the health and prescription drug insurance markets, making it difficult for that organization to retain current contracts or obtain new ones with insurers and remain in business. We therefore believe that entities that seek to qualify on the basis of their experience as PBMs or Third Party Administrators should be required to have provided services in these key areas for five continuous years, rather than merely two.

We believe our proposal will not have significant impact on the availability of stand-alone PDP plans in the marketplace, but that it will simply function to keep out a small number of inexperienced organizations who are likely to perform poorly as stand-alone PDPs. Fortunately, the vast majority of new sponsors of stand-alone PDPs each year have the requisite experience. For example, eight organizations filed initial applications during 2013 to qualify to offer stand-alone PDPs in 2014 and 6 of them had at least two years' experience as a health insurer or 5 years' experience managing prescription drug benefits for health insurers. Of the six new stand-alone Part D plans in 2013, five had the level of experience we are proposing to require. Thousands of entities nationally possess the requisite experience providing health insurance, health benefits coverage, or PBM services.

If this proposed change is finalized, we intend to incorporate it into our existing Part D application process. At the time of application, an entity seeking a Part D sponsor contract must provide evidence that it is currently licensed or is in the process of being licensed in a state and provide certain information about its organizational experience and history. New application procedures would require an applicant for a stand-alone PDP contract to submit evidence that the entity, its parent, or a subsidiary of the same parent has actively provided health insurance or health benefits coverage for the prior 2 years, or has engaged in the three key functions identified here continuously for the prior 5 years.

19. Limit Parent Organizations to One Prescription Drug Plan (PDP) Sponsor Contract per PDP Region (§ 423.503)

Each year, we accept and review applications from organizations seeking to qualify to offer stand-alone prescription drug plans in one or more PDP regions. With limited exceptions (for example, poor past contract performance, limited Part D experience), we approve all applications submitted by organizations that demonstrate that they meet all Part D application requirements. CMS proposes, under our authority at section 1860D–12(b)(3)(D) of the Act to adopt additional contract terms, not inconsistent with the Part C and D statutes, that are necessary and appropriate to administer the Part D program, to add as a basis upon which we may deny a PDP sponsor application the fact that the applicant is applying for qualification in a PDP Region where another subsidiary of the applicant's parent organization already holds a PDP sponsor contract. In our description of this proposal, the term ''parent organization'' refers to an entity that controls a subsidiary through ownership of more than 50 percent of the subsidiary's shares.

During the 2013 contract year, there are 72 unique contracting entities (that is, entities licensed as risk bearing entities) holding 75 PDP sponsor contracts. There are 57 parent organizations that hold more than one PDP sponsor contract through a subsidiary contracting organization over which they maintain a controlling interest.

To promote the effective administration of a Part D program that involves so many parent organizations and contracting entities, we have consistently taken steps to ensure that the numbers of PDP sponsors, PDP sponsor contracts, and plan offerings are kept at a level that allows sponsors to fully exercise their rights as PDP sponsors but avoids the duplication and confusion that can result when reasonable limits are not placed on sponsors' requests for contracting arrangements that serve only their internal business operations. During the initial Part D contracting conducted during 2005, we approved a handful of contracts that were held by subsidiaries of a common parent organization. Since then, we have worked with the affected parent organizations to consolidate almost all of those ''duplicate'' contracts down to one PDP contract per participating parent organization per PDP region. The remaining duplicate contracts accommodate parent organizations that made binding business arrangements while acting in reliance on our previous allowance of multiple PDP sponsor contracts in the same PDP region. We expect to continue to work with those parent organizations to explore options for discontinuing their reliance on the second PDP sponsor contract in the immediate future.

Section 1860D–12(b)(1) of the Act provides that PDP sponsors may offer multiple plan benefit packages (referred to as PBPs or plans) under one PDP sponsor contract. Therefore, parent organizations need only one PDP sponsor contract to offer the full range of the possible plan options in a particular PDP Region. We recognize that many parent organizations that offer plans in multiple PDP regions must use more than one subsidiary to administer their full array of plans throughout the United States and the territories. For example, parent organizations may adopt these arrangements to accommodate unique state licensure requirements or the terms of trademark licensing agreements. However, none of these justifications, which are based on a parent organization's need to serve more than one PDP Region, would support a request, like several we have received during the CY 2014 contract qualification application cycle, by a parent organization to be granted a second PDP sponsor contract in a PDP Region it already serves. As discussed more fully in the following paragraphs, there are significant inefficiencies to the program of having duplicate contracts that do not provide more benefit plan options than could be offered under a single contract. Additionally, informal communications made by past requestors of duplicate contracts indicated that the purpose has been to either (a) segregate low income beneficiaries into their own contract, or (b) corral the experience of a particular low-performing plan into its own CMS contract so as not to taint the performance rating of the better performing plan offering, as performance ratings are calculated at the contract level. CMS opposes the

inefficiencies of duplicate contracts and the gaming duplicate contracts can support. That said, we welcome comments from industry, advocates, and others as to circumstances for our consideration under which duplicate contracts may be beneficial.

One of the fundamental principles of the Part D program is that the selection of plans made available to beneficiaries is the product of true competition among PDP sponsors. Two subsidiaries of the same parent organizations offering plans in the same PDP region are not truly competitors as decisions concerning their operations are ultimately controlled by a single entity, or parent organization. Also, we only approve those PDP offerings that meet the meaningful differences test stated at § 423.265(b)(2), and we apply that test at the parent organization level. A parent organization would not gain an opportunity to offer more plan benefit packages under two or more contracts it controlled through its subsidiaries than it would under one contract because we would, as part of our bid review, evaluate whether all the plans proposed by the same parent organization met the meaningful differences test.

The proposed limitation on the number of PDP sponsor contracts a parent may control in a PDP Region is also necessary to preserve the integrity of CMS' star ratings. CMS assigns star ratings at the contract level, and they are intended to reflect all aspects of the PDP operations controlled by a unique contracting entity. However, that principle is compromised when a parent organization to one of the contracting entities is permitted to control, through other subsidiaries, more than one PDP contract. While the contracting entities (that is, PDP sponsors) are legally accountable for the delivery of benefits under a PDP sponsor contract, when those sponsors are subsidiaries to a parent organization, it is the parent that, in reality, controls the quality of the sponsor's contract performance. The parent does this by using its controlling interest in the subsidiaries to establish the budget priorities and operational policies of those entities. As a result, allowing a parent organization to effectively administer two or more PDP sponsor contracts would allow it potentially to artificially inflate the star ratings on one contract by excluding the poor performance under its other contract from the rating calculation. In that instance, some beneficiaries could make a plan election without complete information about the performance of the organization ultimately responsible for the quality of services they would receive by enrolling in that plan. A beneficiary for whom quality ratings are an important factor in choosing a plan is best served by contracting arrangements and rating systems that provide the most transparency about the performance of all the PDP products offered under the authority of the single parent organization. This goal is best served by limiting parent organizations to one PDP sponsor contract per PDP Region.

Based on our experience in administering the Part D prescription drug benefit program we do not believe that there is a compelling justification for parent organizations to administer two PDP sponsor contracts in the same PDP region. Moreover, such arrangements impede our ability to efficiently administer the PDP and provide a means by which the integrity and reliability of our star ratings system can be compromised. Therefore, we propose to amend § 423.503(a) by adding a paragraph (3) stating that CMS will not approve an application when it would result in the applicant's parent organization holding more than one PDP sponsor contract in the PDP region for which the applicant is seeking qualification as a PDP sponsor. We anticipate that we would most frequently use this authority to deny an application in instances where the applicant's parent organization already controls a PDP sponsor contract, either directly by acting as a PDP sponsor itself (in instances when the parent is licensed as a risk-bearing entity) or through its ownership of a subsidiary that qualifies as a PDP sponsor and is a party to a stand-alone PDP sponsor contract. In the less likely situation where two or more subsidiaries of the same parent organization each submit applications in the same year for PDP regions where the parent organization controls no PDP sponsor contracts, we would request that the parent withdraw all but one of the applications. In the absence of a withdrawal election, CMS will deny all of the parent organization's applications.

20. Limit Stand-Alone Prescription Drug Plan Sponsors To Offering No More Than Two Plans per PDP Region (§ 423.265)

Under our authority at section 1860D–11(d) of the Act, we conduct negotiations with stand-alone prescription drug plan (PDP) sponsors concerning our approval of the bids they submit each year. As the Part D program has evolved, we have adopted regulations designed to authorize us to use that negotiating authority to ensure that the number of plans offered in a given PDP region reflects a balance between sponsors' interest in providing options tailored to meet the needs of a diverse Medicare population and the need to avoid creating undue confusion for beneficiaries as they consider various plan offerings. We continue here our process of updating our bid review authority to reflect the evolution of the Part D program by proposing to limit to two the number of plans stand-alone PDP sponsors may offer in each PDP region.

PDP sponsors must offer throughout a PDP region at least one basic plan that consists of: Standard deductible and cost sharing amounts (or actuarial equivalents); an initial coverage limit based on a set dollar amount of claims paid on the beneficiary's behalf during the plan year; a coverage gap during which a beneficiary pays more of his drug costs; and finally, catastrophic coverage that applies once a beneficiary's out-of-pocket expenditures for the year have reached a certain threshold. Prior to our adopting regulations requiring meaningful differences among each PDP sponsor's plan offerings in a PDP Region, CMS guidance allowed sponsors that offered a basic plan to offer in the same region additional basic plans, as long as they were actuarially equivalent to the basic plan structure described in the statute. These sponsors could also offer enhanced alternative plans which provide additional value to beneficiaries in the form of reduced deductibles, reduced copays, coverage of some or all drugs while the beneficiary is in the gap portion of the benefit, or some combination of those features.

As we have gained experience with the Part D program, we have made consistent efforts to ensure that the number and type of plan benefit packages PDP sponsors may market to beneficiaries are no more numerous than necessary to afford beneficiaries choices from among meaningfully different plan options. In addition to setting differential out-of-pocket-cost (OOPC) targets each year to ensure contracting organizations submit bids that clearly offer differences in value to beneficiaries, we issued regulations in 2010 that established at § 423.265(b)(2) our authority to deny bids that are not meaningfully different from other bids submitted by the same organization in the same service area. Our application of this authority has effectively eliminated PDP sponsors' ability to offer more than one basic plan in a PDP region since all basic plan benefit packages must be actuarially equivalent to the standard benefit structure discussed in the statute. That regulation also effectively limited to two the

number of enhanced alternative plans that we can approve for a single PDP sponsor in a PDP region. As part of the same 2010 rulemaking, we also established at § 423.507(b)(1)(iii) our authority to terminate existing plan benefit packages that do not attract a number of enrollees sufficient to demonstrate their value in the Medicare marketplace. Both of these authorities have been effective tools in encouraging the development of a variety of plan offerings that provide meaningful choices to beneficiaries without creating undue confusion for beneficiaries.

We believe that the progressive closure of the coverage gap provided for in the Affordable Care Act affords us another opportunity to promote even greater clarity in the set of stand-alone PDP plan options from which beneficiaries may make an election. Under the statute, beginning in 2011, applicable beneficiaries enjoy discounts of 50 percent off negotiated prices on brand name drugs when purchased while in the coverage gap portion of the benefit. Also, since 2011, the required coverage in the gap has increased and will continue to do so gradually until 2020, when the combination of required coverage and manufacturer discounts covers 75 percent on average for both brand-name and generic drugs. This ''closing'' of the coverage gap effectively will leave the beneficiary with only a 25 percent cost share on average across the entire benefit (or its actuarial equivalent) before the catastrophic threshold.

Our experience in applying the meaningful differences standard indicates that, as the Part D coverage gap is closed, it will become increasingly difficult for a PDP sponsor to qualify to offer more than two plans in the same service area and still meet the meaningful differences test. Since we began applying the meaningful differences standard to our bid reviews, we have generally approved two types of enhanced alternative plans. The first type of plan offers beneficiaries, in exchange for a higher premium than that charged for basic plan coverage, significant reductions in the cost sharing and deductible amounts associated with the basic Part D benefit. The second type offers even greater cost sharing and deductible reductions as well as coverage for many drugs in the gap. Since coverage of Part D drugs in the gap is the distinguishing feature between the two types of enhanced alternative plans currently available, closing the coverage gap also means that sponsors can no longer rely on it to establish that their proposed second enhanced alternative plan is meaningfully different than their first.

Our enrollment data indicate that beneficiaries are already making plan choices based on their recognition of the shrinking significance of the coverage gap and with it, the value of PDP sponsors' second enhanced plans. Since the start of the coverage gap discount program in 2011, enrollment levels in the second enhanced alternative plans offered by PDP sponsors that offer two enhanced alternative plans have declined from approximately 12 percent of those sponsors' total enhanced alternative plan enrollment in 2010 to between 7 percent and 8 percent in the 2011, 2012, and 2013 benefit years. This finding suggests that the proportion of beneficiaries for whom the additional supplemental coverage offered by these plans is worth the supplemental premium continues to decline, and we expect this trend to continue as the coverage gap closes.

Despite these developments, many sponsors continue to submit three bids per region each year, at least in part, we believe (based on conversations with various stakeholders), to ensure that they are not perceived as a weaker participant in the Part D market by offering a smaller set of plans than their PDP competitors. CMS believes that plan sponsors and beneficiaries, as well as the taxpayers, would be better served by a more streamlined bid submission process that limited sponsors to submitting two PDP bids (one basic and one enhanced) per PDP region each year. This limitation would provide a consistent bidding framework for all sponsors, allowing them to focus on quality, rather than quantity, in development of their bids. It would also reduce some of the sponsors' administrative costs associated with preparing, marketing, and administering a third benefit package. It may also help ensure that beneficiaries can choose from a less confusing number of plans that represent the best value each sponsor can offer.

For CY 2013, there are seven parent organizations that offer two enhanced plans (that is, three plans total, one basic and two enhanced alternative) within a given PDP region. This amounts to 264 enhanced alternative plans in total (two for each affected PDP region) among the seven parent organizations. The application of this proposed regulation, if finalized, would result in the elimination of 132 enhanced alternative plans, representing 13 percent of the total number of stand-alone PDP plans, and 25 percent of all enhanced alternative plans in 2013. If implemented today, these proposed reductions would affect a combined 522,742 beneficiaries, approximately 2 percent of the overall stand-alone PDP enrollment of 22,529,197 (based on April 2013 enrollment data). We expect that most sponsors would attempt to consolidate their current beneficiaries in one of their two remaining plan options, so we believe adoption of this proposal would result in minimal disruption to beneficiaries currently enrolled in a sponsor's second enhanced plan.

While the incremental closure of the coverage gap continues until 2020, CMS believes that the observed enrollment trends in these plans demonstrate the reduction in beneficiaries' coverage gap costs that has occurred already has moved the stand alone PDP plan market in a way that warrants the imposition of the two plan limit as soon as possible. The list of plan options today is cluttered with those that the record shows appeal to only approximately 2 percent of the overall stand alone PDP-plan-enrolled beneficiaries of which 522,742 are enrolled in second enhanced plans). In addition, in many cases one of the two enhanced plans offers the minimum level of supplemental coverage required to meet our meaningful differences tests. We refer to these as ''low value enhanced plans'' to distinguish them from second enhanced plans with substantially more supplemental coverage. In some cases, the premiums for these low value enhanced plans have been less than the premiums for the sponsors' basic plans due to favorable risk selection. This occurs because many of the beneficiaries with more serious health issues and higher utilization of prescription drugs are in the low-income subsidy (LIS) eligible population which will not receive the full LIS subsidies in plans with supplemental coverage. For this reason we neither auto-assign the LIS eligible population into such plans, nor will this population generally voluntarily enroll in such plans. Thus, continuing to permit multiple enhanced plans, particularly low value enhanced plans, facilitates risk segmentation. This can increase costs for the Part D program and the taxpayers overall. During the most recently completed CY 2014 bid review cycle, we continued to encounter bids submitted by sponsors for low value enhanced plans with premiums lower than the premiums for their basic plans. We believe it is urgent that we adopt this proposed policy as soon as possible so that we can bring an end to this bidding practice. However, because such a change would entail substantial changes to bidding processes for both

Part D sponsors and CMS that could not realistically be undertaken until the proposal was final, we propose to adopt this policy for the 2016 Part D contracting cycle. We believe that beneficiaries and the Part D program would be better served by sponsors that are focused on developing plans with broad beneficiary appeal rather than those intended to enable the sponsor to either pursue a diminishing niche in the Part D market or segment favorable risk into low value enhanced plans. We solicit comments on whether there is any real need for more than two standalone plan options per PDP sponsor.

Therefore, we propose to amend the Part D regulations at § 423.265 to add a revised subsection (b)(3), which states that ''CMS shall not accept more than one basic bid and one enhanced bid for a coverage year from a single PDP sponsor in the same PDP region.'' We would adopt this provision under our authority at section 1860D–11(d) of the Act. In instances where a parent organization owns a controlling interest in more than one subsidiary that operates as a PDP sponsor in a single PDP region, we would apply subsection (b)(3) at the parent organization level. That is, in the same way that we currently apply the meaningful differences test, a parent organization with two subsidiary PDP sponsors could offer no more than one plan under each sponsors' contract. We anticipate that the need to use this interpretation will be infrequent as existing multi-contract arrangements are phased out through plan consolidation and the creation of new ones would be prohibited by the implementation of the provision described elsewhere in this proposal (if finalized) authorizing CMS to deny applications from organizations owned by a parent that already has a subsidiary operating a PDP sponsor contract in the same PDP region.

In a proposed rule we published in October 10, 2010, announcing our intent to codify the Affordable Care Act provision in the Part D regulations, we solicited comments on whether we should use the Affordable Care Act authority to impose limits on the number of plans in a PDP region. In the preamble to the final rule that followed on April 15, 2011, we noted that among the comments we received were those stating that we should not consider imposing limits on plan offerings until the impact of previous statutory and regulatory changes governing our bid review process could be fully evaluated. At the time we declined to codify such limits. Now, we believe that the record in support of the adoption of a two-plan limit has had time to fully develop, including, as discussed previously, the dwindling popularity of the second enhanced option, the shrinking differences between the first and second enhanced options, and the role the second enhanced option plays in enabling risk segmentation, and therefore we make the proposal described here and seek comment from the public.

In addition to proposing to limit PDP sponsors to submitting one basic and one enhanced bid per coverage year, we are also considering several regulatory proposals for limiting the type of coverage offered in those two plans to reduce or eliminate the risk segmentation described previously. We believe that risk segmentation is not consistent with the Congressional design for the Part D program, or with the policy goal of obtaining the best value for the government and the taxpayer. We believe the Congress intended sponsors to compete in the Part D market by offering their best bids for basic plans, in order to attract the greatest enrollment through the lowest premiums, and that this competition would maintain downward pressure on Part D bids and government subsidies. We do not believe that the Congress intended that instead sponsors would offer their best bids for a segment of the market that represents individuals who are low utilizers of prescription drugs due to better health and who can afford unsubsidized supplemental premiums due to better socioeconomic status. When many healthy individuals are not included in the basic plans, the cost of the basic plans is increased, and this in turn increases low-income premium subsidies. Therefore, permitting risk segmentation does not generate the best value for the Part D program as a whole. To reduce or eliminate risk segmentation, we are considering three options. We solicit comments on our conclusions with respect to risk segmentation and on the effectiveness of the following options.

The first option we are considering would be to continue to allow separate basic and enhanced plans, but require that enhanced plans offer a substantial minimum level of supplemental coverage defined in regulation. This would differ from current practice in that we currently set meaningful differences requirements by observing the distribution of benefits submitted independently by sponsors and using statistical techniques to identify outlier thresholds. The problem with the current approach is that, when all or most sponsors reduce their supplemental coverage over time—the trend that we have observed—the outlier thresholds will decline as well. When this occurs the supplemental coverage will again tend to converge on the value of basic coverage. Instead, for instance, we could require that the enhanced plan offering had to cover a minimum of 50 percent (or another higher percentage) of the remaining actuarial value of the Part D benefit not included in the standard benefit for any coverage year. The additional coverage would be in the form of reduced deductibles and cost sharing and the inclusion of excluded drugs, consistent with the statutory definition of supplemental coverage. We solicit comment on whether such an approach would be sufficient to accomplish our goal of eliminating risk segmentation.

In the second option we are considering, instead of setting minimum supplemental coverage requirements for a sponsor's enhanced plan offering, we would propose to use the authority provided in section 3209 of the Affordable Care Act which amends section 1860D–11(d)(3) of the Act to deny any enhanced plan bid with a premium equal to or lower than the sponsor's basic plan premium. Alternatively we might require the enhanced premium to be no less than a specified multiple of the basic premium, such as 115 percent or another multiple. Again, the additional coverage in the enhanced plan would be in the form of reduced deductibles and cost sharing and the inclusion of excluded drugs. We solicit comments on this approach, and on the appropriate multiple of the basic premium necessary to eliminate risk segmentation. We also solicit comment on whether there is a possibility that this approach might effectively eliminate the offering of supplemental coverage if favorable risk selection were to continue and the actuarial value of such coverage could not generate sufficient premiums to pass these sorts of tests.

The third option we are considering would be to reinterpret the provisions of section 1860D–11(b) and (c) of the Act governing the submission of bids that include supplemental benefits. We would propose that enhanced alternative coverage would be redefined to consist of supplemental coverage added to the sponsor's one basic benefits offering (for an additional premium). This could be thought of as basic benefits plus a supplemental benefit rider. This would mean that all Part D enrollees in a sponsor's Part D plans would be enrolled in the sponsor's one basic plan with the same formulary and pharmacy network, and some portion of those enrollees would

also elect the optional supplemental coverage in the form of the second plan that would be the combination of the basic plan and the supplemental benefits. Thus, the risk of the basic benefits would be estimated at the PDP Regional level and the risk of the supplemental benefits would be estimated in accordance with that of the projected enrollees in the second plans. This means that the supplemental benefits would have to constitute actual enhancements to the basic benefit and that the notion of actuarial equivalence would not apply to the combination of the basic and supplemental benefits. This change would bring standalone PDP coverage more in line with both commercial coverage designs and with the offering of Part C optional supplemental benefits. We believe this option would eliminate the possibility of risk segmentation because every enrollee participating in a sponsor's Part D line of business would be enrolled in the one basic plan and beneficiaries that elect supplemental benefits will be charged the additional premium for the extra coverage. The sponsor's Part D offerings would consist of two plan benefit packages, one comprised solely of basic coverage and the other (if offered) consisting of the combination of the basic coverage with the supplemental coverage.

We solicit comments on this approach and on our belief that this approach would be the most effective strategy for eliminating risk segmentation and providing the best value for the government and the taxpayer.

21. Efficient Dispensing in Long-Term Care Facilities and Other Changes (§ 423.154)

We are proposing changes to the rule requiring efficient dispensing to Medicare Part D enrollees in Long Term Care (LTC) facilities. For background, section 3310 of the Affordable Care Act amended the Act to add a new paragraph (3) to section 1860D–4(c) of the Act. Section 1860D–4(c)(3) of the Act provides that the Secretary shall require Medicare Part D sponsors of prescription drug plans to utilize specific, uniform dispensing techniques, such as weekly, daily, or automated dose dispensing, when dispensing covered Part D drugs to enrollees who reside in a LTC facility in order to reduce waste associated with 30-day fills. The section states that the techniques shall be determined by the Secretary in consultation with relevant stakeholders.

After extensive consultation with stakeholders, in the April 15, 2011 **Federal Register** entitled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes'' (''April 15, 2011 Final Rule''), we published a final rule at 76 FR 21432 which governs the appropriate dispensing of prescription drugs in LTC facilities under Part D plans. Pursuant to this regulation, Part D sponsors generally must require their network pharmacies to dispense certain solid oral brand covered Part D drugs in quantities of 14 days or less, unless an exemption applies. The regulation is found at § 423.154.

We are proposing the following specific changes to the LTC short cycle dispensing requirements:

- Add a prohibition on payment arrangements that penalize the offering and adoption of more efficient LTC dispensing techniques.
- Eliminate language that has been misinterpreted as requiring the proration of dispensing fees.
- Incorporate an additional waiver for LTC pharmacies using restock and reuse dispensing methodologies under certain conditions.
- Make a technical change to eliminate the requirement that Part D sponsors report on the nature and quantity of unused brand and generic drugs.

After providing a summary of the current LTC short cycle dispensing rule, we will address each proposed change in more detail.

Section 423.154 requires that all Part D sponsors require all pharmacies servicing LTC facilities to dispense solid oral doses of covered Part D brand name drugs to enrollees in such facilities in no greater than 14 day increments at a time. Part D sponsors must also require such pharmacies to permit the use of uniform dispensing techniques, as defined by the LTC facility. The regulation refers to definitions in existence at the time of its promulgation. Brand name and generic drugs are defined in § 423.4, and the definition specifically refers to a brand name drug as being one approved under an NDA.

In order to quantify waste more precisely, the regulation requires Part D sponsors to collect and report information to CMS on the dispensing methodology used for each dispensing event, and on the nature and quantity of unused brand and generic drugs dispensed to enrollees in LTC facilities. Reporting on unused drugs is waived for Part D sponsors when both brand and generic drugs are dispensed in no greater than 7-day increments.

The regulation excludes: (1) Solid oral doses of antibiotics; and (2) solid oral doses that are dispensed in their original container as indicated in the Food and Drug Administration (FDA) prescribing information or that are customarily dispensed in their original packaging to assist patients with compliance. Thus, the regulation does not apply to drugs that are not typically dispensed in greater than 14-day supplies (for example: inhalers, eye drops, ear drops, steroid dose packs).

LTC facilities are defined in § 423.100, which definition excludes assisted living facilities. Intermediate care facilities for the mentally retarded and institutes for mental disease are specifically waived from the requirement in the regulation, as are I/T/U pharmacies, due to specific problems with delivery and dispensing to closed (often locked) facilities.

With respect to copayments, the regulation states that regardless of the number of incremental dispensing events, the total cost sharing must be no greater than the total cost sharing that would be imposed if the regulation did not apply.

When permitted under applicable law, the regulation requires Part D sponsors to include provisions that address the disposal of drugs that have been dispensed to an enrollee in an LTC but not used, and then returned to the pharmacy, in the terms and conditions that they must offer to pharmacies, including whether return for credit and reuse is authorized.

a. Prohibition on Payment Arrangements That Penalize the Offering and Adoption of More Efficient LTC Dispensing Techniques (§ 423.154)

Our first proposed change is to add a clause to § 423.154 prohibiting payment arrangements that penalize the offering and adoption of more efficient LTC dispensing techniques. It is our understanding that for 2013, some of the largest PBMs have prorated LTC pharmacy dispensing fees for medications subject to the LTC short cycle requirements. Under such dispensing fee payment arrangements, if a medication is discontinued before a month's supply has been dispensed, a pharmacy that dispenses the maximum amount of medication at a time permitted under § 423.154 collects more in dispensing fees than a pharmacy that utilizes dispensing techniques that result in less than maximum quantities being dispensed at a time.

We provide the following example of two pharmacies—one more efficient at dispensing than the other— to illustrate our concern: A $4.00 dispensing fee for

a 30-days' supply is prorated, and a medication is discontinued after 21 days. The first pharmacy dispenses 14-days' supply at a time and receives approximately $3.73 in total dispensing fees for a 28-days' supply, which results in 7 days' worth of medication waste. The second pharmacy dispenses 3-days' supply at a time and receives approximately $2.80 in dispensing fees for a 21-days' supply in total, which results no medication waste.

We believe this example is contrary to the Congress' intent in enacting section 3310 of the Affordable Care Act. In this example, the second pharmacy's more efficient dispensing techniques save facility, sponsor, and Part D program costs associated with reducing the amount of medication waste, but the pharmacy itself receives less in dispensing fees than it would if it had dispensed in 14-day increments. This approach creates a perverse incentive for LTC pharmacies to adopt less efficient dispensing techniques, if available. Rational self- interest on the part of any LTC pharmacy with the flexibility to dispense greater quantities encourages wasteful dispensing and additional costs to the Part D program, in direct opposition to the intent of the law.

During the extensive industry consultation conducted prior to the rulemaking required to implement section 3310 of the Affordable Care Act, CMS was repeatedly informed by multiple stakeholders that dispensing costs did not vary on the basis of the quantity of medication dispensed, but only by the number of dispensing events and the type of dispensing technique utilized. Therefore, there is no justifiable rationale for proration, since the cost of dispensing is not directly related to the quantity dispensed. In order to align incentives, we encouraged Part D sponsors to do quite the opposite to prorating dispensing fees, and offer differentially higher dispensing fees to promote the adoption of the most efficient dispensing methodologies.

Starting in the fall of 2012, we have received numerous complaints about proration of dispensing fees from multiple LTC pharmacy organizations, LTC pharmacies, and LTC facilities that represent, offer, or have contracted to utilize more efficient dispensing methodologies. Some smaller LTC pharmacies, which rely upon their relative greater efficiency in reducing waste from unused drugs for competitive advantage, have complained that they were unable to negotiate appropriate terms through their intermediary group purchasing and contracting organizations and could not negotiate directly with Part D sponsors. Small LTC pharmacies have also reported that they risked losing their LTC facility contracts to larger LTC pharmacies if they did not accept the payment terms that, in effect, penalize their efficiency. These pharmacies have indicated that prorated dispensing fees are not mutually agreeable terms, and that this fee structure threatens the survivability of the most efficient dispensing techniques.

It is unclear why Part D sponsors and their agents would choose to reimburse LTC pharmacies in a manner that does not promote more efficient dispensing methodologies. One possibility is that the smaller LTC pharmacies lack the leverage to negotiate differential fees due to the market power of the largest LTC pharmacies, which control more than 60 percent of the market. This would be the case only if the largest LTC pharmacies had the market power over the largest PBMs to not only set their own dispensing fees, but also the dispensing fees of their competitors. However, we have not heard any evidence or testimony that would support that conclusion.

Another possibility is that Part D sponsors are not motivated to promote efficiencies in long-term care prescription drug utilization. This could be the case because their liability for these costs is substantially less than that of the federal government. Since most LTC residents are LIS-entitled individuals or likely to incur costs subject to catastrophic coverage, or both, sponsor liabilities are actually minimized when the LTC resident beneficiary reaches the TrOOP threshold as quickly as possible. Thus, sponsors' interests may actually be aligned with those LTC pharmacies with the least efficient dispensing methodologies, since both parties' interests may be served by higher costs.

A final possibility is that Part D sponsors believe the § 423.154 and/or the upcoming daily cost-sharing rate requirement at § 423.153(b)(4)(i) (which becomes effective January 1, 2014) mandate the proration of dispensing fees when less than 30 days is dispensed. This is not accurate, and we discuss this misunderstanding both further in this section and in the section entitled, ''Application and Calculation of Daily Cost-Sharing Rates'' of this proposed rule.

Given the clear intent of the Affordable Care Act to reduce wasteful dispensing in the LTC setting, CMS is proposing to prohibit payment arrangements that penalize the offering and adoption of more efficient LTC dispensing techniques. This would be accomplished by adding a new clause (f) in § 423.154 that would state that a Part D sponsor must not, or must require its intermediary contracting organizations not to, penalize long-term care facilities' choice of more efficient uniform dispensing techniques by prorating dispensing fees based on days' supply or quantity dispensed. This clause would also state that a sponsor or its intermediary contracting organizations must ensure that any difference in payment methodology among LTC pharmacies incentivizes more efficient dispensing techniques.

b. Misinterpretation of Language as Requiring the Proration of Dispensing Fees (§ 423.154)

Our second proposed change to § 423.154 is to eliminate paragraph (e), which we believe has caused confusion. Section 423.154(e) currently states: ''Regardless of the number of incremental dispensing events, the total cost sharing for a Part D drug to which the dispensing requirements, under this paragraph (a) apply must be no greater than the total cost sharing that would be imposed for such Part D drug if the requirements under paragraph (a) of this section did not apply.'' The purpose of this language was to ensure that sponsors did not assess multiple monthly copayments for each incremental dispensing event. We believe misinterpretation of paragraph (e) may have prompted some sponsors to prorate dispensing fees, even though the regulation does not address dispensing fees.

Moreover, effective January 1, 2014, the daily cost-sharing rate requirement will apply whenever a prescription is dispensed by a network pharmacy for less than a 30 days' supply, unless the drug is excepted pursuant to § 423.153(b)(4)(i), regardless of the setting in which the applicable drugs are dispensed. In other words, the daily cost-sharing rate requirement will apply to brand drugs dispensed in LTC facilities to the extent they must be dispensed in supplies less than 30 days pursuant to § 423.154, and to generic drugs, to the extent a sponsor voluntarily dispenses generic drugs in LTC facilities in supplies less than 30 days. Consequently, the requirement of § 423.153(b)(4)(i) will make § 423.154(e) unnecessary, and we believe retaining both provisions could cause further confusion. (Note that we propose some technical changes to the daily cost-sharing rate requirement in the section, entitled ''Application and Calculation of Daily Cost-Sharing Rates'' of this proposed rule) For these reasons, we propose to delete § 423.154(e).

c. Additional Waiver for LTC Pharmacies Using Restock and Reuse Dispensing Methodologies Under Certain Conditions (§ 423.154)

Our third proposed change to § 423.154 is to waive the short-cycle dispensing requirements for LTC pharmacies meeting certain conditions. Currently, § 423.154(c) waives the requirements for pharmacies when they dispense brand name Part D drugs to enrollees residing in intermediate care facilities for the mentally retarded and institutes for mental disease, as well as for I/T/U pharmacies. We have learned that some institutional pharmacies maintain custody of medications within the LTC facilities through operating a closed pharmacy within the facility, and as a result can ensure sufficient quality control over these medications to return all unused medications to stock for reuse that are eligible for return and reuse under applicable law. This has led us to believe there is another category of pharmacies, such as some on site pharmacies in veterans' homes, for which a waiver from the LTC short cycle dispensing requirement may be appropriate, if they meet certain conditions that demonstrate that applying the 14-day dispensing requirements in these instances would not serve to reduce waste.

We are proposing to waive the requirements of § 423.154(a) for an LTC pharmacy that exclusively uses the dispensing technique of returning all unused medications to stock that can be restocked under applicable law for reuse and rebating full credit for the ingredient costs of the unused medication to the PDP sponsor. The proposed waiver would also require that for those drugs that cannot be returned for full credit and reuse under applicable law, such as controlled substances, the pharmacy uses a dispensing methodology that results in the delivery of no more than 14 days of a drug at a time. We would propose that the waiver would apply on a uniform basis to all similarly situated LTC pharmacies, but not to a pharmacy organization that is contracted to use this technique at some, but not all, of its pharmacies. Rather, the waiver would only apply to the qualifying pharmacies themselves. We would not require the pharmacy to credit back any amount of the dispensing fee when drugs are returned for reuse, since the level of effort for the pharmacies would not be expected to be decreased in any way. If anything, the level of effort would be increased to implement the appropriate internal controls for inspection and return to inventory of the unused medication.

We solicit comments on whether there are any variations in operations that may exist among LTC pharmacies that we need to consider in determining whether to implement this waiver. We also solicit comments on how such pharmacies could be identified in industry standard transaction coding, as well as in network contracting and auditing protocols. We believe that such pharmacies would be expected to have documentation of relevant protocols approved by Pharmacy and Therapeutics (P&T) committees of the LTC facility, as well as records supporting the returns to inventory that could be compared with billing credits. We solicit comments on this understanding as well.

We further solicit comments on our proposal that to qualify for the waiver, a pharmacy would have to dispense any drugs that cannot be restocked under applicable law, such as controlled substances, in no greater than 14-day supply increments. Our rationale in proposing this condition to the waiver is that we do not want the waiver to inadvertently result in large quantities of medications being dispensed to Part D enrollees serviced by the pharmacies that would qualify for the waiver because they cannot be restocked under applicable law. Therefore, we are proposing that such drugs should still effectively be subject to the short-cycle dispensing requirement. In this regard we wish to understand the extent of waste in pharmacies that would qualify for the waiver we are proposing, if we did not impose the requirement that drugs that cannot be restocked would be subject to a dispensing increment of 14-day supply or less if they cannot be restocked under applicable law. If persuaded that the waste would be insignificant, we may be persuaded to eliminate this condition to the waiver.

We acknowledge that in the aforementioned April 15, 2011 Final Rule, we responded to some comments requesting that we exempt from the short-cycle dispensing requirement those pharmacies that already utilize low waste practices or ''return for credit and reuse.'' In response, we stated that although ''return for credit and reuse'' could reduce unused drugs in LTC facilities, there are limitations to this approach, especially because not all states allow ''return for credit and reuse,'' and reuse of controlled substances is limited by the Drug Enforcement Administration. Because of these limitations, we stated that we believe financial waste is more effectively reduced by preventing the accumulation of unused drugs in the first place, rather than addressing handling of unused drugs after they have accumulated in the LTC facilities.

This proposal means that we have reconsidered our decision not to waive the short-cycle dispensing requirement for LTC pharmacies that use ''return for credit and reuse'' dispensing practices, because we did not fully consider such a waiver previously in the context of comments received about return and reuse being a universal alternative approach to short-cycle dispensing. In addition, we continue to receive persuasive arguments that such pharmacies should be exempt; for example, from some veterans' homes with on-site pharmacies. However, as we explained previously, we are still concerned about waste associated with drugs that are not permitted to be returned for reuse and credit under applicable law in such LTC pharmacies in considering this additional exemption, and for this reason have specifically solicited comments on the extent of waste in such pharmacies that would qualify for the proposed additional waiver.

d. Technical Change To Eliminate the Requirement That PDP Sponsors Report on the Nature and Quantity of Unused Brand and Generic Drugs (§ 423.154)

Finally, we are proposing to make a technical change to § 423.154(a)(2), which requires Part D sponsors to collect and report information, in a form and manner specified by CMS, on the dispensing methodology used for each dispensing event described by paragraph (a)(1) of this section, as well as on the nature and quantity of unused brand and generic drugs dispensed by the pharmacy to enrollees residing in a LTC facility. This latter reporting requirement is waived for sponsors for drugs dispensed by pharmacies that dispense both brand and generic drugs in no greater than 7-day increments.

In a memorandum titled, ''Modifications to the Drug Data Processing System (DDPS) in Relation to Appropriate Dispensing of Prescription Drugs in Long Term Care Facilities,'' issued by CMS on August 3, 2012, we explained that we planned to use the PDE data in conjunction with other CMS data (such as MDS) to determine the extent to which 14 day or less dispensing to enrollees in LTC facilities reduces the amount of unused drugs in LTC. We did this to lessen the burden on sponsors that would be created by a separate reporting requirement. Therefore, it is no longer necessary to waive the reporting requirement for any Part D sponsor, because Part D sponsors

comply with the requirement (in the form and manner we specified in the previously-referenced memorandum) via PDE submission. Thus, we are deleting the first sentence of § 423.154(a)(2) to eliminate any confusion that there is a separate reporting requirement. 22. Applicable Cost-Sharing for Transition Supplies. Transition Process Under Part D § 423.120(b)(3)

We established transition requirements under § 423.120(b)(3) for Part D sponsors to address the needs of new Part D plan enrollees who are transitioning from other prescription drug coverage (Part D or otherwise), and whose current drug therapies may not be included on their Part D plan's formulary (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under the plan's utilization management requirements). While § 423.120(b)(3)(iii) specifies that PDP plans must provide a temporary fill when an enrollee requests a fill of a non-formulary drug during the transition time period (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules), it does not currently specify the cost sharing that should apply to such fills. Current guidance (at § 30.4.9 of Chapter 6 of the Medicare Drug Benefit Manual, found at *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf*) states that a Part D sponsor may charge cost sharing for a temporary supply of drugs provided under its transition process. Further, cost sharing for transition supplies for low-income subsidy (LIS) eligible beneficiaries cannot exceed the statutory maximum copayment amounts. However, for non-LIS enrollees, we stated that a sponsor must charge cost sharing based on one of its approved drug cost sharing tiers (if the sponsor has a tiered benefit design), and this cost sharing must be consistent with cost sharing that the sponsor would charge for non-formulary drugs approved under a coverage exception. This guidance created a great deal of confusion on the part of sponsors and beneficiaries. Charging the same cost sharing for non-formulary drugs, which are approved during transition, as for formulary drugs subject to utilization management edits (such as prior authorization or step therapy), that are overridden during transition while waiting for the utilization management requirement to be satisfied, is likely to be inconsistent with a tiered benefit design. It is possible that beneficiaries may pay more during transition than for his or her drug's normal designated formulary tier. Conversely, it is also possible that the beneficiary may pay more once the utilization management edit had been satisfied than he or she did under the transition fill. The following examples will illustrate these scenarios, assuming that the beneficiary is eligible for a transition fill, using the following hypothetical formulary structure:

TABLE 3—HYPOTHETICAL FORMULARY STRUCTURE

| Tier | Tier description | Beneficiary cost sharing |
|---|---|---|
| 1 | Generics | $5 copay/30-days' supply. |
| 2 | Preferred Brands | $10 copay/30-days' supply. |
| 3* | Non-preferred Brands | $15 copay/30-days' supply. |
| 4 | Specialty drugs (includes both generics & brands) | 25% coinsurance/30-days' supply. |

* Tier 3 is the designated formulary exception tier.

Each of the following examples shows the fill date, quantity filled, the associated days' supply, whether a transition fill was applied, and as a result, if either formulary tiering or exception tiering was applied to the enrollee's cost sharing. In all cases, if a transition fill was applied, the enrollee's cost sharing used exception tiering.

TABLE 4—EXAMPLE 1—THE BENEFICIARY'S DRUG IS ON TIER 2 WITH A PRIOR AUTHORIZATION REQUIREMENT

| Date of fill | Quantity | Days' supply | Transition fill applied | Cost share used formulary tiering (FT) or exception tiering (ET) |
|---|---|---|---|---|
| 1/1/13 | 30 | 30 | Y | $15.00—ET. |
| The beneficiary obtains the PA, and the drug is no long considered a transition fill. | | | | |
| 2/1/13 | 30 | 30 | N | $10.00—FT. |

In this example, if the exception tier is used on the transition fill, the beneficiary's cost sharing amount is reduced once he or she obtains the prior authorization approval. However, if the drug's designated formulary cost sharing amount had been used, the cost sharing amount would have stayed the same, and would have been the same cost as the cost sharing amount shown on the formulary.

TABLE 5—EXAMPLE 2—THE BENEFICIARY'S DRUG IS ON TIER 4 WITH A PRIOR AUTHORIZATION

| Date of fill | Quantity | Days' supply | Transition fill applied | Cost share used formulary tiering (FT) or exception tiering (ET) |
|---|---|---|---|---|
| 1/1/13 | 30 | 30 | Y | $15.00—ET. |
| The beneficiary obtains the PA, and the drug is no long considered a transition fill. | | | | |
| 2/1/13 | 30 | 30 | N | 25%—FT. |

In this example, if the exception tier is used on the transition fill, the beneficiary's cost sharing amount will increase once he or she obtains the PA since the designated formulary tier has a higher cost sharing amount than the exception tier. If instead, the drug's designated formulary cost sharing had been used, the cost sharing amount would have remained the same for both fills. This scenario is particularly confusing for enrollees, since they pay more after receiving the required approval than they did under transition.

TABLE 6—EXAMPLE 3—THE BENEFICIARY'S DRUG IS NOT ON FORMULARY WITH A FORMULARY EXCEPTION

| Date of fill | Quantity | Days' supply | Transition fill applied | Cost share used formulary tiering (FT) or exception tiering (ET) |
|---|---|---|---|---|
| 1/1/13 | 30 | 30 | Y | $15.00—ET. |
| The beneficiary obtains the FE, and the sponsor continues to treat the drug as non-formulary. | | | | |
| 2/1/13 | 30 | 30 | N | $15.00—ET. |

Plan sponsors are currently required to designate to which tier a non-formulary drug will apply once a formulary exception is granted. Sponsors can continue to treat the drug as non-formulary and continue the exception for the remainder of the coverage year, in which case, cost sharing at the exception tiering continues.

We believe that more consistent treatment of formulary and non-formulary drugs, respectively, will simplify the benefit and reduce sponsor and beneficiary confusion. Consequently, we propose to add a paragraph at § 423.120(b)(3)(vi) clarifying that when providing a transition supply, the cost sharing is determined as follows: A Part D sponsor must charge cost sharing for a temporary supply of drugs provided under its transition process such that the following conditions are met:

- For low-income subsidy (LIS) enrollees, a sponsor must not charge higher cost sharing for transition supplies than the statutory maximum copayment amounts.
- For non-LIS enrollees, a sponsor must charge—
  - ++ The same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non-formulary drugs approved through a formulary exception in accordance with § 423.578(b); and
  - ++ The same cost sharing for formulary drugs subject to utilization management edits provided during the transition that would apply once the utilization management criteria are met.

23. Medicare Coverage Gap Discount Program and Employer Group Waiver Plans (§ 423.2325)

Section 3301 of the Affordable Care Act, codified in section 1860D–43 and 1860D–14A of the Act, established the Medicare Coverage Gap Discount Program (Discount Program), beginning in 2011. Under the Discount Program, manufacturer discounts are made available to applicable Medicare beneficiaries receiving applicable covered Part D drugs while in the coverage gap. Section 1860D–14A(c)(1)(A)(ii) of the Act requires the manufacturer discount to be provided to beneficiaries at the point-of-sale.

Employer Group Waiver Plans (EGWPs) are customized employer-offered plans available exclusively to employer/union health plan Part D eligible retirees and/or their Part D eligible spouse and dependents. Section 423.458(c)(4) requires sponsors offering EGWPs to comply with all Part D requirements unless those requirements have been specifically waived or modified by us using our authority under section 1860D–22(b) of the Act. We do not regulate any supplemental benefits that EGWPs offer outside of Part D prescription coverage. Employers/Unions offering EGWPs must ensure that any supplemental benefits comply with any applicable requirements for issuance under state insurance laws and/or ERISA rules (see January 25, 2013 Insurance Bulletin from the Center for Consumer Information and Insurance Oversight: *http://www.cms.gov/cciio/resources/Regulations-and-Guidance/index.html#Health* Market Reforms).

EGWP benefits are generally structured to provide additional coverage so that their enrollees do not actually experience a coverage gap. However, the Affordable Care Act did not exclude EGWP enrollees from the Discount Program. Therefore, in order for an applicable drug to be covered by EGWPs, it must be covered under a manufacturer agreement, and the manufacturer must pay applicable discounts as invoiced. Beginning in 2014, all EGWP benefits beyond the parameters of the defined standard benefit will be treated as non-Medicare Other Health Insurance (OHI) that wraps around Part D. We specifically excluded supplemental coverage offered through EGWPs from the definition of Part D supplemental benefits in § 423.100. We made this a requirement with respect to EGWPs so that the discount amount could be consistently and reliably determined. This was necessary to ensure that we can determine that the discount is always calculated accurately since we do not collect information on all EGWP retiree benefit arrangements to determine actual supplemental benefits. Not only would collecting such information be impractical, but we also believe instituting a requirement to collect the specific information on all such benefits would be so burdensome as to hinder the design of, the offering of, or the enrollment in employer plans. Consequently, the discount calculation will be based upon the Part D Defined Standard benefit for all EGWPs beginning in 2014. While we believed that our justification for excluding any supplemental benefits offered through EGWPs from Part D benefits clearly indicated that the basic EGWP Part D benefits would be limited to Defined Standard benefit because that is the only way we can determine that the discount is calculated accurately, we are taking the opportunity now to propose this specific requirement in § 423.2325(h)(1) to remove any ambiguity.

Treating EGWP supplemental benefits as OHI and always calculating the manufacturer discount based on the Defined Standard benefit means that discount payments likely will increase for some applicable beneficiaries enrolled in EGWPs over the amounts that would have been calculated when these benefits were considered as supplemental benefits for purposes of the coverage gap discount program. As noted previously, EGWPs' benefits are generally structured to provide additional coverage so that their

enrollees do not actually experience a coverage gap. Now that the Part D portion of the EGWP plan is based on the Defined Standard benefit, the coverage gap discount pays before the EGWP supplemental benefits (that is, OHI) are applied. Consequently, Part D sponsors that administer EGWP plans will receive discount amounts that may not offset the enrollees' final out-of-pocket cost-sharing, as the discounts do in individual market Part D plans when it is applied after Part D supplemental benefits. Nevertheless, we think it is important that these discounts that are calculated and paid prior to the application of OHI are apparent to the employer and union group clients of our Part D sponsors. This transparency ensures that the parties who are ultimately responsible for the both the EGWPs' plan design and the financial integrity of the plans are aware of the discount amounts received. We anticipate that the employer and union group administrators will take the additional funds into account when negotiating and designing retiree prescription drug benefits. We believe that his will ultimately benefit the beneficiaries enrolled in these plans.

We considered several approaches for ensuring that all manufacturer payments accrue to the benefit of beneficiaries enrolled in EGWPs. The most obvious approach would have been to require EGWPs to use manufacturer payments to reduce beneficiary premiums or cost-sharing in the non-Part D portion of benefit. While this approach would have offered the most straightforward benefit for beneficiaries, it has several serious obstacles. First, we do not believe that we have the authority to require any specific application of the coverage gap discount payments to OHI benefits that are by definition non-Medicare private market benefits outside our regulatory purview. In addition, since we do not collect premium or benefit information for EGWPs, monitoring compliance with such requirements would not be feasible. Moreover, establishing an affirmative requirement would necessitate establishing standards for how the discount amounts should be applied to the retiree benefits. We frankly do not have the depth of knowledge of private and public sector retiree benefits necessary to establish such standards. We can envision that more prescriptive requirements about how discount amounts can be used might interfere with critical utilization management and cost control features of these benefits, conflict with employment or bargaining agreements particulars, or have other unintended consequences. We also considered not taking any action since anecdotal evidence suggests that some employer groups are already using the discounts to reduce premiums, and we have no reason to believe that this is not generally the case. However, we cannot be sure that all employer groups are aware of how Discount Program payments are calculated or the value of the payments attributable to their enrollees. After consideration, we believe that our best course is to pursue full disclosure and transparency so that employer groups have the information they need to take full advantage of these discounts to strengthen and safeguard their enrollees' retiree benefits. Through the proposed regulation we are seeking to ensure that employer groups are fully aware of Discount Program payments attributable to their enrollees so that the payments can be accurately anticipated and incorporated into EGWP benefit designs. Equipped with projected and actual payments received, each employer group can design a benefit package that best meets the needs of its retirees.

To ensure that Discount Program payments are communicated to employer groups in a uniform fashion, we propose to codify notification requirements by amending § 423.2325 to add a new paragraph (h) requiring Part D sponsors of EGWPs to disclose to each employer group the projected and actual manufacturer discount payments under the Discount Program attributable to the employer group's enrollees. We further propose that such disclosures happen at least annually or upon request. Part D sponsors must also be prepared to demonstrate to CMS that such notifications have been made upon request.

24. Interpreting the Non-Interference Provision (§ 423.10)

Since the MMA created the Part D benefit in 2003, we have never formally interpreted section 1860D–11(i) of the Act, which is known as the noninterference provision. In practice we have generally invoked the spirit of this provision in declining to intervene in negotiations or disputes involving payment-related contractual terms between participants in the drug distribution channel. However, it is increasingly clear from the many questions that continue to arise when working with stakeholders on matters ranging from lawsuits to policy clearance to complaint resolution that the agency and all Part D stakeholders would benefit from a clear, formal interpretation of these limits on our authority. Some stakeholders appear to believe the prohibition on interference in negotiations extends far beyond the boundaries that we consider relevant, while others insist our authority extends into arbitrating matters that seem to us to clearly fall within the intended prohibition. Therefore, we are proposing an interpretation through rulemaking in order to clarify and codify the extent of these limits on our authority.

The noninterference provision at section 1860D–11(i) of the Act provides that, ''In order to promote competition under this part and in carrying out this part, the Secretary: (1) May not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs.'' In beginning with the words ''In order to promote competition under this part and in carrying out this part . . .'' we believe that the Congress intended that the activities addressed in the rest of the provision should take place through private market competition. We interpret this to mean two separate but related goals. The first goal is that the Secretary through CMS should promote private market competition in the selection of Part D drugs for Part D sponsor formularies. The second goal is that CMS should not create any policies that would be expected to interfere with competitive market negotiations leading to the selection of drug products to be covered under Part D formularies. Therefore, in light of these two goals we believe there is both a duty to act—to promote competition in the private market for Part D drugs—and a duty to refrain from acting—to avoid intervention in private market negotiations that take place in the context of that competitive market.

Economic theory on competitive markets suggests that the duty to ensure a competitive market means that within the limits of our authority we should seek to encourage certain features of the market that promote more perfect competition. This would include such goals as decreasing the transaction cost of acquiring information on products offered in the market, increasing the transparency of prices, ensuring a large number of buyers and sellers, and minimizing barriers to entry to the extent possible while still ensuring quality. We have pursued these types of goals since the start of Part D program implementation through such efforts as the Medicare Prescription Drug Plan Finder, the development of the Medicare star ratings, our extensive efforts to provide technical assistance to

new and existing sponsors, and our meaningful differences policies that improve the comparability of Part D formularies and benefit packages. We will continue to seek opportunities to improve competition. As an initial matter, in light of our interpretation of the general purpose of section 1860D–11(i) of the Act, we propose a general rule at § 423.10(a) that CMS promotes fair private market competition in the market for Part D drugs.

There is also a duty to avoid intervention in private market negotiations that take place in the context of that competitive market. We believe the intent of 1860D–11(i) is to ensure that we do not create any policies or become a participant in any discussions that could be expected to interfere with negotiations leading to the selection of drug products to be covered under Part D formularies. By this we mean selection by Part D sponsors (or other intermediary contracting organizations) of specific manufacturers' products for inclusion on formularies, formulary tier placement, and negotiations of acquisition costs, rebates, and any other price concessions. We believe this interpretation is consistent with a textual reading of 1860D–11(i) and with how private market transactions determine which prescription drug products are covered under Part D plans.

Private market competition for prescription drugs is a complex process that has been described in detail elsewhere, such as in the 2007 CBO report entitled ''Prescription Drug Pricing in the Private Sector'' at: *http://www.cbo.gov/publication/18275*. This process involves specific transactions between manufacturers and distribution channel participants (generally wholesale distributors and dispensing pharmacies) that are different than the transactions that take place between manufacturers and ultimate purchasers (primarily health plans or self-insured employers and/or their intermediate contracting organizations, such as pharmacy benefit managers (PBMs)). Pharmacies will stock most commonly used brand medications but will selectively stock generic products to leverage volume in return for the best prices from competing generic manufacturers. Thus, generally speaking, the price negotiations between manufacturers and pharmacies differentially determine which generic products are stocked and dispensed by pharmacies. These price negotiations are generally based on discounts off manufacturer list prices. Health plans and PBMs, in contrast, will base decisions on which multiple-source or therapeutically equivalent brand drug products will be covered under a plan in part on the evaluation of the relative cost effectiveness of the competing drug products. This will be determined by comparing both the list prices of the drug products and the level of rebates negotiated between the sponsor and the manufacturers of the brand products. Thus the price negotiations between manufacturers and health plans determine which brand products are placed on the plan's formulary and available to enrollees. These additional price negotiations are generally around the level of rebates for both formulary and tier placement. These distinct sets of negotiations in the private market between manufacturers and pharmacies on the one hand, and between manufacturers and plan sponsors on the other hand, support our textual reading of section 1860D–11(i)(1) of the Act to prohibit CMS involvement in negotiations between manufacturers and pharmacies, and between manufacturers and plan sponsors. There are also separate price negotiations between plan sponsors (or their intermediary contracting organizations) and pharmacies around the negotiated prices required for network participation. However, as will be discussed in more detail in this section, since the statute establishes numerous requirements that CMS must regulate concerning access to network pharmacies and negotiated prices, we believe that a CMS role in negotiations between plan sponsors and pharmacies is not prohibited under section 1860D–11(i)(1) of the Act.

We note that in The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Agreement (Conference Agreement), in addition to the statutory language, MMA drafters included the following sentence: ''Conferees expect PDPs to negotiate price concessions directly with manufacturers.'' We believe this statement supports our understanding that the primary focus of section 1860D–11(i) of the Act is on the negotiations between plan sponsors (or their intermediary contracting organizations) and manufacturers for rebates and other price concessions that ultimately determine which multiple source products will be placed on a sponsor's formulary. The outcome of these negotiations also determine tier placement, or the level of cost sharing that will be charged for the drug, whether the drug will be subject to certain utilization management controls, and may even influence the list prices that manufacturers submit to the commercial databases and that form the basis of most purchasing contracts in the drug distribution channel.

Section 1860D–11(i)(1) of the Act states that we ''may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors''. We believe that the term ''interference'' in this context should be interpreted as prohibiting our involvement in discussions between manufacturers and their distribution channel customers (such as wholesalers and pharmacies) or the ultimate purchasers of prescription drugs (such as plan sponsors and PBMs) leading to signed contracts. We believe that the negotiations addressed by the first clause should be read to apply to discussions manufacturers have with their customers because, as discussed previously, this textual reading comports with the nature of the transactions that occur in the private market that determine which drug products will be covered under Part D plans. We also believe section 1860D–11(i)(1) of the Act should be interpreted as prohibiting our involvement in arbitration of agreements already executed between any of these parties. It would not make sense to prohibit CMS involvement in discussions leading up to an executed agreement only to allow involvement in arbitrating the terms of the agreement afterwards. Thus we interpret the word ''negotiations'' to mean not only the initial discussions leading to executed agreements, but also any subsequent discussions between the parties as to what those agreements require. We are periodically asked to become involved in both initial negotiations and in disputes and renegotiations by parties trying to get CMS to weigh in on one side or another on the premise that failure to do so will lead to access issues for Medicare beneficiaries. We also periodically are asked to address terms and conditions of executed agreements that one of the parties believes is unfair. We believe that our involvement in these sorts of issues is precisely what the statute prohibits in section 1860D–11(i)(1) of the Act—our weighing in on a contract negotiation or dispute could influence the outcome. In other words, government involvement could affect market forces around prescription drugs in ways that change the value that would otherwise be assigned to these products in a competitive market. We believe we should not pick winners and losers in formulary selection negotiations, and that the remedies for disputes should be determined in accordance with the terms of the

contracts or in the courts having jurisdiction over the contracts.

Therefore we interpret the prohibition in section 1860D–11(i)(1) of the Act on interference in negotiations to pertain to discussions either between prescription drug manufacturers and pharmacies, or between prescription drug manufacturers and Part D sponsors (or their intermediary contracting organizations, hereafter included by association whenever we refer to Part D sponsors). Our interpretation is based on the sequential phrasing of the clause ''negotiations between drug manufacturers and pharmacies and PDP sponsors.'' Because in general these negotiations are not among all three parties at once, and because manufacturers separately contract with pharmacies for the purchase of inventory and with sponsors for formulary placement, we believe the quoted phrase can be interpreted as recognizing these distinct types of negotiations. Under such a reading, the prohibition on interference in negotiations, as described in section 1860D–11(i)(1) of the Act, would not pertain to negotiations between Part D sponsors and pharmacies.

This does not mean, however, that we would be free to interfere in sponsor-pharmacy negotiations. Indeed, we believe section 1860D–11(i)(2) of the Act sets forth specific limits on our ability to involve ourselves in Part D sponsors' arrangements with their network pharmacies, as discussed in more detail later in this section. However, we believe that our proposed interpretation of section 1860D–11(i)(1) of the Act as not applying to the sponsor-pharmacy negotiations is supported by the provision's context. There are numerous statutory provisions that require us to directly intervene in the contractual relationship between Part D sponsors and network pharmacies, and these provisions clearly signal that the Congress expected CMS involvement in at least some of these negotiations. The Congress has provided many contractual requirements for CMS to enforce between sponsors and pharmacies; just the drug-cost-related of these include: Interpretation of what ''access to negotiated prices'' means, any-willing-pharmacy standard terms and conditions, prohibition on any requirement to accept insurance risk, prompt payment, and payment standard update requirements. So it is clear that Part D sponsors and pharmacies do not have sole discretion to interpret these specific matters. We would be obligated to intervene in disputes over whether proposed or finalized contractual arrangements violated our rules in any area where our oversight is directed under the statute. Therefore, it is clear that such involvement could not be what the Congress intended to prohibit. Moreover, we observe a growth in related-party relationships between Part D sponsors and network pharmacies, where the distinction between the sponsor and the pharmacy is increasingly unclear, and there is no reason to believe that the Congress intended that we are prohibited from oversight of the sponsor's dealings with itself. In addition, we believe the goals of the non-interference provision generally support CMS avoidance of being an arbiter of private disputes. Thus, we would also decline to intervene in contractual disputes between sponsors and network pharmacies except in matters implicating CMS requirements, because to do so might distort private market outcomes in unpredictable ways. Therefore, we propose at § 423.10(b) that CMS may not be a party to discussions between prescription drug manufacturers and pharmacies, or between drug manufacturers and Part D sponsors, and may not arbitrate the meaning of or compliance with the terms and conditions of agreements reached between these parties, except as necessary to enforce CMS requirements applicable to those agreements. Thus, we could only be involved in such discussions in order to explain CMS requirements and to ensure compliance with Part D rules and regulations. We also add that nothing in this prohibition limits our authority to require documentation of and access to all such agreements, or to require the inclusion of terms and conditions in agreements when necessary to implement requirements under the Act.

The first part of the section 1860D–11(i)(2) of the Act states that CMS ''may not require a particular formulary''. The noninterference clause must be read in context of the other provisions that give CMS authority with respect to formularies, so we propose to interpret the term ''particular formulary'' to mean the selection of specific manufacturer licensed drug products to be on formulary, or on any particular tier of a formulary, assuming the product meets the definition of a Part D drug. We interpret the first part of section 1860D–11(i)(2) of the Act to prohibit us from developing formulary guidelines that prefer one manufacturer's product over another's in Part D formularies, leading to more limited formularies such as provided by the Department of Defense and the Veteran's Administration. The most efficient formularies will make formulary selections and then exclude all or most competing multi-source and therapeutically equivalent brand products in order to concentrate volume and maximize rebates. Given the size of the Part D market, if CMS were able to similarly limit access to Part D formularies to certain products, this would bestow significant competitive advantage on the manufacturers of selected products and significant competitive disadvantage on manufacturers of competing products. Such limits would be expected to fundamentally alter supply and demand in the marketplace. This prohibited sort of selection would be distinguished from CMS formulary requirements that may require particular types of drug entities to be on all formularies, or on preferred tiers, in order to provide non-discriminatory access to drugs necessary to treat conditions in all Medicare beneficiaries, or to address drug classes of clinical concern (see section III.A.14 of this proposed rule). Therefore, we propose a provision prohibiting establishment of formulary drug product selection at § 423.10(c) that specifies that CMS does not determine the specific drug products to be included on Part D sponsor formularies or any tier placement of such products, except as required to comply with § 423.120(b)(1)(v) or § 423.272(b)(2).

The second part of section 1860D–11(i)(2) of the Act states that CMS ''may not institute a price structure for the reimbursement of covered Part D drugs''. Again, the noninterference clause must be read in context of the other provisions that give CMS responsibilities in a number of areas that pertain to pricing, so we interpret the phrase ''price structure'' to refer to establishing either absolute or relative indices of price for Part D drugs. Specifically, we believe the intent of this provision is to prohibit two types of intervention by CMS. The first prohibited activity is that CMS may not require Part D drug acquisition costs or sales prices to be a function of (be defined relative to) any particular published or unpublished pricing standard, either existing or future. Thus, we could not require that Part D prices be based on, or be any particular mathematical function (such as a percentage or multiple) of established pricing standards such as Average Wholesale Price, Wholesale Average Cost, Average Manufacturer Price, Average Sales Price, Federal Supply Schedule, 340b pricing, etc. The second prohibited activity is that CMS cannot require price concessions (from any

standard or basis) to be at any specific (absolute) dollar amount or equal to a level specified in other legislative requirements for other federal programs. Thus, we could not, for example, set minimum or maximum dollar prices for a drug product or require that Part D prices be offered at acquisition cost, or at the 'best price' applicable under the Medicaid program. However, since the statute requires us to regulate many aspects of how drug costs are made available and displayed to beneficiaries and treated in Part D bidding and payment processes, it is clear that we have an important role to play in establishing rules for consistent treatment of drug costs in the program. Consequently, we may establish definitions of what constitutes a pricing standard, a price concession, a cost, etc. We may also establish rules concerning how drug costs are treated under Part D, including, but not limited to, how such amounts are disclosed in the marketplace, projected in Part D bids, made available to beneficiaries at point of sale, reported in Explanation of Benefits (EOBs), submitted to CMS, and treated in CMS payments to Part D sponsors. Therefore, we propose a provision prohibiting establishment of drug price reimbursement methodologies at § 423.10(d) that specifies that CMS does not establish drug product pricing standards or the dollar level of price concessions at any stage in the drug distribution channel for Part D drugs. Nothing in this prohibition limits our authority to require full disclosure or uniform treatment and reporting of drug costs and prices.

25. Pharmacy Price Concessions in Negotiated Prices (§ 423.100)

We have learned that some Part D sponsors have been reporting costs and price concessions to CMS in different ways. This reporting differential matters because this variation in the treatment of costs and price concessions affects beneficiary cost sharing, CMS payments to plans, federal reinsurance and low-income cost-sharing (LICS) subsidies, and manufacturer coverage gap discount payments. Differential treatment of costs would also be expected to affect plan bids. We do not collect sufficient detail in price concession data reported to CMS to quantify this impact, but this conclusion follows from the admitted reporting of some pharmacy price concessions in the annual aggregate price concession reporting (that is, the DIR reporting) during the coverage year payment reconciliation process, rather than as part of the negotiated price. (This issue, and its financial effect, have been discussed in the Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (2014 Call Letter), [at *http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2014.pdf*] and will be discussed in more detail in the discussion which follows.) If the projected net costs a sponsor is liable for in its bid are understated because the sponsor has been reporting certain types of price concessions as direct or indirect remuneration (DIR) rather than as price concessions that affect the negotiated price, it follows that the sponsor may be able to offer a lower bid than its competitors and may achieve a competitive advantage stemming not from greater efficiency, but rather from a technical difference in how costs are reported to CMS. When this happens, such differential reporting could result in bids that are no longer comparable, and in premiums that are no longer valid indicators of relative plan efficiency. We are therefore proposing changes to rectify this concern.

The MMA established Part D as a voluntary, private-market-based program that would rely on private plans to provide coverage and to bear some of the financial risk for drug costs. These private plans would determine premiums through a bid process and would compete with other plans based on premiums and negotiated prices. [The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Agreement (Conference Agreement), page 4] Premiums are set through a statutory formula that ensures that premium levels are commensurate with bid levels. Therefore, all other things being equal, the lowest premium for a given level of benefits should signal the most efficient plan. Premiums are established through a prospective bidding process in which costs are projected and evaluated in accordance with actuarial guidelines set by the CMS Office of the Actuary.

Negotiated prices are the payment amounts pharmacies receive from plans for covered Part D drugs dispensed to plan enrollees. CMS payments to plans are based on the reporting of negotiated prices (through PDE reporting) that are actually paid and are then offset by any other price concessions (submitted in aggregate through the separate annual DIR reporting process). CMS establishes rules for cost and price concession reporting through both PDE and DIR guidance and other payment reconciliation rules, and has regulated the definition of negotiated price and how it is to be treated in Part D benefit administration and in payment reconciliation. Since 2010, the regulatory definition has been: ''Negotiated prices means prices for covered Part D drugs that: (1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug; (2) Are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and DIR that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and (3) Include any dispensing fees.''

We intended clause 2 to primarily refer to price concessions from parties other than pharmacies, since these would be price concessions that were not based on the sale of the drug by the pharmacy and calculated when the claim adjudicated and, in fact, could not be calculated until a later date. In particular, we expected these other non-claim-based price concessions to be in the form of rebates offered by prescription drug manufacturers. Since prescription drugs are dispensed by pharmacies and purchased through transactions between Part D sponsors (or their intermediary contracting organizations) and pharmacies, manufacturers are never in a position to apply price concessions to negotiated prices at point of sale. We now understand that clause 2 is ambiguous and permits sponsors and their intermediaries to elect to take some price concessions from pharmacies in forms other than the negotiated price and report them outside the PDE. When this occurs, the increased negotiated prices generally shift costs to the beneficiary, the government and taxpayer, and when applicable to certain brand name drugs, to prescription drug manufacturers. (The mechanism of this sort of cost shift was discussed at length in the analogous context of lock-in pricing in our 2008 proposed rule entitled ''Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs'' which as published on May 16, 2008 in the **Federal Register**,—FR 28563 through 28566.)

In addition, when price concessions from pharmacies are reflected in forms other than the negotiated price, the degree of price concession that the pharmacy has agreed to is no longer reflected in the negotiated prices available at point of sale or reflected on the Medicare Prescription Drug Plan

Finder (Plan Finder) tool. Thus, the true price of drugs at individual pharmacies is no longer transparent to the market. Consequently, consumers cannot efficiently minimize both their costs (cost sharing) and costs to the taxpayers by seeking and finding the lowest-cost drug/pharmacy combination. Moreover, as the coverage gap closes, there are fewer and fewer beneficiaries who are exposed to the full cost of drug products, either at the point of sale or as reflected in Plan Finder estimates. When this occurs, the basis of competition shifts from prices to cost sharing, and the pricing signals available to the market can be distorted when lower cost sharing is not aligned with lower prices. Thus, we believe the exclusion of pharmacy price concessions from the negotiated price thwarts the very price competition that the Congress intended when it said that private plans would compete with other plans on both premiums and negotiated prices.

We are aware that certain pharmacy price concessions are being excluded from the determination of the negotiated price because they are being characterized as ''network access fees'', ''administrative fees,'' ''technical fees'' or ''service fees'' that are frequently imposed through PBM-issued manuals rather than explicit contractual terms. Pharmacies and pharmacy organizations report that they do not receive anything of value for those fees other than the ability to participate in the Part D network. The itemized types of services for which their payments are offset reportedly include things such as transaction fees for submission of claims, help desk support, information technology and telecommunication systems connectivity, electronic funds transfers, and other expenses associated with credentialing, maintaining, and auditing pharmacy networks. These fees take the form of deductions from payments to pharmacies for drugs dispensed, but in our view clearly represent charges that offset sponsor/PBM operating costs. We believe that if the sponsor or its intermediary contracting organization wishes to be compensated for these services and have those costs treated as administrative costs, such costs should be accounted for in the administrative costs of the Part D bid. If instead these costs are deducted from payments made to pharmacies for purchases of Part D drugs, such costs are price concessions and must be treated as such in Part D cost reporting. This is the case regardless of whether the deductions are calculated on a per-claim basis or not. In our view, the decision on how such network management costs are funded between the PBM and the sponsor is not governed by our rules, but our rules do require that price concessions be fully disclosed and net against drug costs in reconciliation.

We have also heard from pharmacies that some sponsors apply dispensing fees to claims when they are adjudicated at point of sale, but require that these fees later be rebated back to the sponsor and deducted from payment remittances. Such practices again misstate the negotiated price. Our proposal would require that dispensing fees could only be applied at point of sale if they are received and retained by the pharmacy in the negotiated price.

In comments on our related discussion in the 2014 Call Letter, one commenter argued that these other amounts charged to pharmacies are actually valid administrative costs. In contrast, all other sponsors and PBMs that commented on that section acknowledged these amounts to be price concessions. More significantly, all pharmacies and pharmacy organizations we have heard from assert that these are price concessions. When reported as DIR, these price concessions have the effect of offsetting price concessions disproportionally against just the costs the plan is most liable for, as discussed in the 2014 Call Letter. If not reported at all, these amounts would result in another form of so-called PBM spread in which inflated prices contain a portion of costs that should be treated as administrative costs. That is, even if these costs did represent services rendered by the PBM or other intermediary organization for the sponsor, then these costs would be administrative service costs, not drug costs, and should be treated as such. Failure to report these costs as administrative costs in the bid would allow a sponsor to misrepresent the actual costs necessary to provide the benefit and thus to submit a lower bid than necessary to reflect its revenue requirements (as required at section 1860D–11(e)(2)(C) of the Act and at § 423.272(b)(1)) relative to another sponsor that accurately reported administrative costs consistent with CMS instructions. Therefore, we agree with the pharmacy position that an amount deducted from the negotiated price otherwise payable to the pharmacy for these sorts of administrative fees is a price concession that should be reflected in the negotiated price. Consequently, we believe that the best interpretation of statutory intent is that all pharmacy price concessions must be reflected in the negotiated price. This would preclude the differential reporting that is taking place today, and put all plans on a level playing field in reporting drug costs and price concessions from network pharmacies. Consistent and transparent pricing would also promote increased price competition among network pharmacies and will align beneficiary and taxpayer interests in minimizing costs. Therefore, we do not believe that other pricing arrangements that cannot be calculated at the point of sale, such as risk sharing or conditional payments based on volume, are compatible with the price competition envisioned under the statute. Such arrangements will tend to overstate negotiated prices at point of sale, and require the subsequent adjustments through DIR reporting that may increase beneficiary and government costs if specified targets are met. We believe that the advantages of any such incentive arrangement could be achieved without the cost shifting by adjusting future negotiated prices. For instance, if specified volume targets were met in one quarter, rather than retroactively adjusting that quarter's prices down through DIR reporting, the negotiated prices for the next quarter could be reduced, and so on. Therefore we propose to reinterpret section 1860D–2(d)(1)(B) of the Act such that negotiated prices are the amounts that a network pharmacy receives in total for covered Part D drugs, and that these prices must reflect all price concessions from network pharmacies. Therefore, any other negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and (DIR) referenced in the statute would be those price concessions offered by sources other than network pharmacies (or their intermediary contracting organizations). In practice, this means prescription drug manufacturers.

Some stakeholders have recommended that certain incentive payments to pharmacies, such as generic dispensing incentive fees, should not be included in negotiated prices. If these payments are included, they explain, the negotiated prices appear higher at the more efficient pharmacy as the result of the additional incentive payment. This higher price then proportionally increases costs borne by beneficiaries, the government, and manufacturers. These incentives really represent amounts that the sponsor is willing to bear in order to encourage the most efficient drug choices, which will drive down total costs overall, and thus the sponsor is willing to bear a disproportionate share of such expense. We agree with this

argument and we believe that this sort of arrangement would not conflict with our proposed requirement that all price concessions be reflected in the negotiated price since such additional payments are the opposite of price concessions. Instead such incentive fees represent contingent price increases that cannot be predicted in advance, and cannot therefore be programmed to be applied at point of sale or reflected in the price posted on Plan Finder. We believe it would be appropriate to treat this particular sort of price increase differently than price decreases because including such amounts in the negotiated price (incentive fee component) at point of sale could disguise the relative competitiveness of the underlying pharmacy prices. Incentive fees also primarily benefit the plan sponsor who benefits from the lower costs associated with the incentivized behavior, rather than the beneficiary. Therefore, in this case, we agree that it would be more appropriate for such incentive payments to be excluded from the negotiated price, and reported later in reconciliation as negative DIR. When reported as negative DIR, these amounts disproportionately affect (increase) the amounts the sponsor is liable for in risk sharing, which is appropriate given the intent of the incentives to promote least-cost drug product selection at point of sale. Least-cost drug product selection will directly reduce the sponsor's allowable risk corridor costs, so any incentive paid to encourage this behavior would be expected to be more than offset by the ingredient costs savings achieved through avoidance of higher-cost drug selection. This is so because, as we learned from numerous commenters to the 2014 draft Call Letter, the incentive payments are generally in the range of a dollar or two and the difference between preferred and non-preferred drug products is generally much greater.

Therefore, we propose to revise the definition of negotiated prices at § 423.100 to require that all price concessions from pharmacies are reflected in these prices. Specifically we propose to redefine negotiated prices to mean prices for covered Part D drugs that: (1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug; and (2) are inclusive of all price concessions and any other fees charged to network pharmacies; and (3) include any dispensing fees; but (4) exclude additional contingent amounts, such as incentive fees, only if these amounts increase prices and cannot be predicted in advance; and (5) may not be rebated back to the Part D sponsor (or other intermediary contracting organization) in whole or in part.

26. Payments to PDP Plan Sponsors for Qualified Prescription Drug Coverage (§ 423.308)) and Payments to Sponsors of Retiree Prescription Drug Plans (§ 423.882)

We propose to revise the definition of the term actually paid at both § 423.308 for the Part D program and § 423.882 for the Retiree Drug Subsidy program in order to reconcile this definition with the changes proposed to the definition of negotiated prices in this regulation. Since our proposal would require that all price concessions from network pharmacies must be reflected in the negotiated price, it would no longer be correct to include pharmacies in the list of sources from which price concessions could be received without qualification. Therefore, we propose to revise the definition of actually paid at § 423.308 to include references to incentive payments, and to clarify that DIR may include additional payments to pharmacies, such as for incentive payments, but may not include any other price concessions from pharmacies as these must be in the form of the negotiated price as proposed in § 423.100. We similarly propose to change the reference to ''from any source'' in the definition of actually paid at § 423.882 to ''from any manufacturer or similar entity'' to align these definitions.

We also propose to remove any reference to coupons in the list of price concession types. The definition of ''actually paid'' relates to costs incurred by Part D sponsors, and coupons would not affect those costs. Similarly, we are considering whether any or all of the surrounding terms ''cash discounts, free goods contingent on a purchase agreement, up-front payments . . . goods in kind, free or reduced-price services, [or] grants'' in both of those paragraphs would affect costs paid by Part D sponsors. We solicit comments on this question. We similarly propose to remove any reference to coupons in the definition of actually paid at § 423.882 to align these definitions. We also solicit comments on whether the surrounding terms ''cash discounts, free goods contingent on a purchase agreement, up-front payments . . . goods in kind, free or reduced-price services, [or] grants'' in both of those paragraphs would affect costs paid by sponsors of qualified retiree prescription drug plans.

Our reason for striking any such term is that we are not aware of any form of coupons (or the other forms of remuneration listed previously) that would affect the amount a Part D sponsor pays to the pharmacy on a claim. Therefore, the terms should be deleted to accurately reflect the types of price concessions a Part D sponsor might receive that would affect its financial obligation to pharmacies. Moreover, we do not want to signal any ambivalence with regard to the permissibility of copayment coupons to eliminate or reduce the cost-sharing obligations of Part D beneficiaries. The anti-kickback statute prohibits the knowing and willful payment of remuneration, directly or indirectly, in cash or in kind, to induce the recipient to purchase any item for which payment may be made in whole or in part under a federal health care program. (42 U.S.C. 1320a–7b(b)(2)). The statute also prohibits the knowing and willful receipt of remuneration in return for such a purchase. (42 U.S.C. 1320a–7b(b)(1)). Because copayment coupons are provided to consumers for the purpose of inducing them to purchase specific prescription drugs, knowing and willful use of such coupons to reduce the cost-sharing obligations of federal health care program beneficiaries is prohibited by the anti-kickback statute. Pharmaceutical manufacturers are aware of this prohibition and typically include language on copayment coupons stating that persons whose prescriptions are paid for by federal programs are not eligible to use them.

27. Preferred Cost Sharing (§ 423.100 and § 423.120)

In our original rule implementing the Part D Program, we codified an interpretation of section 1860D–4(b)(1)(B) of the Act at § 423.120(a)(9) that permitted Part D sponsors to offer lower cost sharing at a subset of network pharmacies, dubbed ''preferred pharmacies,'' than at other in-network pharmacies. This lower cost sharing was subject to certain conditions that seemed straightforward to us at the time, but which have proven to need clarification. We have recently discussed this concern in the Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (2014 Call Letter) on pages 175–176 [at *http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2014.pdf*]

Section 1860D–4(b)(1)(B) of the Act contemplates the possibility of sponsors offering lower cost sharing at some network pharmacies than is offered in conjunction with the any willing pharmacy terms and conditions mandated in the immediately preceding paragraph (A). However, a plan's ability to reduce cost sharing is contingent upon one condition: ''In no case shall such a reduction result in an increase in payments made by the Secretary under section 1860D–15 of the Act to a plan.'' In our original proposed rule entitled ''Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule,'' published on August 3, 2004 in the **Federal Register**, 69 FR 46658 through 46659, we did not offer an interpretation of this language but implied that any assessment of whether the condition was met would be a matter of actuarial equivalence analysis. We proposed to codify the requirements in regulation with the following two conditions: ''. . . the plan must still meet the requirements under § 423.104(e)(2) and (5); and [a]ny cost sharing reduction must not increase CMS payments under § 423.329.'' In the final regulation entitled ''Medicare Program; Medicare Prescription Drug Benefit; Final Rule'', published on January 28, 2005 in the **Federal Register**, 70 FR 4247 through 4255, we reiterated the language from the aforementioned proposed rule (69 FR 46658). ''However, we note that while these within-network distinctions are allowed, the statute also requires that such tiered cost-sharing arrangements in no way increase our payments to Part D sponsors. Therefore, tiered cost-sharing arrangements based on within-network distinctions could be included in Part D plans' benefits subject to the same actuarial tests that apply to formulary-based tiered cost-sharing structures. Thus, a reduction in cost sharing for preferred pharmacies in a Part D plan network could be offered through higher cost sharing for non-preferred pharmacies (or as alternative prescription drug coverage).'' (70 FR 4254, January 28, 2005). This statement was immediately followed by an expression of our intent to ensure that such network benefit designs were non-discriminatory: ''We recognize the possibility that Part D plans could effectively limit access in portions of their service areas by using the flexibility provided in § 423.120(a)(9) of our final rule to create a within-network subset of preferred pharmacies. In other words, in designing its network, a Part D 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 Part D plan. We emphasize that such a network design has the potential to substantially discourage enrollment by certain Part D enrollees, and that we have the authority under section 1860D–11(e)(2)(D) of the Act to disallow benefit designs that are discriminatory.''

And in fact, once sponsors began to submit preferred cost sharing benefit designs, we imposed limits on non-preferred cost sharing in such plans (through plan benefit package (PBP) bid review) to ensure that non-preferred cost sharing in these designs did not represent a cost sharing outlier in comparison to Part D plans without preferred cost sharing. If we were to allow cost sharing in pharmacies not offering preferred cost sharing to rise above this outlier level, beneficiaries with significant utilization due to severe or chronic illness would clearly see that such plans were disadvantageous, and would avoid them. Thus, we would find any such designs to be discriminatory and would not approve the plan benefit package. However, what we failed to sufficiently explain in 2005 was that if cost sharing cannot rise beyond a certain level, then in return for lower cost sharing, preferred networks must reduce drug costs paid by the plan in order to prevent an increase in CMS payments to the plan. In part this omission may have been because we presumed that Part D sponsors would motivate enrollees to go to a subset of pharmacies through lower cost sharing only if those pharmacies offered significantly lower negotiated prices, and thus would provide a competitive advantage for the sponsor in lowering costs. As the concerns expressed in the 2014 Call Letter indicate, this does not seem to have been the case for some sponsors. However, if drug costs (negotiated prices) are not lower in return for lower cost sharing, and the lower cost sharing cannot be completely offset by higher cost sharing on other beneficiaries due to our cost-sharing-outlier limits, then the amount that must be subsidized by the government and the taxpayer will increase.

As noted in the Call Letter, we conducted an analysis of 2011 Part D drug costs in standalone PDPs with preferred networks, and compared these to costs in their non-preferred networks, as well as to costs in other PDPs without preferred networks. (The April 2013 analysis by CMS, ''Negotiated Pricing between Preferred and Non-Preferred Pharmacy Networks'', is posted at: *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/PharmacyNetwork.pdf*). We expected to find that costs were consistently lower, although we had no preconceived estimate of how much lower. Instead we found that aggregate unit costs weighted by utilization (for the top 25 brand and top 25 generic drugs) were slightly higher in a few preferred networks than in non-preferred networks in some plans. The majority of sponsors offering preferred networks did not have these higher costs, although the range of cost savings in their preferred networks ranged from a high of 24.2 percent to as little as 0.1 percent when measured in this particular way. Surprisingly, the most significant driver of excess costs in the outlier sponsor preferred networks appeared in mail-order claims. In these cases the retail pharmacies in the non-preferred network were actually offering savings through discounted generics at prices below those offered by pharmacies with preferred cost sharing. This is a primary reason we have proposed to interpret the any willing pharmacy requirements (see section III.A.29 of this proposed rule) to require plan sponsors to offer preferred cost sharing for any pharmacy that can offer sufficient discounts to qualify. Even assuming that preferred pharmacies were to offer lower negotiated prices than those available in the rest of the network, failure to allow access to any pharmacy willing to meet the pricing terms necessary to be included in the preferred network could mean that fewer beneficiaries would have convenient access to both lower cost sharing and lower negotiated prices than would otherwise obtain. We seek to not only ensure that preferred cost sharing is aligned with lower drug costs, but also to maximize the number of beneficiaries who can take advantage of such savings. We note that most PBMs own their mail order pharmacies, and we believe their business strategy is to move as much volume as possible to these related-party pharmacies to maximize profits from their ability to buy low and sell as high as the market will bear.

Our findings—that a few sponsors have actually offered little or no savings in aggregate in their preferred pharmacy pricing, particularly in mail-order claims for generic drugs—are troubling. Instead of passing through lower costs available through economies of scale or steeper discounts, a few sponsors are actually charging the program higher negotiated prices. When these higher

prices are combined with significantly lower cost sharing offered in preferred pharmacy pricing, such pricing increases the proportion of costs borne by the plan and the government. All other things being equal, this increases payments to plans in violation of section 1860D–4(b)(1)(B) of the Act. Moreover, the lower cost sharing provides a defective price signal that distorts market behavior. As the coverage gap closes, there are fewer and fewer beneficiaries who are exposed to the full cost of drug products, either at the point of sale or in Medicare Plan Finder estimates. When sponsors compete on cost sharing unrelated to the underlying negotiated prices of drugs, beneficiaries may make choices that are rational and aligned with plan interests, but not in the best interests of the Medicare program and the taxpayer. In these cases, the lower cost sharing does not motivate enrollees to select pharmacies with lower prices and thus make more efficient choices in the market, but rather, motivates enrollees to do the opposite. This results in higher costs to the Part D program overall.

Therefore, we propose to clarify that preferred cost sharing should signal consistently lower costs. When lower cost sharing correctly signals the best prices on drugs, then choosing pharmacies on the basis of that lower cost sharing lowers not only beneficiary out-of-pocket costs, but also Part D plan and other government subsidy costs. Lower plan and government subsidies translate into lower CMS payments to plans, consistent with the statutory requirements at section 1860D–4(b)(1)(B) of the Act. Therefore, we propose to revise § 423.120(a)(9) to state: ''Preferred cost-sharing in network pharmacies. A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a subset of network pharmacies, as long as such preferred cost sharing is offered in accordance with the requirements of § 423.120(a)(8) and for Part D drugs with consistently lower negotiated prices than the same drugs when obtained in the rest of the pharmacy network.'' We propose that by 'consistently lower' we mean that sponsors must offer beneficiaries and the Part D program better (lower) negotiated prices on all drugs in return for the lower cost sharing. In practice we believe this would mean that whatever pricing standard is used to reimburse drugs purchased from network pharmacies in general, a lower pricing standard must be applied to drugs offered at the preferred level of cost sharing. For instance, if drugs offered at the standard retail level of cost sharing were reimbursed at 20 percent off the average wholesale price (AWP) pricing standard, then any drugs offered at the preferred level of cost sharing must be reimbursed at deeper discount than AWP minus 20 percent. If generic drugs offered at the standard retail level of cost sharing were reimbursed according to a sponsor's proprietary maximum allowable cost (MAC) pricing standard, then generic drugs offered at the preferred level of cost sharing must be reimbursed at deeper discount than the MAC pricing rates. We believe this is not only consistent with the statutory intent, but also reasonable since the mail-order operations and other large pharmacies where preferred cost sharing is currently offered have significantly more purchasing leverage with manufacturers and wholesalers than do smaller pharmacies. Our analysis shows that some sponsors are already achieving these levels of savings, and our proposed policy would apply a consistent standard across all sponsors to compete on negotiated prices, including in related-party pharmacy operations. We would welcome comments on alternative approaches to ensuring that the offering of preferred cost sharing does not increase our payments. We believe that any alternative methodology must be based solely on the level of negotiated prices and thus consistent with our proposal to amend that definition (section III.A.25 of this proposed rule). As discussed in that section, we proposed to revise the definition to specify that all price concessions from pharmacies must be reflected in the negotiated price in order to promote transparent price competition, as well as to eliminate differential cost reporting and cost shifting that interfere with a fair and transparent competitive bidding process. We request that any alternative methodology suggestions be accompanied by specific proposals for how we could objectively validate compliance through data we already collect.

In addition, we solicit comments on whether we should also establish standards on how much lower drug costs should be in return for preferred cost sharing. We are aware that there is a wide range of savings projections associated with the use of limited networks. For instance, a January 2013 study prepared for the Pharmaceutical Care Management Association (PCMA) provides various estimates ranging from 5 percent to 18 percent [at *http://www.pcmanet.org/images/stories/uploads/2013/visante-pcma%20pharmacy%20networks%20study%201-24-13%20final.pdf*]. We solicit comment on whether Medicare should require a minimum level of savings, such as 10 percent or 15 percent, over the costs available at retail cost-sharing rates. We believe that substantial discounts in this range would be necessary to balance the extremely low preferred cost sharing rates offered by many sponsors in 2013. We also solicit comments on how broadly preferred cost sharing should be applied to drugs on a sponsor's formulary. For instance, is it reasonable to offer cost sharing as low as $0 for only the least expensive generics on formulary? Or should preferred cost sharing have to apply to a minimum percentage of formulary products to be a meaningful benefit instead? Or should preferred cost sharing have to apply to all drugs available at pharmacies offering preferred cost sharing? This would require that the prices of all drugs at those pharmacies could be no higher than the prices at the other network pharmacies. Such a policy would prevent sponsors from offering lower prices on drugs with preferred cost sharing while offering higher prices on other drugs not subject to preferred cost sharing. Our concern is that without such rules, it is possible that the beneficiary is motivated to change pharmacies in order to pay very low copays on some drugs, but the program may end up paying higher costs on other drugs the beneficiary purchases at the same pharmacy out of convenience.

We also propose a clarification in terminology to better describe the application of the policy to a sponsor's approved Part D pharmacy network. As illustrated in the proposed revision to § 423.120(a)(9), we would like to change the point of reference in our guidance away from ''preferred pharmacies'' to ''preferred cost sharing''. This is not only a more accurate interpretation of the statute, but it also avoids the use of the corollary term ''non-preferred''. We regret the unintended connotation that some network pharmacies are ''non-preferred pharmacies'' when, in most cases, these pharmacies have had no opportunity to meet the terms and conditions for qualifying for preferred cost sharing. The use of the term non-preferred also has caused confusion for some stakeholders since non-preferred is also a term of art referring to non-contracted and, therefore, non-network pharmacies. In addition, we believe it is generally misleading for our sponsors to refer to preferred pharmacies, when

only a limited number of tiers (for instance, generics) may be available at the lower preferred cost sharing rates at these pharmacies. Consequently, we are proposing to delete the definitions of ''preferred pharmacy'' and ''non-preferred pharmacy'' from § 423.100 and to add a new definition of preferred cost sharing. ''Preferred cost sharing'' would mean lower cost sharing for certain covered Part D drugs at certain network pharmacies offered in accordance with the requirements of § 423.120(a)(9). We would then require that Part D sponsors would revise any marketing materials to reflect the revised nomenclature, and eliminate any references to preferred or non-preferred network pharmacies. We solicit comment on whether any further clarifications of terminology are needed for this policy proposal.

28. Prescription Drug Pricing Standards and Maximum Allowable Cost (§ 423.505(b)(21))

We are proposing a change to the regulations governing the disclosure and updating of prescription drug pricing standards used by Part D sponsors to reimburse network pharmacies to make clear that drug pricing based on maximum allowable cost (MAC) is subject to these regulations. Section 173 of MIPPA amended sections 1860D–12(b) and 1857(f)(3) of the Act to add a provision requiring the regular updating of prescription drug pricing standards. Thus, for plan years beginning on or after January 1, 2009, CMS's contracts with Part D sponsors must include a provision requiring sponsors to update any standard they use to reimburse network pharmacies based on the cost of the drug to accurately reflect the market price of acquiring the drug. These updates must occur not less frequently than once every 7 days, beginning with an initial update on January 1 of each year.

We codified this requirement in § 423.505(b)(21). We also amended § 423.505(i)(3) with respect to contracts or written arrangements between Part D sponsors and pharmacies or other providers, first tier, downstream and related entities, to ensure that Part D sponsors' contracts with these entities include provisions for regularly updating any prescription drug pricing standard used by sponsors to reimburse their network pharmacies, as provided in § 423.505(b)(21). Specifically, § 423.505(i)(3)(viii)(A) requires that sponsors' pharmacy contracts include a provision establishing regular updates of any prescription drug pricing standard used by the Part D sponsor, consistent with § 423.505(b)(21), and § 423.505(i)(3)(viii)(B) requires that a Part D sponsor's pharmacy contract indicate the source used by the Part D sponsor for making any such pricing updates. We finalized these regulations in a final rule entitled, ''Medicare Program; Medicare Advantage Program and Prescription Drug Benefit Programs'' at 76 FR 54600 (September 1, 2011) (''September 2011 final rule'').

When we finalized these regulations, we did not provide a specific definition for ''prescription drug pricing standard,'' because we believed that it was unnecessary at that time. Instead, we provided the following examples of prescription drug pricing standards: ones that are based on ''wholesale average cost, average manufacturer price, and average sales price.'' At the time, we believed these examples sufficiently illustrated what is meant by a prescription drug pricing standard, which we described as ''an accepted methodology based on published drug pricing.'' We also stated that defining the standard beyond this may be overly prescriptive and might not be flexible enough to evolve with industry changes.

Since publication of the September 2011 final rule, we have concluded that our description of ''prescription drug pricing standard'' in the preamble to the final rule was unintentionally too restrictive. Pharmacy representatives have noted that many contracts between Part D sponsors/PBMs and their network pharmacies set reimbursement through the application of MAC prices. It is our understanding that MAC prices generally refer to lists of drugs that include the maximum amount that a plan will pay for multi-source drugs, whether generics or multi-source brands. Based on numerous conversations with pharmacy representatives, we further understand that there is no standardization in the pharmacy benefits industry as to the criteria used to determine inclusion of drugs on MAC lists or as to the methodology used to determine the MAC prices, but that the latter is based in part on the costs of the drugs and fluctuate, sometimes frequently. We also understand that MAC prices seem to be set in some relation to a lowest cost generic product alternative available on the market at a given time. Additionally, we understand that MAC prices are not typically based exclusively on published drug pricing, but are based at least in part on internal Part D sponsor/PBM methodologies. Finally, we understand that many Part D sponsors and PBMs have asserted that because MAC prices are not based solely on published drug pricing, MAC prices are not a ''prescription drug pricing standard,'' and thus, not subject to the updating requirements.

Pharmacy representatives further report to us that pharmacies are forced to sign contracts that reimburse based on MAC prices that change without notice. These representatives state that pharmacies consequently do not know exactly what price they will be paid for which drugs, and thus the pharmacies cannot confirm that their reimbursements are correct nor engage in proper business planning.

As noted previously, we stated in the preamble to the final regulation that a ''prescription drug pricing standard'' is an accepted methodology based on published drug pricing. This is because we were unaware at the time that there is at least one standard based on costs of the drugs that is not based strictly on published drug pricing. Now that we have become aware of these types of pricing standards, we wish to clarify our regulatory requirement. We believe that the updating requirement should apply to pricing standards based on the cost of a drug, even when the standard is not based on published drug pricing, an approach consistent with the intent of the statute. The text of MIPPA section 173 itself indicates the provision's purpose—Part D sponsors must update their prescription drug pricing standards regularly ''to accurately reflect the market price of the drug.'' We believe that this statement of purpose indicates that the Congress intended to provide pharmacies with a means of ensuring that they have current data on the amount of reimbursement that they can expect.

When the source of a prescription drug pricing standard is published publicly, such as with AWP or WAC, pharmacies can determine their reimbursement for all drugs at any given time and can monitor these sources to ensure they are being reimbursed correctly. However, when a prescription drug pricing standard is not published publicly, network pharmacies are unable to promptly determine whether their reimbursement is consistent with their contractual arrangements. This, in turn, presents risks to the Medicare Part D program in a number of ways. For example, disclosure of the source used to determine drug prices is necessary for pharmacies to ensure accurate payment of their claims, which is necessary for accuracy in the costs submitted to CMS by Part D sponsors on PDEs without unnecessary later adjustments that are disruptive to the operation of the Part D program.

In addition, when network pharmacies are unable to determine whether their reimbursement is

consistent with their contractual arrangements, the accuracy of the prices displayed in the Medicare Prescription Drug Plan Finder (''MPDPF'') is questionable. While these prices only provide an estimate of Part D drugs costs at particular pharmacies, beneficiaries do use the MPDPF to make drug purchasing choices. If a pharmacy does not know what it will be paid for drugs on any given day, it cannot test the MPDPF and validate the prices. Thus, there is no assurance that the posted prices are accurate, and pharmacies are deprived of the opportunity to compete based on more accurate prices, and beneficiaries may make choices based on erroneous estimated drug costs. This is contrary to the public policy goal of facilitating competition in the health care system and supporting consumers to be informed purchasers of health care. Also, when CMS compares posted prices to prices submitted on PDEs to evaluate the estimates provided in the MPDPF, there can be no assurance that those values correspond to the payments pharmacies actually receive.

For these reasons, we now believe it is necessary to define ''prescription drug pricing standard'' in regulation. Therefore, we propose to add a definition to § 423.501 that would state that a ''prescription drug pricing standard'' means ''any methodology or formula for varying the pricing of a drug or drugs during the term of a pharmacy reimbursement contract that is based on the cost of a drug, which includes, but is not limited to, drug pricing references and amounts that are based upon average wholesale price, wholesale average cost, average manufacturer price, average sales price, maximum allowable cost (MAC), or other cost, whether publicly available or not.'' We propose to include the phrase, ''includes, but is not limited to,'' to signify that the examples specified in the regulation text are not exhaustive.

We expect some commenters may ask what pharmacy reimbursement method would not be considered a ''prescription drug pricing standard,'' since the regulations apply only ''if'' a Part D sponsor uses a standard for reimbursement that is based on the cost of the drug. In our view, a fixed fee drug price schedule that is not expected by the parties to vary during the term of the contract between the Part D sponsor/PBM would be not be a ''prescription drug pricing standard,'' as there would be no reason to update the list at least every 7 days.

In addition, in order to make the regulations regarding prescription drug pricing standards easier to reference, we are proposing the following technical changes for consolidation purposes: (1) To combine the current requirements contained in § 423.505(b)(21) (i) and (ii) into (i) and eliminate the reference to the effective contract year 2009 as no longer necessary. These requirements generally state that Part D sponsors agree to update any prescription drug pricing standard (as would be defined in § 423.501) on January 1 of each contract year and not less frequently than once every 7 days thereafter. We also propose to move the current requirement to indicate the source used for making any such updates to (b)(21)(ii) from § 423.505(i)(3)(viii)(B). We propose this latter move of regulation text, so that it is clearer by its placement in the regulation that this requirement is on Part D sponsors.

For new paragraph § 423.505(b)(21)(iii), to be clear, we are proposing a new requirement and not a technical change. We are proposing that Part D sponsors agree in their contracts with CMS to disclose all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims, if the source for any prescription drug pricing standard is not publicly available. This means, in conjunction with the proposed definition of a ''prescription drug pricing standard'' discussed previously, that Part D sponsors would have to convey to network pharmacies in advance the actual MAC prices to be changed. We are requiring that the actual MAC prices be disclosed in advance because, if the pharmacies are not able to use the updates as a reference against which they can check their reimbursements, there would be no point to the statutory requirement.

As a final technical change, we are proposing to eliminate language in § 423.505(i)(3)(viii)(A) about establishing regular updates of any prescription drug pricing standard used by the Part D sponsor which is and would be duplicative to language in 423.505(b)(21). As a result of the changes described previously, there would be no paragraphs (A) and (B) to § 423.505(i)(3)(viii), and this provision would simply require that, if applicable, each and every contract governing Part D sponsors and first tier, downstream, and related entities, must contain provisions addressing the prescription drug pricing standard requirements of § 423.505(b)(21). We believe these proposed technical changes will make the regulation text easier to reference and understand.

29. Any Willing Pharmacy Standard Terms & Conditions (§ 423.120(a)(8))

Section 1860D–4(b)(1)(A) of the Act requires Part D plans to permit any pharmacy meeting the standard Terms and Conditions (T&C) to participate in the plan's network. We used this authority to establish requirements under § 423.120(a)(8) and § 423.505(b)(18) that plan sponsors have reasonable and relevant T&C for network participation in their standard contract, and allow any pharmacy meeting the T&C to participate as a network pharmacy for that plan. Section 1860D–4(b)(1)(B) of the Act permits sponsors to reduce cost sharing ''below the level otherwise required,'' notwithstanding paragraph (A). Thus, the statute permits a ''preferred'' cost sharing level (using the definition specified in section III.A.27 of this proposed rule) to be offered at some network pharmacies. Since the beginning of the program, we have required sponsors to offer standard T&Cs to any willing pharmacy in order to achieve broad network access, but have permitted sponsors to offer different T&Cs in return for preferred cost sharing to a smaller subset of its network. We have previously stated that we believed our interpretation of these two seemingly conflicting statutory provisions struck an appropriate balance between the need for broad pharmacy access and the need for Part D plans to have appropriate contracting tools to lower costs. In this section we are proposing that in place of sponsors having one contract with standard terms for any willing pharmacy and a second preferred cost sharing contract for a limited subset of pharmacies, that sponsors instead have standard T&C for network participation that list all combinations of cost sharing and negotiated prices possible for retail settings under the plan, allowing any willing pharmacy the opportunity to offer preferred cost sharing if the pharmacy can offer the requisite level of negotiated prices.

When discussing cost sharing, distinctions are made in this section between plans offering a preferred cost sharing level and plans that do not. For the purposes of this section, the cost sharing levels offered at retail pharmacies not contracted to offer preferred cost sharing (previously referred to as ''non-preferred pharmacies'') are referred to as standard cost sharing levels. Cost sharing levels offered at retail pharmacies at the preferred T&C (previously referred to as ''preferred pharmacies''), are referred to as preferred cost sharing levels.

Because under our proposal for preferred cost sharing, pricing terms for pharmacies offering preferred cost sharing could not exceed the pricing terms for pharmacies offering standard cost sharing (see discussion in section III.A.27 of this proposed rule), we will use the terms ''ceiling price'' and ''floor price'' to refer to the upper and lower limits put on pricing terms. As proposed, the negotiated prices charged by pharmacies offering preferred cost sharing must be at or below the agreed upon ceiling price (determined by using the defined preferred cost sharing T&C pricing), which must be less than the floor price, or lowest negotiated price, charged at network pharmacies offering standard cost sharing.

We heard from many pharmacies, many of them small independent community pharmacies, that plans do not offer any willing pharmacy the opportunity to offer preferred cost sharing. Instead, some pharmacies are being offered only the plan's standard T&C, at the highest level of beneficiary cost sharing. We received more than 200 comments in response to our discussion of this topic in the Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and PDP Payment Policies and Final Call Letter (2014 Call Letter) pp. 175–176 at *http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2014.pdf*. Most of these comments were from pharmacies concerned about barriers to entry for participation in preferred networks, and many of these argued that such limited networks violate the statutory intent of the network access provisions at section 1860D–4(b)(1) of the Act. In particular, these commenters disagreed that such barriers were consistent with the any willing pharmacy requirement as stated in 1860D–4(b)(1)(A) of the Act.

Consequently, we have reviewed our original regulatory interpretation of these provisions, not only in light of these complaints, but also in light of our experience in the Part D program. We believe that an alternative reading of sections 1860D–4(b)(1)(A) of the Act and (B) of the Act to reduce barriers is not only permissible, it would have the following key policy benefits, which we describe as follows:

- Increased access for beneficiaries to preferred level cost sharing with any willing pharmacy able to agree to the T&C that include preferred cost sharing.
- Improved opportunity for competition among pharmacies contracting with the sponsor to charge no more than the ceiling price stated in the contract for preferred cost sharing, reducing costs charged to the program.
- Improved clarity for beneficiaries surrounding cost sharing levels available at retail and mail order pharmacies.

Elsewhere in this proposed regulation we discuss clarifications to the requirements for offering preferred cost sharing within a sponsor's network (see section III.A.27 of this proposed rule). In III.A.27 we discuss our analysis of 2011 benefit designs incorporating preferred cost sharing. We found that some retail pharmacies are actually offering to sell Part D drugs (particularly generic versions) at prices below those offered by the network pharmacies eligible for preferred cost sharing. In such cases, the lower negotiated prices offering the program superior savings are offered to enrollees at the higher standard cost sharing levels, while the same drugs being offered to enrollees at lower preferred cost sharing levels may be costing the program as much or more. The lower cost sharing ''price'' signal is not aligned with either the true price of the drug or better overall value to the program, and therefore the defective signal incentivizes inefficient purchasing decisions from the perspective of the Part D program. If some retail pharmacies are willing to provide deeper discounts than those that sponsors are currently negotiating with pharmacies in return for offering preferred cost sharing, we can conclude that, all other things being equal, competition will be increased and aggregate negotiated prices will be reduced if these more competitive retail pharmacies have the opportunity to qualify for preferred cost sharing. Therefore, we now believe that this opportunity for pharmacies to gain entry into previously limited networks should be a component of the any willing pharmacy requirements for retail pharmacies, allowing more pharmacies the option to offer preferred level cost sharing if they are willing to charge no more than the ceiling price stated in the contract.

We have heard the assertion that limited networks achieve greater savings than broader networks, and that moreover, allowing more participants into a limited network than those hand-picked by the sponsor will necessarily lead to increased prices. However, we have been running a natural experiment of sorts relative to this assertion in the Part D program. If limited networks *per se* led to significantly lower costs, we would see consistently significant savings in those network segments relative to the rest of the sponsors' networks. However, an April 2013 analysis by CMS, ''Negotiated Pricing Between Preferred and Non-Preferred Pharmacy Networks'', reviewed actual program experience and indicated that this is not the case across the board (see *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/PharmacyNetwork.pdf*). As the 2012 claims show, there is wide variation in discounting across sponsors. Consistent savings are not seen uniformly. In some cases, pharmacies extending high discounts are ones that have been excluded from limited networks offering preferred cost sharing, while some pharmacies within the limited networks offer effectively no discounts compared to the rest of the network. Therefore, we believe that opening up these limited networks to any pharmacy willing to charge no more than the contract's ceiling price to qualify for offering the lower preferred cost sharing is necessary to restore price competition in these networks. Consequently, for any sponsor that offers both standard and preferred cost sharing under any of its benefit packages, we propose that the sponsor's contracts for network retail pharmacies include not only the T&C for standard cost sharing, but also the T&C for offering preferred cost sharing, stating negotiated pricing levels that must be agreed upon to qualify for offering preferred cost sharing. As discussed previously, the ceiling price that a pharmacy can charge for a drug filled at a preferred cost sharing level, must be less than the floor price, or minimum price, charged by network pharmacies under that plan offering standard cost sharing levels. Retail pharmacies would elect to participate according to one set of terms or the other, but not both.

We have also heard the argument that the pharmacies in currently limited networks are offering deeper discounts solely in return for increased market share and that they will withdraw such offers if the limited network is opened up to other pharmacies that can meet those T&C. We are skeptical that such participants in the highly competitive retail market will abandon their market share by returning to the broader network T&C. As some network pharmacies offering standard cost sharing have been able to extend discounts in pricing even deeper than what is seen in some pharmacies offering preferred cost sharing, it is not obvious that negotiated prices would necessarily increase in the aggregate in the event that a limited number of pharmacies consider changing from preferred to standard cost sharing. We

have also been informally told by one sponsor with preferred cost sharing in a limited network that its preferred cost sharing T&C already are offered to any willing pharmacy. For these reasons, we do not believe that our proposal would result in increased prices. We note that our proposed alternative statutory interpretation still would permit sponsors to limit preferred cost sharing to those pharmacies accepting T&C with stated ceiling prices. Aggressive price concessions to fall below the stated ceiling price (solely in the form of lower negotiated price, in accordance with our proposed change to that definition at § 423.100 discussed at section III.A.25 of this proposed rule) would have to be met by all pharmacies offering preferred cost sharing, including pharmacies that are related parties of the Part D sponsor or its PBM. Sponsors could not offer preferred cost sharing for higher negotiated prices than the ceiling price listed in the T&C, but would be free to negotiate even deeper discounts from individual pharmacies in the limited network. Publicly posted pricing standards would effectively set a pricing floor for all pharmacies accepting a plan's standard T&C and set a pricing ceiling for pharmacies accepting the preferred cost sharing T&C. These benchmarks better align price with value, while maintaining sponsor flexibility to negotiate with all pharmacies in its network. Therefore, we are confident that requiring that a Part D plan sponsor offer T&C for every level of cost sharing approved in its benefit packages to any willing pharmacy would not limit competitive negotiations, nor would it in and of itself lead to increased negotiated prices.

We also believe that there is a limit to the number of cost sharing levels offered under a benefit plan that can be well understood by beneficiaries. When establishing its network, a Part D sponsor does not offer identical T&C for network participation to every pharmacy. Certain terms will necessarily differ among contracts with the different types of pharmacies needed to provide all Part D drugs, if for no other reason than to address the different access and service standards established by CMS. These various types include at a minimum: Retail, mail-order, long-term care institutional, limited-distribution-drug specialty, and home infusion therapy pharmacies. Terms will also differ with respect to negotiated prices and the level of cost sharing that a pharmacy's claims will be subject to. For instance, long-term care institutional, specialty, and infusion pharmacies are generally offered at the standard level of cost sharing (for the applicable formulary tier) for a month's supply of a covered drug. Retail and mail-order pharmacies, in contrast, currently may contract with plans to be offered at more than one cost sharing level.

Cost sharing at retail and mail-order pharmacies currently vary on three dimensions: Whether the cost sharing is standard or preferred, on the quantity dispensed (or ''days' supply''), and on dispensing location.

a. Preferred Cost Sharing

Under § 423.120(a)(9), sponsors can offer lower preferred cost sharing levels to some retail and mail order pharmacies in their network who agree to offer superior price concessions. While beneficiaries may actively seek out preferred cost sharing among retail and mail order pharmacies, this is less common among long term care, specialty, and infusion pharmacy settings. Any preferred cost sharing structure would be required to meet certain conditions as previously proposed and would be required to be submitted to CMS for approval as part of a sponsor's plan benefit package. Plans are not currently required to offer a preferred cost sharing level, nor would they be required to if this proposal is implemented. However, for pharmacies that do contract to offer preferred cost sharing, our proposal means that preferred cost sharing must be available to all enrollees covered by that plan's contract and electing to use that pharmacy. This would include consistently charging preferred cost sharing and consistently billing no more than the ceiling price for all prescriptions, whether a one month or extended days' supply is dispensed.

b. Extended Days' Supply

Additionally, different cost sharing levels may be offered for extended days' (generally greater than 34 and no more than 102) supplies, at both retail and mail order pharmacies. To avoid unnecessarily complicated benefit designs, plans should create no more than two cost sharing distinctions based on days' supply: One month supply (not to exceed 34 days) or extended days' supply (greater than 34-days' supply). In manual guidance (see section 50.10 of Chapter 5 of the Medicare Prescription Drug Benefit Manual) we have further interpreted the ''level playing field'' provision to mean that sponsors electing to offer extended days' supplies of covered Part D drugs need to make available to retail pharmacies, upon request, an ''Extended Supply Addendum'' to their standard contracting terms and conditions for retail pharmacies. This Addendum provides one of two extended-days'-supply contracting options: (1) To be offered at the same cost sharing rate as mail order if a retailer can match the mail-order T&C, or (2) to be offered at another higher cost-sharing level, but in no case higher than three times the amount enrollee would have paid at the same retail pharmacy had the enrollee had his or her prescription filled in multiple 1-month supply increments at the applicable retail pharmacy cost sharing (standard or preferred) cost sharing rate. The nature of long term care, specialty, and infusion pharmacy dispensing makes a price differential based on days' supplies largely unnecessary.

c. Mail Order Cost Sharing

Section 1860D–4(b)(1)(D) of the Act (and § 423.120(a)(10)) require sponsors to provide for extended days' supplies at retail when extended days' supplies are available at mail, but explicitly permits differential cost sharing between the two settings. For plans offering both preferred cost sharing and mail order options, the mail order cost sharing for an extended days' supply can be less than the preferred cost sharing for an extended days' supply filled at retail. However, for 1-month supplies, we propose that the cost sharing at mail order (for prescriptions for 34 days or less) cannot be less than the standard cost sharing at retail (for prescriptions for 34 days or less), regardless of whether a preferred cost sharing level is available. In general, we believe that filling initial prescriptions or routine 30-day supplies at mail-order is not good practice. Given the need to order or re-order mail order prescriptions well in advance of when the medication runs out (to allow time for shipping), the opportunity for gaps in therapy caused by delayed orders rises. When using mail order for one month supplies, a beneficiary would have to order the next month's supply shortly after receiving a new order, and complaints received by CMS indicate that billing errors and delayed shipments occur. It is our understanding that mail order is most efficient when processing extended days supplies, when all billing and processing can be addressed well in advance of needing to ship the next supply. However, we recognize that for some populations, monthly mail order supplies are an acceptable option, so we are not seeking to disincentivize this option. Rather, we are proposing that 1-month supplies filled by mail order pharmacies cannot

have cost sharing lower than a comparable one month supply filled at retail, so as not to provide an incentive to fill short supplies of chronic medications through mail order.

We believe that a more simplified benefit design, incorporating these three variables and accommodating a more clearly defined set of cost sharing levels, would promote better understanding of Part D plan benefits, both in terms of beneficiary cost sharing and prices charged to the program, as well as streamlined contracting options. We also find it important to expressly state the total number of possible cost-sharing levels, to clarify expectations and to preempt the introduction of additional or unauthorized cost-sharing levels in the future.

For prescriptions not subject to Long Term Care, specialty pharmacy, or home infusion pricing, the interaction of the following four provisions of section 1860D–4(b)(1) of the Act point to three authorized levels of cost sharing: Standard, preferred, and extended days' supplies for retail and mail order pharmacies.

- Section 1860D–4(b)(1)(A) of the Act details the participation of Any Willing Pharmacy in a plan's network, provided that they meet T&C offered by the plan, authorizing a standard cost sharing level. This proposal offers retail and mail order pharmacies a chance to not just participate in the plan's network, but to select among a plan's various T&C for participation. By listing the T&C required for offering preferred cost sharing on the contract offered to any willing pharmacy, instead of only offering these T&C to select pharmacies, a greater percentage of network pharmacies can offer beneficiaries the lower cost sharing, while also offering reduced negotiated prices and savings to the Part D program.
- Section 1860D–4(b)(1)(B) of the Act permits discounting for some network pharmacies, authorizing a preferred cost sharing level. This proposal continues to permit both a standard and preferred cost sharing level within a plan's network.
- Section 1860D–4(b)(1)(C) of the Act defines the authority to establish rules defining convenient access, permitting a mail order cost sharing level. Expanding requirements for any willing pharmacy contracts, with any pharmacy (and presumably a greater number of pharmacies) now offered the opportunity to compete for preferred cost sharing if the pharmacy can offer the requisite level of negotiated prices, would expand beneficiary access to lower cost sharing options within the network.
- Section 1860D–4(b)(1)(D) of the Act creates a level playing field by ensuring that if extended days' supply benefits are available at mail order, beneficiaries can get the same benefit at retail pharmacies. Extended days' supply cost sharing at mail order does not have to equal extended days' supply cost sharing at retail, however, we propose to require that it cannot be less than the standard cost sharing offered at retail pharmacies for extended days' supply. As previously discussed, it is our understanding that mail order is most efficient when processing extended days supplies, when all billing and processing can be addressed well in advance of needing to ship the next supply. While we are not proposing to disincentivize mail order for supplies of less than 90 days, nor do we believe it is appropriate to incentivize through lower cost sharing the use of mail order in situations where gaps in therapy may be more likely to occur.

When assessed together, we believe these four sections direct Part D plans to create a network offering convenient access not only to various types of pharmacies but also to various types of cost sharing. Permitting three retail cost sharing levels, as the statute implies, reflects the levels of cost sharing also observed in the commercial market. However, unique to Part D, the available cost sharing levels must also meet the Medicare requirements assuring pharmacy access for Medicare beneficiaries.

We would like to minimize the number of variations on these three levels to the following options and to ensure that standard T&C for network participation offer every level available for each respective pharmacy type. First, we propose to limit long term care, specialty, and infusion pharmacy cost sharing to the standard monthly rate, as is industry practice today. Second, we propose to limit retail pharmacies to the three authorized levels; either the standard or preferred monthly rate (for supplies up to 34 days), and one extended days' supply cost sharing rate not exceeding three times the monthly retail rate (either three times the standard monthly retail rate or three times the preferred monthly retail rate, depending upon the T&C of the pharmacy's contract). Third, we propose to limit the levels of cost sharing at mail-order pharmacies to one monthly rate and one extended day mail order cost sharing rate (for any supplies greater than 34 days) for reasons discussed previously. We additionally solicit comments on the frequency of mail order being used to fill prescriptions lasting one month or less. We note that these proposals would not alter our requirements around the dispensing of any days' supplies less than 30 days, which is still subject to the ''daily cost sharing'' provision at § 423.153(b)(4) (which we propose to further clarify in section III.E.9 of this proposed rule).

In summary, we propose to use the authority in section 1860D–4(b)(1)(C)(i) of the Act to establish rules defining convenient access within a Part D pharmacy network, combined with the authority in section 1860D–4(b)(1)(A) of the Act to revise the any willing pharmacy requirements, to ensure that any pharmacy that can meet the applicable T&C for offering standard or preferred cost sharing can join the network on those terms. We believe the network access provisions in section 1860D–4(b)(1) of the Act support expanding § 423.120(a)(8) to all levels of cost sharing offered under a sponsor's benefit plans. We believe that doing so supports the Congressional intent to have plans compete on negotiated prices by making this price competition more open and accessible to pharmacies. Specifically, we propose to revise § 423.120(a)(8) to require that, in establishing its contracted pharmacy network, a Part D sponsor offering qualified prescription drug coverage must comply with all of the following requirements:

- Must offer and publicly post standard terms and conditions for network participation for each type of pharmacy in the network subject to the following:
  - ++ May not require a pharmacy to accept insurance risk as a condition of participation in the PDP sponsor's contracted pharmacy network.
  - ++ Must offer payment terms for every level of cost sharing offered under the sponsor's plans consistent with CMS limitations on the number and type of cost sharing levels, and for every type of similarly situated pharmacy.
- Must contract with any willing pharmacy able to meet one set of the terms and conditions offered by that plan for that type of pharmacy.

We also propose to make conforming changes to the contracting provisions at § 423.505(b)(18) to require Part D sponsors to agree to have standard T&C for network participation that meet the requirements described in § 423.120(a)(8), with reasonable and relevant T&C of participation for each type of pharmacy in its network. We believe these proposed requirements would better ensure that each Part D plan: (1) Provides convenient access to Part D drugs in all Part D settings and to the extent practical, at all cost sharing

levels; and (2) offers cost sharing levels that encourage beneficiaries to make choices that minimize costs not only for themselves, but also to the Medicare Part D program as a whole.

We solicit comments on these proposals to expand the any willing pharmacy T&C and to streamline the levels of cost sharing offered under those standard T&C. Based on the current level of negotiated prices in the Part D program, we conclude that if a greater number of pharmacies were given the option to compete for each cost-sharing level offered under the plan, that beneficiaries would have more pharmacy options offering the lowest cost-sharing level for reduced prices. We cannot compel sponsors to negotiate lower negotiated prices, nor can we compel pharmacies to accept plan sponsors' T&C for participation, but we can create benefit specifications and network access standards that promote streamlined benefit comparisons and that maximize opportunities for price competition. We believe these proposals will increase beneficiary understanding of and access to cost sharing that is better aligned with the lowest negotiated prices, improve market competition, and increase downward pressure on total program costs.

30. Enrollment Requirements for the Prescribers of Part D Covered Drugs (§ 423.120(c)(5) and (6))

To improve our ability to oversee the Medicare Part D program, we are proposing to implement section 6405(c) of the Affordable Care Act effective January 1, 2015. This section provides the Secretary with authority to require that prescriptions for covered Part D drugs must be prescribed by a physician enrolled under section 1866(j) of the Act (42 U.S.C. 1395cc(j)) or an eligible professional as defined at section 1848(k)(3)(B) of the Act (42 U.S.C. 1395w–4(k)(3)(B)). We are proposing in revised 42 CFR 423.120(c)(5) and new (6) that a prescriber of Part D drugs must have: (1) An approved enrollment record in the Medicare FFS program (that is, original Medicare); or (2) a valid opt-out affidavit on file with a Part A/Part B Medicare Administrative Contractor (A/B MAC) for a prescription to be eligible for coverage under the Part D program.

Our long-standing Part D policy has been that drugs cannot be eligible for Part D coverage unless they are dispensed upon prescriptions that are valid under applicable state law. We incorporated this policy (§ 423.100 and § 423.104) in the April 12, 2012 final rule (77 FR 22072) entitled, ''Medicare Program: Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes.''

Inherent in this policy is the notion that valid prescriptions of covered Part D drugs are written by qualified prescribers, meaning prescribers who have an active professional health care license that conveys prescribing privileges to them under applicable state law. A prescription is not valid under any state law if it is not written by a qualified prescriber. Indeed, we note that not all of the eligible professional types under section 1848(k)(3)(B) of the Act can necessarily prescribe drugs under state law.

To help ensure that Part D drugs are prescribed only by qualified prescribers, we are proposing that physicians and eligible professionals enroll in the Medicare program in order to prescribe covered Part D drugs. We are proposing an enrollment deadline of January 1, 2015, which would provide physicians and eligible professionals with at least 6 months after the publication of a final rule to initiate and complete the Medicare enrollment process for the purposes of prescribing covered Part D drugs. We are soliciting comments regarding the effective date of this provision and the reason(s) why we should consider an earlier or later implementation date for this provision.

Our proposal to implement section 6405(c) of the Affordable Care Act with respect to Part D prescribers complements our recent steps to help ensure that prescriptions covered by the Part D program are written by qualified health care practitioners. In 2012, we provided sponsors with guidance in an October 1, 2012 HPMS memorandum titled, ''Revised Reporting Requirements for Prescriber Identifiers and Other Prescription Drug Event Fields.'' We also required every PDE record submitted by a Part D sponsor to CMS to contain an active and valid individual prescriber national provider identifier (NPI) beginning January 1, 2013. PDE records are summary records of every prescription filled under the Part D program and contain prescription drug cost and payment data that enables CMS to make payments to plans and otherwise administer the Part D benefit. Thus, the PDE NPI requirement ensures that we have a record of the prescriber's active and valid individual NPI for every prescription covered under the program.

In the final rule implementing the NPI PDE requirement, we explained that the consistent use of a single validated identifier would enable us to provide better oversight over possible fraudulent activities in the Part D program. When promulgating § 423.120(c)(5) (77 FR 22143, April 12, 2012), we stated that CMS, the National Benefit Integrity Medicare Drug Integrity Contractor, and oversight agencies would be able to more efficiently, and therefore more effectively, identify patterns of unusual prescribing that may be associated with improper and/or fraudulent activities.

While requiring NPIs on every PDE record was an important first step in identifying and monitoring prescribers in the Part D program, the system that assigns and maintains NPI data—the National Plan and Provider Enumeration System (NPPES)—is not a practitioner credentialing system. The information stored in NPPES is self-reported by the applicant and is not required to be independently verified by HHS or CMS. This has left open some program vulnerabilities as described in recent OIG reports on this issue. For instance, in a June 2013 report, the OIG found that the Part D program inappropriately paid for drugs ordered by individuals who clearly did not appear to have the authority to prescribe. (See ''Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority'' (OEI–02–09–00608). This raises concerns about patient safety and the appropriateness of Part D payments. In addition, there have been reports that the prescriptions of physicians with suspended licenses have been covered by the Part D program. This should not happen, and we believe we can better address this type of vulnerability by verifying the credentials of prescribers as physicians or eligible professionals through either their enrollment in the Medicare FFS program with an approved enrollment record or their submission of a valid opt-out affidavit on file with a NPI at an A/B MAC.

The Medicare FFS enrollment process requires that an A/B MAC screen and validate each enrollment application submitted by a physician or eligible professional prior to the decision to approve or deny enrollment in the Medicare program. Thus, when a physician, including an intern or resident, or eligible professional submits an enrollment application (for example, the CMS–855I or CMS–855O or the Internet-based Provider Enrollment, Chain and Ownership System (PECOS) version of these enrollment forms) to an A/B MAC, the A/B MAC approves or denies the application to enroll into the Medicare FFS program based on whether the practitioner meets the program requirements for his/her for medical specialty. The Medicare FFS enrollment application collects and

verifies identifying information about the applicant, and his or her credentials, such as the license number. For example, an A/B MAC verifies each applicant's social security number and NPI at the time of enrollment, when changes or updates are submitted, and during the 5-year revalidation process. The A/B MAC also verifies state licensing board information prior to enrolling an individual practitioner, and monthly thereafter, to determine if the state suspended or revoked a physician or eligible professional's medical license. In addition, A/B MACs verify that physician and eligible professionals are not excluded from receiving payments under any federal health program by checking the System for Award Management (SAM), a process similar to that which Part D sponsors currently use to ensure that physicians and eligible professionals are not excluded by the OIG). Thus, by leveraging the state licensing and OIG exclusion information maintained within PECOS, CMS' national fee-for-service enrollment database, we believe that we can help ensure that physicians and eligible professionals are State licensed to prescribe covered Part D drugs.

As an alternative to submitting an enrollment application for Medicare billing privileges, physicians and certain eligible professionals may enroll in Medicare for the sole purpose of ordering and certifying services in the Medicare program by completing the Medicare enrollment application—Registration for Eligible Ordering and Referring Physicians and Non-Physician Practitioners (CMS–855–O). Once an A/B MAC determines that a physician or eligible professional meets all program requirements to solely order services, they are enrolled in the Medicare program and are placed into an approved status in PECOS. A physician or eligible professional may submit a CMS–855O application as a means of complying with our proposed requirement, if he or she is enrolling solely to order or certify Medicare items or services.

Section 1861(r) of the Act, defines a physician as a doctor of medicine, doctor of osteopathy, doctor of dental surgery or dental medicine, doctor of podiatric medicine, doctor of optometry, or a chiropractor who is acting within the scope of his license when he/she prescribes a drug within Part D of Medicare. We note that physicians and eligible professionals may enroll in the Medicare program, but whether these individuals can prescribe is a matter of state law where the physician specialty or eligible professionals practices. For instance, a doctor of optometry may enroll in Medicare, but only be able to prescribe certain drugs within a state, and a clinical psychologist may enroll in Medicare, but may or may not be able to prescribe medications under state law. Our proposal to require physicians and eligible professionals to enroll in the Medicare program to prescribe covered Part D drugs does not solicit comment on the types of health care physicians and eligible professionals who can write a valid prescription under state law. We will continue to defer to state law regarding the physicians and eligible professionals that can prescribe covered Part D drugs. As such, a Part D sponsor would remain responsible for ensuring that a prescriber has the authority to prescribe under state law.

Depending on state law, interns and residents may enroll in the Medicare FFS program to receive Medicare billing privileges or to solely order/certify services in Part A and Part B of the Medicare program. Under our proposal, interns and residents with an approved enrollment record in PECOS would also be allowed to prescribe covered Part D drugs in the Medicare program as long as the state permits this practice. We believe that this approach is consistent with the policy that we previously established in the April 27, 2012 final rule (77 FR 25284) entitled, ''Medicare and Medicaid Programs: Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements.

A small number of physicians and eligible professionals elect to opt out of enrolling in the Medicare program for a 2-year period by submitting an affidavit to the A/B MAC and only bill the Medicare program for covered emergency or urgent care furnished to a Medicare beneficiary. Under section 1802(b) of the Act and the implementing regulations at 42 CFR 405.400 et seq., certain physicians and eligible professionals can opt out of the Medicare program and enter into private contracts with Medicare beneficiaries. By entering into these types of contracts, these individuals do not bill the Medicare program for non-emergency services that they furnish to Medicare beneficiaries. In addition, § 422.220 states, ''An MA organization may not pay, directly or indirectly, on any basis, for services (other than emergency or urgently needed services as defined in § 422.2) furnished to a Medicare enrollee by a physician (as defined in section 1861(r)(1) of the Act) or other practitioner (as defined in section 1842(b)(18)(C) of the Act) who has filed with the Medicare carrier an affidavit promising to furnish Medicare-covered services to Medicare beneficiaries only through private contracts under section 1802(b) of the Act with the beneficiaries. An MA organization must pay for emergency or urgently needed services furnished by a physician or practitioner who has not signed a private contract with the beneficiary.''

Generally, a physician or eligible professional makes the decision to opt out of the Medicare program because they have decided to furnish services on a private contracting basis. Therefore, we are proposing a similar opt-out policy as the Medicare FFS program uses for ordering services within Part B of the Medicare program and certifying services within Part A of the Medicare program. We believe that allowing opt-out physicians and eligible professionals to continue to prescribe covered Part D drugs to a Medicare enrollee would ensure consistency with the Part B program in this regard. In addition, an A/B MAC verifies medical licensure for opt-out physicians and eligible professionals on a monthly basis. Accordingly, we are soliciting comments on whether a prescription of opted-out physicians and eligible professionals should be considered covered under the Part D program as long as the opt-out physician or eligible professional furnishes their NPI to an A/B MAC.

Under our proposal, the prescriptions of physicians or eligible professionals who are not enrolled in the Medicare FFS program or who are not enrolled in Medicare in an approved status would not be coverable under the Part D program. Specifically, in revised § 423.120(c)(5), we are proposing that beginning January 1, 2015, a Part D sponsor must deny or must require its PBM to deny a claim for a Part D drug from a pharmacy, including at the point of sale, if the claim does not contain an active and valid physician or eligible professional NPI. Also, the Part D sponsor must deny or must require its PBM to deny a pharmacy claim for a Part D drug if: (1) The physician or eligible professional is not enrolled in Medicare in an approved status and (2) the physician or eligible professional does not have a valid opt-out affidavit on file with an A/B MAC. We believe that the implementation of this policy will promote quality health care and prevent fraud by ensuring that prescribers of Part D drugs are physicians and eligible professionals who have a valid state license. We note that a prescriber NPI is essential on the pharmacy claim for Part D sponsors and PBMs to determine whether the

prescriber is enrolled in Medicare in an approved status or has a valid opt-out affidavit on file with the Medicare FFS program.

We also note this provision, if adopted, would preclude almost all prescribers located outside of the United States, Puerto Rico, Guam, the Virgin Islands, and the Northern Mariana Islands from prescribing covered Part D drugs to a Medicare beneficiaries, since these physicians and eligible professionals may not be eligible to enroll in the Medicare program. In the April 12, 2012 final rule entitled, ''Medicare Program; Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes'' (77 FR 22144), we stated that it was our understanding that seven states (Arizona, Florida, Maine, North Dakota, Texas, Vermont and Washington) currently permit pharmacies to fill prescriptions from foreign prescribers, to varying degrees. Under our current requirements (see Publication 100–18, Chapter 5 (Medicare Prescription Drug Benefit Manual), section 90.2.1 (Foreign Prescribers) of the Internet-Only Manual), Part D sponsors must pay a claim with an active and valid NPI of a foreign prescriber. If there is not one at point of sale, sponsors do not have to cover the claim and research the NPI, as they do with domestic prescribers under current 423.120(c). Our proposed policy would change this, as no prescription would be covered if the prescriber is not enrolled in Medicare and does not have a valid opt-out affidavit on file with an A/B MAC.

We are also proposing that beginning January 1, 2015, a beneficiary's request for reimbursement from a Part D sponsor must be for a Part D drug that was dispensed in accordance with a prescription written by a physician or eligible professional who—

- Is identified by his or her legal name in the request; and
- Is enrolled in Medicare in an approved status; or
- Has a valid opt-out affidavit on file with an A/B MAC.

Finally, we are also proposing to add provisions to 42 CFR 423.120(c)(6) that a Part D sponsor would not be able to submit a PDE to CMS, unless it pertains to a claim for a Part D drug that was dispensed pursuant to a prescription written by a physician or, when permitted by applicable law, an eligible professional who: (1) Is enrolled in Medicare in an approved status; or (2) has a valid opt-out affidavit on file with the A/B MAC. Proposed § 423.120(c)(6) would also provide that a Part D sponsor must submit to CMS only a PDE that contains an active and valid prescriber NPI.

Under our proposal, CMS would furnish or make available to Part D sponsors a list of physicians and eligible professionals that have an approved enrollment record within the Medicare FFS program or who have a valid opt-out affidavit on file with the A/B MAC. Part D sponsors would no longer be required to check the NPPES database to determine whether a prescriber has an active and valid individual prescriber NPI. For these reasons, the language of 423.120(c)(5) would be revised, as Part D sponsors would have to determine from the list whether the prescriber is enrolled in the Medicare FFS program in an approved status or has a valid opt-out affidavit on file with an A/B MAC before allowing coverage of a prescribed Part D drug. We believe that verifying whether a prescriber is enrolled in Medicare with an approved enrollment record (or valid opt-out affidavit) would involve an effort similar to the one sponsors use now to determine if a prescriber has an active and valid individual NPI. If the prescriber were not listed as enrolled in Medicare in an approved status or on file with the A/B MAC with a valid opt-out affidavit, the drug would not be covered under the Part D program and a claim, including a non-standard claim from a Medicare enrollee, would be denied by a pharmacy or the sponsor. Our proposal to require a prescriber to be enrolled in the Medicare FFS program or have an opt-out affidavit on file with an A/B MAC, would allow a sponsor to confirm that a prescriber's license had been previously verified to ensure that the prescriber is a physician or eligible professional and has an active health care license under applicable state law.

With more than 1 million physicians and eligible professionals enrolled in the Medicare FFS program and more than 9,000 valid opt-out affidavits on file with an A/B MAC, we do not believe that there are a large number of physicians or eligible professionals who prescribe covered drugs for Part D enrollees who are not enrolled in an approved status in Medicare. Our proposed revisions to § 423.120 reflect the existing usage of the CMS–855I, Medicare Enrollment Application—Physicians and Non-Physician Practitioners (OMB Approval Number 0938–0685) and the CMS–855O (OMB Approval number 0938–1135), and, as such, we do not believe that it is necessary to change our existing paperwork burden estimates associated with completing the CMS–855I or the CMS–855O.

We are also soliciting comments on whether we should consider requiring all pharmacies (for example, network, non-preferred, home infusion, non-retail or mail order, and out-of-network) to enroll or maintain enrollment in the Medicare FFS program in order to dispense covered Part D drugs. In a May 2013 OIG report titled, ''Retail Pharmacies with Questionable Part D Billing, (OEI–02–09–00600),'' the OIG found that 2,637 or approximately 4.4 percent of pharmacies, had questionable billing in 2009. The report also highlighted several cities (Miami, Florida, Los Angeles, California, and Detroit, Michigan) with significantly high levels of questionable billing than the national average.

We believe that requiring Medicare FFS enrollment for network pharmacies would leverage the credentialing, identity verification and other safeguards that are part of the FFS enrollment process, allowing Part D sponsors to leverage an important program integrity tool for their networks. Alternatively, we seek comment on whether requiring FFS enrollment for network pharmacies is a ''best practice'' in pharmacy contracting by plan sponsors, and should be an integral part of sponsors' required fraud, waste and abuse programs.

Finally, we are soliciting public comments from doctors of dental surgery or dental medicine, including family dentists, regarding our proposal that doctors of dental surgery or dental medicine enroll in the Medicare program in order to prescribe covered Part D drugs. While many dentists have enrolled in Medicare program within the last 2 years to order bill the Medicare program or order services within the Medicare program, we will continue to conduct outreach to professional organizations/associations to increase the likelihood that all dentists have sufficient notice and therefore time to enroll in the Medicare program in order to prescribe covered Part D drugs.

31. Improper Prescribing Practices (§ 424.535)

a. Background and Program Integrity Concerns

Notwithstanding our proposal discussed in the previous section, we believe that additional program safeguard enhancements are necessary to protect the Medicare Trust Funds from fraud, waste and abuse while ensuring that Part D enrollees and Part B Medicare beneficiaries maintain access to quality health care.

As alluded to earlier, the OIG has conducted several studies addressing program integrity issues related to the Medicare Part D program. Two such reports are of particular relevance to the provisions we are proposing in this section.

The first, which we have already referenced, is titled, ''Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority'' (OEI–02–09–00608), issued on June 21, 2013. The report found that Medicare paid $26.2 million for drugs prescribed by individuals with National Plan & Provider Enumeration System (NPPES) taxonomy codes indicating that they did not have the authority to prescribe these drugs. Such persons included counselors, chiropractors, social workers, physical therapists, registered nurses, occupational therapists, and speech-language pathologists. Some of these individuals—specifically, chiropractors, physical therapists, occupational therapists, and speech language pathologists—are eligible to enroll in the Medicare program to furnish Part B services.

The second study is titled, ''Prescribers with Questionable Patterns in Medicare Part D'' (OEI–02–09–00603), also issued in June 2013. This report highlighted a number of instances in which physicians and eligible professionals prescribed inordinate amounts of drugs to Part D beneficiaries in 2009. For example—

- Medicare paid a total of $9.7 million—151 times more than the average—for one California physician's prescriptions; most of this physician's prescriptions were filled by two independent pharmacies, both of which the OIG had identified as having questionable billing;
- One hundred and eight general-care physicians each ordered an average of 71 or more prescriptions per beneficiary, more than 5 times general-care physicians' national average of 13; and
- An Ohio physician ordered more than 400 drugs each for 13 of his 665 beneficiaries.
- A Texas physician ordered more than 400 prescriptions each for 16 beneficiaries and prescribed 700 or more drugs for 3 of these beneficiaries.

The OIG also noted examples of physicians prescribing a high percentage of Schedule II and III drugs in 2009. In one case, 78 percent of the prescriptions a Florida physician ordered were for Schedule II drugs even though the OIG found that 4 percent of the prescriptions ordered by prescribers nationwide were for Schedule II drugs. For one beneficiary, the physician prescribed a 605-day supply of morphine sulfate, a 524-day supply of oxycodone HCl, a 460-day supply of fentanyl, and a 347-day supply of hydromophone HCl.

In both reports, as well as in other Part D studies, the OIG recommended that CMS exercise greater oversight of the Part D program, not only to curb the specific practices outlined previously but also to stem the overall risk of fraud and abuse that the program presents. The OIG has expressed particular concern over the potential for beneficiaries to become addicted to or otherwise be seriously harmed by certain drugs if they were inappropriately prescribed in dangerously excessive amounts. We share this concern.

Although we have recently taken steps to tighten and strengthen our supervision of the Part D program, problems remain. We continue to receive reports of questionable prescribing practices. Some of these prescribers have been referred to our Medicare Drug Integrity Contractor (MEDIC) for investigation. Yet even if we find improper practices, such as a particular physician's unreasonably high volume or unsafe amounts of Schedule III controlled substance prescriptions, CMS does not possess the legal authority to take administrative action against the prescriber. This means, in many cases, that the prescriber can continue prescribing drugs that will be covered under Part D and, if he or she is enrolled in Medicare FFS, remain so enrolled to furnish medical services. We believe this is inconsistent with the OIG's recommendations in its various Part D reports, and with our goal of protecting and promoting the health and safety of Medicare beneficiaries and safeguarding the Medicare Trust Funds.

b. Drug Enforcement Administration (DEA) Certification of Registration

The DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, and the Controlled Substances Import and Export Act, as amended, and collectively referred to as the Controlled Substances Act (CSA) (21 U.S.C. 801–971); the implementing regulations for these statutes are in 21 CFR Parts 1300 through 1321. The CSA makes possession of authority under state law to dispense controlled substances a requirement for both obtaining and maintaining a DEA Certificate of Registration. Consistent with 21 U.S.C. 822(e), 21 CFR 1301.12(a) states: ''A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.'' The term ''dispense'' under 21 U.S C. 802(10) means ''to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance . . .''

We view a DEA Certificate of Registration to prescribe controlled substances as similar to a state's requirement that a physician or eligible professional be licensed or certified by the state to furnish health care services. We have required that physicians and eligible professionals meet state licensure or certification requirements in order to enroll in the Medicare FFS program to furnish health care services. In fact, certain suppliers, such as air ambulance suppliers, must also meet national certification standards by a federal agency (the Federal Aviation Administration (FAA)) to enroll or remain enrolled in the Medicare program. Failure to obtain or maintain appropriate licensure or certification can result in the denial or revocation of the provider or supplier's Medicare under § 424.530 and § 424.535, respectively.

We believe there is a similarity between the need to obtain and maintain DEA registration to dispense controlled substances, and the need for an air ambulance supplier to meet FAA certification requirements, and for a physician or eligible professional to meet state licensure or certification requirements in order to enroll in and maintain enrollment in Medicare FFS. The Medicare FFS licensure and certification requirements are designed to ensure that physicians, eligible professionals, and other suppliers are qualified to furnish health care services within the Medicare program. In a similar way, the DEA Certificate of Registration is designed to ensure that physicians and eligible professionals meet the statutory criteria established by the CSA to dispense controlled substances.

Physicians, eligible professionals, and pharmacies with a valid DEA Certificate of Registration are allowed to dispense controlled substances. A DEA Certificate of Registration is not required to dispense non-controlled substances, including covered Part D drugs that are not considered to be controlled substances. Thus, under our current regulations, a physician or eligible professional may prescribe covered Part

D non-controlled drugs to a Part D enrollee even though his or her DEA Certificate of Registration has been suspended or revoked. As the agency that administers the Part D drug program, we believe it is both appropriate and necessary to expand our Medicare FFS provider enrollment requirements to ensure that only physicians and eligible professionals who are in good standing with state licensing boards and, as applicable the DEA, are writing prescriptions for covered Part D drugs in the Medicare program.

c. Proposed Provisions

In light of the foregoing discussion, we are proposing several changes to 42 CFR Part 424, subpart P, in order to enhance our Medicare Part D and Part B program integrity efforts.

(1) DEA Certificate and State Authority

We propose to add a new § 424.530(a)(11) granting CMS the authority to deny a physician or eligible professional's Medicare enrollment application if: (1) His or her DEA Certificate is currently suspended or revoked; or (2) the applicable licensing or administrative body for any state in which the physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs; and (3) such suspension or revocation is in effect on the date he or she submits his or her enrollment application to the Medicare contractor. We believe this approach is consistent with our policy under § 424.530(a)(1) of denying enrollment to providers and suppliers that do not meet applicable licensure and certification requirements.

Similarly, we propose to add a new § 424.535(a)(13) granting CMS the authority to revoke a physician or eligible professional 's Medicare enrollment if (1) his or her DEA Certificate is suspended or revoked, or (2) the applicable licensing or administrative body for any state in which the physician or eligible professional practices suspends or revokes the physician or eligible professional's ability to prescribe drugs. Again, this approach is consistent with our requirement that providers and suppliers maintain compliance with all applicable licensure and certification requirements.

We believe that the loss of the ability to prescribe drugs via a suspension or revocation of a DEA Certificate or by state action is a clear indicator that a physician or eligible professional may be misusing or abusing his or her authority to prescribe such substances. This raises concerns that the physician or eligible professional's improper practices may be duplicated in the Medicare program. We must therefore take steps to ensure that Medicare beneficiaries are protected and the Medicare Trust Funds.

(2) Patterns or Practices of Prescribing

(a) Grounds for Revocation

We also propose to add a new § 424.535(a)(14) that would permit CMS to revoke a physician or eligible professional's Medicare enrollment if CMS determines that he or she has a pattern or practice of prescribing Part D drugs that—

- Is abusive and represents a threat to the health and safety of Medicare beneficiaries, or
- Fails to meet Medicare requirements.

We believe we have several bases for the legal authority for this proposal. First, sections 1102 and 1871 of the Act give the Secretary the authority to establish requirements for the efficient administration of the Medicare program. Second, section 1866(j) of the Act states that the Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers.

We also note that on April 29, 2013, we published in the **Federal Register** a proposed rule entitled, ''Medicare Program: Requirements for the Medicare Incentive Reward Program and Provider Enrollment'' (78 FR 25013). We proposed therein to add a new § 424.535(a)(8)(ii) that would give CMS the discretion to revoke a provider or supplier's Medicare enrollment if the provider or supplier has a pattern or practice of submitting claims for services that fail to meet Medicare requirements. Our purpose was to place providers and suppliers on notice that they were under a legal obligation to always submit correct and accurate claims and that failure to do so may result in the revocation of Medicare enrollment if such failures establish a pattern of incorrect or inaccurate claims. We believe that this concept should also extend to revoking Medicare enrollment for Part D prescribers who engage in abusive prescribing practices. In our view, if a physician or eligible professional repeatedly and consistently fails to exercise reasonable judgment in his or her prescribing practices, we should have the ability to remove such individuals from the Medicare program to protect beneficiaries' safety and health as well as Medicare Trust Funds.

(b) Criteria To Be Considered

Many patterns and practices of prescribing, though perhaps questionable on their face, do not upon investigation involve abusive or fraudulent behavior nor involve substandard medical care. Therefore, we are proposing to base any revocation under proposed § 424.535(a)(14) on situations that fall outside the norm of appropriate prescribing, and only after carefully considering the factors outlined later in this section. A thorough, detailed investigation by CMS of the physician or eligible professional's prescribing practices would be a prerequisite for the use of § 424.535(a)(14). Honest physicians and eligible professionals who engage in reasonable prescribing activities would not be impacted by our proposal. We note further that CMS, rather than the Part D plans, would make all determinations under our proposed provisions, though information contained in referrals from Part D Plan sponsors may be used as part of CMS' analysis to make revocation decisions.

We choose not to define ''abusive'' and ''threat to the health and safety of Medicare beneficiaries'' in this proposed rule, primarily because the myriad of questionable situations that warrant the possible application of § 424.535(a)(14) requires that CMS have the flexibility to address each case on its own merits. We believe that the sounder approach would be to propose a list of criteria that CMS would use in determining whether a prescriber is engaging in prescribing practices sufficient to warrant a revocation.

In determining instances of a pattern or practice of prescribing that is abusive and a threat to the health and safety of Medicare beneficiaries, CMS proposes to consider several factors, including—

- Whether there are diagnoses to support the indications for which the drugs were prescribed;
- Whether there are instances where the necessary evaluation of the patient for whom the drug was prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit);
- Whether the physician or eligible professional has prescribed controlled substances in excessive dosages that are linked to patient overdoses;
- The number and type(s) of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the state or states in which he or she practices, and the reason(s) for the action(s);
- Whether the physician or eligible professional has any history of ''final adverse actions'' (as that term is defined under § 424.502);

• The number and type(s) of malpractice suits that have been filed against the physician or eligible professional related to prescribing that have resulted in a final judgment against the physician or eligible professional or in which the physician or eligible professional has paid a settlement to the plaintiff(s) (to the extent this can be determined);

• Whether any State Medicaid program or any other public or private health insurance program has restricted, suspended, revoked, or terminated the physician or eligible professional's ability to prescribe medications, and the reason(s) for any such restriction, suspension, revocation, or termination; and

• Any other relevant information provided to CMS.

In determining whether a physician or eligible professional has a pattern or practice of prescribing that fails to meet Medicare requirements, CMS would consider the following factors, including whether the physician or eligible professional—

• Has a pattern or practice of prescribing without valid prescribing authority;

• Has a pattern or practice of prescribing for controlled substances outside the scope of the prescriber's DEA Certificate of Registration;

• Has a pattern or practice of prescribing drugs for indications that were not medically accepted—that is, for indications neither approved by the Food and Drug Administration (FDA) nor medically accepted under 1860D–2(e)(4) of the Act—and whether there is evidence that the physician or eligible professional acted in reckless disregard for the health and safety of the patient.

To be covered under Part D, Medicare requires that a drug be dispensed upon a prescription that is valid under state law, that the drug meets the definition of a Part D drug, and that it be prescribed by a valid prescriber for a medically accepted indication. Therefore, a physician or eligible professional evidencing a pattern or practice of prescribing without valid prescribing authority, or for controlled substances outside the scope of the prescriber's DEA Certificate of Registration, would face potential revocation of Medicare enrollment. In addition, a physician or eligible professional with a consistent pattern or practice of prescribing drugs for indications that were not medically accepted—that is, for indications neither approved by the FDA nor medically accepted under 1860D–2(e)(4) of the Act—could potentially face revocation. In the latter example, we would anticipate revoking enrollment only in cases where there is evidence of reckless disregard for the health and safety of the patient, not when the prescribing is based on peer reviewed literature or community standards of medical practice.

We reiterate our earlier statement that all criteria would be carefully examined before determining whether a revocation under § 424.535(a)(14) is warranted. In the vast majority of cases, no single factor would or could be dispositive. Nonetheless, there are certain criteria that, if met, would weigh very heavily and perhaps decisively towards a finding that a revocation is justified. A primary example would be that the physician or eligible professional is prescribing drugs without legal authorization. Even if a review of the other criteria did not indicate a pattern of improper activity, unauthorized prescribing is so serious a matter that the practitioner's continued retention of his or her Medicare enrollment would be unacceptable.

We stated in section III.A.30, of this proposed rule that prescriptions ordered by physicians and eligible professionals who are not enrolled in Medicare in an approved status would not be coverable under the Part D program.

We welcome and indeed encourage comments on our proposed additions of § 424.530(a)(11) and of § 424.535(a)(13) and (14). We are especially interested in receiving comments on the following issues:

• Whether certain proposed criteria should not be used.

• Whether criteria that we did not propose should be used.

• Whether certain criteria should be given more or less weight than others.

• Whether our proposed additions of § 424.530(a)(11) and of § 424.535(a)(13) and (14) should be expanded to include pharmacy activities.

32. Transfer of TrOOP Between PDP Sponsors Due to Enrollment Changes During the Coverage Year (§ 423.464)

Sections 1860D–23 and 1860D–24 of the Act specify that requirements for Part D sponsor coordination of benefits with State Pharmaceutical Assistance Programs and other plans providing prescription drug coverage, including treatment of expenses incurred by these payers toward a beneficiary's out-of-pocket (TrOOP) threshold. Part D coordination of benefit requirements are codified at § 423.464 which define ''other prescription drug coverage'' for COB purposes to include, among other entities, other Part D plans and specify Part D plan requirements for determining when an enrollee has satisfied the out-of-pocket threshold.

Related regulations at § 423.104(d), codifying the requirements in section 1860D–2(b) of the Act, require sponsors to track beneficiary TrOOP and gross covered drug costs and correctly apply these costs to the benefit limits to correctly position the beneficiary in the benefit and provide the catastrophic level of coverage at the appropriate time. When a beneficiary transfers enrollment between Part D plans during the coverage year, the enrollee's gross covered drug costs and TrOOP must be transferred between plans and applied by the subsequent plan in its administration of the Part D benefit. The procedures for a prior plan to report these TrOOP-related data and for the plan of record to receive, upload, and use the data position the beneficiary in the correct phase of the benefit was expressed in guidance outlining sponsor responsibilities related to the 2006 Enrollment Reconciliation process. CMS April 2006 guidance detailing instructions for the Enrollment Reconciliation-related data transfer noted the process would be applicable on an on-going basis when a beneficiary's enrollment in a plan terminated due to enrollment in another plan.

This initial manual data transfer process was replaced in 2009 by an automated process for TrOOP-related data transfer developed by CMS and the industry in collaboration with National Council for Prescription Drug Programs (NCPDP). Our guidance released in 2008 describing sponsor implementation of the automated TrOOP balance transfer process reiterated sponsor requirements for data reporting by the prior plan and use of the data for proper positioning of the beneficiary in the benefit by the current plan. We have continued to specify these requirements in subsequent updated versions of the guidance.

Automated TrOOP balance transfer is supported by the NCPDP Financial Information Reporting (FIR) transaction standard, which is used to electronically transfer TrOOP-related data between plans. When a beneficiary transfers enrollment to another plan during the coverage year, transactions are sent sequentially by the CMS Part D Transaction Facilitator to all Part D plans in which the beneficiary was enrolled during the coverage year or that paid claims on the beneficiary's behalf. Sponsors must receive and respond to each transaction, accept the data reported by the enrollee's prior plan, and use these data in the administration of the Part D benefit.

To ensure Part D benefits are correctly administered when a beneficiary transfers enrollment during the coverage year, we propose to codify these requirements in federal regulations. Specifically, we propose to amend § 423.464(f)(2) by adding a new paragraph (C) requiring Part D sponsors to—

- Report benefit accumulator data in real-time in accordance with the procedures established by CMS;
- Accept in real-time data reported in accordance with CMS-established procedures by any prior plans in which the beneficiary was enrolled, or that paid claims on the beneficiary's behalf, during the coverage year; and
- Apply these costs promptly.

In our guidance on automated TrOOP balance transfer, we express our expectation that sponsors successfully transfer accumulator data for beneficiaries making enrollment changes during the coverage year in a timely manner 100 percent of the time. Although sponsors may be reporting and accepting these data in accordance with our expectations, we have been informed that some sponsors may not be promptly loading the data received into their systems so it is available for claims processing. As a result, the beneficiary's previously incurred costs and gross covered drug costs are not considered in the processing of claims received by the new plan sponsor soon after the enrollment change. With this change we seek to clarify that, since the automated TrOOP transfer process enables the accumulators to available to the new plan within a day or 2 of the new enrollment effective date or, if later, the date CMS processes the enrollment change, we expect the new plan sponsor to apply the data promptly after receipt and use it in benefit administration.

33. Broadening the Release of Part D Data (§ 423.505)

We are proposing to revise our regulations governing the release of Part D data to expand the release of unencrypted prescriber, pharmacy, and plan identifiers contained in prescription drug event (PDE) records, as well as to make other changes to our policies regarding release of Part D PDE data. In the May 28, 2008 **Federal Register** (76 FR 30664) we published a final rule entitled ''Medicare Program; Medicare Part D Claims Data,'' (hereinafter referred to as the Part D data final rule) to implement regulations that govern the collection of PDE data under the authority of section 1860D–12(b)(3)(D) of the Act and the disclosure of this data in accordance with section 1106 of the Act. The provisions governing the collection and disclosure of PDE data are codified at § 423.505(b)(8), (f)(3) and (l).

PDE data are summary records of individual claim transactions at the pharmacy containing CMS-defined standard fields submitted by Part D sponsors that document the final adjudication of a Part D dispensing event. The Part D data final rule governed the collection and disclosure of the original 37 elements of PDE data, but was updated to apply to any additional elements that were added to the PDE record. This update was in a final rule issued in April 2010 (75 FR 19678) entitled, ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (hereinafter referred to as the April 2010 final rule).

In the preamble to the Part D data final rule (73 FR 30671), we stated, ''we [ ] believe that it is in the interest of public health to share the information collected under [the authority of 1860D–12(b)(3)(D)] with entities outside of CMS.'' We explained that the release of PDE data assists CMS in evaluating the Medicare Part D program and assessing related policies. We further stated such release was in the interest of public health and would improve the clinical care of beneficiaries.

In addition to setting forth the significant public policy reasons for disclosure of PDE data, we made clear in the preambles of both the Part D data final rule and the April 2010 rule that our primary concerns in releasing PDE data are protecting the confidentiality of beneficiary identifiable information and commercially sensitive data of Part D sponsors. Part D sponsors are private organizations that contract with the federal government to administer the Part D benefit by offering prescription drug plans to Medicare beneficiaries who may voluntarily enroll in one. Therefore, as described in the Part D data final rule and the April 2010 rule, the release of PDE data is subject to certain protections, described here generally, such as encryption of beneficiary information and aggregation of commercially sensitive data of Part D sponsors. In addition, whenever PDE data is released, we only release the minimum data necessary for a given purpose, as determined in the sole discretion of CMS after review of the requestor's detailed request for data. If releasing data to an external entity, in the Part D data final rule, CMS indicated that the requestor must be a legitimate researcher, meaning the requestor has the requisite experience and is working for, or on behalf of, a reputable institution. (In the preamble to the Part D data final rule (73 FR 30674 citing 45 CFR 164.501), we used the definition of ''research'' contained in the HIPAA Privacy Rule, which defines the term as ''a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.'' In the Part D data final rule (73 FR 30674), we also indicated that, consistent with our current policies for Part A and B data, identifiable Part D data would not be disclosed for commercial purposes.

The following describes the current policy for the release of Part D data more specifically by PDE element: Beneficiary, prescriber, pharmacy, and plan identifiers are generally encrypted when released. We only release unencrypted beneficiary, prescriber, pharmacy, or plan identifiers to other government agencies or states, if these identifiers are necessary for the project, and we only release unencrypted beneficiary, prescriber, and pharmacy identifiers to external entities if needed to link to another dataset. We do not release unencrypted plan identifiers to external entities, except to HHS grantees, as permitted under the criteria described in the April 2010 rule and codified in the regulations at 42 CFR 423.505(m)(1)(iii)(C).

Under the Part D data final rule, drug cost data in PDE records are generally aggregated when released. Drug cost data are available in disaggregated format only to other HHS entities and congressional oversight agencies. Drug costs data in PDE records consist of the drug ingredient cost, applicable dispensing fee and any required state sales tax. However, upon request we would exclude sales tax from the aggregation at the individual claim level if necessary for a project.

As this is a time of unprecedented change for CMS and the health care system in general, we believe the current regulations governing the release of PDE data need to be re-considered. The agency has an important role to play in supporting opportunities to accelerate the transition to a data-driven and information-based health care delivery system in this country. CMS itself is transforming from a passive payer of claims towards a value-based purchaser of health care, while at the same time, other health care payer and provider incentives have shifted toward broader coverage and coordinated care. These trends are all a positive and expected outgrowth of the passage and implementation of the Affordable Care Act.

Concurrent with the changes to CMS' role and the health care system in general is the fact that we now have several years of experience with release of PDE data from the Medicare Part D program. We believe the current limitations on the release of certain data elements hinder the use of PDE data in this new health care environment, and inhibit accompanying insights into prescription drug benefit plans that could result from broader release of the data. Our experience has led us to conclude that broader release of PDE data to external entities can increase the positive contributions researchers make to the evaluation and function of the Part D program, and improve the efficiency of the program and the clinical care of its beneficiaries, which is in the interest of public health. Expanded access to PDE data by external entities will allow the researchers to study additional aspects of the Medicare program and health care, and their findings will be released publicly. Such contributions are in the interest of the Medicare Part D program and public health now more than ever as the Affordable Care Act transforms CMS's role and the nation's health care system.

For these reasons, we believe increased access to prescriber, pharmacy, and plan identifiers by all categories of requestors is of utmost importance. This new policy would facilitate research by entities outside CMS that involves identifiable plans, prescribers, and pharmacies. Furthermore, we believe we can relax the current policies on the release of this PDE data, while still protecting beneficiary confidentiality and commercially sensitive data of Part D sponsors.

Accordingly, we are proposing to permit the release of unencrypted prescriber, pharmacy, and plan identifiers contained in PDE records to all current categories of requestors (including, other HHS entities and the Congressional oversight agencies, non-HHS executive branch agencies and states, and external entities). We note that because the minimum necessary policy will still apply to all such releases, this proposed policy change with respect to HHS entities/Congressional oversight agencies and non-HHS executive branch agencies/states is more a formality, since this data is available in unencrypted format to these same entities under the current Part D data regulations ''if needed.'' For this reason, we focus on the release of unencrypted prescriber, pharmacy, and plan identifiers to external entities as discussed later in this section.

We emphasize that we are not proposing any changes to our release policies with respect to beneficiary identifiable data and the drug cost data of Part D sponsors. In addition, other data that is still viewed by some at this time to be commercially-sensitive data of Part D sponsors, for example, data on bids, rebates and other price concessions, are outside the scope of the changes to current PDE data release policies that we are proposing here. We note that bid data is not collected through PDE records, and while rebates and other price concessions may be reflected in PDE records, we are not proposing to make any changes to the policies governing release of such data.

We understand that there may be concerns about releasing unencrypted prescriber, plan, and pharmacy identifiers to external entities, as they have been raised in the past, and we would like to address them upfront. In the preamble to the Part D data final rule (73 FR 30675), we addressed specific concerns about expanding access to prescriber information by external entities, particularly for pharmaceutical companies and others who may want to influence physicians' prescribing patterns and interfere with a physicians' professional judgment. We stated that an encrypted version of the prescriber identifier, which allows for the linkage of all of a prescriber's claims without divulging the prescriber's identity, would meet the needs of most researchers.

However, in our view today, the vast majority of physicians have prescribed and do prescribe what they believe are the appropriate medications for their patients, and they should have no concerns with transparency in their prescribing patterns. Moreover, there are other measures in place to prevent inappropriate influence by external entities on prescribers. For example, section 6002 of Affordable Care Act requires applicable manufacturers of drugs covered under the Part D program to report annually to the Secretary certain payments or other transfers of value to physicians. This requirement was implemented through a final rule that appeared in the February 8, 2013 **Federal Register** (78 FR 9458) entitled, ''Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership of Investment Interests''. In addition, the federal Anti-Kickback Law (section 1128B(b) of the Act) provides that anyone who knowingly and willfully solicits, receives, offers, or pays anything of value to influence the referral of federal health care program business, including Medicare and Medicaid, can be held accountable for a felony. Finally, we would point out that when data are completely transparent, it is easier for the attempts of some to use the data for purposes of inappropriate manipulation to be countered by others who have access to the same data. We note that it appears that prescriber data are already available commercially from pharmacy data aggregators. For these reasons, we believe that our earlier concerns about the release of unencrypted prescriber identifiers in PDE data to external entities are no longer warranted.

Our proposal to release unencrypted prescriber identifiers means that legitimate external researchers will be able to conduct research that involves identifiable prescribers using PDE data. In the Part D data final rule (73 FR 30676), a commenter argued that providing access to linked physician identifiable claims in order to pool them with employer data would allow analysis to reduce cost of care delivery and improve the quality of care. In response, we did not disagree with the commenter, but referenced a variety of pay for performance and value-based health care initiatives being undertaken by CMS in an effort to encourage health care providers to furnish high quality health care and to provide cost and quality information to consumers. We noted that we intended to use PDE data in those activities. We declined, however, to adopt a policy that would include making unencrypted prescriber identifiers available for release to external entities (except when needed to link to another data set).

However, in light of the goals of the Affordable Care Act to improve the quality of health care, including through better access to information, we now acknowledge our agreement with the commenter regarding the importance of providing access to prescriber-identifiable claims. As we noted previously in this section, now more than ever, it is vital that researchers have more data to investigate ways to reduce the cost of care and improve its quality. Studying the prescribing trends of identifiable prescribers can assist all stakeholders in the health care system, from both public and private health care payers, to patients, and even to physicians themselves, by identifying prescribing benchmarks and determining the reasons for variations.

With respect to the release of plan identifiers, we recognized that it might be asserted that in the Part D data final rule and April 2010 rule we included this data when discussing commercially sensitive data of Part D sponsors that would generally be encrypted when

released to external entities. However, we point out that we focused on the separate costs paid by Part D sponsors for ingredient costs or dispensing fees as being the confidential data on the claim (73 FR 30668), and we are not proposing any changes to our policies with respect to the release of ingredient costs or dispensing fees. However, we are proposing to release unencrypted plan identifiers to all categories of requestors.

In comments in response to the Part D data proposed rule, commenters requested clarification that the plan-specific information we were proposing to disclose related only to Part D claims data and would not include competitively sensitive financial data regarding rebates, discounts, or other negotiated price concessions. The commenters expressed concerns that release of competitively sensitive data could undermine the competitive bid process, asserting that plans would be able to adjust their bids on the basis of knowledge of each other's data, resulting in higher drug costs for all. In response to these concerns, we replied in the preamble to the Part D data final rule that we shared the commenters' concerns about the need to protect sensitive data under the Part D program. We stated that because the Medicare drug benefit is based on a competitive business model, we believe releasing commercially or financially sensitive data to the public could negatively impact Part D sponsors' ability to negotiate for better prices, and ultimately could affect the ability of sponsors to hold down prices for beneficiaries and taxpayers. Therefore, we explained (73 FR 30668) that we were adopting a number of protections to mitigate these concerns, which include our minimum necessary, legitimate researcher, and aggregation policies described previously.

These policies would also not change under our current proposal, except that plan identifiers (including internal plan/pharmacy identification numbers on the claim that represent reference numbers assigned by the plan at the time a drug is dispensed), would be available for release to all categories of requestors without encryption. In other words, our current policy on release of ingredient cost and dispensing fee data would not change under our proposal, meaning the minimum necessary data regarding ingredient costs and dispensing fees would continue to be available for release in disaggregated form only to other HHS entities and congressional oversight agencies. Non-HHS executive branch agencies and external entities could still only obtain the minimum necessary ingredient cost and dispensing fee data, only in aggregated form, and only if it is released to a legitimate researcher.

We are proposing this change to our regulations governing the release of plan identifiers, because we no longer believe plan identifiers in PDE data are commercially sensitive data of Part D sponsors that should not be available for release (unless encrypted). Indeed in the April 2010 rule (75 FR 19675 through 19676), in which we expanded access to unencrypted plan identifiers to include HHS grantees under certain conditions on the basis that it would allow for the study of beneficiary plan choices, which would assist CMS in better understanding and improving the Medicare program, we responded to opposing comments that we believed allowing broader access by grantees of non-HHS entities and external researchers could also further assist CMS, even though we declined to adopt such broader access at the time, because we believed that additional time was needed to evaluate the issue.

Moreover, an analysis of Part D plans, their network pharmacies, and average drug costs, can already be accomplished through data posted on CMS' Web site and/or purchased in public use files. Additionally, the MPDPF allows users to view and compare all available prescription drug plan choices, including plan and pharmacy specific estimates of the costs of individual drugs. These data can be manipulated by researchers to reveal information about specific plans and pharmacies that contributes to the evaluation and functioning of the Part D program and can be used to improve the public health. Therefore, in light of the public policy rationale for increasing access to PDE data by all categories of requestors, we believe that plan identifiers should be available in unencrypted format.

We did not respond to any comments specifically addressing pharmacy identifiers in our Part D data final rule and April 2010 rule. However, for the same reasons that we are proposing to make prescriber and plan identifiers available for release in an unencrypted format, we no longer see a reason that pharmacy identifiers should not be available for release in unencrypted format. Accordingly, we also propose to release unencrypted pharmacy identifiers to all categories of requestors, which would also be a change in the current regulations governing the release of PDE data.

We would like to address one final aspect of our policies governing the release of Part D data. As discussed previously, in the preamble to the Part D data final rule, we explained that consistent with CMS's existing policies with respect to Parts A and B data, CMS would not release PDE data for commercial purposes (but external researchers may be funded by commercial firms if the researchers are free to publish their results regardless of the findings). However, given reasons that we have highlighted previously which provide the impetus for the changes that we are proposing to make to our rules governing the release of PDE data, we are also soliciting comment on the current restriction on the release of PDE data for commercial purposes. We are not making a specific proposal in this regard, but rather wish to receive comments for consideration in light of the proposed changes to the requirements governing the release of Part D data that are included in this proposed rule.

In addition to the proposed changes with respect to prescriber, pharmacy, and plan identifiers described previously, and our request for comment on the restriction on the release of Part D PDE data for commercial purposes, we are proposing a few other changes to our regulations governing the release of PDE data and also wish to clarify our existing policies with respect to several issues related to the PDE data. First, we are proposing to add supporting program integrity purposes, including coordination with states, as an additional purpose deemed necessary and appropriate by the Secretary for which a Part D sponsor must agree to submit all data elements included in all its drug claims under section 1860D–12(b)(3)(D) of the Act. The regulation at § 423.505(f)(3) currently contains a non-exclusive list of purposes deemed necessary and appropriate. We believe that the use of these data for supporting program integrity purposes has always been included, even though not explicitly listed. However, given the importance of our ability to release PDE data for program integrity purposes, including for coordination with states on program integrity, we are proposing to add this purpose explicitly to the non-exclusive list in § 423.505(f)(3).

Second, we are clarifying that non-final action data (for example, information on claims subject to subsequent adjustment) are available to entities outside of CMS. Non-final action data are captured through the data element, ''Original versus Adjusted PDE (Adjustment/Deletion code).'' This is a PDE field which distinguishes original from adjusted or deleted PDE records, so CMS can adjust claims and make accurate payment for revised PDE records, and is thus not point-of-sale

data. With the increasing focus on coordination of care, requests for access to non-final action PDE data have also increased. Such data are also routinely requested for evaluation and research projects. The Part D data final rule (73 FR 30683) included an appendix that explained in more specific detail the restrictions relative to the available PDE elements for the different categories of requestors. This appendix stated (73 FR 30685) that the data element ''Original versus Adjusted PDE (Adjustment/Deletion code)'' was available to other (that is, non-CMS) HHS entities and the congressional oversight agencies, while for non-HHS executive branch agencies, states, and external entities, it stated that ''Final Action claims would be provided, so this element should not be needed.'' Thus, this appendix did not explicitly address the question of whether non-final action data would be available for release to these entities, because such data were not expected to be needed. However, since it is clear that these entities do need access to non-final data, we are clarifying that non-final action data are also available for release to non-HHS executive branch agencies, states, and external entities under the Part D data final rule.

Finally, we believe these proposed changes to the Part D regulations governing PDE data release do not raise any new issues under the Privacy Act and that the changes are consistent with the System of Records that currently applies to the relevant data. Thus, we are not proposing any changes to the System of Records, ''Medicare Drug Data Processing System (DDPS),'' System No. 09–70–0553, as we are not proposing any changes to the data we are collecting, to how the data may be used, to the entities that may receive the data, or to the manner of transmission of the data. Rather we are proposing a change in the format in which the data may be provided when released to certain categories of requesters.

In light of the proposed changes to our policies governing the release of PDE data described previously, we are proposing changes to the current applicable regulatory text as described later in this section. We are also proposing to eliminate the appendix that accompanied the Part D data final rule (73 FR 30683) that explained in more specific detail which PDE elements would be available to different categories of requestors, and any restrictions that applied. We believe this appendix is no longer necessary, as our proposals would eliminate most of the distinctions with respect to the PDE data available for release to the different categories of requesters, with the exception of Total Drug Costs, which will continue to be available in disaggregated form only to other (that is, non-CMS) HHS entities and the congressional oversight agencies, and we propose to revise the regulation at § 423.505(m)(1)(iii)(B) to account for this distinction. We also clarify that we will exclude sales tax from the aggregation, if necessary for the project. We also propose changes to the regulatory text to incorporate notes from the current Appendix that are not addressed by the existing reference to CMS data sharing procedures in § 423.505(m)(1)(ii).

Therefore, consistent with the foregoing, we propose the following revisions to the applicable regulatory text:

- Section 423.505(f)(3) would be revised to add supporting program integrity purposes, including coordination with states, as an additional purpose.
- Section 423.505(m)(1)(iii) would be revised to remove references to encrypting certain identifiers since prescriber, plan, and pharmacy identifiers would no longer be subject to encryption when released.
- Section 423.505(m)(1)(iii)(A) would be revised to clarify that, subject to the restrictions contained in paragraph (m)(1), all elements on the claim are available not only to HHS, but also to other executive branch agencies and states, since there is no longer any distinction between the two categories.
- Section 423.505(m)(1)(iii)(B) would be revised to incorporate a note from the appendix, which states: ''Upon request, CMS excludes sales tax from the aggregation at the individual level, if necessary for the project'' at the end of the provision.
- Section 423.505(m)(1)(iii)(C) would be deleted as no longer necessary since unencrypted plan identifiers, including the internal plan/pharmacy identification numbers, would be available for release.
- Section 423.505(m)(1)(iii)(D) would be re-lettered as (C) and references to encryption of pharmacy and prescriber identifiers would be deleted, since these identifiers would be available for release in unencrypted format. Additional language regarding beneficiary identifiers would be added to the existing provision to reflect the current policy on release of this identifier as reflected in the appendix that would be eliminated.
- Section 423.505(m)(3) would be revised to incorporate a note from the appendix that would be eliminated about the status of the Congressional Research Service as an external entity when it is not acting on behalf of a Congressional committee in accordance with 2 U.S.C. 166(d)(1).

34. Establish Authority To Directly Request Information From First Tier, Downstream, and Related Entities (§ 422.504(i)(2)(i), and § 423.505(i)(2)(i))

Pursuant to section 1857(d)(2) and 1860D–12(b)(3)(c) of the Act, existing regulations at 42 CFR 422.504(i) and 42 CFR 423.505(i) establish various conditions that entities contracting as a first tier, downstream, or related entity (FDR) to an MA organization or Part D sponsor must agree to in order to participate in the MA or Part D program. One such condition at § 422.504(i)(2)(i) and § 423.505(i)(2)(i) is that HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and related (FDR) entities related to CMS' contract with the Part C and D sponsor.

CMS (or its designee(s)) conduct routine audits of Part D sponsors and MA organizations, as well as conduct audits to investigate allegations of noncompliance with Part C and/or Part D rules and requirements. While § 422.504(d) and § 423.505(d) address Part D and MA organizations' own maintenance of records and the rights of CMS to inspect those records, § 422.504(i)(2)(i) and § 423.505(i)(2)(i) also require plan sponsors require that their FDRs agree to this CMS right to inspection. Plan sponsors regularly contract with FDRs to perform critical Part C and D operating functions. For example, many (if not most) Part D sponsors delegate critical Part D functions to their PBMs. As a result, many of the records that we or our designees would need to review and evaluate when we audit a Part D sponsor or MA organization reside with its FDRs.

Our existing regulation at § 423.505 (i)(3)(iv) states that the contracts between the Part D sponsor and its FDRs must indicate whether records held by the FDR pertaining to the Part D contract will be provided to the sponsor to provide to CMS (upon request), or will be provided directly to CMS or its designees by the FDR (the Part C regulation is silent on this matter). As such, we have not previously required Part C or Part D FDRs to provide information directly to CMS.

Two separate reports by the OIG (OEI–03–08–00420, dated October 2009 and OEI 03–11–00310, dated January 2013), have highlighted barriers experienced by the Medicare Drug

Integrity Contractor (MEDIC), the entity contracted by CMS to be responsible for detecting and preventing fraud, waste, and abuse in the Medicare Parts C and D programs nationwide, in obtaining requested information in an expeditious manner. The 2009 OIG report discussed that CMS' and its designees' (in this case, the MEDIC) lack of authority to directly obtain information from pharmacies, PBMs, and physicians has hindered the MEDIC's ability to investigate potential fraud and abuse and the OIG recommended that CMS change its regulations to establish its authority to obtain necessary information directly from FDRs. The OIG's 2013 report reiterated the recommendation that CMS have a more direct route to obtain records held by FDRs so that CMS would be able to obtain necessary records in a timely fashion. While the 2013 report pointed out that sponsors and their FDRs generally cooperate in providing the information requested by the MEDIC, it often takes months for it to reach the MEDIC because the MA organization or Part D sponsor acts as a gatekeeper.

In the past, we chose not to be prescriptive regarding whether a first tier, downstream, or related entity must make its books and records available to us directly or through the Part C or D sponsor. As a consequence of what we have learned through the OIG investigations and the seriousness with which we approach our fraud, waste, and abuse oversight obligations, we are now proposing to specify at § 422.504(i)(2)(ii) and § 423.505(i)(2)(ii) that HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any records by obtaining them directly from any first tier, downstream, or related entity. This proposed regulatory change would not grant CMS any investigative or audit authority that we do not already possess. It would merely guarantee us a direct and expeditious route to the information we need to obtain for purposes of program oversight. This regulatory change would also reduce the burden on the plan sponsor. The plan sponsor would no longer need to act as the gatekeeper between CMS and its first tier, downstream, or related entity. Upon making contact with the first tier, downstream, or related entity, we would simultaneously notify the plan sponsor concerning the nature of the request. This will ensure that the plan sponsor will have notice that we are contacting one of its subcontractors.

We are proposing to revise the regulation at § 422.504(i)(2)(i) and § 423.505(i)(2)(i) to make clear that CMS and its designees may ''collect'' records, in addition to our existing authority to ''audit, evaluate, and inspect'' information. The addition of ''collect'' removes any doubt that, in addition to our other options for obtaining records, we have the authority to request information to be reviewed in some location other than onsite at a sponsor's or FDR's facility. Furthermore, the proposed provision is intended to clarify only that CMS may contact FDRs directly and request that they provide Part C or D-related information directly to CMS. The question as to whether CMS has the authority to enter the premises of FDRs, is to be determined by interpreting other applicable statutory and regulatory authority.

We also propose to delete the existing provision at § 423.505(i)(3)(iv) which gives Part D sponsors the choice as to how information sought from their FDRs will be provided to CMS. Section 423.505 would be renumbered so that paragraphs (v)–(viii) would become paragraphs (iv)–(vii).

35. Eligibility of Enrollment for Incarcerated Individuals (§ 417.1, § 417.460, § 422.74, and § 423.44)

Entitlement and enrollment in the Medicare program (Part A and Part B) is contingent on entitlement to Social Security retirement and disability benefits as outlined in sections 226 and 226A of the Act, and enrollment in the Medicare program for individuals not receiving retirement or disability benefits is outlined in sections 1818 and 1818A of the Act. These sections do not preclude entitlement to or enrollment in the Medicare program for individuals who are incarcerated in prisons or other penal facilities. However, section 1862(a)(3) of the Act excludes Medicare payment for services which are paid directly or indirectly by another government entity, including federal, state and local prisons, and penal facilities. Given that Medicare entitlement flows from entitlement to Social Security retirement and disability benefits, we established regulations at § 411.4(b) and implemented section 1862(a)(3) of the Act through a payment exclusion process in the FFS program, outlined in section 50 of Chapter 16 of the Medicare Benefit Policy Manual and section 10.4 of the Medicare Claims Payment Manual.

The Medicare payment exclusion process includes the receipt of incarceration status for individuals via regular data exchanges from the SSA to CMS. Once we receive the data, the incarceration status is noted on the individual's record and is retained in the FFS claims processing systems. Upon receipt of submitted FFS claims, CMS denies payment of both Part A and Part B claims for individuals with records on which incarceration is denoted. The denial of claims continues until the individual is no longer considered incarcerated and that information is reported by SSA to CMS. Individuals who are entitled to premium-free Part A will maintain their entitlement and will remain enrolled in Part B as long as premiums are paid. Similarly, individuals who are enrolled in premium Part A and/or Part B maintain their enrollment as long as premiums are paid. Sections 1851(a)(3)(B), 1860D–1(a)(3)(A), and 1876(a)(1)(A) of the Act outline the eligibility requirements to enroll in MA, Part D, and Medicare Health Maintenance Organization/Competitive Medical Plans (cost plans). In all options, individuals must have active Medicare coverage. Specifically, to enroll in MA, an individual must be entitled to Part A and enrolled in Part B; to enroll in a PDP, an individual must be eligible for Part D by either being entitled to Part A and/or enrolled in Part B; to enroll in a Medicare cost plan, an individual must be enrolled in Part B but Part A is not required.

In addition, sections 1851(b)(1)(A), 1860D–1(b)(1)(B)(i), and 1876(d) of the Act provide that Medicare beneficiaries are eligible to enroll in an MA plan, PDP, or cost plan only if they reside in the geographic area served by the plan, known as the plan's ''service area.'' As noted earlier, an individual who is incarcerated still meets the eligibility requirements for Part A and Part B and is eligible generally to enroll in an MA plan, PDP, or cost plan. However, residence in a plan's service area is also a condition for eligibility to enroll in an MA plan, PDP or cost plan. See § 422.50(a)(3)(i) for MA plans, § 423.30(a)(1)(ii) for PDPs, and § 417.422(b) for cost plans. If a member no longer resides in the service area, plans must disenroll that individual per rules at § 422.74(a)(2)(i) and § 422.74 (d)(4) for MA plans, § 423.44(b)(2)(i) for PDPs, and § 417.460(b)(2)(i) for cost plans.

a. Changes in Definition of Service Area for Cost Plans (§ 417.1)

In order to implement the exclusion from Medicare coverage for incarcerated individuals under section 1862(a)(3) of the Act in the case of MA plans and PDPs, we explicitly excluded facilities in which individuals are incarcerated from an MA plan's service area by including this exclusion in the definition of ''service area'' (54 FR 41734 and 72 FR 47410). Specifically, ''service area'' is defined in § 422.2 for

MA plans and § 423.4 for PDPs and both definitions indicate that facilities in which individuals are incarcerated are considered outside of the service area.

We did not include a similar service area exclusion in the case of cost plans. To the extent that cost plans do not incur costs for incarcerated enrollees because their health care costs are covered by the facility, there would be no costs claimed on the cost report, and no Medicare payment. Nonetheless, to ensure that no cost payments are made, we propose to revise the definition of service area in § 417.1 to specifically note that facilities in which individuals are incarcerated are not a part of the service area. This adjustment will ensure parity among the various Medicare plan coverage options and be the basis for ensuring that services are not paid for by the Medicare Trust Funds for those who are not eligible for them.

b. Involuntary Disenrollment for Incarcerated Individuals Enrolled in MA, PDP and Cost Plans (§ 417.460, § 422.74, and § 423.44)

Sections 1860D–1(b)(1)(B)(i), 1851(b)(1)(A), and 1876(a)(1)(A) of the Act provide that individuals whose permanent residence is outside the plan's service area are ineligible to enroll in or to remain enrolled in the MA, Part D, or cost plan. Based on the definition of service area established in § 422.2 and § 423.4, this applied to individuals who were incarcerated as well. As such, individuals who became incarcerated while enrolled were ineligible to remain enrolled because they did not meet the eligibility criterion of residing in the MA plan or PDP's service area. As noted previously, the regulations for cost plans currently do not exclude incarcerated individuals from enrolling or remaining enrolled in these plans.

At the time of the implementation of Part D, the data regarding incarceration were not as robust as they are at the present time. To compensate, we provided instructions in sub-regulatory guidance that required MA plans and PDPs to investigate a notification from CMS of an individual's incarcerated status. If a plan could not confirm the status, the plan would then apply the policy for investigation of a possible out-of-area status which would allow an incarcerated individual to remain enrolled in the plan for up to 6 or 12 months for MA plans or PDPs, respectively. Cost plans, on the other hand, are not currently subject to similar instructions and therefore individuals are not disenrolled solely because they are determined to be incarcerated.

Today we believe that the data that CMS receives from SSA regarding the incarceration status of Medicare beneficiaries are reliable enough for the purpose of involuntary disenrollment from MA, Part D, and cost plans. Thus, we propose to amend § 417.460(b)(2)(i), § 417.460(f)(1)(i), § 422.74(d)(4)(i), § 422.74(d)(4)(v) and add § 423.44(d)(5)(iii) and § 423.44(d)(5)(iv) to establish that MA organizations, PDPs, and cost plan organizations must disenroll individuals incarcerated for 30 days or more upon notification of such status from CMS. As a part of this change, CMS will review the incarceration data provided by SSA. Where possible, CMS will involuntarily disenroll individuals who are incarcerated based on the data provided by SSA, and will notify the plan in which the individual is enrolled of this action. For all such disenrollments, the effective date of disenrollment will be the first of the month after the start of incarceration date as reported by SSA. We believe these proposed changes will prevent months of improper payments to MA, Part D, and cost plans and significantly lessen the burden for MA plans and PDPs by not requiring investigation to verify residence as outlined in section 50.2.1 in Chapter 2 of the Medicare Managed care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual.

In connection with this change, we would also propose to deny enrollment requests for individuals if CMS data indicates an active incarceration status of at least 30 days. Based on the data received from SSA, if incarceration is denoted, we will deny that enrollment based on the data provided by SSA and will notify the plan of the denial. This would replace the current process requiring plans to accept the enrollment and immediately begin the process to verify that the individual was out of the plan's service area. We will provide operational instructions in subregulatory guidance.

In addition, we will clarify that in instances where a plan receives information about an individual's possible incarceration from a source other than CMS or learns of some other permanent residence change, the existing requirements to research a possible change in address would still apply. Finally, we note that the exceptions to involuntary disenrollment for not residing in the plan's service area (§ 417.460(f)(2) and § 422.74(d)(4)(iii)) would not apply to members who are determined to be incarcerated. However, individuals involuntarily disenrolled will be able to enroll in a plan following their release from incarceration using an existing special enrollment period outlined in section 30.4.1 in Chapter 2 of the Medicare Managed Care Manual and section 30.3.1 in Chapter 3 of the Medicare Prescription Drug Benefit Manual (Special Enrollment Periods (SEP) for Changes in Residence). Individuals wanting to enroll in an open cost plan may do so as long as the cost plan is accepting applications for enrollment, following section 30.1 of Chapter 17–D of the Medicare Managed Care Manual.

36. Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134)

CMS has provided subregulatory guidance regarding the types of rewards and incentives that may be offered to current Medicare Advantage (MA) plan enrollees. (See Section 70.2, Chapter 3 of the Medicare Managed Care Manual). Generally, such activities are limited to a set monetary cap, and cannot be offered in the form of cash or other monetary rebates or considered a health benefit. This guidance generally flows from our authority to regulate marketing by MA organizations and our recognition that certain marketing efforts may be targeted to current enrollees to encourage continued enrollment and reenrollment in a particular plan.

Every year, CMS receives inquiries from MA organizations that wish to expand the scope of the rewards and incentives that currently may be offered to beneficiaries enrolled in their MA plans. In some cases, MA organizations wish to extend rewards and incentives already offered to their commercial members to their Medicare enrollees and there is some evidence to suggest that health-driven reward and incentive programs for currently enrolled members of health plans may lead to meaningful and sustained improvement to their health behaviors and health outcomes.

CMS would like to enable MA organizations to offer health-driven rewards and incentives programs that may be applied to more health-related services and activities than are allowed under current guidance. We are concerned about the possibility that such programs would be targeted only to healthier enrollees, and discourage sicker enrollees from participating in such incentives and in remaining enrolled in the plan. Furthermore, we would like to strengthen our existing subregulatory guidance and offer the opportunity for public review and

comment on our requirements for rewards and incentives programs. We propose to amend our regulations to establish parameters for rewards and incentives programs offered to enrollees of MA plans. We also propose to include specific requirements regarding rewards and incentives so as to ensure that such programs do not discriminate against beneficiaries, including those who are sick or disabled.

Section 1856(b)(1) of the Act provides authority for the establishment of MA standards by regulation, and section 1857(e)(1) of the Act provides authority to impose contract requirements that CMS finds ''necessary and appropriate.'' Section 1852(b)(1)(a) of the Act states that MA organizations may not discriminate against beneficiaries on the basis of health status and that CMS may not approve an MA plan if that offering is susceptible to discrimination based on an individual's health status. Further, section 1857(g)(1)(D) of the Act provides authority for taking intermediate sanction action against an MA organization which ''engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment by eligible individuals'' as a result of their health status or history. We propose to rely upon the aformentioned rulemaking and substantive authority to establish requirements for rewards and incentives programs offered by MA organizations to Medicare beneficiaries enrolled in their MA plans.

Specifically, we propose adding a new provision at § 422.134 that would allow MA organizations to offer reward and incentive programs to their current Medicare enrollees to encourage their participation in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources. We would require that reward-eligible activities be designed so that all enrollees are able to earn rewards without discrimination based on race, gender, chronic disease, institutionalization, frailty, health status, and other impairments. Any rewards and incentives program implemented by an MA organization under our proposal must accommodate enrolled beneficiaries who are institutionalized or who need a modified approach to enable effective participation.

To meet the proposed CMS requirements, a reward or incentive would have to be earned by completing the entire health-related service or activity and may not be offered for completion of less than all required components of the eligible service or activity. Under this proposal, rewards and incentives would be subject to a monetary cap in an amount CMS determines could reasonably be expected to affect enrollee behavior while not exceeding the value of the health-related service or activity itself. We intend to provide guidance on this qualitative standard on a regular basis.

In addition, our proposal would require MA organizations that offer rewards and incentives programs to provide information about the effectiveness of such programs to CMS upon request. If we determine that the rewards and incentives programs are not compliant with our regulatory standard, we may require that the MA organization modify the basic parameters of the program.

37. Expand Quality Improvement Program Regulations (§ 422.152)

Section 1852(e) of the Act requires MA organizations to have an ongoing quality improvement program for the purpose of improving the quality of care provided to enrollees. Our current regulations at § 422.152 require an MA organization to have a quality improvement program that measures, records, and reports on the quality of care it is providing to enrollees and to develop criteria for a chronic care improvement program. We have recently expanded our quality improvement program to include more specific and structured chronic care improvement program requirements that are outcomes based and health driven as well as require each MA organization to have a written quality improvement program plan (approved form CMS–10209). Currently, chronic care improvement programs must be measurable, reported on annually, and has a clinical focus (as determined by CMS).

We propose revising paragraph (a) of § 422.152 in order to codify our recent expansion of the quality improvement program policies and revising paragraph (c) of § 422.152 to codify our recently expanded chronic care improvement program policies. These revised paragraphs will more accurately reflect current quality care improvement program policies and requirements.

Additionally, paragraph (g) of § 422.152 lists quality improvement program requirements that are specific to special needs plans (SNPs). We propose revising paragraph (g) to clarify that the requirements listed there are in addition to program requirements listed in paragraphs (a) and (f) of § 422.152 and are not instead of the regular quality improvement program requirements.

Finally, we propose to delete paragraph (h)(2) of § 422.152 as it pertains to plan year 2010 and is no longer relevant.

38. Authorization of Expansion of Automatic or Passive Enrollment Non-Renewing Dual Eligible SNPs (D–SNPs) to Another D–SNP To Support Alignment Procedures (§ 422.60)

At this time, SNPs are only authorized through 2014. This proposed provision, which would take effect in 2015, is contingent upon, and would only apply, if SNPs continue to be authorized after 2014.

Since D–SNPs were implemented in 2006, expectations for them to serve as a vehicle for aligning Medicare and Medicaid benefits for dually eligible individuals have been articulated. In 2007, the Congress passed the Medicare Improvements for Patients and Providers Act (MIPPA), which set 2013 as the deadline for all D–SNPs to have contracts with states to coordinate their enrollees' Medicaid coverage. In 2010, the Congress passed the Affordable Care Act, section 2602 of which established a new CMS office charged with implementing goals to improve the coordination between the federal government and states for individuals eligible for benefits under both Medicare and Medicaid programs in order to ensure that such individuals get full access to the items and services to which they are entitled. Specifically listed in sections 2602(c)(2) and (6) of the Affordable Care Act, we are tasked with simplifying the processes for Medicare-Medicaid enrollee to access the items and services they are entitled to under the Medicare and Medicaid programs, and improving care continuity and ensuring safe and effective care transitions for Medicare-Medicaid enrollees.

Our current authority does not allow us to limit involvement in the D–SNP program to fully integrated D–SNPs; thus, the majority of Medicare-Medicaid enrollees enrolled in D–SNPs continue to receive their Medicare and Medicaid benefits and services from two different organizations. At the same time, some states are approaching this problem from a slightly different angle, and are attempting to align care for Medicare-Medicaid enrollees under the same organization by requiring that the same organization that provides Medicaid benefits also provide Medicare benefits. However, states' efforts stall when the Medicare-Medicaid enrollee is enrolled with one organization for his/her Medicaid coverage, but in a D–SNP offered by another MA organization. The statute generally requires that

Medicare beneficiaries make an active choice of their health plan, so neither plans nor states can choose where the beneficiary enrolls.

The resulting fragmentation of care can generally be addressed through existing mechanisms. For example, State Medicaid Agencies may pursue waiver authority from CMS to require Medicare-Medicaid enrollees to enroll in Medicaid Managed Care Organizations (MCO) that also offer a D–SNP. Likewise, anMA organization offering a D–SNP could novate its contract with CMS to the organization offering the Medicaid MCO, so that the entire contract, including the D–SNP, and its enrollees, is now held by the same organization that offers the enrollees' Medicaid managed care plan. However, while we can approve novations, we cannot mandate that the parties enter into such arrangements. Moreover, when an MA organization elects to non-renew its Medicare contract, rather than novate the contract, we do not have the authority to move enrollees under that contract to another MA organization offering a D–SNP.

Another possible solution to the problem of fragmented care lies in section 1851(c)(1) of the Act, which we have interpreted to provide flexibility in developing mechanisms by which beneficiaries may complete voluntary MA enrollment elections (per section 1851(a)(1) of the Act). These flexibilities include a process described as ''passive enrollment,'' whereby beneficiaries are notified of the enrollment opportunity and provided sufficient advance information to determine if they will accept this option. A beneficiary who is offered a passive enrollment completes the request to enroll by not declining the offer. However, we have limited passive enrollment to situations in which enrollees in MA plans that are terminating immediately have little or no time to choose another MA plan option or stand-alone PDP, and are at risk for losing their prescription drug coverage (see 42 CFR 422.60(g)).

Generally, we have declined to afford ourselves such discretion to provide passive enrollment in more situations, in part, because of concerns raised by beneficiary advocates about the challenges beneficiaries face in navigating a new provider network and understanding information about new benefits. In addition, we have also been concerned that, were we to widen the scope of our authority to allow passive enrollment in other situations not involving an immediate termination, we would be faced with the seemingly impossible task of sorting through requests by MA organizations to passively enroll members to other plans within their organization, or across organizations, and granting or denying such requests without appearing to act in an arbitrary and capricious manner, or unintentionally interfering with the voluntary nature of the MA program. Thus, we have limited our use of our passive enrollment authority by regulation to those situations in which beneficiaries faced an immediate plan termination or potential harm, and where we could, through passive enrollment, ensure that beneficiaries maintained access to affordable coverage, including prescription drug coverage.

To date, we have not considered D–SNP non-renewals to fall under either category, because, by definition, non-renewals occur with appropriate, 90 days' notice to affected enrollees, just prior to the start of the annual enrollment period, when enrollees have access to the Medicare & You handbook and other materials, as well as ample time to consider their health care choices.

However, it is worth noting that returning to Original Medicare, whether due to an immediate contract termination or non-renewal, poses potential disadvantages for the beneficiary as well, that is, the loss of supplemental benefits such as dental or vision benefits, and beneficiary confusion as he or she attempts to navigate the health care system (and two sets of benefits) without case management or other support that may have been provided by the MA plan. We have the authority to widen the scope of the regulation slightly to allow for passive enrollment when a Medicare-Medicaid enrollee is enrolled in a D–SNP that is non-renewing its contract with Medicare, and is enrolled in a Medicaid MCO (Managed Care Organization) that also offers a D–SNP, and the networks and benefits of the non-renewing D–SNP and the future D–SNP are substantially similar. By exercising passive enrollment in this additional limited circumstance, we could better ensure better continuity of care, particularly prescription drug coverage, but also possibly supplemental benefits, and ensure beneficiaries enjoy use of the same providers, with little or no change in the benefits offered. Our use of passive enrollment in this case would also further promote alignment of Medicare and Medicaid benefits offered by the same organization. Through sub-regulatory guidance, we would interpret the ''substantially similar'' standard as it relates to the networks, benefit packages, formularies, and out of pocket costs of the non-renewing and gaining D–SNP. As already required by § 422.60(g)(2), we would ensure beneficiaries are notified of the costs and benefits of the plan, and of their ability to decline enrollment or choose another plan. As part of our proposal to add this additional basis for passive enrollment, we propose to restructure paragraph (g).

*B. Improving Payment Accuracy*

1. Implementing Overpayment Provisions of Section 1128J(d) of the Social Security Act (§ 422.326 and § 423.360)

This section of the proposed rule would implement section 6402 of the Affordable Care Act, which established new section 1128J(d) of the Act entitled Reporting and Returning of Overpayments. Section 1128J(d)(4)(B) of the Act defines the term overpayment as any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title. The definition of person at section 1128J(d)(4)(C) of the Act includes a Medicare Advantage organization (as defined in section 1859(a)(1) of the Act) and a Part D sponsor (as defined in section 1860D–41(a)(13) of the Act). The definition does not include a beneficiary.

Section 1128J(d)(1) of the Act requires a person who has received an overpayment to report and return the overpayment to the Secretary, the state, an intermediary, a carrier, or a contractor, as appropriate, at the correct address, and to notify the Secretary, state, intermediary, carrier or contractor to whom the overpayment was returned in writing of the reason for the overpayment. Section 1128J(d)(2) of the Act requires that an overpayment be reported and returned by the later of: (1) The date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable. Section 1128J(d)(3) of the Act specifies that any overpayment retained by a person after the deadline for reporting and returning an overpayment is an obligation (as defined in 31 U.S.C. 3729(b)(3)) for purposes of 31 U.S.C. 3729.

Finally, section 1128J(d)(4)(A) of the Act defines ''knowing'' and ''knowingly'' as those terms are defined in 31 U.S.C. 3729(b). Specifically, the terms ''knowing'' and ''knowingly'' mean that ''a person with respect to information: (1) Has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the

information; or (3) acts in reckless disregard of the truth or falsity of the information.'' There need not be ''proof of specific intent to defraud.''

To implement section 1128J(d) of the Act for the Part C Medicare Advantage program and the Part D Prescription Drug program, we are proposing two new sections, § 422.326 and § 423.360, respectively, both titled, ''Reporting and Returning of Overpayments.'' These sections propose rules for MA organizations and Part D sponsors to report and return an identified overpayment to the Medicare program. We are using the term Part D sponsor, as defined at § 423.4, to refer to the entities that offer prescription drug plans (PDPs) under part 423 and thus are subject to section 1128J(d) of the Act.

We propose conforming amendments to § 422.1, § 422.300, and § 423.1 that add a reference to section 1128J(d) of the Act to the existing list of statutory authorities for the regulations governing the MA organizations and Part D sponsors. We also propose to amend § 422.504(l) and § 423.505(k) to incorporate a reference to the proposed § 422.326 and § 423.360, respectively, in order to extend the existing data certification requirement to data that MA organizations and Part D sponsors submit to CMS as part of fulfilling their obligation to return an overpayment under section 1128J(d) of the Act. Section 422.504(l) refers to certification of data ''as a condition for receiving a monthly payment'' and § 423.505(k) refers to certification of data for enrollees ''for whom the organization is requesting payment.'' Our proposal to implement section 1128J of the Act contains requirements that apply after CMS has completed prospective monthly payments for a year, and organizations are no longer ''requesting payment'' because applicable reconciliation has occurred. Applicable reconciliation is the point when organizations submit their final data for the previous payment year. Accordingly, if an MA organization or Part D sponsor has identified an overpayment, there clearly is a different state of ''best knowledge, information, and belief'' than the state of knowledge, information, and belief that existed prior to applicable reconciliation. Thus, we propose to require that the CEO, CFO, or COO must certify (based on best knowledge, information, and belief) that information the MA organization or Part D sponsor submits to CMS for purposes of reporting and returning of overpayments under § 422.326 and § 423.360 is accurate, complete, and truthful.

We remind all stakeholders that even in the absence of a final regulation on these statutory provisions, MA organizations and Part D sponsors are subject to the statutory requirements found in section 1128J (d) of the Act and could face potential False Claims Act liability, Civil Monetary Penalties (CMP) Law liability, and exclusion from Federal health care programs for failure to report and return an overpayment. Additionally, MA organizations and Part D sponsors continue to be obliged to comply with our current procedures for handling inaccurate payments.

a. Terminology (§ 422.326(a) and § 423.360(a))

We propose to adopt the statutory definition of overpayment, where an overpayment exists when—after ''applicable reconciliation''—an MA organization or Part D sponsor is not entitled to funds it has received and/or retained. In order to clarify the statutory definition of overpayment, we propose definitions of two key terms at § 422.326(a) and § 423.360(a): ''funds'' and ''applicable reconciliation.''

We propose to define ''funds'' as payments an MA organization or Part D sponsor has received that are based on data that these organizations submitted to CMS for payment purposes and for which they have responsibility for the accuracy, completeness, and truthfulness of such data under existing § 422.504(l) and § 423.505(k). For Part C, the data submitted by the MA organization to CMS includes § 422.308(f) (enrollment data) and § 422.310 (risk adjustment data). For Part D, data submitted by the Part D sponsor to CMS includes data submitted under § 423.329(b)(3), § 423.336(c)(1), § 423.343, and data provided for purposes of supporting allowable costs as defined in § 423.308 of this part which includes data submitted to CMS regarding direct or indirect remuneration (DIR).

There are additional payment-related data CMS uses to calculate Part C and Part D payments that are submitted directly to CMS by other entities, such as the Social Security Administration (SSA), which is the authoritative source for data they submit to CMS. We believe that MA organizations and Part D sponsors cannot be held accountable for the accuracy of data controlled and submitted to us by other entities.

For example, the SSA is the authoritative source for date of death. An MA organization or Part D sponsor generally do not submit a date of death directly to CMS' systems; it comes from the SSA data feed. When the SSA submits to CMS corrected data regarding a beneficiary's date of death, CMS' systems recalculate the payments made to the plan for that beneficiary and recoup the incorrect payment in a routine retroactive payment adjustment process.

When CMS recoups an incorrect payment from an MA organization or Part D sponsor based on data corrections submitted by authoritative sources such as the SSA, CMS would not consider this recoupment to be the return of an overpayment by an MA organization or Part D sponsor under proposed § 422.326 and § 423.360. Therefore, the proposed meaning of ''funds'' refers to a payment amount that an MA organization or Part D sponsor received from CMS that is based on data that the MA organization or Part D sponsor controls and submits to CMS.

The term ''applicable reconciliation'' refers to an event or events after which an overpayment can exist under section 1128J(d) of the Act. We propose definitions of the term applicable reconciliation that are specific to the Part C and Part D.

For Part C, we propose that applicable reconciliation occurs on the date that CMS announces as the final deadline for risk adjustment data submission. (See section II.B.6 of this proposed rule for a discussion of the final deadline for risk adjustment data submission established at § 422.310(g).) For each payment year, we apply three sets of risk scores to adjust payments: Initial and midyear risk scores during the payment year (both sets are based on incomplete diagnosis data from the data collection year); and final risk scores after the payment year using data MA organizations submit on or before the final deadline for risk adjustment data (which reflects complete data for the data collection year). Currently, the final deadline for risk adjustment data submission is a month after the end of the payment year. In future years, we expect to announce a date that will be about 6 to 8 weeks after the end of the payment year to accommodate the current subregulatory requirement that MA organizations review the monthly enrollment and payment reports they receive from CMS within 45 days of the availability of the reports. Moving this deadline means that the risk adjustment data submission deadline would also function as the Part C applicable reconciliation date. We would announce a final risk adjustment data submission deadline that falls on or just after the conclusion of this 45-day period for the January payment.

For Part D sponsors, we propose that applicable reconciliation is the later of either: The annual deadline for

submitting prescription drug event (PDE) data for the annual Part D payment reconciliations referred to in § 423.343 (c) and (d) or the annual deadline for submitting DIR data. The annual deadline for submitting PDE data is the last federal business day prior to June 30th of the year following the benefit year being reconciled. The annual deadline for submitting DIR data is announced annually through subregulatory guidance and generally occurs around the last business day in June the year following the benefit year being reconciled. We select these events to define the Part D applicable reconciliation because these data are used for the purposes of determining final Part D payment reconciliation. Note that MA organizations would still have to submit all final risk adjustment diagnoses for Part D on the final deadline for risk adjustment data submission.

The proposed approach to defining applicable reconciliation establishes dates that differ for Part C and Part D. One effect of this approach is that risk adjustment and enrollment data for Part D are subject to the § 423.360 overpayment requirements at a later date than risk adjustment and enrollment data for Part C. The final risk adjustment data submission deadline for Parts C and D data would continue to be earlier than the deadline for final submission of PDE and DIR data. For this reason, we considered an alternative approach to defining applicable reconciliation, where there is one date for applicable reconciliation for both Parts C and D risk adjustment data and enrollment data (which would be about 6 to 8 weeks after the end of the payment year, going forward), and then the Part D program would be subject to a second applicable reconciliation date the date for final submission of PDE data or DIR data, whichever is later. We are proposing a single date for each program, and we seek comment on these two approaches.

Note that payment errors identified as a result of any corrections to risk adjustment data submitted by MA organizations (and other organizations required to submit risk adjustment data to CMS) on or before the annual final risk adjustment data submission deadline are handled as part of the current annual process of risk adjustment payment reconciliation. Because these payment errors are prior to the date defined in this proposed rule as ''applicable reconciliation,'' we do not consider these errors to be overpayments for the purpose of § 422.326 and § 423.360. That is, any deletions of risk adjustment data in the file submitted on or before the final risk adjustment data submission deadline for a payment year, would result in payment errors that are addressed with processes that have been in place prior to our codification of section 1128J(d) of the Act in proposed § 422.326 and § 423.360.

Likewise, for Part D, any payment errors identified as a result of any corrections to PDE or DIR data submitted on or before the later of the annual deadline for submitted PDE and DIR data are handled as part of the current Part D reconciliation process.

It is our expectation that MA organizations and Part D sponsors must be continuously diligent regarding the accuracy and completeness of payment-related data they submit to CMS for a payment year, whether during or after that payment year, and whether before or after applicable reconciliation dates. This expectation is based on existing requirements at § 422.310, § 422.504(l), § 423.329(b)(3)(ii), and § 423.505(k), and our proposed amendments that clarify and strengthen these requirements.

b. General Rules for Overpayments (§ 422.326(a) Through (c); § 423.360(a) Through (c))

We propose at § 422.326(b) and § 423.360(b) that if an MA organization or Part D sponsor has identified that it has received an overpayment, the MA organization or Part D sponsor must report and return that overpayment in the form and manner set forth in the section. In paragraphs § 422.326(c) and § 423.360(c), we propose that the MA organization or Part D sponsor has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment. The terms ''reckless disregard'' and ''deliberate ignorance'' are part of the definitions of the ''knowing'' and ''knowingly'' in section 1128J of the Act, which provides that the terms ''knowing'' and ''knowingly'' have the meaning given those terms in the False Claims Act (31 U.S.C. 3729(b)(3)). Without such a proposal to include ''reckless disregard'' and ''deliberate ignorance'', some MA organizations and Part D sponsors might avoid performing activities to determine whether an overpayment exists. We also provide that if an MA organization or Part D sponsor has received information that an overpayment may exist, the organization must exercise reasonable diligence to determine the accuracy of this information, that is, to determine if there is an identified overpayment.

Finally, in paragraphs § 422.326(d) and § 423.360(d), we propose the requirements for reporting and returning an identified overpayment. An MA organization or Part D sponsor must report and return any overpayment it received no later than 60 days after the date on which it identified it received an overpayment. The statute provides an alternative deadline: the date any corresponding cost report is due, if applicable. We propose that this alternative deadline is not applicable to the Parts C or D programs because, in general, MA organizations and Part D sponsors are paid based on their bids, and not based on their actual incurred costs.

The MA organization or Part D sponsor must notify CMS, using a notification process determined by CMS, of the amount and reason for the overpayment. Also within this 60-day time period, the organization must return identified overpayments to CMS in a manner specified by CMS, including the amount and reason for the overpayment. We codify at paragraph (3) the statutory requirement that any overpayment retained by an MA organization or Part D sponsor after the 60-day deadline for reporting and returning is an obligation under 31 U.S.C. 3729(b)(3).

It also is important to note that the MA organization and Part D sponsor are deemed to have returned the overpayment when they have taken the actions that we will specify, in forthcoming operational guidance, to submit the corrected data that is the source of the overpayment. We will recover the returned overpayment through routine processing according to the systems schedule established in the annual operations budget. That is, payments are recovered through the established payment adjustment process, not on the 60-day schedule that applies to each MA organization or Part D sponsor that has identified an overpayment. Rerunning reconciliation each time an entity identifies an overpayment that triggers its 60-day clock is simply not feasible for CMS.

Further, there will be circumstances when we may ask the MA organization or Part D sponsor to provide an auditable estimate of the overpayment amount, reason for overpayment, and make a payment to CMS. This may occur, for example, when the Part D reopening occurs prior to the end of the look-back period or if an MA organization or Part D sponsor had a thoroughly-documented catastrophic loss of stored data. Information about the nature of such a request would be detailed in forthcoming operational guidance.

c. Look-Back Period for Reporting and Returning Overpayments

We propose at § 422.326(e) and § 423.360(e) to codify a look-back period for MA organizations and Part D sponsors. MA organizations and Part D sponsors would be required to report and return any overpayment that they identify within the 6 most recent completed payment years. The statute of limitations related to the False Claims Act is 6 years from the date of the violation or 3 years from the date the relevant government official learns of the situation, but in no case more than 10 years from the date of the violation. CMS proposes 6 years as the look-back period because we believe this best balances government's interest in having overpayments returned with entities' interest in finality. Six years also is consistent with the CMP provisions, and maintenance of records requirements under the contracts. Note that overpayments resulting from fraud would not be subject to this limitation of a look-back period.

2. Determination of Payments (§ 423.329)

Section 423.329 (d) describes the low-income cost-sharing subsidy payment amount. Currently, that amount is defined as the amount described in § 423.782. However, § 423.782 refers to the cost-sharing paid by the beneficiary, not the cost-sharing subsidy paid on behalf of the low-income subsidy eligible individual. As such, we propose a technical change to § 423.329(d) to correctly describe the low-income cost-sharing subsidy payment amount as it is intended by statute and has been implemented and described in interpretive guidance by CMS.

The low-income cost-sharing subsidy amount is correctly described in Chapter 13 of our Medicare Prescription Drug Benefit Manual, Premium and Cost-Sharing Subsidies for Low-Income Individuals (Rev. 13, July 29, 2011). Under the basic benefit defined at § 423.100, the low-income cost-sharing subsidy payment amount is the difference between the cost sharing for a non-LIS beneficiary under the Part D plan and the statutory cost-sharing for the LIS eligible beneficiary. Under an enhanced alternative plan described at § 423.104(f), the cost-sharing subsidy applies to the beneficiary liability after the plan's supplemental benefit is applied. We propose to amend § 423.329(d) consistent with this guidance.

Pursuant to § 423.2305, any coverage or financial assistance other than basic prescription drug coverage, as defined in § 423.100, offered by an employer group health or waiver plans is considered ''other health or prescription drug coverage.'' This definition applied to all of Medicare Part D. (See 77 FR 22071 and 22082; April 12, 2012). Therefore, the subsidy amount received by an employer group health or waiver plan is the subsidy amount received by a Part D plan offering defined standard coverage, as defined in § 423.100.

Based on the preceding, we propose to amend § 423.329(d) by deleting the reference to § 423.782 and amending § 423.329(d) to define the low-income cost-sharing subsidy payment amount on behalf of a low-income subsidy eligible individual enrolled in a Part D plan for a coverage year as the difference between the Part D cost-sharing for a non-low-income subsidy eligible beneficiary under the Part D plan and the statutory cost-sharing for a low-income subsidy eligible beneficiary.

3. Reopening (§ 423.346)

a. Part D Plan Payments Reopening

As stated in our final rule entitled, ''Medicare Program; Medicare Prescription Drug Benefit'' published on January 28, 2005 (70 FR 4194, 4316), the Secretary's right to inspect and audit any books and records of a Part D 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. Therefore, we established reopening provisions that would allow us to ensure that the discovery of any overpayment or underpayment could be rectified. In the rule, we established that a reopening was at our discretion and could occur for any reason within 1 year of the final determination of payment, within 4 years for good cause, or at any time when there is fraud or similar fault. We now propose to amend the reopening provisions such that we may perform one reopening within 5 years after the date of the notice of the initial determination to the Part D sponsors. We also propose to amend the provision to accommodate reopening the Coverage Gap Discount Reconciliation described at § 423.2320(b).

At the time the proposed regulations for reopening were published in our proposed rule entitled, ''Medicare Program; Medicare Prescription Drug Benefit'' in the **Federal Register** on August 3, 2004 (69 FR 46694), we had no experience in Medicare Part D to be able to gauge the need for a reopening of an initial payment determination. We patterned the provisions after the Medicare claims reopening regulations found in part 405. The proposed reopening provisions were subsequently adopted in our final rule published on January 28, 2005 (70 FR 4316) entitled, ''Medicare Program; Medicare Prescription Drug Benefit.

Under the current regulation at § 423.346 (a), CMS may reopen for any reason within 1 year of the final determination of payment, within 4 years for good cause, or any time for fraud or similar fault. ''Good cause'' is defined in the regulation at § 423.346 (b) as: new and material evidence that was not readily available at the time the final determination was made; a clerical error in the computation of payments; or when evidence that was considered in making the determination clearly shows on its face that an error was made. We now better understand the need for reopening a payment determination and modify our regulation at § 423.346 to align with our experience.

We have generally performed global reopenings as a result of plan sponsor requests, and substantial revisions of PDE and DIR data due to plan corrections, CMS corrections of systems error, post reconciliation claims activity, and audit and other post reconciliation oversight activity. To date, contract years 2006, 2007, and 2008 have been reopened, and we have already released guidance stating that we intended to eventually perform a global reopening of 2011 once there is stability in the data for that year. This experience indicates to us that we will likely have to perform a reopening of the initial payment determination for every contract year. Therefore, we propose to remove the current timeframes for a reopening described in § 423.346 (a)(1) through (a)(3), remove paragraphs (b) describing good cause referred to in paragraph (a)(2), modify paragraph (c) to eliminate the reference to ''good cause,'' and amend paragraph (a) such that CMS may reopen one time within 5 years of notice of the initial payment determination.

Based upon our experience, we believe that 5 years is adequate time to allow for data stability. By 5 years after the initial payment determination, additional PDEs or PDE adjustments associated with coordination of benefits will be submitted by Part D sponsors consistent with the timeframe described at § 423.466(b). We know that audits and other post reconciliation oversight activity often take place more than 5 years from notice of the initial payment determination. However, in light of the overpayment provision at section 6402(a) of the Affordable Care Act, which established section 1128J(d) of the Act and that we propose to codify

at § 423.360, we do not believe that it is necessary to reopen a payment reconciliation after that 5-year period, nor do we believe it is necessary to reopen a reconsidered payment determination. Therefore, we propose to amend § 423.346 (a) such that CMS will only reopen the initial payment determination and will not reopen a reconsidered payment determination.

As stated in our final rule entitled, ''Medicare Program; Medicare Prescription Drug Benefit'' published in the **Federal Register** on January 28, 2005 (70 FR 4194), CMS can initiate a reopening on its own or an organization could request a reopening, but such reopenings are at CMS' discretion. In determining whether to reopen, we will consider a number of issues, including, but not limited to, whether the contract has terminated and received a final settlement. We will not approve a request to reopen for a contract that has terminated and received a final settlement. In addition, when we perform a reopening on its own initiative, contracts that have been terminated and settled will not be included in the reopening.

b. Coverage Gap Discount Reconciliation Reopening

Under § 423.2320(b), CMS performs a Coverage Gap Discount Reconciliation in which CMS reconciles interim payments with invoiced manufacturer discount amounts made available to each Part D plan's enrollee under the Discount Program. Since the interim coverage gap payments are estimates (76 FR 63017, 63027 (October 11, 2011)), a cost-based reconciliation is performed to ensure that Part D sponsors are paid dollar for dollar for all manufacturer discount amounts as reported on invoiced PDE data submitted for Part D payment reconciliation. Manufacturer discount amounts reported on PDE records submitted after the PDE submission deadline for reconciliation continue to be invoiced to manufacturers within a maximum of 3 years of the date of dispensing, and manufacturers remit payments for invoiced coverage gap discount amounts to Part D sponsors.

We propose to establish a reopening provision for the Coverage Gap Discount Reconciliation for the same reasons and under the same authority that we established a reopening provision for the Part D payment reconciliation process described in our final rule, ''Medicare Program; Medicare Prescription Drug Benefit'' published on January 28, 2005 (70 FR 4194, 4316). In a Health Plan Management System (HPMS) memorandum dated April 30, 2010, we stated that the final reconciled discount program payments are subject to the reopening provision in § 423.346. We anticipate rarely needing to reopen the Coverage Gap Discount Reconciliation as a result of the invoicing process that continues to occur after the reconciliation process. However, we want to leave open the option to reopen if unforeseen events result in underpayments or overpayments to Part D sponsors. Therefore, we propose to amend § 423.346 to accommodate reopening a Coverage Gap Discount Reconciliation.

Based on the preceding, we propose to revise § 423.346 by removing the phrase ''or reconsidered'' from paragraph (a), amending paragraph (a) to account for the proposed timing of the Part D reopening, removing paragraphs (a)(1) through (3) and (b)(1) through (3); adding a new paragraph (b) to accommodate a Coverage Gap Discount Reconciliation reopening; and revising paragraph (c) to eliminate the reference to ''good cause.''

4. Payment Appeals (§ 423.350)

Pursuant to § 423.2320 (b), we perform a Coverage Gap Discount Reconciliation in which we reconcile interim payments with invoiced manufacturer discount amounts made available to each Part D plan's enrollee under the Discount Program. Current regulations do not describe the appeals process for a Coverage Gap Discount Reconciliation. We propose to establish an appeals provision for the Coverage Gap Discount Reconciliation for the same reasons and under the same authority that was used to establish the Part D payment reconciliation appeals process described in our final rule, ''Medicare Program; Medicare Prescription Drug Benefit'' published on January 28, 2005 (70 FR 4194, 4317). In an HPMS memorandum dated April 30, 2010, CMS stated that the final reconciled discount program payments are subject the appeals provisions in § 423.350, and we now propose to revise § 423.350 to accommodate a Coverage Gap Discount Reconciliation appeals process.

Consistent with the Part D payment appeals process currently described at § 423.350, the proposed changes establish an appeals process whereby the final reconciliation of the interim Coverage Gap Discount Program payments may be subject to appeal. As stated in our final rule describing the Part D payment appeals process (70 FR 4317 (January 28, 2005)), the Part D payment appeals process only applies to perceived errors in the application of the payment methodology and the payment information submitted by the Part D sponsor cannot be appealed through this process. In the January 28, 2005 final rule (70 FR 4317), Part D plans are expected to submit payment information correctly and within the established timelines. We codified at § 423.350(a)(2) that payment information submitted to CMS under § 423.322 and reconciled under § 423.343 is final and may not be appealed nor may the appeals process be used to submit new information after the submission of information necessary to determine retroactive adjustments and reconciliations. We propose to amend § 423.350(a)(2) to include information that is submitted and reconciled under § 423.2320(b) is final and may not be appealed nor may the appeals process be used to submit new information after the submission of information necessary to determine retroactive adjustments and reconciliations.

Also consistent with the Part D payment appeals process, we propose that the request for a reconsideration of the Coverage Gap Discount Reconciliation must be filed within 15 days from the date of the final payment, which is the date of the final reconciled payment made under § 423.2320 (b). Therefore, we propose to amend § 423.350(b)(1) by adding a new paragraph (iv) to define the timeframe for filing a reconsideration of the Coverage Gap Discount Reconciliation.

Based on the preceding, we propose to revise § 423.350 by adding a new paragraph (a)(1)(v) to allow for an appeal of a reconciled coverage gap payment under § 423.2320 (b), by revising paragraph (a)(2) to indicate that the payment information submitted to CMS and reconciled under § 423.2320(b) is final and may not be appealed, and by adding a new paragraph (b)(1)(iv) to define the timeframe for appealing the final reconciled payment under § 423.2320(b).

5. Payment Processes for Part D Sponsors (§ 423.2320)

In our final rule entitled, ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes'' (77 FR 22071, 22086; April 12, 2012), CMS described the payment process for Part D sponsors under the Coverage Gap Discount Program. Under § 423.2320(a), CMS provides monthly interim Coverage Gap Discount Program payments as necessary for Part D sponsors to advance coverage gap discounts to beneficiaries. Part D

sponsors report the gap discount amounts to CMS, and through a contractor, CMS invoices the manufacturers on a quarterly basis for the applicable discount amounts. The manufacturers repay each Part D sponsor directly for the invoiced amounts under the Medicare Coverage Gap Discount Program Agreement (Agreement) described at § 423.2315. Under § 423.2320(b), CMS reconciles the interim payments with amounts invoiced to manufacturers.

In the event that a manufacturer fails to the provide the applicable discounts in accordance with the Agreement, we must impose civil money penalties (CMPs) equal to the sum of the applicable discount the manufacturer would have paid under the Agreement and 25 percent of that amount. The CMP that is equal to the sum of the applicable discount the manufacturer would have paid under the agreement is used to pay the applicable discount that the manufacturer had failed to provide.

In our final rule describing the payment process for Part D sponsors under the Coverage Gap Discount Program, we did not contemplate a payment process in the event that a manufacturer becomes bankrupt and does not pay the Part D sponsors for quarterly invoiced amounts under the Agreement. Even though we will impose a CMP on a bankrupt manufacturer in an effort to collect the unpaid invoiced amounts, the bankruptcy settlements will likely result in the CMP being modified or reduced. In order to ensure that the Part D sponsors have the funds available to advance the gap discounts at the point-of-sale, as required under section 1860D–14A(c)(1)(A)(ii) of the Act, we now propose to amend § 423.2320 such that we will assume financial liability for the applicable discount by covering the costs of the quarterly invoices that go unpaid by a bankrupt manufacturer at the time of the Coverage Gap Discount Reconciliation described at § 423.2320(b). We would then file a proof of claim with the bankruptcy court to recover those costs from the bankrupt manufacturer.

The proposed policy that CMS assume financial liability for the applicable discounts in the event of a manufacturer bankruptcy is consistent with CMS' payment processes for Part D sponsors under the Medicare Coverage Gap Discount Program. Under § 423.2320 (a), CMS provides interim payments to ensure that Part D sponsors have the funds available to advance the coverage gap discount to beneficiaries at point of sale. Under § 423.2320 (b), CMS reconciles the interim payments with the invoiced manufacturer discount amounts in order make the PDP sponsor whole for the gap discount amount provided to the beneficiaries at point of sale. (For more information on these provisions, see October 11, 2011 final rule (76 FR 63017, 63027).) In order to remain consistent with the intent of the Coverage Gap Discount Reconciliation to make the Part D sponsor whole for the gap discounts amounts advanced at point of sale, CMS must provide payments to the Part D sponsor to cover the cost of the applicable discount in the event that the manufacturer cannot pay the quarterly invoices due to a bankruptcy. We propose to cover the costs of unpaid quarterly invoices only in the event that a manufacturer becomes bankrupt. We would not cover the cost of unpaid quarterly invoices for any other reasons because, in the event that a manufacturer fails to pay the quarterly invoices, we will impose CMPs that will cover the cost of the unpaid invoices. In the event that a manufacturer becomes bankrupt, we are concerned that the court will either modify or reduce the amount of the CMP, making the CMP process ineffective for covering the cost of the invoices and leaving the Part D sponsor in the position of having to cover the costs of the gap discount.

We propose to implement this policy by adjusting the Coverage Gap Discount Reconciliation to account for quarterly invoices that go unpaid as a result of a manufacturer becoming bankrupt. This adjustment will only occur for manufacturer discount amounts as they are reported on PDEs submitted by the submission deadline for the Part D reconciliation.

Based on the preceding, we propose to add a new paragraph (c) to § 423.2320 to describe a process for accounting for quarterly invoiced amounts that go unpaid by a bankrupt manufacturer.

6. Risk Adjustment Data Requirements (§ 422.310)

We propose to strengthen existing regulations related to the accuracy of risk adjustment data by amending § 422.310 on risk adjustment data validation. First, we propose to renumber existing paragraph § 422.310(e) as paragraph (e)(2) and add new paragraph (e)(1), which would require that any medical record reviews conducted by an MA organization must be designed to determine the accuracy of diagnoses submitted under § 422.308(c)(1) and § 422.310(g)(2). (Paragraph § 422.308(c)(1) addresses adjustments to payments for health status, and paragraph § 422.310(g)(2) addresses deadlines for risk adjustment data submission, including the final risk adjustment data submission deadline prior to CMS' calculation of the final risk factors for a payment year.) Under our proposal, medical record reviews conducted by an MA organization cannot be designed only to identify diagnoses that would trigger additional payments by CMS to the MA organization; and medical record review methodologies must be designed to identify errors in diagnoses submitted to CMS as risk adjustment data, regardless of whether the data errors would result in positive or negative payment adjustments. This proposed amendment furthers our goals of improving payment accuracy and reducing payment errors.

We also propose to amend § 422.310(g) regarding deadlines for submission of risk adjustment data. Our current procedures generally permit submission of risk adjustment data after the final risk adjustment submission deadline only to correct overpayments. We propose to revise the regulation to explicitly permit late submissions only to correct overpayments but not to submit diagnoses for additional payment.

Finally, we propose to align this regulation with proposed § 422.326 by making two additional changes in paragraph (g). First, we propose the deletion of the January 31 deadline in subparagraph (2) and replacing it with the statement that CMS will announce the deadline by which final risk adjustment data must be submitted to CMS or its contractor. This means that the risk adjustment data submission deadline would also function as the Part C applicable reconciliation date for purposes of proposed § 422.326 on overpayment rules, as discussed in section II.B.1.b. of this proposed rule. Second, we propose to add subparagraph (3) to § 422.310(g). Proposed paragraph (3) cites § 422.326 as the source of rules for submission of corrected risk adjustment data after the final risk adjustment data submission deadline, that is, after applicable reconciliation as defined at § 422.326(a).

7. RADV Appeals

a. Background

We published Risk Adjustment Data Validation (RADV) appeals regulations in the April 15, 2010 **Federal Register**. These rules were proposed and finalized under CMS's authority to establish Medicare Advantage (MA) program standards by regulation at section 1856(b)(1) of the Act and are found at § 422.311 et seq.

As explained in the preamble of that final rule, Subpart G of the MA regulations at part 422 describes how

payment is made to MA organizations. These payment principles are based on sections 1853, 1854, and 1858 of the Act. Subpart G also sets forth the requirements for making payments to MA organizations offering local and regional MA plans, including calculation of MA capitation rates. Section 1853(a)(3) of the Act requires that we risk adjust our payments to MA organizations. Risk adjustment strengthens the Medicare program by ensuring that accurate payments are made to MA organizations based on the health status plus demographic characteristics of their enrolled beneficiaries and ensures that MA organizations are paid appropriately for their plan enrollees (that is, less for healthier enrollees expected to incur lower health care costs and more for less healthy enrollees expected to incur higher health care costs). Accurate payments to MA organizations also help ensure that providers are paid appropriately for the services they provide to MA beneficiaries. In general, the current risk adjustment methodology relies on enrollee diagnoses, as specified by the International Classification of Disease, currently the Ninth Revision Clinical Modification guidelines (ICD–9–CM) to prospectively adjust capitation payments for a given enrollee based on the health status of the enrollee. Diagnosis codes determine the risk scores, which in turn determine the risk adjusted reimbursement. As a result, physicians and providers must focus attention on complete and accurate diagnosis reporting according to the official ICD–9–CM coding guidelines (that is, coding diagnoses accurately and to the highest level of specificity).

MA enrollee Hierarchical Condition Categories (HCCs) are assigned based on risk adjustment diagnoses from FFS claims and from risk adjustment data submitted to us by MA organizations via the Risk Adjustment Payment System (RAPS). The CMS–HCCs contribute to an enrollee's risk score, which is used to adjust a base payment rate. Essentially, the higher the risk score for an enrollee, the higher the expected health care cost for the enrollee. The HCC data that MA organizations submit to CMS via the RAPS system is self-reported by the MA organization and does not go through a validation review before being incorporated into a given beneficiary's risk-profile. Since there is an incentive for MA organizations to potentially over-report diagnoses so that they can increase their payment, the Agency audits plan-submitted diagnosis data a few years later to ensure they are supported by medical record documentation.

Verifiable medical record documentation is the key to accurate payment and successful data validation. We annually select contracts for RADV audits. RADV audits are intended to confirm the presence of risk adjustment conditions (that is, diagnoses that map to HCCs) as reported by MA organizations for their enrollees and confirmed via medical record documentation. RADV audits occur after the final risk adjustment data submission deadline for the MA contract year. We validate the HCC data submitted by MA organizations by reviewing hospital inpatient, hospital outpatient, and physician/practitioner provider medical records. The focus of this medical record review activity is on diagnoses related to the enrollee's HCC profile. Risk adjustment discrepancies are identified when the enrollee's HCCs used for payment (based upon MA organization-submitted data) differ from the HCCs assigned based on the medical record, under the RADV audit process. Risk adjustment discrepancies can be aggregated to determine an overall level payment error. In turn, payment error for a sample of contract enrollees can be extrapolated to calculate a contract-level payment error estimate.

Since finalizing these rules in 2010, we have conducted additional RADV audits and believe that some of the appeals provisions finalized in the 2010 RADV Appeals final rule should now be modified to prevent confusion, and to strengthen the RADV appeals process. We therefore, propose revisions to the RADV appeals regulations finalized in the April 15, 2010 **Federal Register**. These proposed revisions clarify program requirements and simplify the RADV appeals process. These proposed RADV provisions will apply to any RADV determinations issued on or after the effective date of this regulation.

b. RADV Definitions

We propose to amend the RADV definitions at § 422.2 as follows:

- Removing the following definitions:
  - ++ ''Initial Validation Contractor (IVC)'' means the first level of medical record review under the RADV audit process.
  - ++ ''RADV payment error calculation appeal process'' means an administrative process that enables MA organizations that have undergone RADV audit to appeal the CMS calculation of an MA organization's RADV payment error.
  - ++ ''The one best medical record for the purposes of Medicare Advantage Risk Adjustment Validation (RADV)'' means the clinical documentation for a single encounter for care (that is, a physician office visit, an inpatient hospital stay, or an outpatient hospital visit) that occurred for one patient during the data collection period. The single encounter for care must be based on a face-to-face encounter with a provider deemed acceptable for risk adjustment and documentation of this encounter must be reflected in the medical record.
- Adding the following definition:
  - ++ ''RADV appeal process'' means an administrative process that enables MA organizations that have undergone RADV audit to appeal the Secretary's medical record review determinations and the Secretary's calculation of an MA organization's RADV payment error.
- Revising the following definitions:
  - ++ Risk adjustment data validation (RADV) audit means a payment audit of a Medicare Advantage (MA) organization administered by CMS or the Secretary that ensures the integrity and accuracy of risk adjustment payment data.
  - ++ ''Attestation process'' means a CMS-developed RADV process that enables MA organizations undergoing RADV audit to submit CMS-generated attestations for eligible medical records with missing or illegible signatures or credentials. The purpose of the CMS-generated attestations is to cure signature and credential issues for eligible medical records. CMS-generated attestations do not provide an opportunity for a provider or supplier to replace a medical record or for a provider or supplier to attest that a beneficiary has the medical condition.

c. Publication of RADV Methodology

In the October 22, 2009 Notice of Proposed Rule Making (NPRM), and as reinforced in the April 15, 2010 Final Regulation, CMS indicated that we would, ''publish its RADV methodology in some type of public document—most likely, a Medicare Manual, so that the public can review and provide comment as it deems necessary''. We also indicated that we would provide an annual notice of RADV audit methodology. Our last RADV-related notice of methodology was published in February, 2012. We will continue to publish a notice of the methodology employed, but will do so only if there is a change in the RADV methodology that would require publication. We note that these notices of RADV audit

methodology updated information provided on RADV audit methodology provided in the October 22, 2009 proposed rule and April 15, 2010 final rule.

In addition, we provided in the October 22, 2009 proposed rule preamble that we would provide an expanded explanation of methodology and payment error calculation factors as a part of each audit report of findings that we send to MA organizations that undergo RADV audit. Such explanation and factors have been and will continue to be part of the RADV audit report(s) that CMS provides health plans that have undergone RADV audits.

d. Proposal To Update RADV Appeals Terminology (§ 422.311)

Current RADV regulations utilize the following terms for the CMS-issued RADV audit report: Audit report post medical record review; RADV audit report; IVC-level RADV audit report; and RADV audit report of finding. This use of multiple terms to refer to what is the same audit report (the RADV audit report that CMS issues following conclusion of the medical record review portion of the audit) is potentially confusing. Therefore, we propose amending the RADV regulations throughout to adopt one common term to refer to RADV audit reports: ''RADV Audit Report''. By standardizing terminology throughout the RADV regulations, the proposed amendment provides clarity which may lead to increased efficiency. We welcome comment on this proposal.

As mentioned earlier in the description of RADV-related definitions that have changed, we have revised certain RADV-related definitions to accommodate changes to both the RADV audit process and the RADV appeals process. One definition that we have removed from the RADV regulations is Initial Validation Contractor, or IVC. The RADV medical record review process no longer utilizes ''initial'' and ''secondary'' validation contractors to conduct medical record review under RADV. Instead we now utilize medical record reviewers to code medical records undergoing RADV review. These reviewers may be employed by the same or different medical record review contractors. Therefore, the term ''IVC'' is no longer relevant to the RADV audit process. We therefore propose to remove this term from the RADV regulations at the following citations: § 422.311(c)(2)(i)(B) through (D); § 422.311(c)(2)(ii)(B), § 422.311(c)(2)(iii)(A), § 422.111(c)(2)(v), (vi), § 422.311(c)(3)(ii)(A), and § 422.311(c)(3)(iii)(A) and (B). We invite comment on this proposal.

e. Proposal To Simplify the RADV Appeals Process

Currently, there are two types of RADV-related appeals processes described in Federal regulations at § 422.311 et seq.: Medical record review-determination appeals and RADV payment error calculation appeals. RADV medical record review-determination appeal requirements and procedures are discussed at § 422.311(b)(3) and § 422.311(c)(2). Medical record review determination appeal is a two-stage administrative appeal process: The first step is a hearing by a hearing officer, followed by a CMS Administrator-level review. This appeal procedure provides MA organizations with an opportunity to appeal RADV medical record review determinations that are made by coders reviewing the medical record documentation submitted by MA organizations undergoing RADV audit. The second type of RADV appeal, payment error calculation appeal, is discussed at § 422.311(c)(3). Payment error calculation appeal is a three-pronged appeal process: Reconsideration, followed by a hearing officer review, followed by CMS Administrator-level review. This appeal process was specifically designed to afford MA organizations the opportunity to appeal CMS's contract-level RADV payment error calculation.

We propose that the administrative appeals language described at § 422.311(b)(3) and § 422.311(c)(2) for RADV medical record review determination appeals and § 422.311(c)(3) for RADV payment error calculation appeals be replaced with new regulatory language proposed § 422.311(c)(1) et seq., that combines the two existing RADV appeal policies and procedures into one set of requirements and one process. We propose to combine the two RADV appeals processes into one combined RADV appeals process that is comprised of three administrative steps: Reconsideration, hearing officer review, and CMS Administrator-level review. A three-step administrative appeals process comprising reconsideration, hearing officer review, and Administrator-levels of review is a common administrative appeals model used elsewhere within the Medicare managed care program, such as in appealing contract award determinations and intermediate sanctions. The combined RADV appeal process that we are proposing at new § 422.311(c)(1) et seq., also has the benefit of simplifying what is today a complex two-track appeal process into one process. While both CMS and the MA industry will benefit from simplifying this process, MA organizations also obtain an additional level of review under the combined approach since MA organizations will be afforded a reconsideration appeal step for medical record review determinations that is today—not part of the existing RADV appeal process. Shortening the existing two-track appeal process should also reduce the resources and level of effort needed from both MA organizations and CMS in participating in a RADV appeal proceeding. Under this proposal, MA organizations can simply request to appeal their RADV audit findings one time and specify whether they want to appeal either their medical record review determination(s), payment error calculation, or both. The specific details regarding this proposed process follow. We propose these changes based upon our experience with RADV appeals and because we hope to reduce the burden associated with undertaking RADV appeals on both MA organizations and CMS. The details of this proposed policy and procedure follows.

(1) Issues Eligible for RADV Appeal

Current regulations at § 422.311(c)(2) et seq., and § 422.311(c)(3) et seq., specify RADV-related medical record review and payment error calculation documents and issues eligible for the medical record review determination and payment error calculation appeal processes. We propose to amend the policies and procedures around issues eligible for RADV appeals at § 422.311(c)(2) and § 422.311(c)(3) by combining proposed policies and procedures for the existing two-pronged appeal approach into one set of policies and procedures for RADV appeals at the new § part 422.311(c)(2)(iv). At § 422.311(c)(2)(i), we propose that as a general rule, MA organizations may appeal RADV medical record review determinations and RADV payment error calculation, though in order to be eligible to pursue these appeals, we specify at proposed § 422.311(c)(2)(i)(A) and (B) that MA organizations must adhere to established RADV audit procedures and requirements and adhere to RADV appeals procedures and requirements. At § 422.311(c)(2)(ii) we propose that failure to follow RADV audit procedures and requirements and RADV appeals procedures and requirements will render the MA organization's request for RADV appeal invalid. Furthermore, at proposed § 422.311(c)(2)(iii) we stipulate that the

MA organization's written request for medical record review determination appeal must specify the audited HCC(s) that have been identified pursuant to RADV audit as being in error, and further specify that MA organizations must provide a justification in support of the audited HCC(s) that the MA organization elects to appeal. At § 422.311(c)(2)(i) (iv) we propose that for each audited HCC, MA organizations may appeal one medical record that has undergone RADV medical record review and that if an attestation was submitted to cure a signature or credential issue, that attestation may likewise be included in the HCC appeal. For example, if an MA organization submitted a medical record that did not contain a signature and/or credential—and the MA organization submitted an attestation to cure the error that CMS subsequently failed to accept—the MA organization could choose to appeal CMS's determination to not accept the submitted attestation. We reiterate that the purpose of CMS-generated attestations is to cure signature and credential errors associated with an eligible submitted medical record and not to provide an opportunity for a provider or supplier to attest that a beneficiary has a certain medical condition. Evidence for the existence of the medical condition is found in a medical record.

We are proposing to modify our language at § 422.311(c)(2)(i)(v) to clarify existing RADV appeals provisions which stipulate that MA organizations must adhere to the ''one best medical record'' policy. Under changes to the RADV audit methodology announced by CMS in February 2012, we now allow MA organizations to submit more than one medical record (that is, more than the ''one best medical record'') during the RADV audit process to validate an audited CMS–HCC. However, for purposes of appealing a CMS medical record review determination, we will not permit organizations to appeal multiple medical records but will instead—require that MA organizations identify a record from amongst those records submitted, and to submit that record for appeal. For each audited HCC, MA organizations may appeal only one medical record that has undergone RADV review. This policy was published in the February 2012 White Paper and is not included in this proposed rule.

At § 422.311(c)(2)(vi) we propose that a written request for RADV payment error calculation appeal must clearly specify the MA organization's own RADV payment error calculation and must also specify where the payment error calculation was erroneous.

(2) Issues Not Eligible for RADV Appeals

At § 422.311(c)(3) we propose documents and issues that are ineligible for RADV appeals. Consistent with the overall approach of combining into one RADV appeals process what was heretofore two separate RADV appeals processes—by way of this new proposed section, we propose to amend existing regulations at § 422.311(c)(3). At new § 422.311(c)(3), we propose that MA organizations' request for appeal may not include HCCs, medical records or other documents beyond the audited HCC, selected medical record and any accompanying attestation that the MA organization chooses to appeal. We specify at § 422.311(c)(3)(ii) that the MA organizations may not appeal CMS's medical record review determination methodology or CMS's payment error calculation methodology. This is a clarification to existing RADV regulations at § 422.311(c)(3)(D) which specifies that MA organizations may not appeal CMS's payment error calculation methodology. At § 422.311(c)(3)(iii) we specify that MA organizations may not appeal RADV medical record review-related errors when appealing RADV error-calculation issues since medical record review determination issues must be resolved before we can calculate RADV payment errors. And at § 422.311(c)(3)(iv) we specify that RADV errors that result from an MA organization's failure to submit a medical record are not eligible for appeal.

(3) Manner and Timing of a Request for RADV Appeal

We propose to replace existing RADV regulations at § 422.311(c)(2)(iii) et seq., and § 422.311(c)(3)(iii) et seq., regarding the manner and timing of a request for RADV appeals. Again, at § 422.311(c)(5), we propose to combine the formerly two separate sets of requirements and procedures into one RADV appeals process addressing the request for RADV appeal. At § 422.311(c)(5)(i) we propose that at the time the Secretary issues her RADV audit report, the Secretary notifies audited MA organizations that they may appeal RADV HCC errors that are eligible for medical record review determination appeal and may appeal the Secretary's RADV payment error calculation. At § 422.311(c)(5)(ii) we specify that MA organizations have 30 days from the date of CMS's issuance of the RADV audit report to file a written request with CMS for RADV appeal. This request for RADV appeal must specify whether the MA organization requests medical record review determination appeal, whether the MA organization requests RADV payment error calculation appeal, or whether the MA organization requests both medical record review determination appeal and RADV payment error calculation appeal— and in each instance— the issues with which the MA organization disagrees, and the reasons for the disagreements. See proposed regulations at § 422.311(c)(6) et seq.

At new § 422.311(c)(5)(ii) we specify that while MA organizations may now elect to appeal either medical record review determination, payment error calculation, or both—they must notify CMS which issues they will appeal at the same time. This new provision replaces existing RADV appeals requirements regarding notification at § 422.311(c)(2)(iii) and § 422.311(c)(3)(iii)(C).

For MA organizations that elect both medical record review determination appeal and RADV payment error calculation appeal, we specify at § 422.311(c)(5)(iii)(A) and (B) that the Secretary will adjudicate the request for RADV payment error calculation following conclusion of reconsideration of the MA organization's request for medical record review determination appeal. This is necessary because RADV payment error calculations are based upon the outcomes of medical record review determinations. For example, for an MA organization that appeals both medical record review determinations and payment error calculations, the reconsideration official would first adjudicate and rule on the medical record review determinations and then proceed to recalculate the RADV payment error.

(4) Reconsideration Stage

Under current RADV appeals procedures, only the RADV payment error calculation appeal process contains a reconsideration step. We propose to amend existing regulations at § 422.311(c)(3)(iii)(C) and § 422.311(c)(3)(v), (vi), and (vii) by proposing a new reconsideration stage for RADV appeals at § 422.311(c)(6) et seq. Reconsideration is the first stage of the new RADV appeals process and will apply to both medical record review determinations and error calculation issues being appealed. Therefore, MA organizations that elect to appeal RADV audit findings de facto begin the appeal process with the reconsideration step. At proposed § 422.311(c)(6)(i) we specify that a MA organization's written request for medical record review

determination reconsideration must specify the audited HCC identified as being in error that the MA organization wishes to appeal; and to provide a justification in support of the audited HCC chosen for appeal. At proposed § 422.311(c)(6)(ii) we specify that the MA organizations' written request for payment error calculation reconsideration must include the MA organization's own RADV payment error calculation that clearly indicates where the RADV payment error calculation was erroneous. The request for payment error calculation reconsideration may also include additional documentary evidence pertaining to the calculation of the error that the MA organization wishes the reconsideration official to consider.

At proposed § 422.311(c)(6)(iii) we describe the conduct of the reconsideration process that is being proposed. We specify that for medical record review determination reconsideration, a medical record review professional who was not involved in the initial medical record review determination of the disputed HCC reviews the medical record and accompanying dispute justification; and reconsiders the initial audited HCC medical record review determination. For payment error calculation reconsideration, CMS ensures that a third party not involved in the initial RADV payment error calculation reviews the RADV payment error calculation, reviews the MA organization's own RADV payment error calculation, and recalculates the payment error in accordance with CMS's RADV payment error calculation procedures.

At proposed § 422.311(c)(6)(iv), we specify that the reconsideration official issues a written reconsideration decision to the MA organization, and that the reconsideration official's decision is final unless the MA organization disagrees with the reconsideration official's decision. If the MA organization disagrees with the reconsideration official's decision, it may request a hearing.

(5) Hearing Stage

Existing regulations at § 422.311(c)(2)(iv) through (ix) and § 422.311(C)(4) et seq., specify the procedures under which CMS conducts hearings under the RADV appeals process for medical record review and payment error calculation. We propose to replace these provisions with new hearing requirements and procedures at § 422.311(c)(7)(iv).

At § 422.311(c)(7)(i), we propose that at the time the RADV appeals reconsideration official issues his/her reconsideration determination to the MA organization, the reconsideration official notifies the MA organization of any RADV audited HCC errors and or payment error calculations that are eligible for RADV hearing. At § 422.311(c)(7)(ii), we specify that a MA organization that requests a hearing officer review must do so in writing in accordance with procedures established by CMS. At § 422.311(c)(7)(iii), we specify that a written request for a hearing must be filed with the Hearing Officer within 30 days of the date the MA organization receives the reconsideration officer's written reconsideration decision. If the MA organization appeals the medical record review reconsideration determination, the written request for RADV hearing must include a copy of the written decision of the reconsideration official; must specify the audited HCCs that the reconsideration official confirmed as being in error; and must specify a justification as to why the MA organization disputes the reconsideration official's determination. If the MA organization appeals the RADV payment error calculation, the written request for RADV hearing must include a copy of the written decision of the reconsideration official and must include the MA organization's own RADV payment error calculation that clearly specifies where the CMS's payment error calculation was erroneous.

At § 422.311(c)(7)(iv), we propose that a CMS hearing officer conduct the RADV hearing. At § 422.311(c)(7)(v), we specify terms and conditions under which a hearing officer may be disqualified. 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. A party to the hearing who objects to the assigned hearing officer must notify that officer in writing at the earliest opportunity. The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw. If the hearing officer withdraws, another hearing officer will conduct the hearing. 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.

At § 422.311(c)(7)(vi) we propose that the hearing officer reviews the medical record and any accompanying attestation that the MA organization selected for review, the reconsideration official's payment error calculation (if appealed), the reconsideration official's written determination, and the written justification submitted by the MA organization and CMS in response to the reconsideration official's determination.

At § 422.311(c)(7)(vii) we propose RADV appeal hearing procedures. We propose that the hearing officer has full power to make rules and establish procedures, consistent with the law, regulations, and rulings. These powers include the authority to dismiss the appeal with prejudice and take any other action which the hearing officer considers appropriate, including for failure to comply with RADV audit and appeals rules and procedures. We propose that the hearing be altogether on the record unless the hearing officer, at his or her full discretion, approves a parties request for a live or telephonic hearing regarding some or all of the medical records in dispute, or if the hearing office schedules a live or telephonic hearing on its own motion. The hearing officer's review will be solely limited to the record. The record is comprised of the RADV reviewed medical record and any accompanying attestation that the MA organization selected for review, the reconsideration official's payment error calculation (if appealed), the reconsideration official's written determination, the written justification submitted by the MA organization in response to the reconsideration official's determination, and written briefs from the MA organization explaining why they believe the reconsideration official's determination was incorrect. In addition, the record will be comprised of a brief from CMS that responds to the MA organization's brief.

In terms of specifying the conduct of the hearing, we propose at § 422.311(c)(7)(vii)(B) that the hearing officer neither receives testimony nor accepts any new evidence that is not part of the record. At § 422.311(c)(7)(vii) we propose that the hearing officer be given the authority to decide whether to uphold or overturn the reconsideration official's decision, and pursuant to this decision—to send a written determination to CMS and the MA organization, explaining the basis for the decision.

At § 422.311(c)(7)(ix), we propose that in accordance with the hearing officer's decision, a third party not involved in the initial RADV payment error calculation recalculate the MA organization's RADV payment error and issue a new RADV audit report to the appellant MA organization and CMS. For MA organizations appealing the

RADV payment error calculation only, we propose that a third party not involved in the initial RADV payment error calculation recalculate the MA organization's RADV payment error and issue a new RADV audit report to the appellant MA organization and CMS. At § 422.311(c)(7)(x) we propose that the hearing officer's decision be final unless the decision is reversed or modified by the CMS Administrator.

(6) CMS Administrator Review Stage

Existing regulations at § 422.311(c)(2)(x) et seq., and § 422.311(C)(4)(vi) et seq., specify the CMS Administrator-level review procedures that CMS adheres to under the current RADV appeals process for medical record review determinations and payment error calculation. We propose to replace these regulations with new RADV appeal-related CMS Administrator review requirements and procedures at § 422.311(c)(8).

At § 422.311(c)(8)(i) and (ii), we propose that a request for CMS Administrator review must be made in writing within 30 days of receipt of the hearing officer's decision; and must be filed with the CMS Administrator by CMS or an MA organization. At § 422.311(c)(8)(iii), we propose that after receiving a request for review, the CMS Administrator has the discretion to elect to review the hearing officer's decision or to decline to review the hearing officer's decision. At § 422.311(c)(8)(iv) we propose that if the CMS Administrator elects to review the hearing decision—the Administrator acknowledges the decision to review the hearing decision in writing and notifies CMS and the MA organization of their right to submit comments within 15 days of the date of the notification. At § 422.311(c)(8)(iv)(B), we propose that the CMS Administrator be limited to the review of the record and that the record be comprised of the hearing record, and written arguments from the MA organization and/or CMS explaining why either or both parties believe the hearing officer's determination was correct or incorrect.

Regarding Administrator-level review procedures at § 422.311(c)(8)(vi), we propose that the Administrator reviews the record and determines whether the hearing officer's determination should be upheld, reversed, or modified. At § 422.311(c)(8)(v), we propose that the Administrator render his or her final decision in writing to the parties within 60 days of acknowledging his or her decision to review the hearing officer's decision. At § 422.311(c)(8)(vi), we propose that the decision of the hearing officer become final if the Administrator declines to review the hearing officer's decision or does not make a decision within 60 days.

Combining these existing RADV medical record review determination and payment error calculation appeals policies and processes improves the overall appeals process by strengthening the depth and integrity of these procedures. We also believe that doing so improves overall RADV appeals procedures by providing clarity that leads to greater efficiencies in adjudicating RADV appeals. We welcome comments on these proposals.

f. Proposal To Expand Scope of RADV Audits

Federal regulations at § 422.311(a) specify that RADV audits are conducted by CMS. We propose to amend this regulation at § 422.311(a) by specifying that the Secretary of the Department of Health and Human Services, along with CMS, may conduct RADV audits beginning with the effective date of this regulation. We also propose to amend RADV definitions at § 422.2 to specify that The Secretary of the Department of Health and Human Services, along with CMS, may conduct RADV audits. We welcome comment on this proposal.

g. Proposal To Clarify the RADV Medical Record Review Determination Appeal Burden of Proof Standard

Our regulations at § 422.311(c)(3)(iv) specify that for RADV payment error calculation appeals, MA organizations bear the burden to prove that CMS failed to follow its stated RADV payment error calculation methodology. However, RADV regulations do not specify a burden of proof standard for the RADV medical record review determination appeal process. The absence of a clearly-defined burden of proof standard for RADV medical record review determination appeals creates an appeal environment where MA organizations, CMS and RADV appellate officials are free to interpret and apply different burden of proof standards when arguing or reviewing appeals cases. We propose to amend the rule with new § 422.311(c)(4) which specifies that the burden of proof for all RADV determinations—be they payment error calculation or RADV medical record review determinations—is on MA organizations to prove, based on a preponderance of the evidence, that CMS's determination was erroneous.

This approach would stand in contrast to a burden of proof standard in which the MA organization were to prove that a valid diagnoses exists on the record, and that therefore, the audited HCC has been validated. This proposed amendment to the rule provides the medical record review determination process a clear burden of proof standard which more aligns with the existing RADV payment error calculation appeals burden of proof standard. Doing so also improves the overall RADV appeals procedures by providing clarity that leads to greater efficiencies in adjudicating RADV appeals. We invite comment on this proposal.

h. Proposal To Change RADV Audit Compliance Date

Currently, the compliance date for RADV audits is the due date when MA organizations selected for RADV audit must submit medical records to CMS or its contractors. We are proposing to change the compliance date for meeting RADV audit requirements for the validation of risk adjustment data to the due date when MA organizations selected for RADV audit must submit medical records to the Secretary—and not only CMS. See proposed regulation language at § 422.311(b)(2).

*B. Improving Payment Accuracy*

8. Recovery Audit Contractor (RAC) Determination Appeals (Proposed Part 422 Subpart Z and Part 423 Subpart Z)

a. Background

Section 306 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) required the Secretary to conduct a demonstration to determine whether recovery auditors could be used effectively to identify improper payments paid under Medicare Part A and Part B claims. We conducted the demonstration from March 2005 to March 2008 in six states. The Recovery Audit demonstration established recovery auditors as a successful tool in the identification and prevention of improper Medicare payments.

In December 2006, the Tax Relief and Health Care Act of 2006 (TRHCA) (Pub. L. 109–432) was enacted. Section 302(a) of the TRHCA created a permanent Medicare Recovery Audit Contractor (RAC) program and added a new paragraph (h) to section 1893 of the Social Security Act (the Act) that required us to establish a national recovery audit program for Medicare Part A and Part B. The national Medicare Fee-For-Service (FFS) Recovery Audit program was established on January 1, 2010.

Section 6411(b) of the Affordable Care Act amended section 1893(h)(1) of the Act by requiring the establishment of recovery audit programs for Medicare

Parts C and D, in addition to the RAC program already in place for Medicare A and B.

On December 27, 2010, we published a notice in the **Federal Register** (75 FR 81278) requesting comments on how to best implement the RAC program for Parts C and D. Analysis of the comments received assisted us with implementation of the Part C and D RACs.

In January 2011, we entered into a recovery audit contract for Part D. The Part D RAC began recouping identified overpayments in 2012. On December 7, 2012, we published a Request for Quotation (RFQ) via the General Services Administration's (GSA) eBuy seeking quotations on the implementation of a Medicare Part C RAC. We anticipate the award of a Part C RAC contract in FY 2014.

Given that we began recouping overpayments determined by the Part D RAC in 2012, and we anticipate recouping overpayments in Part C after awarding a Part C RAC contract in FY 2014, it is appropriate to provide a codified administrative appeals process to allow for plans to challenge the overpayment findings generated by the RACs just as we provide for challenges to overpayment determinations elsewhere in the Medicare program. In crafting our proposed appeals process for Parts C and D RAC determinations, we reviewed existing appeals processes in other areas, including Parts A and B RAC determinations, Part C RADV Audits, Part D payments, etc.

b. Proposed RAC Appeals Process

After reviewing the agency's existing appeal processes, we determined that the general mechanisms set forth in § 422.311 and § 423.350 offered the most appropriate models for the Part C and D RAC appeals process.

The Part D RAC currently reviews PDE data to identify overpayments and underpayments that are paid back to the plans. When overpayments are identified, Part D plans are notified and funds are recovered. If plans disagree with the calculated overpayment amounts or whether the overpayments are proper, they may appeal the Part D RAC's determination directly to the CMS Center for Program Integrity.

A multilevel independent appeals process is an important component of the Part C and Part D RAC program as it allows plans to appeal determinations they contend are made in error. The administrative appeals mechanisms in this proposed rule would apply to all Part C and Part D RAC determinations. As CMS implements the Part C RAC, we would determine if additional changes to the proposed appeals process are necessary.

Based on the foregoing, we propose to add a new subpart Z in Parts 422 and 423, respectively that would include the proposed provisions discussed in this section. In accordance with CMS direction and criteria, the Part C or Part D RAC would conduct an issue specific audit of CMS' payment(s) to plans. An independent validation of all Part C and Part D RAC-identified improper payments would be conducted. If both the Part C or Part D RAC and the independent validation determine that an improper payment was made, the Part C or Part D RAC would send a notice of improper payment to the plan. If the Part C or Part D RAC determines an overpayment was made to the plan, it would send a demand letter requesting repayment. The demand letter would: (1) Explain the reason for the overpayment determination; (2) explain our recoupment process; and (3) contain instructions on how the plan may appeal the Part C or Part D RAC's finding. There would be no minimum monetary threshold for an appeal at any level.

The following three level process sets forth our proposed administrative appeals process for overpayment determinations by the Part C and Part D RACs. Please note that the appeals process set forth applies to both § 422.2600 and § 423.2600. Because the sections largely mirror one another, discussions in this preamble would apply to both programs, unless otherwise noted.

(1) Reconsiderations (§ 422.2605 and § 423.2605)

At § 422.2605 and § 423.2605, we propose that if the plan believes the part C or Part D RAC did not apply CMS' stated payment methodology correctly, a plan may appeal the determination to an independent reviewer. CMS' payment methodology itself, however, is not subject to appeal. That is, while miscalculations and factual or data errors may be appealed, the plan may not appeal the substantive basis for the overpayment determination. This is consistent with the approach to Part D reconciliation appeals at § 423.350(a)(1), which states that the Part D plan may appeal ''if CMS did not apply its stated payment methodology correctly.'' The Part D reconciliation appeals process does not permit the underlying payment methodology to be appealed.

Examples of appealable issues would include, but are not be limited to: (1) A Part C or Part D RAC determination that a plan provider/pharmacy was excluded from Medicare when the service was furnished; (2) a Part C or Part D RAC determination that a payment was a duplicate payment; or (3) whether the Part C or Part D RAC miscalculated an overpayment.

In paragraph (a), we propose that the plan's request for reconsideration must be filed with the independent reviewer within 60 calendar days from the date of the demand letter. In paragraph (b)(1), we propose that the request for reconsideration must be in writing and must provide evidence or reasons or both to substantiate the request. In paragraph (b)(2), we propose that the plan must include with its request all supporting documentation, evidence, and substantiation it wants the independent reviewer to consider. This material must be submitted in the format requested by CMS. Documentation, evidence, or substantiation submitted after the filing of the reconsideration request would not be considered.

In paragraph (c), we propose that CMS may file a rebuttal to the plan's reconsideration request. The rebuttal must be submitted to the independent reviewer within 30 calendar days of the independent reviewer's notification to CMS that it has received the plan's reconsideration request. CMS would notify and send its rebuttal to the plan at the same time it is submitted to the independent reviewer. In paragraph (d), we propose that the independent reviewer would conduct the reconsideration. Specifically, the independent reviewer would review the notification of improper payment, the evidence, and findings upon which it was based, and any evidence that the plan or CMS submitted in accordance with regulations. In paragraph (e), we propose that the independent reviewer would inform CMS and the plan of its decision in writing. In paragraph (f), we propose that a reconsideration decision would be final and binding unless the plan requests a hearing in accordance with § 422.2605 and § 423.2605. Finally, in paragraph (g), we propose that a plan that is dissatisfied with the independent reviewer's reconsideration decision would be entitled to a review by a hearing official as provided in § 422.2610 and § 423.2610.

(2) Hearing Official Determinations (§ 422.2610 and § 423.2610)

In proposed § 422.2610 and § 423.2610, we outline the process for requesting review of the record by a CMS hearing official. In paragraph (a), we propose that a request for review must be filed with CMS within 15 days from the date of the independent reviewer's issuance of a determination.

The request must be in writing and must provide a basis for the request. In paragraph (b), we propose that the plan must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered. Documentation, evidence, or substantiation submitted after the filing of the request would not be considered.

In paragraph (c), we propose that a CMS-designated hearing official would conduct the review. A hearing would not be conducted, either live or via telephone, unless the hearing official, in his or her sole discretion, chooses such a mechanism. In all cases, the hearing official's review would be limited to information that: (1) The Part C or Part D RAC used in making its determinations; (2) the independent reviewer used in making its determinations; (3) the plan submits with its hearing request; and (4) CMS submits per paragraph (d). Neither the plan nor CMS would be allowed to submit new evidence.

In paragraph (d), we propose that CMS may file a rebuttal to the plan's hearing request. The rebuttal must be submitted within 30 calendar days of the plan's submission of its hearing request. CMS would send its rebuttal to the plan at the same time it is submitted to the hearing official. In paragraph (e), we propose that the CMS hearing official would decide the case within 60 days and send a written decision to the plan and CMS, explaining the basis for the decision. In paragraph (f), we propose that the hearing official's decision would be final and binding, unless the decision was reversed or modified by the CMS Administrator in accordance with § 422.2615 and § 423.2615.

(3) Administrator Review (§ 422.2615 and § 423.2615)

In proposed § 422.2615 and § 423.2615, we discuss the Administrator review process. In paragraph (a), we propose that if a plan is dissatisfied with the hearing official's decision, the plan may request that the CMS Administrator review the decision. The request must be filed with the CMS Administrator within 15 calendar days of the date of the hearing official's decision. The request must provide evidence or reasons or both to substantiate the request. In paragraph (b), we propose that the plan must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered. Neither the plan nor CMS would be allowed to submit new evidence. Documentation, evidence or substantiation submitted after the filing of the request would not be considered.

In paragraph (c), we propose that after receiving a request for review, the Administrator would have the discretion to review the hearing official's decision in accordance with paragraph (e) or to decline to review said decision.

In paragraph (d), we propose that the Administrator would notify the plan of whether he or she intends to review the hearing official's decision. If the Administrator declines to review the hearing official's decision, the hearing official's decision is final and binding. If the Administrator agrees to review the hearing official's decision, CMS may file a rebuttal statement within 30 days of the Administrator's notice to the plan that the request for review has been accepted. CMS would send its rebuttal statement to the plan at the same time it is submitted to the Administrator. In paragraph (e), we propose that if the Administrator agrees to review the hearing official's decision, the Administrator would determine, based upon this decision, the hearing official record, and any arguments submitted by the plan or CMS in accordance with this section, whether the determination should be upheld, reversed, or modified. The Administrator would furnish a written decision to the plan and to CMS. The Administrator's decision would be final and binding.

*C. Strengthening Beneficiary Protections*

1. Providing Good Quality Health Care (§ 422.504(a)(3) and § 423.505(b)(27))

Section 1857(e)(1) of the Act, together with section 1860D–12(b)(3) of the Act, which incorporates its terms for Part D, authorizes CMS to include terms and conditions in our contracts with MA organizations and PDP sponsors that are consistent with Part C and Part D requirements, respectively, and that the Secretary finds are ''necessary and appropriate.'' Furthermore, the requirements set forth in section 1860D–4(b), (c), and (d) of the Act include specifications for a Part D sponsor to administer a benefit that not only accurately and efficiently process claims but also meets beneficiary healthcare needs, and to take affirmative action to improve outcomes and achieve patient satisfaction. Under this authority, we propose to add a requirement to CMS contracts with MA organizations and Part D sponsors that explicitly requires that Part C and Part D plans demonstrate that they are providing good quality health care by achieving good or improving scores on CMS performance standards for outcomes, intermediate outcomes, process, patient experience, and patient access to care. We believe that adding this requirement would help ensure our beneficiaries receive the right care at the right time.

While we believe that we have conveyed this expectation in other ways, such as through our performance and quality measurement and rating methodologies, we have never explicitly articulated this requirement in regulation. In short, we are proposing here that it is not enough to simply administer a benefit plan, but that Part C and Part D sponsors should constantly seek out ways to actively promote and advance the health of its enrollees.

In order to create a requirement that helps ensure that Medicare beneficiaries are receiving consistently good quality care, and to have the ability to enforce such a requirement, we sought existing guidance to shape the meaning of ''good quality health care.'' The Affordable Care Act required HHS to develop the National Strategy for Quality Improvement in Health Care (the National Quality Strategy), which, like our Three-Part Aim, combines the three broad objectives of better health for the population, better care for individuals, and affordable care. In addition, our Star Ratings program was developed to include quality and performance measures to increase the level of accountability for MA organizations and PDP sponsors to administer a good quality benefit to Medicare beneficiaries. By linking a concept as subjective in nature as good quality health care to objective metrics and measures in the Star Ratings program, we believe plans and sponsors can reasonably employ tangible strategies that improve the quality of services and benefits provided to Medicare beneficiaries.

To give concrete and verifiable meaning to this requirement, we propose to specify that good quality health care refers to MA organizations and Part D sponsor performance in the five categories identified in CMS's Star Ratings program—patient outcomes, intermediate outcomes, patient experience, patient access to care, and process. Achievement of this type of performance is based on organizational capability and implementation by the MA organizations and Part D sponsor. Articulating and codifying this requirement underscores for the public and our plans and sponsors the critical importance we place on aligning the administration of Part C and Part D benefits with the achievement of good quality health care as illustrated by, but not limited to, these specific performance standards. Leveraging what

plans have already put into practice with regard to these five categories means that plans should not encounter any additional burden in complying with this proposed regulation. Instead, the proposed change gives plans an opportunity to demonstrate the value they offer their enrollees, while providing a means for us to enforce or take corrective action when a Part C or Part D plan fails to provide good quality health care.

There are several reasons we propose including in regulation a contract requirement that plans administer a benefit promoting good quality health care. We reward MA organizations with quality bonus payments when they achieve high scores within the Star Ratings. At the same time, we believe that it is appropriate that we react correspondingly if an MA organization does not provide good quality care. In addition, our existing requirements that MA organizations have a quality improvement (QI) program (§ 422.152) and Part D sponsors have a Medication Therapy Management Program (§ 423.153(d)) further reinforce our belief that MA organizations and Part D sponsors are already striving to administer a good quality benefit. Moreover, we examined our authority at § 422.502(b) and § 423.503(b), which allows us to ensure that plan performance is routinely evaluated. Based on the methodology we use to calculate plan performance for both MA organizations and Part D sponsors, we are able to determine which plans are outliers—that is, those organizations whose performance is consistently poor. With regard to the particular proposed contractual requirement to administer a good quality benefit, we can evaluate a plan's scores in Performance Metrics category within the plan performance review. Plans are held accountable for achieving good scores on the review, and this evaluation allows us to appropriately deny an organization's application to operate if it is determined that they are an outlier.

Therefore, we propose adding paragraph (b)(27) to § 423.505, Requirements for contracts, to state, ''A PDP sponsor is required to administer a PDP benefit that provides good quality health care demonstrated by scores of 3 or higher on CMS performance standards for patient outcomes, intermediate outcomes, process, patient experience, and patient access to care.''

Similarly, we propose adding paragraph (a)(3)(iv) to § 422.504, Contract Provisions, to state that MA organizations agree to provide benefits, ''in a manner that provides good quality health care demonstrated by scores of 3 or higher on CMS performance standards for patient outcomes, intermediate outcomes, process, patient experience, and patient access to care.''

2. MA–PD Coordination Requirements for Drugs Covered Under Parts A, B, and D (§ 422.112)

Under § 422.112(b) of the MA program regulations, coordinated care plans must ensure continuity of care and integration of services through arrangements with contracted providers. We believe that an important aspect of this coordination is ensuring that all needed services, including drug therapies, are provided in a timely manner. We have become aware of situations in which enrollees' access to needed Medicare-covered drugs has been delayed or denied due to the MA organization's failure to effectively coordinate Part B and Part D benefits for certain drugs, both at the point-of-sale (POS) and during the coverage determination process.

As defined in § 423.100, ''Part D'' drugs do not include drugs for which payment as so prescribed and dispensed or administered to an enrollee is available for that enrollee under Part A or Part B. In other circumstances, these drugs are covered under the Part D benefit, but coverage generally cannot be determined based solely on the drug itself. These drugs include certain infusion agents, oral anti-cancer therapies, oral anti-emetics, immunosuppressants, and injectables.

We do not believe MA–PD plans are adopting or administering uniform policies that allow them to expeditiously determine whether a drug is covered under Part A/Part B or Part D at the POS. The resulting POS rejection of coverage under the Part D benefit does not uniformly include messaging that a Part B prior authorization determination is required, nor consistently result in a corresponding authorization under Part B. This can result in lengthy drug treatment delays while the enrollee or his or her provider attempts to determine why the drug was not covered and then pursues a coverage determination from the MA–PD plan. For example, an MA–PD enrollee may present a prescription for a covered chemotherapy drug at his or her pharmacy only to be told that the claim has been rejected under the Medicare Part D benefit, resulting in the enrollee leaving the pharmacy counter without his/her drug. The enrollee may not know that the drug is covered under Part B. In some cases, the enrollee must take steps on his or her own to find out why coverage for a prescription was rejected at the POS and then contact the plan to obtain the Part B-covered medication. Unless the MA–PD plan has a robust process in place to make a timely and appropriate payment determination at the POS, there may be unnecessary delays, during which the enrollee is denied access to the needed medication.

We have issued guidance in section 20.2.2. Chapter 6 of the Medicare Prescription Drug Benefit Manual related to how Part D plan sponsors should make determinations whether a drugs is covered under Part B or Part D. We have also outlined in Appendix C of Chapter 6 considerations for Part D plan sponsors—and by extension, MA organizations that offer MA–PD plans—to take into account when making determinations as to whether a drug is covered under Part B or Part D. We expect plans to work with network pharmacies and providers to determine coverage and payment for these drugs with the goal of limiting disruptions to beneficiaries and pharmacies and ensuring access to medically necessary prescription drugs. For example, we have stated in subregulatory guidance that, when adjudicating claims for these drugs, Part D plan sponsors are permitted to rely on information submitted on the prescription (for example, to determine whether the prescription is related to a Medicare covered organ transplant) and may require their network pharmacies to obtain documentation to determine whether payment should be made under Part B or Part D.

During recent MA–PD plan audits, we also have seen that some plans are not adequately coordinating the respective Part D and Part B drug benefits when an enrollee or his or her provider requests a drug coverage determination from the plan. For example, in response to a POS claim rejection for an immunosuppressant drug that cannot be resolved at the POS, an enrollee's provider may submit a coverage determination request to the MA organization offering an MA–PD, which is generally processed under the Part D benefit. In some cases, MA–PD plans deny coverage and issue a denial notice under the Part D benefit on the basis that the drug is, or may be, covered by Part B, but the plan either fails to make a determination regarding Part B coverage or does not authorize payment under the Part B benefit.

Occurrences like these cause inappropriate and avoidable delays, or, even worse, result in situations in which the enrollee fails to receive needed medication altogether. In the case of chemotherapy or

immunosuppressive drugs, such delays could have rapid and serious medical consequences for the beneficiary.

Part D drug benefits and drug benefits under Parts A and B should be coordinated by MA organizations offering MA–PDs so that enrollees receive needed medications on a timely basis. We are proposing to add a new paragraph (b)(7) to § 422.112 to require MA–PDs to establish adequate messaging and processing requirements with network pharmacies (that is, Part D contracted providers) to ensure that appropriate payment is assigned at the POS, and to ensure that, when coverage is denied under Part D due to available coverage under Part A or Part B, such Part A or Part B coverage is authorized or provided to the enrollee as expeditiously as the enrollee's health condition requires. Our proposed regulation would require that MA PDs have systems in place to accurately and timely adjudicate claims at the POS.

In addition, we would like to ensure that MA–PD plans are coordinating their drug benefits appropriately during the coverage determination process. If an MA organization offering Part D denies Part D coverage due to the availability of Part A or Part B coverage, we expect the MA organization to ensure the decision results in authorization or provision of the drug under Part A or Part B pursuant to the requirements in parts 422 and 423, subpart M under our proposed regulation. We do not expect MA–PD enrollees to have to request an initial coverage determination more than once.

To avoid unnecessary delays and inappropriate denials of critical medications, we have considered requiring MA–PD plans to authorize coverage of all Part A, Part B and D medications at the POS so that the enrollee can receive covered medication without delay. The determination as to whether the drug is covered under Part A, Part B or Part D and the amount of the appropriate cost sharing would occur later if necessary. However, we recognize that such a requirement may interfere with medically appropriate pre-authorization requirements, and may trigger retrospective enrollee liability depending on the difference in enrollee cost sharing for coverage under Part A, Part B and Part D and retrospective TROOP adjustments and Part D reconciliation.

We solicit comments on our proposal, as well as other possible approaches to minimizing delays in beneficiary access to needed medications caused by inadequate coordination of the Part A, Part B and Part D drug benefits at the POS and during the coverage determination process. In particular, we would appreciate organizations sharing their expertise regarding best practices for this benefit coordination at the POS and plan processes that enhance those coverage determinations. We also are soliciting comments on challenges MA organizations offering Part D currently encounter in their efforts to integrate these benefits.

3. Good Cause Processes (§ 417.460, § 422.74 and § 423.44)

Section 1851(g)(3)(B)(i) of the Act provides that MA organizations may terminate the enrollment of individuals who fail to pay basic and supplemental premiums after a grace period established by the plan. Section 1860D–1(b)(1)(B) of the Act generally directs us to use rules related to enrollment, disenrollment, and termination for Part D plan sponsors that are similar to those established for MA organizations under section 1851 of the Act. In addition, section 1860D–13(a)(7) of the Act mandates that the premiums paid by individuals with higher incomes be increased by the applicable Part D Income Related Monthly Adjustment Amount (Part D IRMAA), for the months in which they are enrolled in Part D coverage.

Consistent with these sections of the Act, subpart B in both the Part C and Part D regulations sets forth our requirements with respect to involuntary disenrollment procedures at § 422.74 and § 423.44, respectively. An MA or Part D plan that chooses to disenroll beneficiaries for failure to pay premiums must be able to demonstrate to us that it made a reasonable effort to collect the unpaid amounts by notifying the beneficiary of the delinquency, providing the beneficiary a period of no less than 2 months in which to resolve the delinquency, and advising the beneficiary of the termination of coverage if the amounts owed are not paid by the end of the grace period.

In addition, current regulations at § 417.460(c) specify that a Health Maintenance Organization (HMO) or competitive medical plan (cost plan) may disenroll a member who fails to pay premiums or other charges imposed by the plan for deductible and coinsurance amounts. While there is not a grace period parallel to MA and Part D, the other procedural requirements for cost plans to disenroll a member on this basis are similar to those for MA and Part D plans. The cost plan must demonstrate that it made reasonable efforts to collect the unpaid amount and send the enrollee written notice of the pending disenrollment at least 20 days before the disenrollment effective date.

In the April 2011 final rule (76 FR 21432) we amended both the Parts C and D regulations at § 422.74(d)(1)(v), § 423.44(d)(1), and § 423.44(e)(3) regarding involuntary disenrollment for non-payment of premiums or Part D–IRMAA to allow for reinstatement of the beneficiary's enrollment into the plan for good cause. In the April 2012 final rule (77 FR 22071), we extended the policy of reinstatement for good cause to include beneficiaries enrolled in cost plans in § 417.460(c)(3); thus aligning the cost plan reinstatement provision with the MA and PDP plan provisions.

These good cause provisions authorize CMS to reinstate a disenrolled individual's enrollment without an interruption in coverage in certain circumstances where the non-payment was due to circumstances that the individual could not reasonably foresee and could not control, such as unexpected hospitalization. Since the inception of these provisions, we have received feedback from plans on ways to improve the good cause process and make it more efficient for both the plans and us. Over the past year, we have already used this feedback to improve the operational aspects of the policy by updating Chapter 2 of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual to clarify notice language and the process and timing of receiving payments during the extended grace period, as outlined in § 417.460(c)(3), § 422.74(d)(1)(v), and § 423.44(d)(1)(vi). In addition, we updated the Complaints Tracking Module (CTM) Standard Operating Procedures (SOP) to permit plans to transfer requests for reinstatement for good cause to CMS. We are now proposing to make additional revisions to § 417.460, § 422.74, and § 423.44 to make changes to the good cause review process.

The ability for individuals to be reinstated during the extended grace period for good cause is outlined in § 417.460, § 422.74 and § 423.44. Since its inception, the process of accepting, reviewing, and processing beneficiary requests for reinstatement for good cause has been carried out exclusively by CMS. In multiple cases, individual MA organizations and Part D plans have indicated that they wanted to be the point of contact for their current and past members. In addition, several plans have raised concerns regarding complaints by their members who are seeking reinstatement and who have to contact CMS instead of the plan to make this request.

In light of this feedback, the experience we have gained since the initial implementation of the good cause

process, and in the interest of making the process more efficient, we solicited public input on improving the process in the draft 2014 Call Letter issued on February 15, 2013. In the Call Letter, we indicated that we were considering making changes to the good cause process. Specifically, we stated that we were exploring expanding the plans' role in the process to include accepting the initial requests for reinstatement by former plan members and gathering information prior to submitting the requests to us. We requested comments from MA organizations and Part D plan sponsors on our proposal to expand the plans' role and any other ways we might improve the process to receive and review good cause requests for reinstatement.

The vast majority of the comments we received from stakeholders in response to the Call Letter were in favor of expanding the plans' role, given the fact that plans can readily access a former enrollee's premium billing and payment history and, as such, are in a position to identify and efficiently resolve other disenrollment disputes that are erroneously being received as good cause requests. A number of plans indicated a preference to independently implement the good cause process through enhanced subregulatory guidance. A few commenters indicated that CMS should retain responsibility over all aspects of the good cause process to ensure objectivity.

In response to this feedback we are proposing to amend § 417.460(c)(3), § 422.74(d)(1)(v), and § 423.44(d)(1)(vi) to permit an entity acting on behalf of CMS to effectuate reinstatements when good cause criteria are met. This regulatory change would allow us to designate another entity, including the plans or an independent contractor, to complete portions or all of the good cause process. It is our intent to expand the role of plans to include accepting incoming requests for reinstatement directly from former enrollees and making the good cause determinations using the existing regulatory standard. This proposed change would enable plans to be more responsive to their current and former members, and lessen the burden the plans have in coordinating with us regarding the good cause and reinstatement process. It further aims to lessen the number of complaints generated due to miscategorization of the reinstatement requests as an allegation of plan error, which the plans must then resolve and refer back to us for a good cause determination.

Ensuring objectivity in the review of these cases and equity among beneficiaries regarding the determination of good cause for cases is critically important. Thus, we would establish operational policy and processes in subregulatory guidance to set parameters for the application of the good cause standard, including the submission to CMS of certain cases for review to ensure that plans remain impartial and equitable in their assessment and treatment of former members who have been disenrolled for nonpayment of premiums. These changes would be accompanied by the development of an oversight protocol for any activities currently carried out by us for which we name the plans or an independent contractor our designee to carry out.

In addition to our proposal here to permit a CMS designee to determine reinstatements for good cause, we are taking this opportunity to propose a technical change to the language in § 417.460 to clarify that good cause protections for enrollees in cost plans apply to instances where there was a failure to pay either plan premiums or cost sharing. In extending the good cause provision to cost plans in the April 2012 final rule, we correctly referenced failure to pay premiums as a basis for disenrollment from a cost plan, but in two instances we neglected to include a reference to ''other charges'' as a basis for disenrollment. We propose to make a technical change to § 417.460(c)(3) and (c)(4) to clarify that the good cause provisions are applicable to individuals who have been disenrolled for non-payment of other charges (for example, deductible or coinsurance amounts), in addition to non-payment of premiums.

4. Definition of Organization Determination (§ 422.566)

Based on our updated guidance, program experience, and information collected during audits of MA organizations, we are proposing to revise the current regulatory definition of ''organization determination'' set forth at § 422.566(b) to create a single, uniform definition. As described later in this proposed rule, the definition of organization determination referenced in our manual guidance (Chapter 13 of the Medicare Managed Care Manual, section 30), required plan marketing documents (such as the EOC), and Part C data requirements (*Medicare Part C Plan Reporting Requirements, Technical Specifications Document*—Measure 6) is more inclusive than the definition currently reflected in this regulation.

Section 1852(g) of the Act requires MA organizations to have a procedure for making determinations regarding whether an enrollee is entitled to receive a health service and the amount (if any) that the individual is required to pay for such service. Our regulations at 42 CFR part 422, subpart M codify the procedures MA organizations must follow when processing organization determinations. Section 422.566(b) defines which actions are considered organization determinations, but does not currently include all types of coverage decisions made by a provider under contract with an MA organization.

Our current manual guidance, required model EOC documents, and Part C plan reporting requirements clarify that organization determinations include fully favorable, partially favorable, and unfavorable decisions made by an MA organization concerning payment or provision of an item or a service. Additionally, requirements elsewhere in Part 422 provide certain beneficiary protections in the MA program, including a requirement that MA organizations provide or make payment for all services covered by Medicare Parts A and B (see § 422.101(a)), and contract requirements that limit beneficiary financial liability for fees that the MA organization is legally obligated to pay for services provided by contract and non-contract providers (see § 422.504(g)). Our proposed changes would clarify what actions are included and therefore ensure that enrollees receive required Medicare notices (for example, notice of termination in certain healthcare settings) and due process rights.

We are proposing to make minor modifications to regulatory language at § 422.566(b)(1) through (b)(3) to improve the uniformity of our guidance on what actions are considered organization determinations. We are restating these provisions for consistency within this section and to further underscore an ''organization determination'' includes any coverage decision—fully favorable, partially favorable, and unfavorable—made by an MA organization concerning payment or provision of an item or a service. At § 422.566(b)(1) and (b)(2), we refer to an organization determination as ''any determination'' by an MA organization (that is, fully favorable, partially favorable, and unfavorable). At 422.566(b)(3), we are proposing to replace the reference to the MA organization's ''refusal to provide or pay'' with reference to ''any determination not to provide or pay for'' items or services made by the MA organization to improve consistency of the regulatory language.

Chapter 13, section 30 of the Medicare Managed Care Manual states that

approval for an item or service by the plan or its delegated entity (that is, provision of an item or service by a contract provider, such as inpatient admission to a contract hospital) is an organization determination. We are also proposing to add new language to the regulation text at § 422.566(b)(6) that clarifies that a provider under contract with an MA organization that furnishes an item or service to an enrollee has made a favorable organization determination on behalf of the MA organization. We believe this clarification to the regulatory definition is necessary to clearly distinguish when a contract provider is making an organization determination on behalf of the MA organization from instances where a contract provider is not making an organization determination on behalf of the MA organization. We have repeatedly stated that a contract provider's refusal to furnish an item or service is a treatment decision, not an adverse organization determination made on behalf of the MA organization. In a case where a contract provider refuses to furnish an item or service, the enrollee has the right to request an organization determination from the MA organization. In addition, the provider may request the organization determination on the enrollee's behalf.

The proposed revision to the regulation text at § 422.566(b)(6) would also clarify that a service or item provided by a noncontract provider due to a referral from a contract provider constitutes a favorable organization determination, and therefore ensures that enrollees would be protected by limitations on their financial liability. (For more information, see § 422.504(g) of the regulations and Chapter 4, section 170 of the Medicare Managed Care Manual). We stated in the January 28, 2005 final rule (70 FR 4618) that if a network physician performs a service or directs an MA beneficiary to another provider to receive a plan covered service (regardless of whether the provider is following the plan's internal procedures, such as obtaining the appropriate plan pre-authorization), the enrollee cannot be held liable for more than applicable plan cost sharing for those services. When a contract provider refers an enrollee out of the network, the enrollee has a reasonable expectation that the items or services provided by the non-contract provider will be covered by the plan. Enrollees cannot be held to a higher standard than plan contracting providers to adhere to plan rules.

Proposed new paragraph § 422.566(b)(6) would also clarify that a favorable organization determination has been made if: (1) The MA organization decides to provide or pay for an item or service, including a decision to continue providing or paying for an item or service; or (2) a contract provider or facility, acting on behalf of the MA organization, furnishes (or continues to furnish) an item or service.

Together, our proposed revisions to § 422.566(b) are intended to codify our current guidance, creating a single, uniform definition of organization determination.

5. MA Organization Extension of Adjudication Timeframes for Organization Determinations and Reconsiderations (§ 422.568, § 422.572, § 422.590, § 422.618, and § 422.619)

Section 1852(g)(2) of the Act requires MA organizations to provide for reconsideration, or review, of organization determinations within a timeframe specified by the Secretary, but generally no later than 60 days from the date of receipt of the request for reconsideration. Section 1852(g)(3)(B) of the Act requires MA organizations to maintain procedures for expediting organization determinations and reconsiderations when a physician's request indicates that applying the standard timeframe could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function or when, in the case of an enrollee's request, the MA organization makes such a determination on its own. In expedited cases, the MA organization generally must issue its decision no later than within 72 hours of receipt of the request. Section 1852(g)(3)(B)(iii) of the Act permits the Secretary to extend this 72-hour decision making timeframe in certain cases.

Our regulations at 42 CFR part 422, subpart M codify the procedures MA organizations must follow in issuing standard and expedited organization determinations and reconsiderations. Specifically, the current regulations at § 422.568(b), § 422.572(b), and § 422.590(a)(1) and (d)(1) set forth the standard and expedited timeframes within which plans are required to process such decisions and describe the circumstances under which plans are permitted to extend decision making timeframes by up to 14 calendar days.

Based on information ascertained during recent MA program audits, we have found that some MA organizations are routinely and inappropriately invoking extensions of the adjudication timeframes for organization determinations and reconsiderations. We have identified circumstances in which MA organizations are routinely invoking the 14 day extension: (1) In cases where the plan lacks adequate internal controls to ensure coverage requests are reviewed and adjudicated within the required regulatory timeframe; and (2) in cases where the plan is awaiting receipt of supporting clinical documentation from one of its contract providers. We believe the current language that permits extension of the adjudication timeframes set forth in § 422.568(b), § 422.572(b), § 422.590(a)(1) and § 422.590(d)(2) is being interpreted more broadly than our intent in adopting these rules. Therefore, we propose to revise these regulatory provisions to more clearly define our intended standard for when it is appropriate for an MA organization to extend an adjudication timeframe.

Routinely invoking an extension of the applicable adjudication timeframe is counter to the intent of the statutory and regulatory requirements for timely determinations that emphasize the health needs of the beneficiary in determining the appropriate adjudication timeframe. Extensions should be permitted only in limited circumstances, and only if the extension is in the enrollee's interest. MA organizations are required by regulation to render all coverage decisions as expeditiously as the enrollee's health condition requires. When plans choose to subject an item or service to a prior authorization requirement, we expect them to have the resources to process those requests in a timely manner.

We believe MA organizations have interpreted existing regulations to mean that there is a broader set of circumstances in which it would be appropriate to invoke an extension than we intended, such as the need for medical evidence from a contract provider. We are proposing to amend the regulation text to clarify our original intent that an extension should not be routinely invoked for any category of coverage request, but in particular not for purposes of obtaining additional medical evidence from contract providers. Thus, we propose to revise the extension language in § 422.568(b), § 422.572(b), and § 422.590(a)(1), and to add new § 422.590(e), which would incorporate and clarify existing text at § 422.590(a)(1) and (d)(2) in order to more clearly identify when it is appropriate for an MA organization to invoke an extension of the adjudication timeframe. We also propose revisions to § 422.590(d) and redesignation of existing subparagraphs § 422.590(e) through (g) as part these changes.

First, we propose to retain the current provisions in these various regulations

that permit an extension at the request of the enrollee. Additionally, we propose to modify the current regulatory provisions that permit an extension ''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).'' Our proposed revised language would result in two more specific provisions permitting an extension, which we believe clarifies the intent of our existing requirements.

Additionally, we propose language to clarify at § 422.568(b)(1)(ii), § 422.572(b)(1)(ii), and § 422.590(e)(1)(ii) that an extension may be justified and in the enrollee's interest due to the need to obtain additional medical information that may result in changing the MA organization's denial of coverage of an item or service only from a non-contract provider. We believe the arrangement between an MA organization and its contract providers is such that clinical documentation should generally be readily available and that there are mechanisms for an MA organizations to ensure that contract providers produce necessary documentation in a timely manner (for example, via their contract). We believe that any delay in decision-making caused by an extension to obtain additional medical evidence from a contract provider would be in the plan's interest but not generally in the interest of the enrollee. Therefore, we are proposing to specify at § 422.568(b)(1)(ii), § 422.572(b)(1)(ii), and § 422.590(e)(1)(ii) that one circumstance in which it may be appropriate for an MA organization to invoke an extension is when the extension is in the enrollee's interest due to the need for additional medical evidence from a non-contract provider only.

When the MA organization needs additional information that may change a decision to deny coverage, it is our expectation that the MA organization promptly solicit necessary clinical documentation in all cases and that extension of the timeframe not be routinely invoked. It is also our expectation that the full 14 days not be routinely taken, even if an extension is warranted, and that all coverage requests be reviewed, and decisions issued, as expeditiously as the enrollee's health condition requires within that period, as required by regulation.

In addition, we propose to include a provision (new language to be codified at § 422.568(b)(1)(iii), § 422.572(b)(1)(iii), and § 422.590(e)(1)(iii)) to clarify that an extension of the adjudication timeframe may be permitted when the extension is justified due to extraordinary, exigent or other non-routine circumstances, and it is in the enrollee's interest. We recognize that there may be limited, non-routine circumstances in which the adjudication timeframe may need to be extended even if the enrollee does not request the extension and no additional documentation must be obtained from a non-contract provider. We emphasize that the extension must be both: (1) Due to extraordinary, exigent or other non-routine circumstances; and (2) in the enrollee's interest. For example, a natural or man-made disaster may impede a contract provider's ability to provide the MA organization with timely clinical information, and invoking an extension may be in the enrollee's interest if that information is necessary to approve coverage. It is our expectation that these exceptions would be rare. MA organizations that overuse or misuse the authority to invoke an extension may be subject to corrective action.

In all cases where an extension is invoked, the MA organization is responsible for documenting the justification for the extension in the case file, complying with the requirement to notify the enrollee in writing of the reasons for the delay, and informing 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.

In an effort to improve clarity in our guidance related to extensions and to remove duplicative language, we have made corresponding, technical edits to subpart M. Specifically, we are proposing in § 422.590 to remove paragraph (d)(2) and add a new paragraph (e). To correspond with this proposed change, we propose to update related cross-references and language accordingly. Specifically, at § 422.618(a)(1), we propose to replace the reference to § 422.590(a)(1) with a reference to § 422.590(e). In § 422.619(a), we propose to replace the reference to § 422.590(d)(2) with a reference to § 422.590(e). Also, we propose to make corresponding changes within § 422.568(b), § 422.572(b), and § 422.590(d) to ensure consistency in the structure and language of these provisions.

*D. Strengthening Our Ability To Distinguish Stronger Applicants for Part C and D Program Participation and To Remove Consistently Poor Performers*

1. Two-Year Prohibition When Organizations Terminate Their Contracts (§ 422.502, § 422.503, § 422.506, § 422.508, and § 422.512)

Section 1857(c)(4)(A) of the Act prohibits organizations from re-entering the MA program in the event that a previous contract with the organization was terminated at the request of the organization within the preceding 2-year period, except in circumstances that warrant special consideration. Furthermore, section 1857(e) of the Act permits us to add contract provisions that are not inconsistent with Part C of the Act and that we find necessary and appropriate for the administration of Medicare Part C. We propose to amend the text and application of regulations implementing these provisions of the Act. In the April 15, 2010 final rule (75 FR 19678), we characterized our current policy on the 2-year ban applicable to voluntary non-renewals and mutual terminations as applying the ban based on plan type and service area. We provided the following example to illustrate application of the rule: an MA organization's non-renewal of a Private Fee-for-Service MA plan would not prohibit the MA organization from immediately applying for an MA HMO contract for the same service area. Similarly, our current policy, absent this proposal, would not apply the 2-year ban on an MA organization that non-renewed a contract in one region from applying immediately for the same type of MA product in a different region.

This current policy unnecessarily narrows the scope of the 2-year prohibition and precludes us from preventing poor performing MA organizations from reentering the MA program. We have reconsidered the wisdom of this policy and believe that the MA program would be better served if we applied the 2-year ban flowing from non-renewals and mutual terminations to new contracts or service area expansions regardless of the product type or service area of the non-renewed or terminated contract. We note that we are retaining our ability to exercise discretion in applying the 2-year ban when there are special circumstances that warrant special consideration, as provided in the current regulations text at § 422.503(b)(6)(ii), § 422.506(a)(4), and § 422.512(e).

First, we propose to address how a non-renewal or mutual termination of an MA contract would be treated.

Specifically, we propose to amend the regulation text at § 422.506(a)(4) and § 422.512(e) to explicitly apply the 2-year prohibition to applications for service area expansions in addition to applications for new contracts. These changes to § 422.506 and § 422.512 would make the text of these regulations consistent with the text at § 422.503(b)(7) and § 422.508(c) with regard to the 2-year prohibition imposed as a condition of a mutual termination of an MA contract. We read the current text at § 422.503(b)(7) to permit us to deny a contract to a MA organization that has participated in a mutual contract termination, regardless of contract type, product type, or service area, within the past 2 years. We also note that the current text of § 422.503(b)(6) is not explicit on this point but may be read to permit contract denials for new contracts and service area expansions, consistent with our proposal; we intend to apply this interpretation to the existing text at § 422.503(b)(6). We also propose to add the following sentence to paragraphs (c) and (d) of § 422.508 to make it clear that a mutual termination of a MA contract would result in a ban of all contract types and service area expansions: ''This prohibition may apply regardless of the product type, contract type or service area of the previous contract.'' These proposed amendments are in harmony with our policy, as articulated in the preamble to the April 15, 2010 final rule (75 FR 19703) to apply the 2-year ban consistently in the context of voluntary non-renewals and mutual terminations.

2. Withdrawal of Stand-Alone Prescription Drug Plan Bid Prior to Contract Execution (§ 423.503)

Occasionally, organizations new to Part D that have qualified for a Medicare PDP sponsor contract withdraw their bids after we have announced the low-income subsidy (LIS) benchmark but prior to executing the contract for the coming plan year. These withdrawals interfere with our administration of the Part D program, in particular the auto assignment of LIS beneficiaries. To address this problem, we are proposing to adopt regulatory provisions that would impose a 2-year application ban on organizations not yet under contract with us as PDP sponsors that withdraw their applications and bids after we have issued our approvals. We are making this proposal under our authority at section 1860D–12(b)(3)(D) of the Act to adopt additional contract terms, including the conditions under which we would enter into contracts, not inconsistent with the Part D statute.

In February of each year, we solicit applications from organizations seeking to qualify to enter into a contract to offer stand-alone PDPs in the upcoming plan year. These organizations, along with current PDP sponsors who wish to continue participating in the Part D program, submit bids in June for our review and approval. We review these applications and bids with the expectation that, upon approval, the organizations would enter into PDP sponsor contracts with us in September to provide the Part D benefit for the plan year starting the following January.

As part of the annual bid review, we calculate the LIS benchmark for each PDP Region based on the bids for basic PDPs submitted annually by current PDP sponsors that will operate in that region in the coming year. Sponsors whose monthly premiums fall at or below the benchmark in a region receive auto-enrollments from us of LIS-eligible beneficiaries in those regions. We normally announce the LIS benchmark in late July or early August.

In recent years, some organizations have withdrawn their applications and bids following the announcement of the LIS benchmark. Because these organizations withdrew prior to executing a contract, and we cannot compel them to sign the contract, they are not subject to our compliance or oversight authority, and nothing in our current regulations prevents these applicants from withdrawing their applications late enough in the process to cause significant disruption. In contrast, when an existing PDP sponsor withdraws its bid, we treat such an action as an election by the PDP sponsor to non-renew its contract in that PDP Region, which renders the sponsor ineligible to submit another application for 2 years, under our regulations at § 423.507(a)(3). We propose to make a regulatory change to ensure equal treatment between new applicants and existing PDP plan sponsors, which would allow us to maintain an accurate depiction of the contracting landscape. Specifically, we propose to amend § 423.503 by adding paragraph (d) which would impose a 2-year Part D application ban on organizations approved by CMS as qualified to enter into stand-alone PDP sponsor contracts but which elect, after our announcement of the LIS benchmark, not to enter into such contract and withdraw their PDP bids. This proposed regulatory change, in effect, would subject a withdrawing applicant to the same penalty we may apply to an organization already under contract that elects to terminate or non-renew its PDP contract.

It is critical that we have an accurate portrayal of the number and type of plan benefit packages that would be available to beneficiaries in every PDP Region, especially during the end of the summer when much of the bid review, both the formulary and actuarial components, has been completed. During this period, we need to confirm that there are the required minimum number of plans available in each PDP region. We also need accurate plan information at the end of the summer so that we can meet the production deadlines associated with the annual election period, including publication of the Medicare & You handbook as well as updating the Medicare Plan Finder Web site and our payment and enrollment systems. An applicant that withdraws its application late in the process alters the contracting landscape, potentially disrupting preparations we have already made, including those related to the auto assignment of LIS beneficiaries, for the upcoming plan year.

We acknowledge that PDP plan applicants may need to withdraw their pending contracts for a variety of legitimate business reasons. For this reason, we afford applicants several months to withdraw their applications, without penalty, following the application due date in February and the bid submission deadline of the first Monday in June. However, in adopting the proposed regulatory authority, we would place a reasonable limit on prospective PDP sponsors' option to withdraw bids and applications without penalty. By imposing consequences on applicants that withdraw their bids following the announcement of the LIS benchmark, we also would discourage any ''gaming'' of the bid review and auto assignment processes (for example, by participating in the bid review process until it learns that it will not qualify for auto assignments) that can occur when applicants opt out of participation in the PDP at the last minute.

3. Essential Operations Test Requirement for Part D (§ 423.503(a) and (c), § 423.504(b)(10), § 423.505(b)(28), and § 423.509)

We propose to create, through regulation, a new step in the application and contracting process with newly contracted entities operating as stand-alone PDP sponsors or MA organizations offering Part D plans (MA–PDs). This step will be an ''essential operations'' test which we would administer to ''newly contracted entities.'' We use the term ''newly contracted entity'' in this preamble to describe an organization that has

entered or applied to enter into a Part D contract with us for the first time for the upcoming plan year, and neither it, nor another subsidiary of the organization's parent organization, is offering Part D benefits during the current benefit year. This would include organizations that are offering EGWPs for the first time.

Currently, with the exception of the LIS readiness audits, we have no test for assessing the effectiveness of the arrangements organizations represent to us in their applications and bids prior to the actual start of delivery of benefits on January 1. An essential operations test would allow us to test whether an organization's arrangements appear likely to allow the organization to effectively administer its contract. We are proposing to require organizations to pass an essential operations test either—(1) as a qualification to contract, with failure to pass the test nullifying our approval of the application; or (2) after contract execution as a contract requirement but prior to the start of the benefit year, with a failure to pass the test triggering an immediate contract termination under § 423.509.

Pursuant to section 1860D–12(b)(3)(D) of the Act, which incorporates by reference section 1857(e)(1) of the Act, we have the authority to add contract provisions that are necessary and appropriate to carry out the Part D program; section 1860D–11(b) provides authority for the collection of additional information as part of the bid as we may require to carry out the Part D program. Based on this authority we propose adding § 423.504(b)(10) and § 423.505(b)(28) to include passing the essential operations test as a condition to enter into and a term of the Part D contract. Additionally, pursuant to our authority at section 1860D–12(b)(3)(B) and (b)(3)(F) of the Act (which incorporate by reference section 1857(c)(2) and (h) of the Act, respectively, to apply to the Part D program), the current regulations at § 423.509(a) and (b)(2)(i), authorize immediate termination of contracts with Medicare Part D plan sponsors in certain circumstances. We believe that immediate termination would be authorized under the standard of section 1857(h)(2) of the Act because the inability of a plan sponsor to ensure future members' access their drug benefit, as evidenced by failure to pass the essential operations test, would constitute an imminent and serious risk to beneficiary health and safety. We propose adding § 423.509(a)(4)(xii) and (b)(2)(i)(D) to subpart K to reflect this new cause for immediate termination. (Of note, we are reorganizing § 423.509(a) to group the statutory basis for termination together followed by examples of violations that would meet the statutory basis. This new regulation is an example of a violation.) Additionally, we propose to explicitly include the essential operations test as a means to evaluate Part D applicants in § 423.503(a)(1) and to add § 423.503(c)(4) to subpart K to establish failure of an essential operations test as grounds for nullifying a CMS approval of application notice.

The heart of the Part D benefit is the sponsor's ability to process claims for prescription drugs in real-time because, unlike health benefits, where claims payment normally follows the delivery of services, pharmacies require confirmation of claims payment at the point-of-sale either from an insurer or the covered individual. Success in Part D claims processing depends largely on the sponsor's ability to perform enrollment, benefit administration, and claims adjudication operations seamlessly at the point-of-sale. That is, the sponsor must be able to do all of the following essential operations in real time and at the point-of-sale to a satisfactory level: Identify a beneficiary as a member of one of its Part D plans; determine whether the drug requested is, in fact, appropriately covered under Part D (for example, that the drug is not covered: (a) Under Part B, (b) as part of end-stage renal disease (ESRD) treatment, or (c) as a hospice benefit); determine the phase of the benefit the beneficiary is currently in; and provide the pharmacy with instructions so that the beneficiary can be charged appropriate copays/coinsurance and deductibles.

We are proposing the essential operations test and associated regulatory changes because of our experience with certain newly contracted entities in the Part D program that experienced significant operational difficulties at the start of the benefit year as a result of their inexperience administering Part D benefits. To prevent the recurrence of this problem and ensure that new sponsors are prepared to and actually can deliver Part D benefits at an acceptable level, starting with the 2015 contract year application cycle, we propose that we may require newly contracted entities to pass an essential operations test conducted by us beginning in the fall of 2014.

Often these newly contracted entities have little or no prior experience in administering health and drug benefit plans. Unfortunately, by the time deficiencies in the sponsor's operations and ability to provide the Part D benefit become apparent (typically when we receive complaints about significant numbers of inappropriately rejected claims at the pharmacy), the sponsor has already executed an agreement with us, which has prevented us from moving quickly to remove the sponsor from the program and prevent further beneficiary harm. In these instances, we have found it necessary to provide inordinate amounts of resource-intensive technical assistance to sponsors that were not prepared to effectively administer Part D benefits when they signed their contract. The essential operations test would help to prevent the recurrence of problems of this nature.

The essential operations test for newly contracted entities would entail testing of sponsors' command of Part D benefit administration rules and systems related to these areas. Initially, the testing would consist of scenario testing with sponsors' key staff to show us that they have a firm grasp of the Part D policies and essential operations. The test would be able to verify whether an applicant's administrative and management arrangements, as attested to in its application, are sufficient for the applicant to carry out functions listed in § 423.504(b)(4)(ii) such as furnishing prescription drug services and implementing utilization management programs.

Provided we have the resources, in the future, the test would likely become significantly more sophisticated and involve live testing of sponsors' systems with test data. The more involved test would also likely include testing the processes related to enrollment such as MARx communication and processing; LIS processing and determinations; coverage determinations, appeals, and grievances (CDAG) processing; and real-time coordination of benefits data exchange and processing. For instance, the sponsor would need to demonstrate the ability to pay test claims correctly in real-time consistent with its CMS-approved benefit packages (including formulary) and the Part D transition fill policy.

The timing of the essential operations test must fit within the timeline of the annual Part D contracting process, which is driven largely by the bid deadline and plan election period dictated by statute. In preparation for an upcoming benefit year beginning on January 1, we must solicit and review applications from organizations seeking a MA–PD or PDP sponsor contract in February of the preceding year. We issue application determinations (that is, approval or denial) in May. All existing Part D sponsors and new applicants must submit their plan

benefit package (PBP) bids (including formularies) in June. Then, we complete the bid review approval and negotiation processes at the end of August. Once we have approved the submitted bids, sponsors can then execute their contracts with us. Historically, we have executed all contracts by mid-September so we can finalize preparations for the marketing season, which begins on October 1, and the annual election period (AEP), which begins on October 15. These preparations include publishing the Medicare & You handbook in September, which lists approved plans; releasing the Medicare Plan Finder Web site using plan-specific data; reviewing and approving sponsors' marketing materials; and granting sponsors access to our enrollment systems.

In contrast to an audit, the application process currently only requires that sponsors demonstrate to us that they have the necessary legal arrangements in place (for example, a risk-bearing license, executed contracts with first-tier and downstream entities, pharmacy network descriptions, etc.). Likewise, bid and formulary approvals indicate that the plans to be offered by the new sponsor are acceptable to us, not that the sponsor will necessarily be successful in implementing those plans.

Under our current schedule, the essential operations test we propose to require as part of the application and contracting process would occur after contracts are signed in September but before the start of the benefit year on January 1. We would most likely complete the tests by November 15. In the future, we aim to conduct the essential operations tests prior to signing contracts with applicants which is why we are also proposing to add passing the test as a qualification to contract. Ultimately, in the event of an organization failing the test, we would apply the appropriate proposed regulatory provision based on the timing of the test administration.

a. Failing Essential Operations Test as Cause for Immediate Termination

Once a sponsor signs its contract, it is obligated to perform all of the required functions to support the benefits described in the contract even though the sponsor does not start offering benefits until January 1. Given the volume of preparations and tight resource constraints between our approving bids in late August and the start of the AEP in October, the first opportunity we currently have to devote resources to the essential operations test is most likely in late September to November. We are currently not likely to be in the position to conduct essential operations tests prior to contracting because it would be challenging to conduct the test prior to approving the benefit structure against which we would test a sponsor's ability to process claims accurately. If we find that a sponsor does not have the requisite systems and processes in place to offer Part D benefits in real-time, we would consider this cause for immediate termination of the sponsor's Part D contract in order to protect beneficiaries from harm at the start of the contract year.

Pursuant to section 1857(h)(2) of the Act (incorporated by reference into PDP by section 1860D–12(b)(3)(F) of the Act), we have the authority to immediately terminate a contract with a sponsor (without notice and opportunity for a hearing) when a delay in termination would pose an imminent and serious risk to the health of beneficiaries enrolled in the sponsor's plans. Also, under § 423.509(b)(2)(i) and § 423.652(b)(2), unlike standard CMS terminations, the effective date of an immediate termination is not stayed when the sponsor requests a hearing under § 423.650(a)(2). Because enrollment and accurate benefit administration through real-time claims processing are so fundamental to the delivery of the Part D benefit, if a sponsor fails to demonstrate to us that it can perform these essential operations, we would view this as a substantial failure to meet the Part D contract requirements on the following grounds: (1) Evidence that the sponsor was carrying out the contract in a manner that was inconsistent with the effective and efficient administration of the plan; and (2) evidence that the sponsor did not substantially meet the applicable conditions set out in the Part D regulations which would ultimately justify, depending upon timing of the test, our termination of a contract consistent with § 423.509(a)(1) through (3) based on the sponsor's failure to meet our proposed contract terms at § 423.504(b)(10) and § 423.505(b)(28). We believe that a newly contracted entity's failure to demonstrate certain critical capabilities and failing the essential operations test represents a substantial failure to carry out its Part D contract and is evidence that the sponsor is not prepared to carry out the contract in a manner that is consistent with the efficient and effective administration of the Part D program. Such a failure poses an unacceptable risk to the new sponsor's future members' access to Part D drugs, which would constitute an imminent and serious risk to beneficiary health and safety, justifying our immediate termination of the sponsor's contract. For MA organizations that must offer Part D benefits pursuant to § 423.104(f)(3)(i), failing the test would support the termination of the organization's Part D addendum as well as its MA contract under § 422.510(a)(3) because the inability to offer Part D benefits means that the organization no longer meets the applicable conditions associated with offering Part C benefits.

Given our experience with sponsors' abilities to resolve systemic systems problems in a timely manner, we believe that sponsors that fail the test would most likely not have sufficient time before the start of the benefit year to remedy the breadth and magnitude of the failures we would have identified during the test. Even if the sponsor attested that it had corrected problems we identified, we would not have time to conduct a second test to validate the sponsor's corrections prior to the start of the new benefit year. Simply put, we believe the risk of harm to enrollees' health and safety is too great to move forward with a sponsor that has such significant and critical problems so close to the start of the plan year. Thus, an immediate termination of the contract before the start of the year would be the only way to protect beneficiaries and ensure successful operation of the Part D program by absolving the sponsor and us of the responsibilities in the contract.

b. Failing Essential Operations Test as Failure of a Qualification to Contract and Grounds for Nullification of Approval

If an organization fails an essential operations test we conducted prior to contract signature, no termination would be necessary as we would simply nullify our previous conditional approval of the organization's Part D contract qualification application. Section 423.503(a) describes the mechanisms we use to evaluate an applicant and determine whether the applicant is qualified to contract. These mechanisms currently include application review and on-site visits. The general term ''on-site visit'' is used to describe interactions with applicants that include our visiting the applicant's facility and vice versa, either in person or virtually. We are proposing to explicitly include the essential operations test as a qualification to contract at § 423.503(a)(1) to authorize our use of the test and any information learned in the course of the essential operations test in making the contract determination. Our experience over the

past few years with newly contracted entities that have passed the paper-based application, but failed to have fully-functional administrative and management arrangements in place to effectively offer benefits in January, has demonstrated to us that implementing an essential operations test is key to the successful administration of the Part D program for all beneficiaries.

We would view failure of the essential operations test as a determination that the applicant would not be qualified to contract with us. As a result, we would nullify our approval on that basis. Successful applicants receive a conditional approval at the end of May of their Part D application pursuant to § 423.503(c)(1). The letter informs applicants that the conditional approval is based on the information contained in their application, and if we subsequently determined that any of the information was inaccurate or that qualification requirements are not met, we would withdraw the approval of the application. Through that notice, we preserve the right to nullify our approval. If that occurs, we would not provide appeal rights described in subpart N to applicants that have their approval nullified based on failing the essential operations test.

We are proposing to not afford applicants appeal rights because CMS would not be able to conduct the appeals process provided for in Part 423, Subpart N, within the timeframe imposed by § 423.650(c), which requires CMS to have all contract application appeals decided by September 1 for contracts to be effective on January 1 of the following year. We could not conduct a test in late August, find that the applicant failed the test, and move through a fair appeal process for both parties in less than 2 weeks. Therefore, we would not afford appeal rights to applicants that fail the test prior to contracting under our proposal.

4. Termination of the Contracts of Medicare Advantage Organizations Offering PDP for Failure for 3 Consecutive Years To Achieve 3 Stars on Both Part C and Part D Summary Star Ratings in the Same Contract Year (§ 422.510)

In the final rule adopted April 12, 2012 (77 FR 22168), we set forth at § 422.510(a)(14) and § 423.509(a)(13) that a Medicare contracting organization's consistent failure to achieve at least a 3-star summary star rating for 3 consecutive years provides a sufficient basis for us to make a decision to terminate our contract with a MA organization or stand-alone PDP sponsor. This termination standard was based on the criteria we used then to mark low-rated contracting organizations with a ''low performing icon (LPI)'' on the Medicare Plan Finder Web site. Recently, we revised our LPI assignment criteria for MA organizations that offer PDP benefits (MA–PDs) to more accurately reflect their contract performance. We propose here to revise the contract termination regulation related to consistent low star ratings to reflect the new LPI assignment methodology announced in the contract year 2014 Call Letter. Specifically, we are proposing to modify our existing authority at § 422.510(a) [3] by clarifying that MA–PD organizations that do not achieve at least 3 stars in both their Part C and D ratings in the same year for 3 consecutive years may be subject to termination.

In the April 12, 2012 final rule (77 FR 22072), we finalized the contractual requirement at § 422.504(a)(18) and § 423.505(b)(25) that MA organizations and PDP plan sponsors attain each year summary ratings of at least 3 stars (the ''average'' performance rating). We explained that, because the star rating calculations are based on an organization's performance across a wide array of operational measures, the summary star ratings are an accurate indicator of the extent to which the organization has in place effective administrative and management arrangements necessary to administer Part C and Part D benefit plans, as required under § 422.504(a)(17) and § 423.505(b)(24).

We further established, as part of the same rulemaking, our authority at § 422.510(a)(14) and § 423.509(a)(13) to terminate the contracts of organizations offering MA and stand-alone PDPs when those organizations fail to achieve at least 3 stars on either their Part C or Part D summary rating for at least 3 consecutive years. At the time, we stated that since the measures that make up the star ratings provide evidence of the sufficiency of a contracting organization's administrative and management capability, it was reasonable for us to conclude that an organization receiving a summary rating below 3 stars for 3 consecutive years had substantially failed to meet that requirement, providing us justification for terminating the contract of that organization. We also explained that 3 consecutive years was sufficient time for sponsors to analyze the underlying causes of their low ratings and take corrective action that would result in at least a 3-star summary rating. The rulemaking also called for an MA–PD organization's Part C summary rating to be tracked separately from its Part D summary rating. That is, we could terminate an MA–PD organization contract if it failed for 3 straight years to achieve at least a 3-star Part C summary rating, regardless of its Part D summary ratings. Similarly, we could terminate the same organization if it failed to achieve at least a 3-star Part D summary rating for 3 straight years, regardless of its Part C performance. Since in most instances an MA organization must also offer Part D benefits, consistently low Part D summary ratings justify a termination of the entire MA–PD contract since the organization could no longer meet its obligation to offer Part D benefits. We stated that we would allow a 3-year transition period before we would begin using the star rating-based termination authority to issue termination notices to any sponsors whose performance met the criteria in late 2014 with an effective date of January 1, 2015.

At the time we adopted this regulation, we identified certain organizations on the Medicare Plan Finder (MPF) Web site as consistently low performing organizations with the display of the LPI next to the organization's other plan information. In the contract year 2014 Call Letter released in April 2013, we announced a change in the methodology for assigning the LPI mark to plan sponsors. On page 105 of the notice, we noted that some stakeholders had raised concerns that MA–PD contractors could switch back and forth from poor performance on Part C to poor performance on Part D from year to year without ever being identified as a poor performer and marked with the LPI. We noted that such a situation was potentially misleading to beneficiaries, and we decided to address the matter by revising, effective in 2014, the criteria for the assignment of the LPI indicator to those organizations that fail for 3 consecutive years to achieve both Part C and Part D summary ratings of at least 3 stars in the same year for 3 consecutive years. We concluded this announcement by observing that MA–PD organizations are responsible for providing adequate care and services across both Part C and Part D and that the LPI methodology change encourages consistent improvement in the quality of care by MA–PD organizations across all of the Part C and Part D measures.

We believe that the justification for the change in the LPI methodology also requires a change in the way we would

[3] Elsewhere in this proposed rule, we proposed to reorganize and renumber § 422.510(a). The discussed provision is current codified at § 422.510(a)(14) but we are proposing to redesignate it as § 422.510(a)(4)(xi).

apply the standard for MA–PD contract termination based on star rating performance. The performance of an MA–PD organization must be assessed across the totality of its obligations under its Medicare contract. Organizations should not be permitted to target their compliance efforts from year to year on alternating sets of contract requirements, just barely meeting our minimum requirements in order to stay one step ahead of our enforcement authorities. Beneficiaries rightly expect quality in the delivery of all of their Medicare benefits, covering both health care and prescription drugs. MA–PD organizations that alternate their low star ratings from year-to-year between Part C and Part D are in fact subjecting their members to substandard performance every year. This is an unacceptable outcome that does not promote the best interests of Medicare beneficiaries.

If an MA–PD organization is not able to achieve at least an ''average'' star rating across all of its Part C and Part D operations in at least 1 year out of 3, it would become clear that the organization had both substantially failed to meet the administrative and management requirements of a Medicare contractor and could not take effective corrective action over the same 3-year period.

The artificiality of the division between Part C and Part D star rating performance becomes apparent when one notes the extent to which the measures for each part assess the MA–PD organization's performance of similar functions or responsibilities. According to the most recent methodology we used to calculate star ratings, ''The Medicare Health & Drug Plan Quality and Performance Ratings—2013 Part C & Part D Technical Notes,'' (*http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html*) the Part C measures are divided into 5 domains and the Part D measures into 4. Three of the Part C domains are virtually identical to those of Part D, with variations where necessary to reflect differences in terminology and features between health and drug plans. For example, Domain 1 for Part D, ''Drug Plan Customer Service,'' consists of measures that largely correspond to those of Part C's Domain 5, ''Health Plan Customer Service.'' Both contain measures that reflect call center performance (including foreign language availability) and processing of appeals. The Part D Domain 2, ''Member Complaints, Problems Getting Services, and Improvement in the Drug Plan's Performance,'' measures an organization's performance in largely the same categories as Part C's Domain 4, ''Member Complaints, Problems Getting Services, and Improvement in the Health Plan's Performance.'' Both domains consist of measures that reflect beneficiaries' complaints about the plan, their access to benefits, their decision to leave the plan, and the plan's quality improvement. Domain 3 of both the Part C and Part D measures are entitled ''Member Experience with the Health/Drug Plan'' and reflect plan members' experience with their plans such as assessment of their ability to access covered services (needed prescription drugs in the case of Part D, physician appointments, and coordination of care in the case of Part C). Domain 4 for Part D, ''Patient Safety and Accuracy of Drug Pricing,'' corresponds to Part C's Domain 1, ''Staying Healthy: Screenings, Tests and Vaccines,'' and Domain 2, ''Managing Chronic (Long Term) Conditions,'' in that they all capture an MA–PD organization's attention to the clinical impact of the Medicare services they provide to their members. The Part D measures in Domain 4 reflect the extent to which plan members maintain adherence to their medication regimens and receive prescriptions for high risk medications. The Part C Domains 1 and 2 address clinical performance as it is carried out by a health plan, including the extent to which it has conducted screenings of its members for breast cancer, colorectal cancer, and high cholesterol and manages long term conditions such as diabetes, high blood pressure, and rheumatoid arthritis.

The similarity in the Part C and Part D measures means that the operations associated with these 2 programs are not so different as to justify separate Part C and Part D analyses of MA–PD organization's delivery of Medicare benefits to the same set of beneficiaries in the same service area. MA–PD organizations do not contract with us to provide separate Part C and Part D benefits. Rather, it is more correct to say that their contract obligates them to provide effective customer service, access to care, and promote clinical outcomes across the entire range of Medicare benefits. Therefore, the better way to assess an MA–PD organization's administrative and management compliance is not to see whether it can meet Part C or Part D requirements, but whether it can meet the customer service, access to care, and clinical performance requirements in the delivery of all types of Medicare benefits. The only way to accurately measure the performance of such functions is to examine the organization's ratings in the Part C and Part D measures in the related domains. For example, an MA–PD organization cannot be said to be providing satisfactory customer service to its members if it achieves a 3-star rating in only its Part C operations.

Therefore, we propose to revise § 422.510(a) [4] to clarify that MA-only contracts are subject to CMS termination when they fail for 3 consecutive years to achieve a Part C star rating of at least 3 stars. Additionally, we propose to add a subparagraph to § 422.510(a) to establish as a basis for termination of MA–PD contracts the failure for 3 consecutive years of the contract to achieve at least 3 stars in both its Part C and D ratings in the same year. When we first adopted the star rating-based contract termination authority in April 2012, we stated that we would afford organizations a 3-year transition period before we would use that authority to make contract termination decisions. This period was necessary to allow organizations to make adjustments to their operations to reflect the dramatic increase in the consequences associated with low star rating performance created by our new termination authority. Accordingly, the regulation states that we may use only those star ratings issued after September 1, 2012, to make a decision to terminate a contract based on consistently low star ratings. Thus, organizations that fail to achieve at least a 3-star rating upon the release in September 2014 of the 2015 ratings would be the first group of Medicare contractors eligible for termination under our new authority. We are not proposing to extend this grace period as part of this proposed adjustment to the current policy, because there is no reason why failures under the current regulations (which contain the ''loophole'' we are closing here) should not count towards the 3-year mark along with failures under the revised standard once in place.

[4] Elsewhere in this proposed rule, we would reorganize and renumber § 422.510(a) and § 423.509(a) to better reflect the bases for contract termination in connection with our statutory authority to terminate. Using the current numbering, this proposal would be codified as § 422.510(a)(14) but under our proposal here, it would be codified as § 422.510(a)(4)(xi).

## III. Provisions of the Proposed Regulation

### *E. Implementing Other Technical Changes*

1. Requirements for Urgently Needed Services (§ 422.113)

Our regulations at § 422.113(b) require MA organizations to cover urgently needed services furnished outside a plan's service area or contracted network of providers when the enrollee is in need of such services but is outside of the service area or is in the service area but the plan network is temporarily unavailable due to extraordinary and unusual circumstances. Further requirements built in to the definition of ''urgently needed services'' specify additional criteria for out-of-network coverage of these services: (1) The need for services was a result of unforeseen illness, injury or condition; and (2) it is not reasonable, given the circumstances, for the enrollees to obtain the services through the organization offering the MA plan.

In the preamble to our June 29, 2000 final rule implementing the current requirements (65 FR 40199), we clarified the intended meaning of ''extraordinary and unusual circumstances'' as ''an earthquake or strike.'' However, it is our experience in administering the MA program that there are other much less severe circumstances in which the plan network may be unavailable or inaccessible to an enrollee who is in the authorized service area and needs immediate care due to an unforeseen illness, injury or condition. Examples of such circumstances include the need for urgent care outside of the network's business hours, (for example, during the weekend or at night).

Many MA plans have responded to the need for urgently needed services by contracting with clinics that have hours of operation well beyond those of traditional physicians' offices to furnish services to their enrollees when the plan network is not available.

To better align the regulations with current practices regarding access to urgently needed care services, we are proposing to revise the regulation by removing the phrase ''under extraordinary and unusual circumstances'' at § 422.113(b)(1)(iii). The proposed regulatory language would read as follows:

(iii) Urgently needed services means covered services that are not emergency services as defined in this section, provided when an enrollee is temporarily absent from the MA plan's service (or, if applicable, continuation) area (or provided when the enrollee is in the service or continuation area but the organization's provider network is temporarily unavailable or inaccessible) when the services are medically necessary and immediately required—

2. Skilled Nursing Facility Stays (§ 422.101 and § 422.102)

Under section 1814(a)(2)(B) of the Act, Medicare Part A generally only covers skilled nursing facility services (SNF) following a qualifying 3-day hospital stay. However, under section 1812(f) of the Act, we may authorize Part A coverage of SNF care without a prior hospital stay if two conditions are met. First, the coverage of these services must not result in any increase in Medicare program payments, and second, the coverage must not alter the acute care nature of the benefit. For reasons discussed later in this proposed rule, in an August 22, 2003 final rule (68 FR 50847), we exercised this authority under section 1812(f) of the Act with respect to SNF services covered under MA plans.

The reason that we took this step is that, in the absence of this exercise of this authority, MA organizations could only cover SNF services without a 3-day prior hospital stay as a supplemental benefit. In such a case, if an MA enrollee is in a SNF pursuant to such coverage in the middle of a 100-day covered stay, and disenrolls from the MA plan, or the MA plan is terminated or non-renewed during such a stay, the beneficiary would lose SNF coverage, as it would not be covered under Medicare Part A because it would not have met the condition for coverage of a 3-day prior hospital stay. By exercising the authority under section 1812(f) of the Act to make the stay a Part A covered benefit, the stay would remain covered even if the individual is no longer enrolled in the MA plan.

Our determination that SNF services provided by MA organizations without a 3-day prior hospital stay met the two tests in section 1812(f) of the Act was based on the fact that MA organizations are paid a monthly per-Medicare enrollee payment to provide all contracted services. Thus, Medicare costs would not be affected by permitting SNF services to be covered by Medicare without the prior 3-day hospital stay for so long as the beneficiary was enrolled in the MA plan because the plan is paid a fixed amount without regard to services received. We determined that this would provide incentives for the MA organizations to provide care more cost effectively. Some evidence at the time indicated that MA organizations, particularly coordinated care plans, could shorten hospital stays and shift patients to post-acute or subacute settings, such as SNFs, more quickly than under the original Medicare program. If SNF care is the appropriate level of care, MA organizations are then able to use SNF care rather than more expensive hospital care for similar patients requiring posthospital care. For some patients and diagnoses, the MA organization is able to bypass the hospital stay and admit the beneficiary directly to a SNF.

Because the previously discussed rulemaking exercised authority under section 1812(f) of the Act to authorize Part A coverage in the absence of an otherwise-required 3-day prior hospital stay, the regulations addressing ''basic benefits'' (which include benefits under Part A) at § 422.101 were revised to include provision for this Part A coverage at § 422.101(c).

Notwithstanding the fact that, when the option under § 422.101(c) is elected by an MA organization, the services are covered under Part A, at least some MA organizations did not include the costs of such stays in the Part A portion of their adjusted community rate (ACR) submissions, and in later years, in their bids. Rather, they continued to treat these Part A-covered services as ''supplemental benefits.'' We understand why MA organizations did this, as the services (other than in the case described previously when an MA enrollee receiving such services is no longer enrolled in an MA plan covering them) would not be covered under Part A if the enrollee were not enrolled in the MA plan. However, because of the section 1812(f) of the Act waiver, these services technically were services ''covered under Part A,'' included under § 422.101(a), not supplemental benefits under § 422.102.

We had determined in promulgating the August 2003 final rule that the services in this situation had to be treated as covered under Part A in order to protect coverage for a beneficiary who changes from MA coverage to original Medicare coverage mid-stay. However, in light of the fact that MA organizations have, over a period of years, been treating these benefits as supplemental benefits, we have determined that we can protect a beneficiary in the situation described without requiring an MA organization to include a SNF stay without a 3-day prior hospitalization as a Part A benefit under its MA plan by modifying our exercise of section 1812(f) of the Act authority to waive the 3-day prior hospitalization requirement *only* in cases in which an MA enrollee receiving SNF services without a 3-day

prior hospital stay changes from coverage under the MA plan to Medicare coverage under Original Medicare (or another MA plan that does not cover such stays as a supplemental benefit). This addresses the concern we were addressing in our August 2003 final rule without requiring MA organizations to change their treatment of this MA plan benefit.

In order to effectuate this proposed change in the scope of our section 1812(f) waiver, we are proposing to move the provision describing an MA organizations' authority to furnish covered SNF stays without the qualifying inpatient hospital stay required under original Medicare to a new § 422.102(f) in the section of the regulations governing supplemental benefits.

We also propose to make a conforming revision in the cross-reference to this provision that currently appears at § 409.30(b)(2)(ii), to—(1) reflect this provision's relocation from § 422.101 to § 422.102; and (2) reflect the fact that the Part A coverage provided for thereunder is not for the entire ''duration of the SNF stay'', but only for the period after the individual is no longer enrolled in the MA plan offering the coverage of the SNF stay as a supplemental benefit.

3. Agent and Broker Training and Testing Requirements (§ 422.2274 and § 423.2274)

Pursuant to our authority under sections 1851(h)(2), 1860D–1(b)(1)(B)(vi), 1851(j)(2)(E), and 1860D–4(l)(2) of the Act, we previously codified agent and broker training and testing requirements at § 422.2274(b) and (c) and § 423.2274(b) and (c) to require all agents and brokers selling Medicare products be trained and tested annually through a CMS endorsed or approved training program, or as specified by us, on Medicare rules and regulations specific to the plan products they intend to sell.

Since the training and testing requirements were implemented, we have embarked on various activities to improve and ensure the efficacy of training and testing. Specifically, we launched an online training and testing pilot in 2009 to increase understanding of the standardized Medicare program requirements. Although the pilot was successful, our ability to accommodate all agents and brokers nationally is limited and maintaining the training and testing module requirements creates a significant financial burden. Additionally, endorsing other entities limits our oversight of training and testing information, and assurance of consistency among program requirements. Moreover, through our monitoring efforts, we have found that MA organizations and Part D sponsors are complying with the annual guidance released by us. Specifically, we found that plans provided adequate detail on the level of information that must be covered in agent and broker training and testing materials. As a result, we propose to revise § 422.2274(b) and (c) and § 423.2274(b) and (c) to accomplish several things (i) remove CMS endorsed or approved training and testing as an option; (ii) require that agents and brokers be trained annually on Medicare rules and regulations; and details specific to the plan products they intend to sell: And (iii) require agents and brokers to be tested annually to ensure appropriate knowledge and understanding of the training topics. We believe this proposed change continues to ensure that all agents and brokers selling Medicare products have a comprehensive understanding of Medicare program rules. We previously proposed (see the provisions for ''Reducing the Burden of the Compliance Program Training Requirements (§ 422.503(b)(4)(vi)(C) and § 423.504(b)(4)(vi)(C)'') to require a standardized compliance training program. Under those provisions, MA organizations and Part D sponsors will not be permitted to develop and implement plan specific training materials or supplemental materials. The proposed change in this section is exclusive to the requirements for conducting marketing activities under the MA and Part D program.

4. Deemed Approval of Marketing Materials (§ 422.2266 and § 423.2266)

Sections 1851(h) and 1860D–1(b)(1)(B)(vi) of the Act establish the requirements regarding the review and approval of marketing materials created by MA organizations and Part D sponsors. Sections § 422.2266 and § 423.2266 provide the regulatory requirements for materials that are deemed approved. If we have not disapproved the distribution of marketing materials and forms submitted by an MA organization or Part D sponsor with respect to the plan in the area, we are deemed not to have disapproved in all other areas covered by the MA organization or Part D sponsor except with regard to any portion of the material or form that is specific to the particular area. Sections § 422.2262 and § 423.2262 also provide the requirements for the review and distribution of marketing materials. The provisions stated in § 422.2266 and § 423.2266 are also part of the review and distribution process of marketing materials, and therefore should be moved to align with the requirements in § 422.2262 and § 423.2262. Therefore, we propose moving the substance of the current requirements in § 422.2266 and § 423.2266 to § 422.2262 (a)(2) and § 423.2262(a)(2), respectively. We propose reserving § 422.2266 and § 423.2266.

In addition, we also believe that the current regulatory requirements in § 422.2266 and § 423.2266 do not clearly state when and to what extent marketing materials are considered deemed approved. Therefore, we propose to simplify the language presently contained in § 422.2266 and § 423.2266 by stating, ''if CMS does not approve or disapprove marketing materials within the specified review timeframe, the materials will be deemed approved. Deemed approved means that an MA organization or Part D sponsor may use the material.'' We believe this change clarifies the present regulatory requirement for deemed marketing materials.

5. Cross-Reference Change in the Part C Disclosure Requirements (§ 422.111)

Prior to the publication of subpart V, Medicare Marketing Requirements, marketing-related rules were found in subpart B, Eligibility, Election, and Enrollment. These rules (codified in § 422.80) included review of marketing materials and election forms. With the publication of our September 18, 2008 final rule (73 FR 54208), the marketing-related requirements were moved into the new subpart V and § 422.80 was removed. Since that time, we have discovered an incorrect cross-reference to § 422.80 at § 422.111(d)(1) for procedures MA organizations must follow when submitting its rules changes to us for review. The correct reference should be subpart V, Medicare Advantage Marketing Requirements. We are proposing in these regulations to correct the reference contained in § 422.111(d)(1).

6. Managing Disclosure and Recusal in P&T Conflicts of Interest: Formulary Development and Revision by a Pharmacy and Therapeutics Committee Under Part D (423.120(b)(1))

Section 1860D–4(b)(3)(A)(ii) of the Act requires Part D sponsors who use formularies to include on their P&T committees at least one practicing physician and at least one practicing pharmacist, each of whom is independent and free of conflict with respect to the sponsor and the plan and who has expertise in the care of elderly or disabled persons. In our August 3,

2004 proposed rule (69 FR 46659), we proposed to interpret ''independent and free of conflict'' to mean that such P&T committee members could have no stake, financial or otherwise, in formulary determinations. In our January 28, 2005 final rule (70 FR 4256), we adopted this interpretation, and clarified that we would consider a P&T committee member not to be free of conflict of interest if he or she had any direct or indirect financial interest in any entity—including Part D plans and pharmaceutical manufacturers—that would benefit from decisions regarding plan formularies.

In a recent report (''Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions,'' OEI–05–10–00450), the HHS OIG recommended improvements in our requirements for Part D plan P&T committees. Specifically, the OIG report recommended that we establish minimum standards to ensure that these committees have clearly articulated and objective processes to determine whether disclosed financial interests are conflicts and to manage recusals due to conflicts of interests. The OIG report also suggested that we tell sponsors that they need to designate an objective party, such as a compliance officer, to flag and enforce the necessary recusals. In other words, the identification and evaluation of whether a disclosed financial interest represents a conflict of interest should be made by a knowledgeable and accountable representative of the sponsor's organization, such as the compliance officer, and not solely by the P&T committee members themselves. We concurred that P&T committees should have clearly articulated and objective processes to determine whether disclosed financial interests are conflicts, and to manage recusals arising from any such conflicts. Therefore, to address these recommendations, we propose to revise our formulary requirements pertaining to development and revision by a P&T committee at § 423.120(b)(1) to make it clear that the sponsor must establish such processes. Moreover, we propose that these processes must be clearly articulated and documented, and enforced by an objective party.

In our response to the OIG report, we noted that statutory and regulatory provisions (section 1860D–4(b)(3) of the Act and 42 CFR § 423.120(b)) indicate that it is the plan sponsor's responsibility to meet the formulary requirements, which include development of these processes. We also noted that we believe the agency's current Part D formulary review provides appropriate protections to beneficiaries from any adverse effects resulting from potential conflicts of interest. The agency thoroughly reviews Part D formularies to prevent discrimination against Medicare beneficiaries based on age, disease, or setting in which they receive care. The review process ensures inclusion of a broad distribution of therapeutic categories and classes by using reasonable benchmarks to ensure drug lists are robust. Further, we ensure that cost-sharing levels and utilization management strategies are appropriate and non-discriminatory. We identify potential outliers at each review step for further investigation and require reasonable clinical justification when outliers appear to create beneficiary access problems. We devote extensive resources to plan formulary oversight—and reserve the right to reject any formulary—to ensure compliance with industry best practices for formulary development and to ensure beneficiaries' access to clinically appropriate therapies.

Therefore, if a P&T committee, while operating under a potential conflict of interest were to create a formulary representative of such conflicts, the formulary would likely be discriminatory. Because a discriminatory formulary would not be approved, the only potential impact we can envision would be that the bid could be more expensive and, therefore, less competitive. However, in this case, beneficiaries could easily evaluate these higher premiums in the marketplace and choose a more efficient plan to meet their needs. As a result, we would expect that, given our level of formulary review, a conflict of interest in the P&T committee would disadvantage the sponsor rather than the beneficiary or the Medicare program.

We have also been asked to consider whether the practicing physician and the practicing pharmacist on the P&T committee who must be free of conflict of interest from Part D plans and pharmaceutical manufacturers should also be free of conflict of interest from Pharmacy Benefit Managers (PBMs). As discussed previously, we believe that our current formulary review process confers appropriate protections to beneficiaries from any potential adverse effects of conflicts of interest. Additionally, we have devoted extensive resources to the oversight of plan formularies and audit of P&T committee proceedings to ensure that they comply with industry best practices for development and management, and ensure beneficiaries' access to clinically appropriate therapies.

P&T committees must first base their 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, consistent with the program goal of maintaining a competitive market. Therefore, given that sponsors must balance both quality and costs in developing formularies, and that PBMs are the entities that negotiate for price concessions on behalf of sponsors, we believe that it is appropriate that PBMs have an interest in formulary decisions. However, we solicit comment on the pros and cons of defining PBMs as entities that could benefit from formulary decisions from which one practicing and one practicing pharmacy on the P&T committee must be free of conflict of interest.

As discussed previously, we believe the potential effects of conflicts of interest would theoretically result in either discriminatory or inefficiently priced plans. However, our formulary review process prevents discrimination, and higher priced plans will be subject to competition on premiums in the marketplace. Nonetheless there may be risks to formularies that we have not anticipated. In addition, we believe that sponsors should be accountable for objectively managing potential conflicts of interest as directed by the statute. Therefore, we propose revising our regulations at § 423.120(b)(1) to renumber the existing provisions and add a new paragraph (b)(1)(iv) to require that the sponsor's P&T committee clearly articulates and documents processes to determine that the requirements under paragraphs (b)(1)(i), through (iii) have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts.

7. Definition of a Part D Drug (§ 423.100)

Section 1860D–2(e) of the Act defines a covered Part D drug as a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1927(k)(2) of the Act; or a biological product described in clauses (i) through (iii) of subparagraph (B) of such section, or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary), and such term includes a

vaccine licensed under section 351 of the Public Health Service Act (and, for vaccinations administered on or after January 1, 2008), its administration, and any use of a covered Part D drug for a medically accepted indication (as defined in paragraph (4)). We codified this definition in § 423.100.

a. Combination Products

The FDA approves and regulates many products that include drug-drug and drug-device combinations. However, for the purposes of the Part D program, only combination products approved and regulated by the FDA as drugs, vaccines, or biologics (or any approved combinations of these) are potentially eligible for Part D coverage, in line with the Part D drug definition. We have previously addressed the status of combination products through guidance, including initially a published Q&A response and later in Section 10.3 of Chapter 6 of the Medicare Prescription Drug Benefit Manual (Part D Manual). This guidance has specified that combination products that contain at least one Part D drug component are Part D drugs when used for a medically accepted indication, unless such product, as a whole, belongs in one of the categories of drugs excluded from coverage under the Part D program. We now propose to address this issue in regulation to codify and clarify our policy.

We propose to add paragraph (vii) under the definition of a Part D drug to further clarify that only those combination products approved and regulated in its combination form by the FDA as a drug, vaccine, insulin, or biologic, as described in paragraph (i), (ii), (iii), or (v) of the Part D drug definition, may be eligible for Part D coverage. Our proposal would make it clear that the definition of a Part D drug excludes products where a combination of items are bundled or packaged together for convenience (such as one box packaging together multiple products, each in separate bottles), where the bundle has not been evaluated and approved by the FDA. This proposal would not affect products where multiple active ingredients (including at least one Part D eligible prescription-only ingredient) are incorporated into a single pill or single injection, as such products would have had to go through FDA approval in this combined form, meeting the Part D requirement. Combination products that are FDA approved would then be treated like other Part D drugs, eligible for coverage only when being used for a medically accepted indication and not otherwise excluded from Part D coverage (for example, because it is covered as prescribed and dispensed or administered under Medicare Part B).

This proposed policy is intended to clarify that a combination product containing at least one constituent ingredient that would, if dispensed separately, meet the definition of a Part D drug is eligible for Part D coverage only if it has received FDA approval in its combined form. Combination products not FDA approved as drugs under the Federal Food, Drug, and Cosmetics Act would not satisfy section 1927(k)(2)(A)(i) of the Act, defining covered outpatient drugs as those approved for safety and effectiveness as a prescription drug. Combination vaccines not licensed as a vaccine under section 351 of the Public Health Service Act similarly would not satisfy the definition of a Part D drug as defined in section 1927(k)(6).

Our proposal would not require that all constituent ingredients of a combination product be FDA-approved prescription drugs. An example would be an FDA-approved prescription drug that combines a Part D drug with a non-Part D covered vitamin. Conversely, a product combining a Part D drug with a medical food, dietary supplement, or another Part D drug, where the combined product has not received FDA approval as a prescription drug, vaccine, or biologic would not be eligible for Part D coverage.

b. Barbiturates and Benzodiazepines

We also propose to amend the definition of a Part D drug to address certain exclusions by revising paragraph (2)(ii). When the Part D benefit started in 2006, all uses of barbiturates and benzodiazepines were excluded from coverage by statute. In 2008, section 175 of the MIPPA amended section 1860D–2(e)(2)(A) of the Act to include coverage for barbiturates when used in the treatment of epilepsy, cancer, or a chronic mental health disorder and for benzodiazepines when used for any medically accepted indication, effective January 1, 2013. In 2010, section 2502 of the Affordable Care Act amended section 1927(d) of the Act, to remove barbiturates and benzodiazepines from the list of drugs subject to exclusion from coverage, effective for services provided on or after January 1, 2014. Thus, this subsequent statutory change effectively includes barbiturates as a Part D drug for all medically accepted indications. The proposed revision to § 423.100 would conform our definition of Part D drug to the new statutory requirement.

c. Medical Foods

We propose to add paragraph (2)(iii) to the list of exclusions from the definition of Part D drug to specify that medical foods, as defined in 21 U.S.C. 360ee, are not Part D drugs. Medical foods are not described in subparagraphs A(i), A(ii) or A(iii) of section 1927(k)(2) of the Act, and therefore do not meet the statutory definition of a covered Part D drug, nor do they fall under other categories eligible for Part D coverage listed in the Part D drug definition, such as biologics, vaccines, and insulin.

Moreover, as described previously in the section on combination products, a product with relevant components including some or all ingredients meeting the definition of a Part D drug would not be eligible for Part D coverage unless the combined product has also been approved by the FDA as a drug, vaccine, or biologic.

The proposed clarifications involving coverage for approved combination products and non-coverage of medical foods would not affect current policies surrounding Part D coverage of parenteral nutrition. (See the Part D manual guidance, Chapter 30.7 regarding the payment for parenteral and enteral nutrition items and services.) Extemporaneously compounded prescription drug products (addressed separately in Chapter 6 of the Part D manual and in § 423.120) also would not be affected by the proposed changes. Part D coverage for extemporaneously compounded prescriptions is available for the ingredients that independently meet the definition of a Part D drug when the product needed is one requested by the provider to meet a specific medical need, where there is no commercially available alternative. The convenience packaging of unapproved combination products for broad distribution does not meet the criteria set out specifically for extemporaneously compounded prescriptions.

8. Thirty-Six Month Coordination of Benefits (COB) Limit (§ 423.466(b))

In our April 15, 2010 final rule (75 FR 19819), we exercised our authority under sections 1860D–23 and 1860D–24 of the Act to impose a timeframe on the coordination of benefits between PDP sponsors and other payers including State Pharmaceutical Assistance Programs (SPAPs), other providers of prescription drug coverage, or other payers. In the preamble of the final rule, we explained our approach to determining the 3-year timeframe,

including the benefits derived from its establishment.

We stated, ''PDP sponsors must coordinate benefits with SPAPs, other entities providing prescription drug coverage, beneficiaries, and others paying on the beneficiaries' behalf for a period not to exceed 3 years from the date on which the prescription for a covered PDP drug was filled.'' The phrase ''a period not to exceed 3 years'' has caused confusion among some sponsors, who interpreted this to mean that the coordination of benefits period could be shorter than 3 years, and have consequently imposed tighter timeframes for coordination of benefits.

To clarify the requirement and avoid further confusion, we are proposing to remove from the regulation the phrase ''not to exceed,'' and adding the word ''of.'' This would clarify that sponsors must employ a coordination of benefits period of 3 years, and would remove any uncertainty about whether they may impose a shorter coordination of benefits period.

We also propose to revise the heading of § 423.466 to reference claims adjustments, which are addressed in § 423.466(a).

9. Application and Calculation of Daily Cost-Sharing Rates (§ 423.153)

We are proposing technical changes to the daily cost-sharing rate rule to clarify the application and calculation of daily cost-sharing rates and cost-sharing under the rule. We reminded Part D sponsors in the contract year 2014 Final Call Letter that, beginning January 1, 2014, in accordance with § 423.153(b)(4)(i), they must establish and apply a daily cost-sharing rate whenever a prescription is dispensed by a network pharmacy for less than a 30 days' supply, unless the drug is excepted in the regulation. These provisions were finalized in a rule entitled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes'' (77 FR 22072) (''April 12, 2012 final rule''). We provided information in the contract year 2014 Final Call Letter about changes to the PBP to accommodate a mandatory Daily Copayment field for any tier where the plan enters a Copayment Field to assist sponsors that have been confused about how to calculate daily cost-sharing rates. We also noted in the contract year 2014 Final Call Letter that the daily cost-sharing rate rule does not address how pharmacy dispensing fees are to be negotiated, calculated, or paid. We did so because we had heard that some sponsors are prorating dispensing fees as part of implementing the LTC short-cycle dispensing requirement of § 423.154 effective beginning January 1, 2013 and may be incorrectly referencing the upcoming daily cost-sharing rate rule as the reason. We made clear that there is no necessary connection between daily cost-sharing rates charged to beneficiaries and how dispensing fees are paid to pharmacies. Nothing in the daily cost-sharing rate rule at § 423.153(b)(4) requires the proration of dispensing fees, and we proposed a prohibition on the proration of dispensing fees in the LTC setting in another section of this proposed rule, because we believe it encourages inefficient dispensing in LTC facilities. In light of continuing confusion among some Part D sponsors about the daily cost-sharing rate rule, we believe technical changes to the rule are warranted.

Currently, under § 423.100, in cases when a copayment is applicable, ''daily cost-sharing rate'' is defined as the ''monthly copayment under the enrollee's Part D plan, divided by 30 or 31 and rounded to the nearest lower dollar amount, if any, or to another amount, but in no event to an amount that would require the enrollee to pay more for a month's supply of the prescription than would otherwise be the case.'' When we drafted this definition, we used the numbers ''30'' and ''31,'' as these are the numbers of days that are typically in a month's supply in Medicare Part D prescription drug benefit plans. However, we clarified in the Call Letter that the maximum amount that can be entered for the Daily Copayment field in the PBP will be based on the 1-month copayment amount divided by the actual number of days entered for the 1-month supply for that specific tier. Therefore, we are proposing to replace these numbers with the phrase ''the number of days in the approved month's supply for the drug dispensed'' to address how Part D sponsors that have other days' supplies as their month's supplies are to calculate daily cost-sharing rates.

Also, under our existing definition of ''daily cost sharing rate'' in § 423.100, as noted above, and with respect to copayments, the daily copayment cannot be an amount that would require the enrollee to pay more for a month's supply of the prescription than would otherwise be the case. For example: If a plan uses a 31-day supply as its 1-month supply and establishes a one-month copayment of $70 for Tier 3, then the Daily Copayment field entry for that tier could not be higher than $2.25 ($70/31 = $2.258). Thus, if a plan must round the daily cost-sharing rate to a dollar and cents figure, the highest amount the plan could round to would be the nearest lower dollar and cents amount, as shown in the example. If a plan rounded the daily cost-sharing rate up, then if an enrollee eventually received a month's supply of a medication, the enrollee would pay more than ''would otherwise be the case,'' meaning more than the 1-month cost sharing specified in the approved benefit package. In the example, if a plan were to round the daily cost-sharing rate up to $2.26, an enrollee who eventually receives a month's supply of the medication would pay $70.06, which is higher than the approved $70 copay for that tier. In other words, rounding up is not permitted under the current definition of ''daily cost-sharing rate'' and this has been another cause of confusion for some Part D sponsors.

While our original intention was to prohibit significant increases in cost sharing, such as charging the full 30-day copay for both the trial supply and any subsequent refill of a medication, the current limitation on any increase in cost sharing over the 30-day supply amount has reportedly led to unnecessarily complicated programming, as well as proration of other amounts on the claim, such as the dispensing fees, as discussed previously. Therefore, we are proposing to replace the language ''lower dollar amount, if any, or to another amount,'' with ''the nearest cent.'' We believe this language would be the simplest way to convey the concept of rounding, while realizing this language would allow Part D sponsors to round daily cost-sharing rates up or down to the nearest 2 decimal places. For instance, in the example provided previously, the daily cost-sharing rate would actually be rounded to $2.26, as this amount would be the nearest cent. For the reasons we describe in the following paragraph, we believe this slight change in policy is not significant and that the proposed revised regulation text would address current confusion about the daily cost-sharing rate rule. The revised definition of ''daily cost-sharing rate'', if adopted, would read with respect to copayments: ''as applicable, the established monthly copayment under the enrollee's Part D plan, divided by the number of days in the approved month's supply for the drug dispensed and rounded to the nearest cent.''

As noted previously, the daily cost-sharing rate rule applies whenever a prescription is dispensed by a network pharmacy for less than a 30 days' supply, unless the drug is excepted in the regulation. However, as detailed in

the preamble to the April 12, 2012 final rule (77 FR 22072), it is primarily expected to incentivize Part D enrollees to talk with their prescribers about trial supplies, when they are prescribed an expensive chronic medication for the first time. By obtaining a less-than-30-days' supply, beneficiaries reduce their cost sharing when the medication is discontinued in the first month due to poor tolerance or side effects, which also benefits the Part D program by reducing costs of unused medications. In addition, as noted in the April 12, 2012 final rule (77 FR 22072), we believe some enrollees will be encouraged to request that their pharmacists assist them with synchronizing the refill dates of multiple medications, because they could do so without having to pay a full month's cost sharing for the shortened days' supplies necessary to synchronize refill dates. Although permitted under the rule, we do not foresee enrollees choosing to continue to receive chronic medications incrementally on a sequential basis. We anticipate that enrollees who tolerate a chronic medication would obtain months' supplies after the first incremental fill, and enrollees who are synchronizing medications are expected to do so through one incremental fill of all medications except one. Therefore, even though the proposed revised definition of ''daily cost-sharing rate'' could result in an enrollee who receives the remainder of month's supply after receiving an incremental fill paying slightly more than he or she otherwise would have for a month's supply, we believe such cases would be rare, if any, and the amounts involved are nominal anyway. We are more concerned that the regulation text with respect to rounding is clearer, and in this regard, we solicit comments on whether sponsors need any additional rounding guidance.

We are also proposing other technical changes to the daily cost-sharing rate rule at § 423.153(b)(4)(i) to improve the regulation's clarity. First, we are proposing to consolidate the language of § 423.153(b)(4)(i)(A) into § 423.153(b)(4)(i) and to consolidate § 423.153(b)(4)(i)(B)(1) and (2) into a new paragraph § 423.153(b)(4)(ii). Second, we are proposing that the language in § 423.153(b)(4)(i) that addresses the application of the daily cost-sharing rate in the case of a monthly copayment be revised for clarity, and moved to a new paragraph (b)(4)(iii)(A). This paragraph would state that in the case of a drug that would incur a copayment, the Part D sponsor must apply cost-sharing as calculated by multiplying the applicable daily cost-sharing rate by the days' supply actually dispensed when the beneficiary receives less than a 30 days' supply. Again, this is not a change in policy but is merely a technical change to the regulation text for better clarity. Third, we are proposing that § 423.153(b)(4)(iii)(B) would state that, in the case of a drug that would incur a coinsurance percentage, the Part D sponsor shall apply the coinsurance percentage for the drug to the days' supply actually dispensed. We note that this means, with respect to dispensing fees, that the enrollee's portion of additional dispensing fees for the incremental supply would be calculated by application of this percentage. We believe all the foregoing technical clarifications will assist sponsors in correctly setting, calculating, and applying daily cost-sharing rates in the retail and LTC settings beginning January 1, 2014 whenever a prescription is dispensed by a network pharmacy for less than a 30 days' supply, unless the drug is excepted in the regulation.

10. Technical Change To Align Regulatory Requirements for Delivery of the Standardized Pharmacy Notice (§ 423.562)

The current regulations at § 423.562(a)(3) require Part D plan sponsors to make arrangements with their network pharmacies to distribute notices instructing enrollees how to contact their plans to obtain a coverage determination or request an exception. This is accomplished through delivery of a standardized notice, CMS–10147—''Medicare Prescription Drug Coverage and Your Rights'' (''pharmacy notice''). Section 423.562(a)(3) cross-references § 423.128(b)(7)(iii), added in our April 2011 final rule (76 FR 21432), which requires plans to have a system in place that transmits codes to network pharmacies so the pharmacy is notified to deliver the pharmacy notice at the point of sale (POS) in designated circumstances where the prescription cannot be filled as written.

Pursuant to the 2011 regulatory change, we issued subsequent guidance (HPMS memoranda dated October 14, 2011 (''Revised Standardized Pharmacy Notice'') and December 27, 2012 (''Revised Guidance for Distribution of Standardized Pharmacy Notice'') which clarifies that distribution of the pharmacy notice is required upon receipt of certain transaction responses indicating that the claim is not covered by Part D, as well as revised manual guidance in Chapter 18, section 40.3.1 of the *Medicare Prescription Drug Benefit Manual* related to operationalization of this requirement specific to a variety of specialty pharmacy settings.

In practice, we have never based distribution of or referral to the pharmacy notice on whether or not the enrollee disagrees with information provided by the pharmacist, but rather on whether the drug in question can be provided under Part D and whether the enrollee is able to obtain the covered drug at the pharmacy counter. Because the existing regulation text at § 423.562(a)(3) ties delivery of the pharmacy notice to the enrollee's disagreement with information provided by the pharmacist, we are proposing to remove this reference.

This proposed technical change would not alter the circumstances under which the pharmacy notice must be delivered to an enrollee and will align the regulation and the operational requirements for distribution of the pharmacy notice. In addition, this proposed change would be consistent with both the current OMB-approved instructions regarding the pharmacy notice and current CMS manual guidance.

We do not prohibit distribution of the pharmacy notice in any circumstance, so pharmacies may choose to also provide a copy of the notice in circumstances where the enrollee disagrees with the information provided (for example, if the enrollee believes they are being charged an incorrect cost-sharing amount), but the notice is not required under the standards established in § 423.128(b)(7)(iii). Provision of the pharmacy notice is not a prerequisite for an enrollee to request a coverage determination or access the appeals process. Similarly, a plan sponsor's failure to comply with the requirements of § 423.128(b)(7)(iii) or § 423.562(a)(3) does not in any way limit an enrollee's right to request a coverage determination or appeal.

11. Special Part D Access Rules During Disasters or Emergencies (§ 423.126)

Section 1860D–4(b) of the Act requires us to ensure beneficiaries have access to covered Part D drugs. When a disaster strikes or is imminent, beneficiaries may find they have trouble accessing drugs through normal channels or must move to safer locations far away from their regular pharmacies. In order to ensure that beneficiaries do not run out of their medications during or as a result of a disaster or emergency, we issued guidance on December 18, 2009 identifying when, in the course of a disaster, Part D sponsors would be

expected to relax ''refill-too-soon'' (RTS) edits. We now propose to codify a revised version of that policy. Proposed § 423.126(a)(1)(i) would require Part D sponsors to relax RTS edits in the event of any imminent or occurring disaster or emergency that would hinder an enrollee's access to covered Part D drugs. By this we mean that there is an anticipated or actual disaster or emergency, as evidenced by a declaration of a disaster or emergency issued by an appropriate federal, state, or local official, and it is reasonable to conclude that such disaster or emergency or preparation therefore would make it difficult for beneficiaries to obtain refills of their medications because the disaster or emergency or anticipation thereof has affected, or will affect, their ability to have timely access to their usual pharmacies. For example, if federal, state or local authorities issue mandatory evacuation orders to populations or segments of the population in a geographic area, it would be reasonable to conclude that the evacuation would hinder an LTC resident's ability to get a refill after he or she is evacuated from the facility. In such an instance, then, Part D sponsors with enrollees in the affected area would be required to relax RTS edits so that the LTC pharmacies could provide beneficiaries with refills to take with them to the location to which they are being evacuated. Our proposed requirement would apply to one refill for each drug the beneficiary is taking for refills sought within 30 days of the date the plan sponsor began relaxing RTS edits. We believe this timeframe would be sufficient to ensure that beneficiaries who are unable to obtain refills during the emergency or disaster will be able to do so as soon as they can safely access a network pharmacy. We solicit comment as to whether 30 days after the date of the triggering declaration provides an appropriate amount of time to ensure that beneficiaries do not run out of their medications. In particular, we would be interested in learning about any situations in which a beneficiary affected by an actual or impending disaster or emergency would be likely to go to a pharmacy more than 30 days after the triggering declaration such that the resumption of RTS edits after 30 days would be problematic. We also solicit comment as to how it would be feasible for Part D sponsors to identify pharmacies or beneficiaries located in affected areas for which they would be required to relax edits and, how long it might then take to program the necessary changes.

Although we believe our proposal provides a general framework for when RTS edits must be relaxed, we solicit comment on whether we should impose more particular requirements in cases where a disaster or emergency could result in a voluntary or mandatory evacuation of an LTC facility. We are also concerned that if a disaster strikes the area in which an LTC facility is located but not the area in which its servicing LTC pharmacy is located, the appropriate edits may not be relaxed. Accordingly, we solicit comment as to whether it would be more feasible to establish beneficiary specific edits limited to residents of LTC facilities in affected areas given that evacuation decision-making is rarely a straightforward, linear process (for example, not just based on the declaration of a disaster or emergency), but rather, often involves a myriad of facility-specific factors. In particular, we solicit comment on the practicality of requiring Part D sponsors to relax RTS edits for residents of a particular LTC facility after that facility decides on its own initiative to evacuate through use of National Council on Prescription Drug Programs (NCPDP) Submission Clarification Code (SCC) code 13, which conveys that there is an emergency. We solicit comment as to whether use of this code number, 13, is specific enough to signal that sponsors need to loosen RTS edits and whether it would be practical for LTC facilities to request that their LTC pharmacies enter the SCC code 13. Lastly, we would be interested in any other ideas on how to structure workable edits or institute manual procedures to best target only enrollees who live in LTC facilities located in areas affected by a disaster.

We would also be interested in hearing from any commenters who would recommend any other triggering events that would require Part D sponsors to relax RTS edits. In particular, we solicit comment as to whether it would be feasible to require sponsors to relax edits after the issuance by the National Weather Service (NWS) of a Hurricane or Tropical Storm watch or warning. The NWS typically issues watches 36 hours in advance of adverse weather conditions possibly hitting an area, while the NWS issues watches 48 hours (2 days) in advance of those conditions possibly hitting an area. All watches/warnings are posted on the NWS Web site immediately after their issuance. We solicit comment as to whether watch/warnings would require RTS overrides in the whole state, or just areas under the watch or warning. We are also interested in comments regarding the time generally needed to move residents of LTC facilities with their medication supplies to safety.

Lastly, we believe that sponsors are in the best position to determine how to relax the specific RTS edits when required under our proposal. However, we also wish to ensure that all sponsors relax RTS edits in a consistent manner in order that enrollees have the same critical access to drugs when disasters and emergencies are imminent or have occurred—regardless of the specific plan in which they are enrolled. Accordingly, we solicit comments on the types of situations that might arise and the extent to which sponsors should be allowed to exercise some discretion in complying with this proposed requirement.

And, as has been the case under our current guidance, Part D sponsors may consider extending the implementation of the RTS edits but are not required to do so. However, if sponsors choose to reinstate the RTS edits, they need to work closely with enrollees who indicate that they are still displaced or otherwise impacted by the disaster or emergency.

12. MA Organization Responsibilities in Disasters and Emergencies (§ 422.100)

Section 1852(d) of the Act requires MA organizations to provide proper and continued access to services, including making medically necessary benefits available and accessible 24 hours a day and 7 days a week. When a disaster occurs or is imminent, beneficiaries may find they have trouble accessing services through normal channels or must move to safer locations that are outside of their service areas. To date, we have relied on issuing subregulatory guidance for MA organizations through the HPMS system and have included that guidance in Chapter 4 of the Medicare Managed Care Manual. During a disaster, we expect MA organizations to continue to follow applicable standing regulations, including ensuring continuing access to care in addition to complying with our subregulatory guidance.

We are proposing to add paragraph (m) to § 422.100 to codify and further clarify an MA organization's responsibilities when health plan services are affected by public health emergencies or disasters. This provision is intended to ensure that beneficiaries continue to have access to care in situations where normal business operations are disrupted due to public health emergencies, disasters and warnings of imminent disasters. The proposed new paragraph (m) requires MA organizations to ensure access to

covered services that are furnished at non-contracted facilities and to charge no more cost sharing for services obtained by enrolled beneficiaries out-of-network than they would pay in-network. These requirements provide protections for enrolled beneficiaries, including those who move to safer locations that are outside of their service areas, who have trouble accessing services through normal channels due to the unusual circumstances created by the disaster or emergency. Additionally, the proposed new paragraph (m) provides MA organizations with guidance on the bases for determining the beginning and end of a disaster or emergency and requires that the organization post on its Web site and convey to enrollees and contracted providers at least annually, the disaster and emergency policies in order to facilitate enrollee access to needed services while normal care delivery is unavailable. In addition, this enables out-of-network providers to be informed of the terms of payment for furnishing services to affected enrollees.

13. Termination of a Contract Under Parts C and D (§ 422.510 and § 423.509)

a. Cross-Reference Change (§ 423.509(d))

Section 1857(h)(1)(B) and 1860D–12(b)(3)(F) of the Act describes the procedures for termination for both Part C and Part D plan sponsors respectively. These statutory provisions give an organization an opportunity for a hearing before its contract is terminated.

We codified organizations' appeal rights under subpart N of parts 422 and 423. Under the Part C § 422.510(d), a reference to the appeal rights ''in accordance with subpart N'' is made. However, in the corresponding section for Part D Plan sponsors at § 423.509(d), the reference to the appeal rights reads ''in accordance with § 423.642.'' The Part C and Part D references should be the same. We are proposing to align the Part C and Part D appeal rights language under § 422.510(d) and § 423.509(d) by replacing the inconsistent language at § 423.509(d) to now read ''in accordance with subpart N of this part.'' This change is proposed only to ensure consistent wording is used in both regulatory sections and in no way changes the meaning or policy encompassed in this provision.

b. Terminology Changes (§ 422.510 and § 423.509)

Sections 1857(c) and 1860D–12(b)(3)(B) of the Act authorize contract terminations for Part C MA organizations and Part D plan sponsors respectively. In the current termination regulations at § 422.510 and § 423.509, there is inconsistent use of the terms ''days'' and ''calendar days''. Calendar days are the appropriate term that should be used consistently throughout these sections. Therefore, we are proposing to replace the word ''days'' with ''calendar days'' in both § 422.510 and § 423.509. This change is proposed only to ensure consistent wording is used in § 422.510 and § 423.509 and in no way changes the meaning or policy encompassed in these provisions.

c. Technical Change To Align Paragraph Headings (§ 422.510(b)(2))

Sections 1857(c)(2) and 1860D–12(b)(3)(B) of the Act provide us with the authority to terminate contracts, for Part C and Part D sponsors respectively. The Part C paragraph heading at § 422.510(b)(2) incorrectly reads ''Expedited termination of contract by CMS.'' The Part D corresponding paragraph heading at § 423.509(b)(2) correctly reads ''Immediate termination of contract by CMS''. The Part C and Part D paragraph headings should be the same. Therefore, we are proposing to revise the paragraph of § 422.510(b)(2) to read ''Immediate termination of contract by CMS''. This change is proposed only to ensure consistent wording is used in both regulatory sections and in no way changes the meaning or policy encompassed in this provision.

d. Terminology Change (§ 423.509(b)(2)(C)(ii))

Sections 1857(c)(2) and 1860D–12(d)(3)(B) of the Act provide us with the authority to terminate contracts, for Part C and Part D sponsors respectively. In § 423.509(b)(2)(C)(ii) the regulation incorrectly references ''MA organization.'' This section concerns Part D, so the correct reference is ''Part D Plan Sponsor''. Therefore, we are proposing to change § 423.509(b)(2)(C)(ii) to appropriately reference Part D plan sponsor; not MA organization (Part C), as it currently states. This change is proposed only to ensure accurate wording is used in both regulatory sections and in no way changes the meaning or policy encompassed in this provision.

14. Technical Changes To Align Part C and Part D Contract Determination Appeal Provisions (§ 422.641 and § 422.644)

Sections 1857(h) and 1860D–12(b)(3)(F) of the Act describe the procedures for termination for both Part C MA organizations and Part D Plan sponsors, respectively. These statutory provisions provide an organization with an opportunity for a hearing before its contract is terminated. Appeal procedures were established under sections 1856(b)(2) and 1860D–12(b)(3) of the Act for both Part C and Part D sponsors, respectively. Sections 422.641 and 423.641, list the types of Part C and Part D contract determinations that may be appealed.

(a) Technical Change (§ 422.641)

Currently in § 422.641, the contract termination is discussed in paragraph (b) and contract non-renewal is discussed in (c). Conversely, in § 423.641 the contract terminations are discussed in (c) and contract non-renewal is discussed in (b). Therefore, we are proposing to align the Part C list order for (b) and (c) in the contract determinations section at § 422.641 with its Part D corresponding section at § 423.641. This change is proposed only to ensure consistency between the two parts and in no way changes the meaning or policy encompassed in this provision.

(b) Technical Changes (§ 422.644(a) and (b))

Sections 1857(h)(1)(B) and 1860D–12(b)(3)(F) of the Act describe the procedures for termination for both Part C and Part D sponsors, respectively. These statutory provisions provide an organization with an opportunity for a hearing before its contract is terminated. Appeal procedures were established under § 1856(b)(2) of the Act for both Part C and Part D sponsors. In § 423.642 we specify that the notice is based upon a contract determination made ''under § 423.641.'' Therefore, since Part C and Part D language should be consistent the same reference should be made in the Part C corresponding § 422.644. To remedy this error, we are proposing to insert ''under § 422.641'' into § 422.644(a) for Part C contract determinations. This change is proposed only to ensure consistent wording is used in both regulatory sections and in no way changes the meaning or policy encompassed in this provision.

In addition, the Part D Plan sponsor language in § 423.642(b) states that ''(b) The notice specifies the—(1) Reasons for the determination; and''. The Part C language in § 422.644(b) states that ''(b) The notice specifies—(1) The reasons for the determination; and''. Part C and Part D language should be consistent, therefore, the same reference should be made in the Part C corresponding section § 422.644. To remedy this error, we are proposing to align the Part C language at § 422.644(b) with that of the Part D language at § 423.642(b) for consistency between both the Part C and

Part D termination regulations. Specifically, we propose to change § 422.644(b) by deleting the word ''the'' and revising it to read ''(b) The notice specifies the—(1) Reasons for the determination; and''. This change is proposed only to ensure consistent wording is used in both regulatory sections and in no way changes the meaning or policy encompassed in this provision.

15. Technical Changes To Align Parts C and D Appeal Provisions (§ 422.660 and § 423.650)

Sections 1857(h)(1)(B) and 1860D–12(b)(3)(F) of the Act describe the procedures for termination for both Part C and Part D, respectively. These statutory provisions provide organizations with an opportunity for a hearing before its contract is terminated. Appeal procedures were established under § 1856(b)(2) of the Act for both Part C and Part D sponsors. We propose to make technical changes in our regulations at § 422.660(a)(2), § 422.660(a)(3), and § 423.650(a)(2) to ensure consistency. Specifically, we are proposing to replace the term ''under'' with the phrase ''in accordance with'' in § 422.660(a)(2), § 422.660(a)(3), and § 423.650(a)(2). This change is proposed only to ensure consistent wording is used in § 422.660 and § 423.650 and in no way changes the meaning or policy encompassed in these provisions.

In addition, we are proposing to make a technical change in our regulations at § 423.650(a)(4) to ensure consistency with the authorizing language contained in sections 1856(b)(2), 1857(h), and 1860D–12(d)(3)(F) of the Act which gives us the authority to terminate contracts for both Part C and Part D sponsors. Under the Part C § 422.660(a)(4), a reference to imposing intermediate sanctions and civil money penalties ''in accordance with § 422.752(a) through (b) of this part'' is made. The corresponding section for Part D is at § 423.650(a)(4). However, the reference to imposing intermediate sanctions and civil money penalties reads ''in accordance with § 423.752(a) and (b)''. The Part C and Part D references should be the same and both state ''(a) through (b)''. Specifically, we are proposing to replace the word ''and'' with ''through'' in § 423.650(a)(4). This change is proposed only to ensure consistent wording is used in both regulatory sections and in no way changes the meaning or policy encompassed in this provision.

Sections 422.660(b)(4) and 423.650(b)(4) give a general reference to § 422.752 and § 423.752, but do not refer the reader to the applicable paragraphs contained in those sections. Therefore, we are proposing to modify § 422.660(b)(4) and § 423.650(b)(4) to add the language ''§ 422.752(a) through (b)'' and ''§ 423.752(a) through (b)'', respectively, to refer the reader to the applicable regulations for intermediate sanctions. This change is proposed only to accurately reflect applicable regulatory requirements and in no way changes the meaning or policy encompassed in this provision.

16. Technical Changes Regarding Intermediate Sanctions and Civil Money Penalties

Sections 1857(g) and 1860D–12(b)(3)(E) of the Act provides us with the authority to impose intermediate sanctions (sanctions) and CMPs on Part C and Part D sponsors, respectively.

a. Technical Changes to Intermediate Sanctions Notice Receipt Provisions (§ 422.756(a)(2) and § 423.756(a)(2))

Under § 422.756(a)(2) and § 423.756(a)(2) the current language states that written requests for rebuttal by the MA organization or Part D plan sponsor must be received within ''10 calendar days from the receipt of notice''. This language is inconsistent with other the language that appears in other sections within subpart O, the appeals section in subpart N and the termination sections in subpart K. In those sections we state that written requests must be received within ''10 calendar days after receipt of the notice''. The language in all sections should be consistent. Therefore, we are proposing to modify the language at § 422.756(a)(2) and § 423.756(a)(2) to state ''10 calendar days after receipt of the notice''. This change is proposed only to ensure consistent wording is used in all sections and in no way changes the meaning or policy encompassed in this provision.

In addition, we are proposing to correct the grammatical error that exists in current § 422.756(a)(2) and § 423.756(a)(2). The Part C and Part D language currently reads, ''CMS considers receipt of notice as the day after notice is sent by fax, email, or submitted for overnight mail''. To fix the grammatical errors we are proposing to revise the language in both § 422.756(a)(2) and § 423.756(a)(2) to read ''CMS considers receipt of the notice as the day after the notice is sent by fax, email, or submitted for overnight mail.'' This change is proposed only to make a grammatical correction and in no way changes the meaning or policy encompassed in this provision.

b. Cross-Reference Changes (§ 422.756(b)(4) and § 423.756(b)(4))

Under § 422.756(b)(4) and § 423.756(b)(4), we furnish our procedures for imposing intermediate sanctions and civil money penalties on MA organizations and Part D sponsors, respectively. The current language at § 422.756(b)(4) states that MA organizations, if sanctioned, must follow the right to a hearing procedure as specified at § 422.660 and § 422.684. The current language at § 423.756(b)(4) states that Part D sponsors, if sanctioned, must follow the right to a hearing procedure as specified at § 423.650 and § 423.662. However, MA organizations and Part D sponsors must adhere to procedures promulgated within subpart N of the regulations, not just § 422.660 and § 422.684; and § 423.650 and § 423.662, respectively. Therefore, we are proposing to modify the language at § 422.756(b)(4) and § 423.756(b)(4) to state that MA organizations and Part D sponsors ''must follow the right to a hearing procedures as specified in subpart N''. This change is proposed only to accurately reflect applicable regulatory requirements and in no way changes the meaning or policy encompassed in this provision.

c. Technical Changes (§ 422.756(d) and § 423.756(d))

In § 422.756(d) and § 423.756(d) we provide alternatives to sanctions, including non-renewal or termination of the organizations contract. However, the paragraph heading of both § 422.756(d) and § 423.756(d) only refers to terminations by CMS. Therefore, we are proposing to revise the paragraph heading to ''Non-renewal or termination by CMS'' in both sections to reflect the content specified within the provision. This change is proposed only to accurately reflect applicable regulatory requirements and in no way changes the meaning or policy encompassed in this provision.

Within § 422.756(d) and § 423.756(d) we state that we may decline to authorize the renewal of an organization's contract in accordance with § 422.506(b)(2) and (b)(3) for MA organizations and in accordance with § 423.507(b)(2) and (b)(3) for Part D sponsors. However, in both § 422.756(d) and § 423.756(d), all of paragraph (b) applies to the provisions. Therefore, we are proposing to change both provisions § 422.756(d) and § 423.756(d) to read ''§ 422.506(b)'' and ''§ 423.507(b)'', respectively. This change would accurately reflect that all of paragraph (b) applies in both provisions. This

change is proposed only to accurately reflect applicable regulatory requirements and in no way changes the meaning or policy encompassed in this provision.

Within § 422.756(d) and § 423.756(d), we refer to the sanctions described in paragraph (c) of each section but in each section, paragraph (c) refers to the effective date and duration of sanctions, rather than sanctions which are described in § 422.750 and § 423.750, respectively. Therefore, we are proposing to change the current language at § 422.756(d) to read ''In addition to or as an alternative to the sanctions described in § 422.750 . . .'' and change the language at § 423.756(d) to read ''In addition to or as an alternative to the sanctions described in § 423.750.'' This change would accurately reflect the applicable provision referenced in both § 422.756(d) and § 423.756(d). This change is proposed only to accurately reflect applicable regulatory requirements and in no way changes the meaning or policy encompassed in this provision.

d. Technical Changes To Align the Civil Money Penalty Provision With the Authorizing Statute (§ 422.760(a)(3) and § 423.760(a)(3))

The provisions at § 422.760(a)(3) and § 423.760(a)(3) state, ''the harm which resulted or could have resulted from conduct of an MA organization'' and ''the harm which resulted or could have resulted from conduct of a Part D plan sponsor'', respectively. However, this language is not consistent with the authorizing statutory provisions, nor is it consistent with other provisions in the corresponding sections. Therefore, we are proposing to align the language with paragraph (b) in both § 422.760(a)(3) and § 423.760(a)(3). The language would be revised to state ''The adverse effect to enrollees which resulted or could have resulted . . .'' in both § 422.760(a)(3) and § 423.760(a)(3). This change is proposed only to accurately reflect applicable statutory requirements and in no way changes the meaning or policy encompassed in this provision.

e. Technical Changes To Align the Civil Money Penalty Hearing Notice Receipt Provisions (§ 422.1020(a)(2), § 423.1020(a)(2), § 422.1016(b)(1), and § 423.1016(b)(1))

Sections 1857(g)(4) and 1860D–12(b)(3)(E) of the Act provides us with the authority to impose civil money penalties on Part C and Part D sponsors, respectively. Under § 422.1020(a)(2) and § 423.1020(a)(2), we discuss our procedures for appealing CMPs. The current language in both sections state written requests for appeal by the MA organization or legal representative or authorized official must be filed within 60 calendar days from the receipt of notice of initial determination, to request a hearing before the Administrative Law Judge to appeal any CMS decision. However, this language does not align with the appeal language in subpart N. Therefore, we are proposing to change the language at § 422.1020(a)(2) and § 423.1020(a)(2) to align it with the language within subpart N for appeals. Specifically, we are changing both § 422.1020(a)(2) and § 423.1020(a)(2) to state ''within 60 calendar days after receipt of the notice of initial determination''. This change is only to ensure consistent wording is used in all sections and in no way changes the meaning or policy encompassed in this provision.

In addition, under § 422.1016 and § 423.1016, we furnish our procedures for filing briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal. The provisions at § 422.1016(b)(1) and § 423.1016(b)(1) state, ''the other party will have 20 days from the date of mailing or personal service to submit any rebuttal statement or additional evidence''. However, this language is not consistent with provisions in other corresponding sections. Therefore, we are proposing to revise the language at § 422.1016(b)(1) and § 423.1016(b)(1) to state ''The other party will have 20 days from the date of mailing or in person filing''. This change is proposed only to ensure consistent wording is used in all sections and in no way changes the meaning or policy encompassed in this provision.

17. Technical Change to the Restrictions on Use of Information Under Part D (§ 423.322)

We are proposing a technical change to § 423.322 due to section 6402(b)(1) of the Affordable Care Act which amended section 1860D–15(f)(2) of the Act. For background, most of the payment provisions for the Part D program are found in section 1860D–15 of the Act. Subsections (d) and (f) of section 1860D–15 of the Act authorize the Secretary to collect any information needed to carry out this section. However those subsections, as originally enacted, also stated that ''information disclosed or obtained under [section 1860D–15 of the Act] may be used by officers, employees, and contractors of [HHS] only for the purpose of, and to the extent necessary, in carrying out [section 1860D–15 of the Act].'' Thus, section 1860D–15 of the Act contains provisions that limit the use of information disclosed or obtained under its authority.

Section 6402(b)(1) of the Affordable Care Act amended section 1860D–15(f)(2) of the Act to relax the limitation on the use of information that is disclosed or obtained under section 1860D–15 of the Act. Specifically, the Affordable Care Act removed the word ''only'' from subsection (f)(2)(A) and added a new subsection (ii) which states that information disclosed or obtained under section 1860D–15 of the Act may be used by officers, employees, and contractors of HHS for the purposes of, and to the extent necessary, in ''conducting oversight, evaluation, and enforcement under this title.'' Section 6402(b)(1) also added a new subsection (B) which states that information disclosed or obtained pursuant to section 1860D–15 of the Act may be used ''by the Attorney General and the Comptroller General of the United States for the purposes of, and to the extent necessary in, carrying out health oversight activities.'' Thus, the Affordable Care Act considerably broadened the purposes for which HHS, its contractors, and the Attorney General and Comptroller General may use the information disclosed or obtained pursuant to section 1860D–15 of the Act by removing the word ''only'' in subsection (A) and adding a new clause (ii) and a new subsection (B). However, we note, that the Affordable Care Act did not change the existing restriction on the use of information under subsection (d).

In light of the Affordable Care Act amendment to section 1860D–15(f) of the Act, we are proposing to make conforming changes to § 423.322.

## IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

*A. ICRs Related to Eligibility of Enrollment for Individuals Not Lawfully Present in the United States (§ 417.2, § 417.420, § 417.422, § 417.460, § 422.1, § 422.50, § 422.74, § 423.1, § 423.30, and § 423.44)*

We are proposing to amend § 417.2, § 417.420, § 417.422, § 417.460, § 422.1, § 422.50, § 422.74, § 423.1, § 423.30, and § 423.44 to include the eligibility requirement of citizenship or lawful presence to enroll in MA, Part D, or cost plans. To implement these regulations, we would relay data regarding an individual's lawful presence status to plans through the MARx system so that the plans will be aware of an individual's eligibility when requesting enrollment and notify plans when current members lose lawful presence status. This data is already available to us; thus no new data will be collected, and there is no new information collection or burden on organizations.

*B. ICRs Related to Improper Prescribing Practices and Patterns (§ 424.535(a)(13) and (14))*

Our proposed additions of § 424.535(a)(13) and (14) would result in an increase in revocations and associated appeals. However, we are unable to estimate the number of revocations and appeals. We do not have data available that can be used to make such a projection, as each situation would have to be carefully reviewed and addressed on a case by case basis. Since we would invoke § 424.535(a)(8)(iii) only in the most egregious of circumstances, we believe that the number of revocations under this provision would be small. The concomitant increase in the ICR burden would therefore be minimal.

*C. ICRs Related to Applicants or Their Contracted First Tier, Downstream, or Related Entities To Have Experience in the Part D Program Providing Key Part D Functions (§ 423.504(b)(8)(i) Through (iii))*

Proposed § 423.504(b)(8)(i) through (iii) would require that Part D organizations seeking a new Medicare contract must have arrangements in place such that either the applicant or a contracted entity that will be performing certain key Part D functions has at least 1 full benefit year of experience providing the function or providing the function for another Part D plan sponsor. The burden associated with this requirement is the time and effort put forth by Part D applicants to answer questions about such experience as part of the Part D application process. For entities that hold an existing Part D contract, or whose parent or another subsidiary of that parent has already held a Part D sponsor contract for at least a year, it is estimated that it will take each Part D applicant for a new contract 2 minutes to provide 1 or 2 new sentences in the organizational history section of the application, and 1 minute to respond to yes-no questions about experience with the 3 functions for which experience is required, for a total of 3 minutes per applicant. For entities new to Part D, it is estimated that it will take each Part D applicant for a new contract 2 minutes to provide 1 or 2 new sentences in the organizational history section of the application, 1 minute to respond to yes-no questions about experience with the 3 functions for which experience is required, and 1 additional minute to provide at least 1 contract number of an existing or recent Part D sponsor under which the entity to provide the key function obtained its experience, for a total of 4 minutes. Based on the number of Part D applications we receive each year, we would anticipate no more than 60 Part D applications for a new contract, of which no more than 15 would be entities new to Part D. Thus, the burden for the 45 existing entities at 3 minutes each, plus the burden for the 15 new entities at 4 minutes each, brings the total burden hours to approximately 3.25 hours. If approved, the new application questions would be addressed under currently approved OMB control number (OCN) 0938–0936.

*D. ICRs Related to Eligibility of Enrollment for Incarcerated Individuals (§ 417.460, § 422.734, and § 423.44)*

We are proposing to amend § 417.460(b)(2)(i), § 417.460(f)(1)(i), § 422.74(d)(4)(i)(A), § 422.74(d)(4)(v), and § 423.44(d)(5) to clarify the eligibility requirement for residing in the plan's service area related to incarceration for the purposes of enrolling into and remaining enrolled in MA, Part D, and Medicare cost plans. To implement these regulations, we would relay data to plans regarding an individual's incarceration through the MARx system so that the plans would be aware of the individual's eligibility when requesting enrollment and notify the plans of loss of eligibility for current members. This data is already available to us. Thus no new data would be collected, and there is no new information collection or burden on organizations.

*E. ICRs Related to Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134)*

This requirement does not impose any new information collection requirements. This is an existing recordkeeping requirement in which MA organizations must retain information pertaining to any rewards and incentives programs in accordance with our regulations at 42 CFR 422.118. We believe the burden associated with this requirement is exempt from the PRA under 5 CFR 1320.3(b)(2) as we believe this is a usual and customary business practice. Furthermore, any requests to furnish the information in a form and manner we designate are unique, that is, non-standardized and specific to each individual MA organization.

*F. ICRs Related to Expanding Quality Improvement Program Regulations (§ 422.152)*

This requirement does not impose any new information collection requirements. PRA approval is current under OCN 0938–1023.

*G. ICRs Related to Revisions to Good Cause Processes (§ 417.460, § 422.74, and § 423.44)*

We are proposing to amend § 417.460, § 422.74, and § 423.44 to establish the ability for us to designate an entity other than CMS to implement the good cause process. To implement these regulations, the plan will already have the enrollment data necessary to make the good cause determinations within the process. Thus no new data would be collected. However, there would be additional burden to the plan in terms of completing the operational process, such as responding to requests for reinstatement from former members, gathering the attestation from the individual regarding his or her reason for not paying the plan premiums within the grace period, making the determination as to whether the individual meets the good cause criteria and maintaining the case notes and documentation to support its determination should it need to be reviewed. As plans already provide customer service to their current and past members, we estimate that this burden would be approximately 30 minutes for each reinstatement request. According to the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2012, the mean

hourly wage for the category of ''Customer Service Representatives''—which we believe, considering the common point of entry for all issues at the plan, is the most appropriate category—is $15.92. With fringe benefits and overhead, the per hour rate is $24.03. It is calculated that the cost for 30 minutes would be $12.01. Not all plans disenroll for non-payment of premiums. However, for those who do implement this voluntary policy, it results in an average of 20,000 disenrollments each month. In response, we receive an average of 698 requests for reinstatement per month. The plan representative cost of $12.01 for each case is multiplied by 698 cases. Therefore, based on the proposed change, handling of these requests would result in a total monthly cost of $8,383 for all plans in the MA, Part D, and cost plan programs.

*H. ICRs Related to the Definition of Organization Determination (§ 422.566)*

The burden associated with this proposal is the time necessary for MA organizations to process organization determination requests, issue a decision and, where appropriate, effectuate any approved coverage decision. When an MA organization issues an adverse organization determination, it must give the enrollee written notice pursuant to the requirements in § 422.568(d) and (e) and § 422.572(e). This requirement is subject to the PRA, and the burden associated with it is currently approved under OCN 0938–0829. The information collection requirements are not expected to change because the proposed revisions to the definition of organization determination would not alter the frequency with which the current OMB-approved notice is required, nor the time required to issue the notice. The proposed change to § 422.566(b)(3) would codify certain adverse decisions which MA organizations already treat operationally as adverse organization determinations subject to the standardized denial notice. The proposed addition of § 422.566(b)(6) applies only to favorable organization determinations which do not require written notice.

*I. ICRs Related to Skilled Nursing Facility Stays (§ 422.101 and § 422.102)*

We propose to relocate the MA regulation language currently located at § 422.101(c), ''Requirements Related to Basic Benefits'' to § 422.102(a)(5), ''Supplemental Benefits.'' We are proposing to move the provision because it describes MA organizations' authority to furnish covered SNF stays without the qualifying inpatient hospital stay required under original Medicare. For the past 10 years, MA organizations have offered the waiver of the 3-day inpatient hospital stay as a supplemental benefit. Thus, placing the provision in the section related to supplemental benefits is appropriate.

We also propose to make a conforming revision in the cross-reference to this provision that currently appears at § 409.30(b)(2)(ii), in order to reflect this provision's relocation from § 422.101 to § 422.102. This is a simple relocation of current regulation. There are no new PRA requirements.

*J. ICRs Related to Changes to Audit and Inspection Authority (§ 422.503(d)(2) and § 423.504(d)(2))*

We are proposing a change to § 422.503(d)(2) and § 423.504(d)(2) to include authority that will permit CMS to require MA organizations and Part D sponsors to hire an independent auditor to conduct full or partial program audits and/or perform validation exercises to confirm correction of deficiencies found during an audit. We currently conduct these audits and validation exercises, and collect data associated with these activities under OCN 0938–1000. We do not believe that requiring MA organizations and Part D sponsors to hire an independent auditor to conduct these audits or validation exercises will impose any additional burden on MA organizations and Part D sponsors.

*K. ICR Related to Recovery Audit Contractor Determinations (Part 422, Subpart Z and Part 423, Subpart Z)*

The information collection burden associated with our proposed requirements consists of the submission of requests for: (1) Reconsiderations; (2) CMS hearing official determinations; and (3) CMS Administrator reviews. Based on existing Part D appeals data, we estimate that plans will file the following numbers of requests on an annual basis:

TABLE 7— ESTIMATED NUMBER OF PART C & D RAC APPEAL REQUESTS

| Type of request | Number of requests per year |
|---|---|
| Reconsideration | 104 |
| CMS Hearing Official | 10 |
| Administrator Review | 2 |
| Total | 116 |

The reasons for the decrease in requests at higher appeal levels are that: (1) The plan may succeed in its appeal and thus have no need to appeal to the next level; and (2) the plan may simply wish to forgo further appeals. We stress that the figures in Table 7 are mere projections, though, again, they are based on the number of Part D appeals that have been submitted to date.

We estimate that it would take a plan 5 hours to prepare and file an appeal request. In terms of cost, it has been our experience that most appeals have been prepared by high-level officials of the plan. According to the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2012, the mean hourly wage for the category of ''General and Operations Managers''—which we believe, considering the variety of officials who have submitted appeals, is the most appropriate category—is $55.22. With fringe benefits and overhead, the per hour rate is $83.35. Multiplying this figure by 580 hours (or 116 submissions × 5 hours) results in a projected annual cost burden of $48,343, as outlined in Table 8.

TABLE 8—ESTIMATED ANNUAL REPORTING/RECORDKEEPING BURDEN

| Regulation section(s) | OMB Control No. | Respondents | Responses | Burden per response (hours) | Total annual burden (hours) | Hourly labor cost of reporting ($) | Total labor cost of reporting ($) | Total capital/ maintenance costs ($) | Total cost ($) |
|---|---|---|---|---|---|---|---|---|---|
| § 422.2605 | N/A | 52 | 52 | 5 | 260 | 83.35 | 83.35 | 0 | 21,671.00 |
| § 422.2610 | N/A | 5 | 5 | 5 | 25 | 83.35 | 83.35 | 0 | 2083.75 |
| § 422.2615 | N/A | 1 | 1 | 5 | 5 | 83.35 | 83.35 | 0 | 416.75 |
| § 423.2605 | N/A | 52 | 52 | 5 | 260 | 83.35 | 83.35 | 0 | 21,671.00 |
| § 423.2610 | N/A | 5 | 5 | 5 | 25 | 83.35 | 83.35 | 0 | 2083.75 |

TABLE 8—ESTIMATED ANNUAL REPORTING/RECORDKEEPING BURDEN—Continued

| Regulation section(s) | OMB Control No. | Respondents | Responses | Burden per response (hours) | Total annual burden (hours) | Hourly labor cost of reporting ($) | Total labor cost of reporting ($) | Total capital/ maintenance costs ($) | Total cost ($) |
|---|---|---|---|---|---|---|---|---|---|
| § 423.2615 ..... | N/A | 1 | 1 | 5 | 5 | 83.35 | 83.35 | 0 | 416.75 |
| Total ..... | N/A | 116 | 116 | N/A | 580 | ..... | ..... | 0 | 48,343 |

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS–4159–P

Fax: (202) 395–6974; or

Email: *OIRA_submission@omb.eop.gov*

## V. 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.

## VI. Regulatory Impact Analysis

### *A. Statement of Need*

The purpose of this proposed rule is to make revisions to the MA program (Part C) and Prescription Drug Benefit Program (Part D), implement provisions specified in the Affordable Care Act, and make other changes to the regulations based on our continued experience in the administration of the Part C and Part D programs. These latter revisions are necessary to: (1) Clarify various program participation requirements; (2) make changes to strengthen beneficiary protections; (3) strengthen our ability to identify strong applicants for Part C and Part D program participation and remove consistently poor performers; and (4) make other clarifications and technical changes.

### *B. Overall Impact*

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This proposed rule has been designated an ''economically significant'' rule under section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a regulatory impact analysis that details the anticipated effects (costs, savings, and expected benefits), and alternatives considered by proposed requirement. Finally, in accordance with the provision of the Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

Two provisions result in a total of 4,768 annual burden hours and a total annualized monetized impact of $148,939. See sections IV.G. and IV.K. of this proposed rule for details regarding the burden associated with the requirements of this proposed rule. The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.0 million to $34.5 million in any 1 year). Individuals and states are not included in the definition of a small entity. This proposed rule primarily affects the Federal government, Medicare Advantage plans, and Part D Sponsors.

Part D sponsors and MA plans, entities that will be affected by the provisions of this rule, are not generally considered small business entities. MA plans and Part D sponsors must meet minimum enrollment requirements (5,000 in urban areas and 1,500 in nonurban areas) and because of the revenue from such enrollments, these entities are generally above the revenue threshold required for analysis under the RFA. We determined that there were very few MA plans and Part D sponsors that fell below the size thresholds for ''small'' businesses established by the Small Business Administration (SBA). Currently, the SBA size threshold is $7 million in total annual receipts for health insurers (North American Industry Classification System, or NAICS, Code 524114) and we have confirmed that most Part D sponsors have Part D receipts above the $7 million threshold.

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. A fraction of MA organizations and sponsors are considered small businesses because of their non-profit status. HHS uses as its measure of significant economic impact on a substantial number of small entities, a change in revenue of more than 3 to 5 percent. Consequently, we do not believe that this threshold would be reached by the proposed requirements in this proposed rule because this proposed rule would have minimal impact on small entities. Therefore, an analysis for the RFA will not be prepared because the Secretary has determined that this proposed rule

would not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year by state, local, or tribal governments, in the aggregate, or by the private sector of $100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately $141 million. This proposed rule is not expected to reach this spending threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Based on CMS Office of the Actuary estimates, we do not believe that this proposed rule imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications.

Table 14 details the proposed rule's impacts by entity, including the federal government and MA organizations and Part D sponsors. We note that the estimated savings do not represent net social benefits because they consist of transfers of value from drug manufacturers, pharmacies, incarcerated individuals and individuals not lawfully present in the United States to the federal government, MA organizations, Part D sponsors and beneficiaries who continue in the programs.

*C. Anticipated Effects*

1. Effects of Closing Cost Contract Plans to New Enrollment

In our proposal to ensure that organizations do not move enrollees from one of their cost or MA plan types to another based on financial or some other interest, we propose to revise § 422.503(b)(5) so that an entity seeking to contract as an MA organization must ''not accept new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan if the MA organization and reasonable cost contract are offered by the same parent organization.'' We believe this provision will have minimal or no financial impact as only a handful of parent organizations currently offer MA and cost plans in the same service area. In addition, as the regulation requires that affected cost plans close to new enrollment, not that they terminate operations, we believe that there will be little or no impact to beneficiaries.

2. Effects of Two-year Limitation on Submitting a New Bid in an Area Where an MA Has Been Required To Terminate a Low-Enrollment MA Plan

Under § 422.506(b)(1)(iv), we must non-renew a MA plan that does not have a sufficient number of enrollees to establish that it is a viable independent plan option. We have established the threshold for termination due to insufficient number of enrollees at fewer than 500 enrollees for non SNPs and fewer than 100 enrollees for SNPs over a specified time period of 3 years. If we did not implement this, an MA organization required to terminate or consolidate one of its MA plans due to sustained low enrollment could avoid the consequences of such a requirement by submitting a bid for a new plan in the same service area.

We are proposing to amend the MA regulations at § 422. 504(a)(19) to impose a contractual requirements that when CMS non renews, or asks the MA organization to terminate an MA plan due to sustained low enrollment pursuant to § 422.506(b)(1)(iv), the MA organization may not introduce any new MA plan in that service area for 2 contract years. We believe this requirement will enhance our ongoing efforts to ensure that MA organization offerings in a service area present beneficiaries with viable plans that are responsive to their needs. We see no financial impact on MA organizations as this requirement has very limited application and imposes no independent financial burden.

3. Effects of Authority To Impose Intermediate Sanctions and Civil Money Penalties

We are proposing to make two changes to existing authority for the imposition of intermediate sanctions and civil money penalties (CMPs). First, under the Affordable Care Act, new authority was provided to the Secretary, which now permits CMS to impose intermediate sanctions for additional contract violations in the areas of marketing and enrollment. This new authority further permits CMS to impose intermediate sanctions on contracting organizations' that employ or contract with organizations, agents, and suppliers who commit any of the contract violations contained in § 422.752 and § 423.752.

Second, we are clarifying our authority to impose CMPs for the aforementioned contract violations. Current regulations designate the OIG as the sole government agency with the authority to impose CMPs for the contract violations contained in § 422.752 and/or § 423.752. We are modifying the language of these provisions to clarify that CMS or the OIG may impose CMPs for these contract violations except the provision that relates to the misrepresentation of falsification of information furnished to CMS, an individual or entity.

We believe these provisions would not result in additional burden to sponsors nor would they have a financial impact on sponsors.

4. Effects of Contract Termination Notification Requirements and Contract Termination Basis

In current regulations, we are required to provide 90-day notice to organizations whose contracts are being terminated by CMS. The authorizing statute at section 1857(h)(1)(B) and 1860D–12(b)(3)(F) of the Act states that the Secretary must provide reasonable notice and opportunity for hearing (including the right to appeal the initial determination) before terminating a contract (except under certain circumstances). We are proposing to modify the notice timeframe from 90 days to 45 days. We believe these provisions would not result in additional burden to sponsors nor would it have a financial impact on sponsors.

5. Effects of Reducing the Burden of the Compliance Program Training Requirements

We are proposing to lessen the burden placed on contracting organizations and their first tier, downstream and related entities (FDRs). Current regulations specify that contracting organizations are required to provide general compliance program training for their FDRs upon initial contracting and annually thereafter. To lessen this burden, we would require all contracting organizations to accept a

certificate of completion of the CMS Standardized General Compliance Program Training and Education Module as evidence of satisfaction of this program requirement. Under this program change, contracting organizations would not be permitted (or required) to develop or implement organization specific training for FDRs. We anticipate that this would greatly reduce the burden on various sectors of the industry including, but not limited to, insurance providers, hospitals, suppliers, pharmacists and physicians. We anticipate that this change would actually provide savings for sponsors and the FDRs since FDRs would only have to take one training as opposed to the possible numerous trainings they may take under current requirements. Additionally, sponsors would save because they would not be required to provide training materials to each FDR with which they contract.

We believe these provisions would not result in additional burden to sponsors nor would they have a financial impact on sponsors.

6. Effects of Audit and Inspection Authority

We are proposing two changes to § 422.503(d)(2) and § 423.504(d)(2) that would allow CMS to require sponsors (MA organizations and Part D sponsors) to hire an independent auditor to conduct full or partial program audits of the sponsors' operational areas and/or correction validation exercises. We currently conduct program audits of approximately 30 sponsors per year. Under this proposal, each MA organization and/or Part D sponsor would be required to hire an independent auditor to perform a full or partial program audit at least every 3 years. There are currently 298 sponsors in the Parts C & D programs. Under this new authority, approximately 99, or one-third of these organizations would be required to hire an independent auditor to perform a program audit, beginning in contract year 2015. Once the sponsor's audit is concluded in the year in which it was chosen, the sponsor would not be subject to another audit until its third year occurs (that is, plans selected for audit in contract year 2015, would not be selected for audit again until contract year 2018); unless the sponsor demonstrates behavior that we believe poses a risk to Medicare beneficiaries, the Trust Fund or both. Sponsors demonstrating this type of noncompliance may be subjected to a CMS program audit at any time in order to identify and mitigate any risk of potential harm to our beneficiaries. This proposal ensures that all sponsors will be audited on at least a 3-year cycle while continuing to maintain the integrity of the program by allowing CMS to continue to conduct audits when it believes beneficiaries are at risk.

Each independent auditor would work within CMS' specifications and guidelines. We would make available to the sponsors all of the methods of evaluations, methodologies and protocols to be used by the independent auditor when conducting the audit. We would also provide technical assistance to auditors as necessary.

We currently conduct program audits that examine the following operational areas:

- Formulary and Benefits Administration (Part D)
- Coverage Determinations, Appeals & Grievances (Part D)
- Organization Determinations, Appeals & Grievances (Parts C)
- Compliance Program effectiveness (Parts C & D)
- Outbound Enrollment Verification (OEV) (Parts C & D)
- Special Needs Plan Model of Care (SNP MOC) implementation (Parts C & D)

We estimate that the independent auditor hired will need to have a team consisting of the following professionals:

- Formulary and Benefits Administration—pharmacist, a senior claims analyst, and a senior auditor.
- Coverage Determinations, Part D Appeals, Part D Grievances—pharmacist, senior auditor.
- Organization Determinations, Part C Appeals, Part C Grievances—nurse practitioner, senior auditor, auditor.
- Compliance Program effectiveness—two auditors (at least one senior).
- Outbound Enrollment Verification (OEV)—two auditors (at least one senior).
- Special Needs Plan Model of Care (SNP MOC) implementation—two auditors (at least one senior).

We used the most recent (2010) wage statistics supplied by the Department of Labor, Bureau of Labor Statistics to develop estimates of direct wages. We also added fringe benefits, overhead costs, and general and administrative expenses using percentages that are consistent with CMS contracts. Based on our experience and in consultation with program experts, we developed an estimate of the hourly burden. The estimated mean cost per hour for each sponsor is $35.80 (wages, fringe benefits, and overhead). The team of 14 professionals (listed previously) is necessary for the performance of each program audit. The estimated mean number of hours the team will need to perform the audit per sponsor is 160. The mean cost per sponsor to procure and support the auditor is therefore: 14 × 160 × $35.80 = $80,192. The auditing costs will be allowable costs in the plan's bid. Since, sponsors will only be subjected to these audits every 3 years; it is our expectation that sponsors will include one-third of this cost in its bid each year. Therefore, each plan year, the total cost included in a sponsors bid is: $80,192 ÷ 3 = $26,731.

The total annual estimated burden hours related to the time and effort for all sponsors being audited is estimated to be 298 sponsors × $26, 731 per sponsor, per year = $7,965,838. Therefore, the estimated annual cost for this requirement is $7,965,838.

We are also proposing to revise our regulations to permit CMS to require MA organizations or Part D sponsors with audit results that reveal non-compliance with CMS requirements to hire an independent auditor to validate that correction has occurred. As mentioned previously, under our existing authority we currently conduct approximately 30 audits per year. Based on our experience, the number of deficiencies identified and requiring corrective action can vary widely from sponsor to sponsor, which therefore affects the time and effort required for subsequent correction validation. Therefore, we have decided to provide an estimate that assumes that each sponsor audited has failed 50 percent of all elements audited; thereby requiring correction validation. We recognize that some sponsors may have far fewer elements that require validation and some sponsors may have more elements that require validation, but we believe that this is the most accurate estimate we can provide of the number of sponsors that will undergo validation and the associated effort required with that validation.

Under these circumstances we estimate that the independent auditor hired will need to have a team consisting of the following professionals:

- Formulary and Benefits Administration—pharmacist, a senior claims analyst, and a senior auditor.
- Coverage Determinations, Part D Appeals, Part D Grievances—pharmacist, senior auditor.
- Organization Determinations, Part C Appeals, Part C Grievances—nurse practitioner, senior auditor.
- Compliance Program effectiveness—one senior auditor.
- Outbound Enrollment Verification (OEV)—one senior auditor.

• Special Needs Plan Model of Care (SNP MOC) implementation—one senior auditor.

We used the same wage statistics provided previously to develop an estimate of the hourly burden (which includes fringe benefits, overhead costs, and general and administrative expenses that use percentages that are consistent with CMS contracts). The estimated mean cost per hour for these sponsors is $35.80. A team of 10 professionals (listed previously) is necessary for the performance of each correction validation. The average hourly cost for a validation with a team of 10 professionals is the same as the average hourly cost of an initial audit with a team of 14 professionals because in both scenarios, the mix of auditors to specialists (or non-auditors) is roughly 70 percent auditors and 30 percent specialists. Since the need for specialists can vary widely (that is, in some validations they may not be needed at all, and in other cases, all of the specialists from the original audit may be needed), we determined that the average breakdown of the team is the same for initial audit and validation. Therefore, the average hourly cost has not changed, despite the change in the number of team members. The estimated mean number of hours the team will need to perform the correction validation per sponsor is 80. The mean cost per sponsor to procure and support the independent auditor is therefore: 10 × 80 × $35.80 = $28,640. The validation costs will be allowable costs in the plan's bid. Under existing regulations the total annual estimated burden hours related to the time and effort for sponsors to perform the correction validation is estimated to be 30 sponsors × $28,640 per sponsor, per year = $859,200. Therefore, the estimated annual cost for this requirement under existing regulations is $859,200.

If the provision proposing that we acquire the authority to require sponsors to hire an independent auditor to conduct program audits is finalized, the number of sponsors being audited per year will increase from 30 (current) to 99 (proposed). Using the same weighted data assuming that each sponsor audited has failed at least 50 percent of audited elements, the estimated mean cost per sponsor to procure and support the independent auditor is: 10 × 80 × $35.80 = $28,640. The correction validation costs will be allowable costs in the plan's bid. Since, sponsors will only be subjected to these audits/validations every 3 years; it is our expectation that sponsors will include one-third of this cost in its bid each year. Therefore, each plan year, the total cost included in a sponsors bid is: $28,640 ÷ 3 = $9,547. The total annual estimated burden hours related to the time and effort for all sponsors being audited to perform the correction validation is estimated to be 99 sponsors × $9,547 per sponsor, per year = $945,120. Therefore, the potential estimated annual cost for this requirement is $945,120.

7. Effects of Procedures for Imposing Intermediate Sanctions and Civil Money Penalties Under Parts C and D

We are proposing to make changes to our authority for imposing intermediate sanctions and for determining when such sanctions will be lifted. Sections 1857(g) and 1860D–12(b)(3)(E) of the Act provide the Secretary the ability to impose intermediate sanctions on MA organizations and PDP sponsors. Intermediate sanctions consist of suspension of enrollment, suspension of marketing and suspension of payment. Current regulations governing intermediate sanctions are contained in subparts O of part 422 and part 423. Sections 422.756 and § 423.756 provide specific procedures for imposing intermediate sanctions, and include provisions which address the duration of the sanction and the standard that we apply when determining if a sanction should be lifted. As specified in the Act and regulations, when intermediate sanctions are imposed on contracting organizations, the sanctions remain in place until the Secretary/CMS is satisfied that the basis for the sanction determination has been corrected and is not likely to recur.

In the October 2009 proposed rule (74 FR 54634), we proposed a change that included a rule that allows us to require a plan under a marketing and/or enrollment sanction to market or accept enrollments or both for a limited period of time. As we explained in that proposed rule, the purpose of the test period is to assist us in making a determination as to whether the deficiencies that are the bases for the intermediate sanctions have been corrected and are not likely to recur. The test period provides us with the opportunity to observe a sanctioned plans ability to enroll or market to Medicare beneficiaries prior to lifting the sanction.

We are proposing to extend the applicability of such a test period to include all intermediate sanctions and to clarify that while we may require a sponsor to receive enrollments during this test period, the sponsor would not receive any LIS annual or auto facilitated reassignments.

We believe these provisions would not result in additional burden to sponsors nor would they have a financial impact on sponsors.

8. Effects on Timely Access to Mail Order Services

We believe it is necessary and appropriate to establish mail order fulfillment requirements defining maximum turnaround times from when the pharmacy receives the prescription order to when it is shipped. This would underscore the importance of consistent and reliable access to medications, protecting beneficiaries from inconsistent or unreliable practices that may otherwise jeopardize timely access to prescriptions. The proposed standards are in alignment with requirements already in place in the market, and as such we do not expect significant financial impacts to implement.

9. Effects of Collections of Premiums and Cost Sharing

In the proposed provision, ''Waivers and Incorrect Collections of Premiums and Cost Sharing,'' we propose to codify our existing guidance pertaining to the waiver of premiums and cost sharing by Part D sponsors and to specifically require sponsors to refund incorrect collections of premiums and cost sharing or retroactively collect underpayments of cost sharing. Since our policy on waivers of premiums and cost sharing has been specified in informal guidance since the beginning of the Part D program and the timeframe for sponsor refunds and recoveries is codified in regulations at § 423.466(a) indicating that such refunds and collections are required, we do not believe the proposed changes would result in any additional costs.

10. Effects of Enrollment Eligibility for Individuals Not Lawfully Present in the United States

In section III.A.10. of this proposed rule, we discuss our proposals to add 'citizenship or lawful presence' as an eligibility requirement to enroll and remain enrolled in MA, Part D, and section 1876 cost contracts to align with section 401 of the PRWORA mandating that aliens not lawfully present in the United States are not eligible to receive any federal benefit. In CY 2012, there were close to 50 million Medicare beneficiaries. Approximately 34.4 million beneficiaries were enrolled in MA plans, PDPs or cost plans, which accounted for 68.8 percent of the total Medicare population. In the same year, an average of 4,285 Medicare beneficiaries enrolled in MA or Part D plans were identified by SSA as being unlawfully present. By directing MA

plans, PDPs, and cost plans to disenroll individuals who, at the time of notification from CMS, are not lawfully present, we intend to prevent improper payment for these individuals to MA plans, PDPs, and cost plans for periods when these individuals were ineligible to receive such services. Based on data for capitation payments for MA and PDPs, as well as the prepayments provided to cost plans, we estimate that the disenrollment of individuals who are unlawfully present would result in a decrease in payments made by CMS and would result in a cost savings of $10 million in 2015. We estimate, based on the numbers previously mentioned, that this change could save the MA program approximately $5 million in 2015, increasing to $8 million in 2019, and could save the Part D program (includes the Part D portion of MA–PD plans) approximately $5 million in 2015, increasing to $9 million in 2019. As cost plans are paid based on the reasonable costs delivering Medicare-covered services to their enrollees, instead of the fixed capitation amounts paid to MA plans and PDPs, we believe the impact to cost plans associated with this provision to be negligible.

TABLE 9—PROJECTED NUMBER OF INDIVIDUALS DISENROLLED DUE TO LOSS OF LAWFUL PRESENCE AND ESTIMATED SAVINGS TO THE MEDICARE ADVANTAGE PROGRAM BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2019

| | 2015 | 2016 | 2017 | 2018 | 2019 | Totals (CYs 2105–2019) |
|---|---|---|---|---|---|---|
| Projected number of unlawfully present beneficiaries enrolled in MA plans | 1,118 | 1,247 | 1,375 | 1,503 | 1,632 | 6,875 |
| Projected federal impact due to unlawfully-present individuals disenrolled 6 months sooner | [1] – $5 | [1] – $6 | [1] – $6 | [1] – $7 | [1] – $8 | – $32 |

**Note:** Estimates reflect scoring by the CMS, Office of the Actuary, and 2012 lawful presence data provided by the SSA.
[1] Million.

TABLE 10—PROJECTED NUMBER OF INDIVIDUALS DISENROLLED DUE TO LOSS OF LAWFUL PRESENCE AND ESTIMATED SAVINGS TO THE MEDICARE PART D PROGRAM BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2019

| | 2015 | 2016 | 2017 | 2018 | 2019 | Totals (CYs 2015–2019) |
|---|---|---|---|---|---|---|
| Projected number of unlawfully present beneficiaries enrolled in Part D plans (including MA–PDs) | 5,780 | 6,276 | 6,771 | 7,267 | 7,762 | 33,856 |
| Projected federal impact due to unlawfully-present individuals disenrolled 6 months sooner | [1] – $5 | [1] – $6 | [1] – $7 | [1] – $8 | [1] – $9 | [1] – $35 |

**Note:** Estimates reflect scoring by the CMS, Office of the Actuary, and 2012 lawful presence data provided by the SSA.
[1] Million.

11. Effects of Part D Notice of Changes

This section would codify current guidance for Part D sponsors to inform beneficiaries about changes to plan benefits from year to year and also correct an oversight whereby such a regulation currently exists for Part C but not for Part D. We anticipate that this proposal would result in no additional costs because Part D sponsors already typically provide this information.

12. Effects of Separating the Annual Notice of Change (ANOC) From the Evidence of Coverage (EOC)

Currently, members must receive the plan's combined ANOC/EOC prior to the Annual Election Period (AEP). We propose to separate the distribution and dissemination requirements, such that, the ANOC is received by beneficiaries before the AEP and the EOC is received closer to the enrollment effective date. This way, beneficiaries who choose to leave their current plans and enroll in other plans will only receive an EOC from the plan in which they have enrolled. We believe that this will reduce confusion among beneficiaries about which EOC is for the plan in which they have enrolled. It eliminates the unnecessary waste from the production of EOCs that end up being discarded. It also allows MA organizations and Part D sponsors additional time to develop better quality documents.

We propose to revise the language in § 422.111(a)(3) and § 423.128(a)(3) to allow the EOC to be sent to members a few months after the ANOC. We believe this provision will have minimal or no financial impact as the proposal would merely change the timing of notices that MA organizations and Part D sponsors already provide. Further, the delay in providing the EOC could result in savings as MA organizations and Part D sponsors have additional time to ensure that these documents are accurate, thus eliminating the need for updates and correction notices.

13. Effects of the Modification of the Agent/Broker Compensation Requirements

The current independent agent compensation structure (as originally published as CMS–4138–IFC2 in November 2008) is comprised of a 6-year cycle and is scheduled to end December 31, 2013. MA organizations and Part D sponsors provide an initial compensation payment to independent agents for new enrollees or unlike plan changes (Year 1), and pay a renewal rate (equal to 50 percent of the initial year compensation) for Years 2 through 6. CMS is proposing to revise this existing compensation structure. MA Organizations and PDP sponsors would have the discretion to decide, on an annual basis, whether to pay initial and/or renewal compensation payments to their independent agents. For new or unlike plan change enrollments, MA Organizations and PDP sponsors could make an initial payment that is no greater than the fair market value (FMV)

amount for such services, set annually by CMS in guidance interpreting these regulations. For renewals in Year 2 and subsequent years, the MA organization or PDP sponsor could pay up to 35 percent of the FMV amount for that year. We are proposing that recovery of compensation payments not happen when the disenrollment does not result from the agent's behavior. In addition to the agent and broker compensation structures, we are amending the training and testing requirements and setting limits on referral fees for agents and brokers.

We do not believe that any of these revisions will add additional burden or have financial impact. We are simply revising the existing compensation structure under which MA organizations may pay independent agents and believe that the total compensation amounts will generally remain unaffected. Furthermore, we believe these proposed changes would actually lessen the burden and impact on MA organizations by simplifying the compensation structure for independent agent brokers.

14. Effects of Drug Categories or Classes of Clinical Concern and Exceptions

We believe that this proposed provision to establish new criteria for identifying Part D drug categories or classes of clinical concern would generate significant Part D savings. This provision would require that Part D sponsors include all Part D drugs on their formularies in categories or classes of clinical concern that CMS specifies for a typical individual with a disease or condition treated by the drugs in the category or class meet the following proposed criteria: (1) hospitalization, persistent or significant disability or incapacity, or death likely will result if initial administration (including self-administration) of a drug in the category or class does not occur within 7 days of the date the prescription for the drug was presented to the pharmacy to be filled; and (2) more specific CMS formulary requirements will not suffice to meet the universe of clinical drug-and-disease-specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.

The expected savings to the Part D program would result from reducing the number of categories or classes of drugs for which Part D sponsors currently must include all Part D drugs on their formularies, as compared to existing requirements. Specifically, in applying the proposed criteria to all categories and classes of Part D drugs, CMS has determined that three existing categories and classes of Part D drugs would meet the new criteria and that no additional categories or classes of drugs would meet the criteria. Specifically, we determined that only the antineoplastic, antiretroviral and anticonvulsant categories and classes would meet the new criteria. This means that Part D sponsors would no longer be required to include all Part D drugs from within the antidepressant and immunosuppressant (used for transplants rejection) classes on their formularies. Relative to the antipsychotic class, however, we are deferring any change in formulary requirements for the antipsychotic class at this time and will continue to require that all drugs within the antipsychotic class be included on all Part D formularies, subject to the exceptions that get finalized in § 423.120(b)(2)(vi).

Based upon this determination, we estimated that full implementation (including the antipsychotic class) of this provision would result in federal savings to the Medicare Part D program of $720 million for the period CY 2015 through CY 2019, with most of these savings generated from the antipsychotic class (see table 14). We note this estimate is based upon the information that is available. Projected savings are based upon full implementation of the criteria and do not reflect that changes for the antipsychotic class of drugs are deferred at this time. However, there could be additional savings when new drugs enter the market and compete with each other by providing higher rebates.

A consensus panel applied our proposed criteria to determine the categories or classes of clinical concern. Our consensus panel determined that of the current six categories or classes of clinical concern, three met both of the proposed criteria, three did not, and no new drug categories or classes met both criteria. Finally, we estimated the impact on drug expenditures for those drugs that ultimately met the criteria, as well as those drug categories or classes that no longer qualify as categories or classes of clinical concern.

To arrive at the cost estimate for the implementation of the categories or classes of clinical concern, we began by putting drug spending into three groupings: (1) Drugs that were already included in the six categories or classes of clinical concern; (2) drugs with a greater likelihood of being affected by this change because formularies without them would be acceptable under our formulary review process; (3) drugs with a lesser likelihood of being affected by this statutory change because formularies without them would not be acceptable under our formulary review process; and (4) drugs in the research and development pipeline in the six categories or classes of clinical concern that would be affected by this statutory change. Because we reduced the number of categories or classes of clinical concern relative to the six for which we currently require formulary inclusion of all Part D drugs, we expect Part D sponsors' negotiating power to increase. As a result, Part D sponsors could incur lower drug costs and could lower their bids, which could result in lower premiums and co-pays. We also believe that direct savings would be generated by the increasing generic utilization by removing brand products from formularies. Although, based on other categories and classes of drugs that exhibit generic saturation, we have reason to believe that some plans would still cover the brand products. Moreover, we believe that the program would avoid future costs because some drugs in the research and development pipeline would not be required on formularies as a result of this change.

To support the panel's conclusion that our formulary checks could efficiently require adequate access to these categories and classes without requiring that every drug in them be included on Part D formularies, we compared a Part D formulary to other formularies. To accomplish this, we took an approved CY 2014 formulary containing the average number of RxNorm Concept Unique Identifiers (RxCUIs). This formulary includes the following: 23 Generic (ANDA) antidepressant drug entities, 7 brand (NDA) antidepressant drug entities, 18 generic antipsychotic drug entities, and 9 brand antipsychotic drug entities. We then reviewed the drugs comprising the previously mentioned list against our formulary review requirements standards for treatment guidelines, common Medicare drugs, and the discrimination review. We found that the formulary could have passed these checks with 9 generic antidepressant drug entities, and 6 generic antipsychotic drug entities. No brands were necessary to meet the formulary review requirements. Thus, this formulary includes an excess of 16 brand drug entities and 26 generic drug entities within these two classes of medications. Because all these products are currently required on all Part D formularies, there is significantly less need for manufacturers to restrain list prices or offer rebates to sponsors for formulary placement. In contrast, under our proposal, 100 percent of the brands

(16/16) and 63 percent of the generics (26/41) would be expected to meet or exceed the price concessions applicable to the least expensive products in those classes to remain competitive. If manufacturers increased price concessions in response, sponsors might elect to keep the products on the formulary. Otherwise, we would expect sponsors to take those products off formulary. Thus, individuals on brand versions of these drugs or on the 63 percent of generic versions would in most cases either stay on the drug at that more competitive price, or switch to an even cheaper alternative that remains on formulary. Either way, the beneficiary's drug costs and costs to the program would decrease. Moreover, to evaluate whether plans would continue to offer brand drugs (because new generic drugs would be available), and therefore whether any rebates would be available, we evaluated CY 2014 formularies for three classes of drugs that face saturation by generics. We found that even though the majority of drugs in those classes were generic, some plans continued to offer brand drugs. We also propose to establish exceptions that we believe permit Part D sponsors to apply meaningful utilization management to these drugs without compromising access. Although these exceptions are generally similar to existing policy, we propose to permit prior authorizations for drugs in the categories and classes of clinical concern to verify medically accepted indications or in Part A/B versus D situations. These lower costs could be reflected in bids submitted to CMS by Part D sponsors and could result in decreased premiums for Medicare beneficiaries.

Although Part D sponsors would be required to include all Part D drugs on their formularies in fewer categories or classes than are currently required, we believe that our formulary review processes are sufficient to ensure that the implementation of this provision would not negatively impact beneficiary access to drugs or enrollment in Part D plans. Moreover, robust transition, exceptions and coverage determination, appeals and grievances processes ensure beneficiary access in the event that they have enrolled, either self-enrolled or auto-enrolled, in a plan where their drugs are not on formulary. We also do not believe that the proposed provisions would lead to greater beneficiary confusion or any increased difficulty in making enrollment decisions. We continue to believe that overall enrollment would increase given demographic trends and the increasing cash prices for drugs paid by beneficiaries who must pay cash because they do not enroll. Accordingly, we believe Medicare beneficiaries would continue to find Part D to be a cost efficient method of obtaining robust drug coverage at a range of acceptable costs.

We plan on working closely with Part D sponsors as our guidance in this area develops to ensure that they continue to provide high quality prescription drug coverage at the most economical price. It is not clear to us whether PBMs would experience a decrease in administrative costs. On one hand, the provisions in this rule may decrease formulary maintenance expenses, such as managing a small formulary. This may result in PBMs decreasing their fees to Part D sponsors. On the other hand, these provisions may increase exception requests, appeals, prior authorizations, and outreach to Part D sponsors, thereby increasing PBMs' administrative costs. However, because these types of administrative costs exist for PBMs today, it is unclear how much of an increase we would see specifically as a result of these provisions. Similar to our ongoing communications with our Part D sponsors, we intend to work closely with the industry to minimize the likelihood of any unanticipated increases in beneficiary costs.

15. Effects of Medication Therapy Management Program (MTMP) Under Part D

Current regulations require that Part D sponsors must have established a Medication Therapy Management Program that targets beneficiaries who: (1) Have multiple chronic diseases with three chronic diseases being the maximum number a Part D plan sponsor may require for targeted enrollment; (2) are taking multiple Part D drugs, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment; and (3) are likely to incur costs for covered Part D drugs in an amount greater than or equal to $3000, as increased by an annual percentage. We specified in guidance that while Part D sponsors are permitted to target beneficiaries with select chronic diseases, they must include at least five of nine core chronic diseases in their criteria. These provisions have generated wide variability in MTM programs. Moreover, despite opt-out enrollment, completion rates for comprehensive medication reviews (CMR) remain very low.

We propose to broaden the MTM criteria to require that Part D sponsors now target beneficiaries who have two or more chronic diseases and are taking two or more covered Part D drugs. We propose to set the annual cost threshold at an amount commensurate with the annual amount of Part D costs incurred by individuals that meet the first two criteria regarding multiple chronic conditions and use of multiple covered Part D drugs. Applying this methodology, we would set the cost threshold at $620, which is the approximate cost of filling two generic prescriptions. We propose to revise this number periodically to reflect more up-to-date information regarding the drug spending of beneficiaries that have two or more chronic conditions and use two covered Part D drugs. We estimate that 2.5 million beneficiaries are currently eligible for MTM services, 13 percent opt-out of the MTM program, and 10 percent of participating beneficiaries will receive an annual CMR. We also estimate that an average CMR requires 35 minutes to complete and the average hourly compensation (including fringe benefits, overhead, general, and administrative expenses and fee) of the MTM provider is $120 (labor cost per CMR is $70), and that it costs $0.91 to print and mail a CMR summary in CMS' standardized format. Therefore, the estimated total annual cost of providing CMRs in all settings is $15,422,925 ($70.91/CMR × 217,500 CMRs). Previously, prior to the availability of more precise opt-out and CMR rates, we estimated that the total burden associated with conducting CMRs and delivering the CMR written summary in CMS' standardized format was 1,192,429 hours with a cost of $143,363,555, including delivery of 1,896,500 CMRs in all settings under the current eligibility criteria, and implementation and mailing costs for the CMR summary in standardized format (see OMB Control No. 0938–1154). We do not currently have data or estimates to determine the costs associated with quarterly targeted medication reviews and follow-up interventions, if necessary.

We estimate that 18 million beneficiaries would be eligible for MTM services based on the proposed criteria. Using the same opt-out, CMR, and expense rates as before, the estimated total annual cost of providing CMRs in all settings is $111,045,060 ($70.91/CMR × 1,566,000 CMRs). This is below previous estimates.

Additionally, there is currently no requirement to ensure that beneficiaries in special populations receive focused targeting, outreach, or engagement for enrollment or participation in MTM. Moreover, the opt-out method of enrolling targeted beneficiaries into MTM at 42 CFR 423.153(d)(1)(v) may only partly address the increased

barriers to care faced by some beneficiaries. Without being prescriptive about what strategies must be employed, we are proposing that sponsors develop an effective strategy to ensure access to services for all MTM-eligible beneficiaries. We would expect to see details concerning sponsors' specialized strategies regarding outreach and service provisions in their bids. We believe that current plan reporting requirements, along with other CMS data sources, will be sufficient for us to evaluate the impact of such strategies.

We cannot definitively score this proposal because the portion of the administrative costs attributable to MTM is not a specific line item that can be easily extracted from the bid. Although the increase in the number of CMRs is estimated to cost $111 million, mounting evidence shows that MTM services may generate overall medical savings.

Supporting this conclusion, a recent study conducted in conjunction with the Center for Medicare and Medicaid Innovation (''CMMI MTM study'') (available at *http://innovation.cms.gov/Files/reports/MTM-Interim-Report-01-2013.pdf*) found that MTM programs effectively targeted high risk individuals who had problems with their drug-therapy regimens and had high rates of hospital and emergency room visits before enrollment as well as those that experienced a recent visit to the hospital or emergency room. The study also found that individuals enrolled in MTM programs—particularly those who received annual CMRs—experienced significant improvements in drug therapy outcomes when compared to beneficiaries who did not receive any MTM services, thus supporting the hypothesis that the annual CMR may be one of the more crucial elements of MTM. Significant cost savings associated with all-cause hospitalizations at the overall PDP and MA–PD levels were found, which may be due to MTM's comprehensive rather than disease-specific approach. This research supports statements in a recent Congressional Budget Office report that programs and services that manage the benefit well or improve prescription drug use might result in medical savings (Congressional Budget Office, ''Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services'', November 2012, available at *http://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf*).

We anticipate that many more beneficiaries will have access to MTM services under the proposed revisions to the eligibility criteria, and believe that these changes will simplify the MTM criteria and minimize beneficiary confusion when choosing or transitioning between plans. Moreover, we believe these changes will reduce disparity and allow more beneficiaries with drug therapy problems to receive MTM services. Similarly, we expect the proposed requirement that sponsors develop an effective strategy to ensure access to services for all MTM-eligible beneficiaries will help to ensure that beneficiaries in special populations receive focused targeting, outreach, or engagement for enrollment or participation in MTM.

16. Effects of Business Continuity for MA Organizations and Part D Sponsors

Proposed § 422.504(o) and § 423.505(p) would, respectively, require MA organizations and Part D sponsors to develop and maintain business continuity plans which assess risks posed by disasters and contain strategies to mitigate those risks. We also would require that essential functions—including at a minimum benefit authorization, claim adjudication, call center and supporting operations—be restored within 24 hours after such functions fail or are disrupted.

Business continuity plans are well established in the business community, and we believe that most MA organizations and Part D sponsors already have business continuity plans in place which cover the basic proposed subject areas. We estimate that 5 percent of the contracting entities (532 MA organizations and Part D sponsors in 2013), or about 27 entities, will be affected by this requirement, resulting in an initial burden of 2,080 hours.

We estimate the first year burden of an emergency management director to help design the plan would be a burden of 56,160 hours (27 × 2,080). The estimated cost associated with such expert is the estimated number of hours multiplied by the estimated hourly rate of $36.50 (hourly rate for an emergency management director, General Medical and Surgical Hospitals, according to May 2012 wage data from Bureau of Labor Statistics Occupational Employment Statistics) plus 48 percent for fringe benefits and overhead, which equals a first year cost of $3,033,763.

In subsequent years, the burden associated with this proposed requirement would be the costs of an emergency management director working on a part time basis for an ongoing burden of 28,080 (27 × 1,040). The estimated cost associated with such expert is the estimated number of hours multiplied by the estimated hourly rate of $36.50 plus 48 percent for fringe benefits and overhead, which equals an annual cost of $1,516,882 for subsequent years.

We do expect that the burden would, should a disaster or other disruption of business occur, ultimately result in savings from planning that would avoid even more losses, but such offsets cannot be calculated here.

Requiring business continuity plans would benefit Medicare beneficiaries in these Part C and Part D plans because planning helps to negate problems: The more prepared that MA organizations and Part D sponsors are for disasters and other disruptions to business, the more likely it would be that these organizations would address timely any problems encountered and ultimately return to regular operations and the less likely it would be that individuals would lose access to benefits as a result of disruptions. Requiring the restoration of essential functions within 24 hours after failure would help by providing a clear deadline by which priority operations must be available to beneficiaries. Our proposal to deem as essential benefit authorization certain minimum functions, including claim adjudications, and all supporting operations would benefit individuals by providing the means to ensure beneficiaries access to their Medicare benefits—and therefore health care and drugs. Designating operation of the call center as essential would provide beneficiaries real time customer support which could be critical to ensuring access to benefits in times of disaster or other disruption. For instance, if beneficiaries could not get to their regular places of business or found their claims were rejected at point of sale, customer service representatives could then send them to providers and pharmacies that could provide them with benefits or resolve questions in real time such that they would be more likely to leave pharmacies with any appropriate drugs in hand.

17. Effects of Requirement for Applicants or Their Contracted First Tier, Downstream, or Related Entities to Have Experience in the Part D Program Providing Key Part D Functions

Based on CMS' authority at section 1860D–12(b)(3)(D) of the Act to adopt additional contract terms, not inconsistent with the Part C and D statutes, that are necessary and appropriate to administer the Part D program, we are proposing at § 423.504(b)(8)(i) through (iii) that Part D organizations seeking a new Medicare contract must have arrangements in place such that either the applicant, or

a contracted entity that will be performing certain key Part D functions, has at least one full benefit year of experience providing key Part D functions. This proposal ensures that applicants take advantage of the abundant Part D industry expertise and experience that exists today in the development of their Part D program operations, rather than relying on technical assistance from CMS and having their inexperience place beneficiaries' access to prescription drugs at risk. We believe this provision will have a very minor savings impact on the federal budget, based on savings of time and effort (staff time and contracted auditor time and resources) that the government would spend on overseeing the disproportionate level of problems experienced by organizations operating Part D plans without prior Part D experience. For each inexperienced organization allowed into the program in the absence of this proposal, we would anticipate a savings of 1,000 staff hours at an average rate of $50 per hour, for a total of $50,000 in employee time, plus an additional savings of $200,000 in contractor dollars to conduct an emergency audit, for a total of $250,000. In the absence of this proposal, we would anticipate no more than two such inexperienced entities beginning Part D operations per year, for a total annual savings of $500,000.

The burden associated with this proposal on industry would be minimal, with a total estimated number of labor hours of 3.25 to submit information during the Part D application process. Using the same average hourly salary as previously mentioned, the total cost to Part D applicants would be $162.50. We do not believe there are any non-administrative costs to industry associated with this proposal, as Part D applicants are already required to have arrangements in place to perform the key Part D functions discussed in our proposal.

The main anticipated effect from this proposal is ensuring that only entities with some experience with Part D in critically important functional areas are permitted to offer new Part D contracts, thus strengthening the Part D program by enhancing the qualification criteria. We considered the alternate proposal of requiring the prior Part D experience to be tied to specific quality outcomes. We rejected the alternative because we believed it added unnecessary complexity and burden to the process, and we believe a simple experience requirement is currently sufficient.

18. Effects of Requirement for Applicants for Stand Alone Part D Plan Sponsor Contracts To Be Actively Engaged in the Business of the Administration of Health Insurance Benefits

Based on CMS' authority at section 1860D–12(b)(3)(D) of the Act to adopt additional contract terms, not inconsistent with the Part C and D statutes, that are necessary and appropriate to administer the Part D program, we proposed at § 423.504(b)(9)(i) through (ii) that organizations seeking to offer a stand-alone prescription drug plans (PDP) for the first time must have either: (i) Actively offered health insurance or health benefits coverage for 2 continuous years immediately prior to submitting an application, or (ii) actively managed prescription drug benefits for a company offering health insurance or health benefits coverage for 5 continuous years immediately prior to submitting an application. This proposal would ensure that applicants have substantial experience in administering health insurance benefits prior to becoming a Part D sponsor. We believe this provision will have a very minor savings impact on the federal budget, based on savings of time and effort (staff time and contracted auditor time and resources) that the government would spend on overseeing the disproportionate level of problems experienced by organizations operating stand-alone PDPs without prior health insurance administration experience. For each inexperienced organization not allowed into the program in the absence of this proposal, we would anticipate a savings of 1,000 staff hours at an average rate of $50 per hour, for a total of $50,000 in employee time, plus an additional savings of $200,000 in contractor dollars to conduct an emergency audit, for a total of $250,000. In the absence of this proposal, we would anticipate no more than two such inexperienced entities beginning Part D operations per year, for a total annual savings of $500,000.

The burden associated with this proposal on industry would be minimal, with a total estimated number of labor hours of 3.25 to submit information during the Part D application process. Using the same average hourly salary as previously mentioned, the total cost to Part D applicants would be $162.50. We do not believe there are any non-administrative costs to industry associated with this proposal, as Part D applicants are already required to be licensed in at least one state prior to offering Part D benefits.

The main anticipated effect from this proposal is ensuring that only entities with some experience administering health insurance benefits will be permitted to offer new stand-alone PDPs, thus strengthening the Part D program by enhancing the qualification criteria. CMS considered the alternate proposal of requiring the prior health insurance benefit administration experience to be tied to specific quality outcomes. We rejected this alternative because we believed it added unnecessary complexity and burden to the process, and we believe a simple experience requirement is currently sufficient.

19. Effects of Limit Parent Organizations to One Prescription Drug Plan (PDP) Sponsor Contract per PDP Region

This provision has no quantifiable impact because the savings that might be achieved likely will be offset by the burden necessary with the consolidation activities and legal work necessary to implement these changes.

20. Effects of Limit Stand-Alone Prescription Drug Plan Sponsors To Offering No More Than Two Plans per PDP Region

This provision has no quantifiable impact because the savings that might be achieved likely will be offset by the burden necessary with the consolidation activities and legal work necessary to implement these changes.

21. Effects of Efficient Dispensing and in Long Term Care Facilities and Other Changes

We are proposing the following specific changes to the LTC short-cycle dispensing requirements at § 423.154: (1) Add a prohibition on payment arrangements that penalize the offering and adoption of more efficient LTC dispensing techniques; (2) eliminate language that has been misinterpreted as requiring the proration of dispensing fees; (3) incorporate an additional waiver for LTC pharmacies using restock and reuse dispensing methodologies under certain conditions; and (4) make a technical correction to eliminate the requirement that Part D sponsors report on the nature and quantity of unused brand and generic drugs. Medicare Part D plan sponsors are already required to comply with the LTC short-cycle dispensing requirements.

The prohibition on payment arrangements that penalize the offering and adoption of more efficient LTC dispensing techniques is a clarification of the Congress' intent in enacting section 1860D–4(c)(3) of the Act, and we

do not believe it will impose any new costs on stakeholders. Indeed, this proposal should reduce Part D sponsors' costs by preventing Part D sponsors from penalizing the most efficient LTC dispensing techniques. The resulting reduction in brand drug costs should offset or surpass increases in dispensing fees.

22. Effects of Applicable Cost-Sharing for Transition Supplies: Transition Process Under Part D

We propose to add at § 423.120(b)(3)(vi) a paragraph clarifying that a Part D sponsor must charge cost sharing as follows: (a) For low-income subsidy (LIS) enrollees, a sponsor must not charge higher cost sharing for transition supplies than the statutory maximum copayment amounts; (b) for non-LIS enrollees, a sponsor must charge: (1) The same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non-formulary drugs approved under a coverage exception; and (2) the same cost sharing for formulary drugs subject to utilization management edits provided (for example, prior authorization and step therapy) during the transition that would apply once the utilization management criteria are met.

Because increases or decreases in cost sharing during transition supplies under the various circumstances are likely to offset one another, we anticipate that there would be no cost impact on plans.

23. Effects of Medicare Coverage Gap Discount Program and Employer Group Waiver Plans

The regulation amends § 423.2325 by adding a new paragraph (h), ''Medicare Coverage Gap Discount Program and Employer Group Waiver Plans''. This new provision requires Part D sponsors to fully disclose to each employer group the projected and actual manufacturer discount payments under the Discount Program attributable to the employer group's enrollees.

We believe that the provision will have negligible regulatory impact because, in the interest of Full Disclosure requirements, the great majority of sponsors with employer group clients have likely already integrated Discount Program data into their existing client reporting. This additional reporting has enabled employer groups to begin to incorporate the manufacturer payments into their benefit packages. Also, for those few Part D sponsors that have not already incorporated the discounts into client reports, the provision creates a minimal financial burden. The requirement does not entail development or gathering of any new data as currently, Part D sponsors report beneficiary-level discounts to CMS on Prescription Drug Event (PDE) data, and report aggregated enrollee utilization to employer group clients. The new provision requires only that sponsors who have not yet modified their existing reports provide the aggregated discount amounts to each employer group, and use the existing processes for report dissemination.

In estimating the associated regulatory costs we assumed that 80 percent of the sponsors were already supplying employer group clients with Discount Program information and that 20 percent of the plans would need to modify the reports as a result of this provision. We used 2013 data to determine the number of sponsors that would be affected by this new requirement. In 2013, 131 Part D sponsors operated one or more EGWP plans. If 20 percent of these Part D sponsors were required to change their client reporting, approximately 26 sponsors would be affected. Our research indicates that it would take each sponsor employing a mid-level analyst about 2-business days to aggregate the manufacturer discounts for each client and modify the existing reports to include the discount payments. Assuming an average hourly wage and benefits of $50,[5] the cost of these 16 hours would be $50 × 16 = $800 for each Part D sponsor or a total of $800 × 26 = $20,800 for all 26 sponsors combined. In subsequent years we do not believe that there will be any incremental costs associated with the regulation as sponsors will update the discount data per their existing processes.

There is no quantifiable monetary value to CMS. Rather, requiring Part D sponsors to report amounts they receive on behalf of employer group enrollees will enable the employer group to use the payments in a way that best serves retirees.

24. Effects of Interpreting the Non-Interference Provision

We are proposing to formally interpret section 1860D–11(i) of the Act, referred to as the non-interference provision. This provision prohibits CMS from interfering with the negotiations between drug manufacturers and pharmacies and Part D sponsors, and requiring a particular formulary or instituting a price structure for the reimbursement of covered part D drugs. We have not previously interpreted the statutory provision, which has resulted in different stakeholders having different views about its scope. Consequently, we believe that a clear interpretation of the statutory provision will remove ambiguity. We do not believe there is any regulatory impact because we are codifying an existing requirement that currently prohibits CMS from interfering in certain activities between Part D sponsors, pharmacies and manufacturers without adding any new requirements.

25. Effects of Pharmacy Price Concessions in Negotiated Prices

We propose to revise the definition of negotiated prices at § 423.100 to specify that all pharmacy price concessions must be included in the negotiated price. This would preclude the differential reporting that is taking place today in the realm of reporting drug costs and price concessions from network pharmacies. This proposal would change current policy that permits sponsors to elect to take some price concessions from pharmacies in forms other than the negotiated price and report them outside the PDE. This practice currently allows price concessions to be applied disproportionately to costs that plans are liable for, and thus may shift more low-income cost-sharing subsidy and reinsurance costs to the government, as well as to manufacturers in the calculation of coverage gap discount payments. A sponsor that engages in this practice can reduce its bid and achieve a competitive advantage relative to a sponsor that applies all price concessions to the negotiated price—a competitive advantage stemming not from greater efficiency, but from a technical difference in how costs are reported to CMS. Meanwhile, the higher the negotiated price, the higher beneficiary coinsurance will be, the faster the beneficiary is moved through the benefit, and the higher government subsidies for low-income cost sharing (LICS) and reinsurance subsidies will be. Our proposal would impose consistent treatment of drug price reporting.

Our proposal to require all price concessions to be reflected in the negotiated price received by the pharmacy would not necessarily change the level of price concessions received from network pharmacies, but would impose a single consistent price concession reporting process on all Part

[5] Depart of Labor quarterly census of Employment and Wages indicates that the average 2011 wage for private health insurance plans was $74,431. To project a 2015 wage this figure was increased 3 percent per year to $83,772 in 2015. This lead to an hourly wage projection of $40.27 or with 20 percent benefits an hourly rate of $48.33, which was in turn rounded upward to derive an hourly rate of $50.

D sponsors. Therefore, it is not clear that any contractual arrangements between a subset of sponsors and network pharmacies would require renegotiation, since only the form of the price concession, rather than its level, would be affected by this proposal.

In addition, when price concessions from pharmacies are in forms other than the negotiated price, the degree of price concession that the pharmacy has agreed is no longer reflected in the negotiated prices available at point of sale or reflected on the Medicare Prescription Drug Plan Finder (Plan Finder) tool. Thus, the true price of drugs at individual pharmacies is no longer transparent to the market. Consequently, consumers cannot efficiently minimize both their costs (cost sharing) and costs to the taxpayers by seeking and finding the lowest-cost drug/pharmacy combination. This proposal would ensure that the actual level of price competition is transparent to the Part D market.

Under current policy, a sponsor may be able to offer a lower bid than its competitors and may achieve a competitive advantage stemming not from greater efficiency, but from a technical difference in how costs are reported to CMS. When this happens, such differential reporting may result in bids that are no longer comparable, and in premiums that are no longer valid indicators of relative plan efficiency. The changes we are proposing would lead to Part D bids being more accurately comparable and premiums more accurately reflecting relative plan efficiencies. The lowest premiums would more accurately direct beneficiaries to the plans that have the lowest costs to the program overall.

We do not collect sufficient detail in price concession data reported to CMS to quantify the impact of this proposed change to standardize price concession reporting. We believe that only certain sponsors are engaging in the differential reporting practices today, and these sponsors face close competition from larger competitors that do not appear to be employing the same strategies. Consequently, if the sponsors employing these tactics increase their bids to maintain margin, they could likely risk losing market share. Therefore, we would expect these sponsors to carefully consider the risk of losing market share before raising their bids in response to our regulatory proposals, particularly those that are committed to the LIS market.

We expect that the effect of our proposal to require consistent and transparent pricing would not only provide higher-quality information to the Part D market, but also promote increased price competition among network pharmacies. This expectation is consistent with economic theory that holds that increased price transparency will increase price competition. We believe pharmacies will support including the full price concession in the point-of-sale price, and fully transparent price competition will align beneficiary and taxpayer interests in minimizing costs. Our proposal would not change the level of price concessions and therefore costs under the program as a whole, but would apply consistency to how these are reported to CMS and treated in bidding and payment processes. Therefore, we anticipate that there would be no cost impact on plans.

26. Effects of Payments to PDP Plan Sponsors for Qualified Prescription Drug Coverage and Payments to Sponsors of Retiree Prescription Drug Plans

This section is not anticipated to have any significant impact since it is only a conforming change, necessary to align with the proposed definition change in another section of the regulation.

27. Effects of Preferred Cost Sharing

We propose to require that sponsors may offer reduced copayments or coinsurance for covered Part D drugs obtained through a subset of network pharmacies, as long as such preferred cost sharing is in return for consistently lower negotiated prices relative to the same drugs when obtained in the rest of the pharmacy network. Therefore, we intend to clarify that preferred cost sharing should consistently be aligned with and accurately signal lower costs. We propose that by ''consistently lower'' we mean that sponsors must offer better prices on all drugs in return for the lower cost sharing. In practice we believe this would mean that whatever pricing standard is used to reimburse drugs purchased from network pharmacies in general, a lower pricing standard must be applied to drugs offered at the preferred level of cost sharing. Our analysis shows that most sponsors offering preferred cost sharing are currently achieving these levels of savings, and therefore our proposed policy would only require a change in price concession levels or reporting for a limited number of sponsors. Our proposal would apply a consistent expectation across all sponsors to compete on the same basis on negotiated prices, including in related-party pharmacy operations.

Instead of consistently passing through lower costs available through economies of scale or steeper discounts, some (but not the majority of) sponsors are actually charging the program higher negotiated prices in some cases. In other cases, the negotiated prices offered for preferred cost sharing are only slightly lower than the prices in the rest of the network. When either higher prices or very nearly the same prices are combined with significantly lower cost sharing, such pricing increases the proportion of costs borne by the plan and the government. Moreover, the lower cost sharing provides a defective price signal that distorts market behavior. In these cases, the lower cost sharing does not incent enrollees to select pharmacies with lower prices and thus make more efficient choices in the market, but the exact opposite. This would be expected to result in higher costs to the Part D program overall. Therefore, we believe our proposed policy change to require consistently lower negotiated prices in return for preferred cost sharing may not only decrease overall price levels in certain sponsor's networks, but would also encourage beneficiaries to make drug purchase decisions that are better aligned with lower costs to the program overall. However, we do not have enough information on how negotiated prices might change—particularly in combination with the requirements for all price concessions from pharmacies to be reflected in negotiated prices, and for any-willing-pharmacy terms and conditions to include minimum price concession terms for preferred cost sharing—to predict the overall change in Part D costs.

28. Effects of Maximum Allowable Cost Pricing Standard

We are proposing a change to the regulations at § 423.505(b)(21) and § 423.505(i)(3) governing the disclosure and updating of prescription drug pricing standards used by Part D sponsors to reimburse network pharmacies to make clear that drug pricing based on maximum allowable cost (MAC) is subject to these regulations. In the final rule at 76 FR 54600 (September 1, 2011), we did not estimate a regulatory impact for Part D sponsors to comply with the prescription drug pricing standard requirements, and we do not believe these proposed changes would result in any regulatory impact. Read together, the new provisions in § 423.501, § 423.505(b)(21), and § 423.505(i)(3)(viii) require sponsors, when applicable, to include provisions in network pharmacy contracts, to address the disclosure of MAC prices themselves to be updated to the applicable pharmacies

in advance of their use for reimbursement of claims, because the source of the MAC prices is not publicly available. Addressing prices that will be paid to a subcontractor is an activity undertaken in the normal course of business. Also, whether to use MAC prices is voluntary for Part D sponsors. Finally, sponsors must have procedures, systems, and technology currently in place to use these prices for reimbursement of pharmacy claims in the normal course of business. These systems would have to be adapted to also disclose the prices to pharmacies in advance of their use, which we believe would involve negligible effort for Part D sponsors' existing employees and/or subcontractors. Therefore, we estimate the impact of these provisions to be negligible.

29. Effects of Any Willing Pharmacy Standard Terms & Conditions

Proposed changes to § 423.120(a)(8) would require Part D sponsors to offer the contract terms and conditions (T&C) for every level of cost sharing offered under a Part D plan (preferred, standard retail, mail order, etc.) to any willing pharmacy. We expect the burden for Part D sponsors to amend contracts, where necessary, to offer every level of cost sharing would be negligible. Sponsors already must meet any willing pharmacy requirements for retail and mail order cost sharing. In 2013, nearly half of non-employer group Part D sponsors were designing and marketing plans with T&C for preferred cost sharing levels. For these sponsors, the only change associated with this proposal will be to ensure that now T&C for all levels of cost sharing, including preferred, are being offered (if they are not already) to all interested pharmacies. For the other half of Part D sponsors not currently offering preferred cost sharing options, this proposal does not require them to start.

Part D sponsors already negotiate contracts regularly with pharmacies in order to meet network access requirements. We estimate that for sponsors who currently offer benefit packages with a preferred cost sharing level (approximately 500 plans), an estimated new burden of 5,000 legal hours (500 plans × 10 hours) for revising contract language and 2,000 hours (500 plans × 4 hours) for additional contract support staff time negotiating with and assisting pharmacies contracting at the preferred cost sharing level for the first time. The estimated cost associated with this change is the estimated number of hours multiplied by available average hourly rates ($62.93 per hour for a lawyer, $32.22 per hour for a financial specialist [May 2012 wage data from Bureau of Labor Statistics Occupational Employment Statistics]), plus 48 percent for fringe benefits and overhead, which equals a first year cost of $561,053.20. Once a sponsor has revised contracts to meet the proposed requirement, no extraordinary additional expenses are anticipated for subsequent years. For a plan not currently offering preferred cost sharing levels, it is expected that preferred cost sharing terms and conditions would be offered to any willing pharmacy if they ever decide to offer them.

Any new burden on pharmacies is similarly expected to be negligible, as they are already reviewing and implementing terms from contracts, often annually. Pharmacies are not being directed to choose one set of T&C over another, but rather are gaining the option to review and implement terms for preferred cost sharing, if they so choose to accept the applicable negotiated pricing terms.

Beneficiaries are expected to benefit from an increased number of pharmacies offering preferred cost sharing levels.

30. Effects of Enrollment Requirements for the Prescribers of Part D Covered

Our proposal is that prescribers must be enrolled in Medicare in order for their prescriptions to be coverable under the Part D program. This will entail Part D sponsors or their designated PBMs checking the prescriber's individual NPI to determine whether the prescriber's is validly enrolled in Medicare before paying a claim from a network pharmacy or request for reimbursement from a beneficiary.

When we promulgated the NPI PDE requirement in a final regulation published on April 12, 2012 (77 FR 22072), we estimated the impact for PBMs and plan organizations to contract for or build prescriber ID validation services. Thus, while this proposal entails a new requirement for Part D sponsors, we do not believe it would have any new or additional impact because Part D sponsors must already have prescriber validation capabilities to meet the NPI PDE requirement.

Additionally, under our proposal, we do not estimate any savings. We presume that if a beneficiary's prescriber is not enrolled or does not enroll in Medicare, the beneficiary will find a new prescriber who is enrolled, rather than go without needed medications. Therefore, we do not estimate any savings from this proposal.

31. Effects of Improper Prescribing Practices and Patterns

Our proposed revisions in § 424.530(a)(11) and § 424.535(a)(13) would likely result in additional application denials and revocations. The DEA Web site found at *http://www.deadiversion.usdoj.gov/crim_admin_actions/index.html* contains a list of physicians, eligible professionals, and pharmacies that have had their DEA Certificate of Registration suspended or revoked since 2000. Based on our review of this data, we believe that approximately 200 Medicare-enrolled physicians and eligible professionals would be affected by proposed § 424.535(a)(13). However, we do not have data available to assist us in calculating the potential costs to physicians and eligible professionals in lost potential billings or the potential costs or savings to the government arising from this provision; nor are we able to estimate the number of denials per year that would result from proposed § 424.530(a)(11).

Our proposed § 424.535(a)(14) would result in an increase in the total number of revocations under § 424.535(a). We are unable, though, to project the number of providers and suppliers that would be revoked under § 424.535(a)(14) because we do not have data available that can be used to make such an estimate. Thus, we cannot project: (1) The potential costs to providers and suppliers in lost billings, or (2) the potential costs or savings to the government arising from our proposed provision.

32. Effects of the Transfer of TrOOP Between Part D Sponsors Due to Enrollment Changes During the Coverage Year

We do not expect that codifying the requirement for Part D sponsors to report TrOOP-related data to a subsequent plan in which a beneficiary enrolls during the coverage year, and for the new plan to accept that data and use it to position the beneficiary in their benefit would generate savings or increase costs.

We expect the requirement to report TrOOP-related data and to accept and use the data to position a beneficiary in a new plan benefit when the member changes plans during the coverage year would ensure the Part D benefit is correctly administered by the new plan and prevent a beneficiary who has already moved through the initial phase(s) of the Part D benefit from starting the benefit anew as a result of the enrollment change.

33. Effects of Broadening the Release of Part D Data

We are proposing to revise our regulations governing the release of Part D data to expand the release of unencrypted prescriber, plan and pharmacy identifiers contained in prescription drug event (PDE) records to external researchers, as well as to make other changes to our policies regarding release of PDE data, as currently codified at § 423.505(f)(3) and (m). This proposal does not impose any new costs on any stakeholders. Medicare Part D plan sponsors are already required to, and do, submit the information that may be released in accordance with this proposal. Therefore, we are not including any assessment of this proposal for the regulatory impact statement.

34. Effects of Establish Authority to Directly Request Information From First Tier, Downstream, and Related Entities

Pursuant to sections 1857(d)(2) and 1860D 12(b)(3)(c) of the Act, we are now proposing to specify at § 422.504(i)(2)(ii) and § 423.505(i)(2)(ii) that HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any records directly from any first tier, downstream, or related entity. This proposed regulatory change would not grant CMS (or the MEDIC, the contractor that conducts fraud investigations on our behalf) any oversight authority beyond what we already possess.

In enabling CMS or its designee(s) to directly request information from a first tier, downstream, or related entity, we would provide a more efficient avenue to obtain necessary information. This proposal would change the current policy, which requires going through the plan sponsor in order to collect information. Our proposal would save money and time for CMS as well as the plan sponsor.

We anticipate that adoption of this proposal would result in cost savings for plan sponsors. Under the current regulatory structure, assuming that the MEDIC (the CMS contractor that typically would put forth such requests) puts forth 1000 requests per year to Part C and D sponsors, each request requires the plan sponsor to spend 5 hours developing and making the request for information from its first tier, downstream, or related entity, and communicating the results of that request back to CMS. At a rate of $55 per hour, plan sponsors may save a total of $275,000 in employee costs in the aggregate. Additionally, we believe this provision will have a very minor savings impact on the federal budget. This calculation is based on the savings in time and effort the MEDIC will experience (2 hours per information request) resulting from the ability to request information directly from first tier, downstream, and related entities. The 2 hours reflects the time the MEDIC currently spends resolving ambiguities in the request or in the information provided in response that are created by the presence of an intermediary (that is, the plan sponsor) between the requestor (MEDIC) and the custodian of the information (that is; first tier, downstream, or related entity).

In addition to cost savings, this proposed regulatory change will reduce the administrative burden on plan sponsors. The plan sponsor will no longer have to act as the gatekeeper between the MEDIC and its first tier, downstream, or related entity.

We do not anticipate any additional burden relating to the proposed requirement that we alert the plan sponsor that we are contacting its first tier, downstream or related entity since CMS will be merely copying the plan sponsor on the request.

35. Effects of Eligibility of Enrollment for Incarcerated Individuals

We are proposing to amend § 417.460(b)(2)(i), § 417.460(f)(1)(i), § 422.2, § 422.74(d)(4)(i)(A), § 422.74(d)(4)(v), § 423.4, and § 423.44(d)(5) to clarify the eligibility requirement for residing in the plan's service area related to incarceration for the purposes of enrolling into and remaining enrolled in MA, Part D, and Medicare cost plans. We expect the impact of this change to be primarily that of savings to the MA and Part D programs. In CY 2012, there were close to 50 million Medicare beneficiaries. Approximately 34.4 million of those beneficiaries were enrolled in MA plans, PDPs, or cost plans which accounts for 68.8 percent of the total Medicare population. In the same year, an average of 21,329 Medicare beneficiaries enrolled in MA or Part D plans were identified by SSA as being incarcerated.

We issued guidance to MA plans and PDPs to investigate each individual's incarcerated status and disenroll the individual for no longer residing in the plan's service area if the plan confirmed incarcerated status. If the MA plan or PDP could not confirm the incarcerated status, those plans were to continue to investigate each instance of incarceration for up to 6/12 months and disenroll the individuals at the end of that time following § 422.74(b)(4)(ii)/ § 423.44(b)(5)(ii) if they couldn't verify the incarcerated status sooner. As a result, the plan received capitated payments when the individual was ineligible to receive payment of Medicare benefits. Section 1876 Cost contracts had no such instructions to disenroll individuals who are incarcerated. By directing MA plans, PDPs, and cost plans to disenroll incarcerated individuals at the time of notification from CMS, we intend to prevent improper payment for these individuals to MA plans, PDPs, and cost plans for periods when they were ineligible to receive such services. Based on the data for capitation payments for MA and PDPs, as well as the prepayments provided to cost plans, we estimate that the disenrollment of incarcerated individuals would result in a decrease in payments made by CMS and would result in a cost savings of $70 million in 2015.

We estimate, based on the numbers mentioned previously, that this change could save the MA program approximately $27 million in 2015, increasing to $62 million in 2019, and could save the Part D program (includes the Part D portion of MA–PD plans) approximately $46 million in 2015, increasing to $90 million in 2019. As cost plans are paid based on the reasonable costs delivering Medicare-covered services to their enrollees, instead of the fixed capitation amounts paid to MA and PDPs, we believe the impact to cost plans associated with this provision to be negligible.

TABLE 11—PROJECTED NUMBER OF INDIVIDUALS DISENROLLED DUE TO INCARCERATION AND ESTIMATED SAVINGS TO THE MEDICARE ADVANTAGE PROGRAM BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2019

| | 2015 | 2016 | 2017 | 2018 | 2019 | Totals (CYs 2105–2019) |
|---|---|---|---|---|---|---|
| Projected number of incarcerated beneficiaries enrolled in MA plans ..... | 6,280 | 7,750 | 9,221 | 10,691 | 12,162 | 46,104 |

TABLE 11—PROJECTED NUMBER OF INDIVIDUALS DISENROLLED DUE TO INCARCERATION AND ESTIMATED SAVINGS TO THE MEDICARE ADVANTAGE PROGRAM BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2019—Continued

| | 2015 | 2016 | 2017 | 2018 | 2019 | Totals (CYs 2105–2019) |
|---|---|---|---|---|---|---|
| Projected federal impact due to incarcerated individuals disenrolled 6 months sooner | [1] – $27 | [1] – $35 | [1] – $43 | [1] – $52 | [1] – $62 | [1] – $219 |

**Note:** Estimates reflect scoring by the CMS, Office of the Actuary, and 2012 incarceration data provided by the SSA.
[1] Million.

TABLE 12—PROJECTED NUMBER OF INDIVIDUALS DISENROLLED DUE TO INCARCERATION AND ESTIMATED SAVINGS TO THE MEDICARE PART D PROGRAM BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2019

| | 2015 | 2016 | 2017 | 2018 | 2019 | Totals (CYs 2015–2019) |
|---|---|---|---|---|---|---|
| Projected number of incarcerated beneficiaries enrolled in Part D plans (including MA–PDs) | 49,275 | 55,970 | 62,666 | 69,362 | 76,058 | [1] 313,331 |
| Projected federal impact due to incarcerated individuals disenrolled 12 months sooner | [2] – $46 | [2] – $55 | [2] – $65 | [2] – $77 | [2] – $90 | [2] – $333 |

**Note:** Estimates reflect scoring by the CMS, Office of the Actuary, and 2012 incarceration data provided by the SSA.
[1] Accumulated; not unique individuals.
[2] Million.

36. Effects of Rewards and Incentives Program Regulations for Part C Enrollees

This proposal would permit plans to provide limited rewards and incentives to enrollees who participate in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources. While there would be a cost associated with providing rewards and incentives, we anticipate that there may be savings as a result of healthier beneficiary behavior. Because plans are not required to provide rewards and incentives and CMS does not have a means of calculating the costs and benefits of rewards/incentives at this time, we are not providing an impact analysis for this provision.

37. Effects of Expand Quality Improvement Program Regulations

The proposed regulation changes are only technical changes for the established quality improvement program requirements. These changes would clarify how MA organizations report quality improvement program information to CMS. As MA organizations are already reporting this information to CMS and the changes are only to codify the process, the changes will not increase costs for MA organizations.

38. Effects of Authorization of Expansion of Automatic or Passive Enrollment Non-Renewing Dual Eligible SNPs (D–SNPs) to Another D–SNP To Support Alignment Procedures

We propose to modify the situations in which CMS may passively enroll beneficiaries to include the situation when a Medicare Advantage Dual Eligible SNP (D–SNP) is non-renewing. More specifically, passive enrollment would be permitted for full-benefit dual eligible beneficiaries in the non-renewing D–SNP when there is another D–SNP in the service area that offers substantially similar benefits, network, and cost-sharing as the non-renewing D–SNP, and that also offers the Medicaid managed care organization in which the beneficiary is enrolled.

SNPs are due to sunset in 2014. Consequently, we are not scoring this provision for contract years 2015 through 2019.

39. Effects of Improving Payment Accuracy: Reporting Overpayments, RADV Appeals, Part D Payment Reopening, LIS Cost Sharing, and Coverage Gap Discount Program

This proposed section proposes only technical changes for overpayment reporting, RADV appeals, Part D payment reopening, LIS cost sharing, and the Coverage Gap Discount Program. These technical changes will not result in costs to MA organizations and Part D sponsors, nor do we expect the impact of these technical changes to result in savings.

40. Effects of Part C and Part D RAC Determination Appeals

In section III.B.x of this proposed rule, to establish an administrative appeals process for overpayment determinations by the Part C and Part D RACs. The cost associated with these provisions involves the preparation and submission of appeal requests by plans. We estimate this cost to be $48,343 as summarized in the following Table 13.

TABLE 13—SUMMARY OF RAC DETERMINATION APPEALS COSTS AND BENEFITS

| Provision description | Costs (in $millions) | Benefits |
|---|---|---|
| Submission of MA plans' first level Request for Reconsideration. | 0.02167 | Administrative appeal rights and accuracy in recovery demands. |
| Submission of Part D plans' first level Request for Reconsideration. | 0.02167 | Administrative appeal rights and accuracy in recovery demands. |
| Submission of MA plans' second level Request for Review | 0.00208 | Administrative appeal rights and accuracy in recovery demands. |

TABLE 13—SUMMARY OF RAC DETERMINATION APPEALS COSTS AND BENEFITS—Continued

| Provision description | Costs (in $millions) | Benefits |
|---|---|---|
| Submission of Part D plans' second level Request for Review | 0.00208 | Administrative appeal rights and accuracy in recovery demands. |
| Submission of MA plans' third level Request for Review by the CMS Administrator. | 0.0004 | Administrative appeal rights and accuracy in recovery demands. |
| Submission of Part D plans' third level Request for Review by the CMS Administrator. | 0.0004 | Administrative appeal rights and accuracy in recovery demands. |

41. Effects of Requirement To Provide High Quality Health Care

The proposal to add contractual requirements for MA plans and Part D plans to provide high quality health care proposes to include in the terms and conditions in our contracts with Part D sponsors and explicit requirement that Part D plans administer a benefit that promotes and supports high quality care. We believe that we have conveyed this expectation in other ways, such as through our performance and quality measurements and methodologies. This proposal provides a basis for enforcement or corrective action for low-performing plans. Therefore, we do not believe there is an impact associated with this proposal.

42. Effects of MA–PD Coordination Requirements for Drugs Covered Under Part D

To ensure that Part A, Part B and Part D drug benefits are coordinated by MA–PDs so that enrollees receive needed medications on a timely basis, we are proposing to add a new section (b)(7) to § 422.112 to require MA–PDs to establish adequate messaging and processing requirements with network pharmacies to ensure that appropriate payment is assigned at the point of sale (POS) and to ensure that when coverage is denied under Part D due to available coverage under Part A or Part B, that such coverage is authorized expeditiously so that the drug may be provided to the enrollee as his or her health condition requires. Our proposed regulation requires that MA–PDs have systems in place to accurately and timely adjudicate claims at the POS.

In addition, we would like to ensure that MA–PD plans are coordinating their benefits appropriately during the coverage determination process. If an MA–PD denies PDP coverage due to the availability of Part A or Part B coverage, we expect the MA organization to ensure that the decision results in authorization or provision of the drug under Part B pursuant to the requirements in parts 422 and 423, subpart M. We do not expect MA–PD enrollees to have to request an initial Part A or B versus Part D coverage determination more than once. We are soliciting comments about our proposal, as well as other possible approaches to minimizing delays in beneficiary access to needed medications caused by inadequate coordination of Part A, Part B and Part D benefits at the POS and during the coverage determination process. In particular, we would appreciate organizations sharing their expertise regarding best practices for benefit coordination at the POS and plan processes that enhance those coverage determinations. We also are soliciting comments on challenges MA–PDs currently encounter in their efforts to integrate these benefits. Under Medicare regulations MA–PD plans are already required to coordinate member coverage for both Part A and B and Part D covered drugs. It is our understanding that the majority of MA–PDs are effectively performing this activity. However, we are aware that some MA–PDs have been less successful. With this regulation we propose to identify drug coverage standards that all MA–PDs can follow that have proven to be both cost effective and efficient. This proposed regulation does impose any new requirements or costs but rather will assist low performing MA–PDs in clarifying the necessary actions to meet existing regulatory requirements for the effective coordination of Part A, Part B and Part D covered drugs.

43. Effects of Revisions to Good Cause Processes

We are proposing to revise § 417.460, § 422.74, and § 423.44 to allow an entity acting on behalf of CMS to conduct good cause reviews. Shifting responsibility for this activity from CMS to entities such as MA, Part D and cost plans would not change the number of individuals requesting reinstatement for good cause nor the number of those individuals who meet the criteria for reinstatement. While some plans may increase their bids to cover the costs to complete this work, the administrative burden to plans is negligible. Therefore, we do not expect this change to have a monetary impact to the Medicare Trust Funds or affect enrollment, as the policies permitting involuntary disenrollment for non payment of premiums and allowing beneficiaries to request reinstatement for good cause have been in existence for some time.

44. Effects of the Definition of Organization Determination

The proposed revisions at § 422.566 are intended to clarify the meaning of organization determination and to maintain consistency between the regulatory definition of organization determination and the definition used elsewhere in CMS documents and subregulatory guidance. Specifically, we are seeking to include additional types of coverage decisions that are subject to Medicare appeals processing requirements set forth in subpart M. In other words, cases where a provider under contract with an MA organization provides a service directly to an enrollee and when a contract provider refers an enrollee to a non-contract provider for an item or service. Because this proposed change codifies the existing definition of organization determination, this proposal does not represent any new burden on MA organizations or burden for small businesses, rural hospitals, states or the private sector.

45. Effects of MA Organization Extension of Adjudication Timeframes for Organization Determinations and Reconsiderations

The proposed changes to § 422.568(b), § 422.572(b), and § 422.590 would clarify the limited circumstances in which MA organizations are permitted to extend the adjudication timeframe for organization determinations and reconsiderations. We believe these proposed changes would have a minimal impact on MA organizations, because they are not likely to alter the number of coverage requests plans would receive or the required clinical resources to process each request. During audits of MA organizations, we identified cases where plans are improperly extending the applicable adjudication timeframe (for example,

where clinical documentation is needed from a contract provider or where the plan has failed to develop and review the case during the required timeframe) but we do not have data on the overall frequency with which extensions are being invoked and what percentage of those cases involve the scenarios described.

46. Effects of Two-Year Prohibition When Organizations Terminate Their Contracts

As part of a group of proposals intended to strengthen our ability to distinguish stronger applicants for Part C participation we propose to revise the regulation text at § 422.506 and § 422.512 to explicitly apply the 2-year prohibition on re-application after an organization has terminated its contract to applications for service area expansions in addition to applications for new contracts. These changes to § 422.506 and § 422.512would make the text of these regulations consistent with the language of a similar provision at § 422.503 and § 422.508 (which bans re-application for 2 years after we have terminated an organization's contract). We believe this provision will have minimal financial impact as it only affects those organizations that choose to non-renew or mutually terminate a contract with CMS. This provision will not affect current beneficiaries as it only applies when an organization is applying for a new contract or to expand the service area of its existing contract; beneficiaries who are currently enrolled in an organization's existing contracts are therefore not affected.

47. Effects of Withdrawal of Stand Alone Prescription Drug Plan Bid Prior to Contract Execution

This provision is not anticipated to have any significant impacts, as the withdrawn bids that this provision would not relate to any existing enrollees.

48. Effects of Essential Operations Test Requirement for Part D

This provision has no quantifiable impact because the requirement affects unknown individuals/entities in the future. Nevertheless, we believe this proposal to require new Part D sponsors to pass an essential operations test prior to being permitted to accept enrollments will enhance our ability to ensure that beneficiaries are permitted to choose only from among those Part D plans offered by sponsors truly qualified to administer the full range of benefits to which beneficiaries are entitled. This approach will reduce both the likelihood of disruptions in beneficiaries' access to outpatient prescription drugs and the resources CMS has to dedicate to addressing such disruptions.

49. Effects of Termination of the Contracts of Medicare Advantage Organizations Offering Part D for Failure for Three Consecutive Years To Achieve Three Stars on Both Part C and Part D Summary Star Ratings in the Same Contract Year

This provision has no quantifiable impact because this affects unknown individuals/entities in the future. We believe the proposal to authorize the termination of contracts that fail to achieve three-star ratings for both Part C and D within three years is consistent with our overall emphasis on ensuring that beneficiaries receive quality services from their plan sponsors. Eliminating poor performing contracts will promote beneficiary satisfaction with the Part C and D programs and reduce the amount of effort we must apply to overseeing and correcting the performance of organizations that consistently fail to demonstrate a commitment to quality.

50. Effects of Requirements for Urgently Needed Services

The proposed revisions of § 422.113(b)(1)(iii) removes the requirement of ''extraordinary and unusual'' for in-service-area, out-of-network coverage for urgent needed services. Typically, this will mean that enrollees with non-emergent weekend medical problems will now be covered for services furnished out of network thus eliminating the need for beneficiaries to seek out-of-network care. Many plans already contract with 24/7 walk-in clinics providing in-network coverage. Historically, the alternative to plan coverage has been emergency-room care. We therefore expect minimal cost and possible savings as a result of this change.

51. Effects of Skilled Nursing Facility Stays

Our proposal that would relocate the MA regulation language currently located at § 422.101(c), ''Requirements Related to Basic Benefits'' to § 422.102(a)(5), ''Supplemental Benefits'' is a technical change only and would have no financial impact.

52. Effects of Agent and Broker Training and Testing Requirements

At § 422.2274 and § 423.2274, we are proposing to revise § 422.2274(b) and (c) and § 423.2274(b) and (c) to remove the concept of a CMS endorsed or approved training and testing, and require instead that agents be trained and tested annually, as specified by CMS. We believe this proposed change continues to ensure that all agents/brokers selling Medicare products have a comprehensive understanding of Medicare program rules. The changes made to this regulation will not result in any additional costs for MA plans or Part D plans, or a new collection of information. We are simply revising the existing language to remove an obligation for CMS to endorse or approve a training program in favor of CMS providing such training directly.

53. Effects of Deemed Approval of Marketing Materials

At § 422.2266 and § 423.2266, CMS provides the regulatory requirements for materials that are deemed approved. It also provides the requirements for the review and distribution of marketing materials. We are proposing to move the current requirements in §§ 422.2266 and 423.2266 to §§ 422.2262(a)(2) and 423.2262(a)(2), respectively. We also propose to simplify the language in §§ 422.2266 and 423.2266 by stating if CMS does not approve or disapprove marketing materials within the specified review timeframe, the materials will be deemed approved. Deemed approved means that a MA organization or Part D sponsor may use the material. Changes to this regulation will not result in additional. We are simply revising the existing language to clarify the existing requirements for deemed approved materials.

54. Effects of Part C Disclosure Requirements

This provision would simply replace the current, incorrect, reference in § 422.111 to the marketing materials and elections form requirements at § 422.80, with the correct reference to subpart V, Medicare Advantage Marketing Requirements. This is a technical change and represents no costs or impact.

55. Effects of Managing Disclosure and Recusal in P&T Conflicts of Interest: Formulary Development and Revision by a Pharmacy and Therapeutics Committee Under Part D

We propose to revise our regulations at § 423.120(b)(1) to reorder the existing provisions and add a new paragraph (b)(1)(iv) to require that a Part D sponsor's P&T committee clearly articulates and documents processes to determine that the requirements under paragraphs (b)(1)(i), (ii), and (iii) have been met, including the determination by an objective party of whether disclosed financial interests are

conflicts of interest and that management of any recusals due to such conflicts of interest.

Because plans were previously required to have these processes in place, and we are only asking that they document them, we anticipate that there would be no cost impact on plans.

56. Effects of the Technical Changes to the Definition of Part D Drug

There is no impact associated with this provision as it is a technical change to regulation language.

57. Effects of Thirty Sixth Month Coordination of Benefits (COB) Limit

There is no impact associated with this provision as it is a technical change to regulation language.

58. Effects of Application and Calculation of Daily Cost-Sharing Rates

There is no impact associated with this provision, as it is a technical change to regulation language.

59. Effects of Technical Change To Align Regulatory Requirements for Delivery of the Standardized Pharmacy Notice

Our proposed revision to § 423.562(a)(3) is a technical change and does not represent a burden for small businesses, rural hospitals, states, or the private sector.

60. Effects of Special Part D Access Rules During Disasters

In proposed § 423.126(a), we would codify requirements similar to existing guidance that pertains to relaxing ''refill-too-soon'' (RTS) edits to permit one refill in the event of any imminent or occurring disaster or emergency that would hinder an enrollee's access to covered Part D drugs.

The proposed changes would not result in any additional costs. For one, we currently expect through guidance that sponsors will relax edits after the issuance of certain federal declarations. We also do not anticipate that providing a general framework for when sponsors must relax RTS edits would necessitate an increase in resources because it is currently not uncommon for Part D sponsors to relax edits for particular individuals under certain circumstances.

The proposed provisions would require Part D sponsors to relax ''refill-too-soon'' (RTS) edits when, as evidenced by a declaration of a disaster or emergency or its imminence by an appropriate federal, state, or local official, it is reasonable to conclude that an occurring or imminent disaster or emergency would make it difficult for beneficiaries to obtain refills of their medications. Relaxing RTS edits in these circumstances would benefit beneficiaries by better ensuring that they do not run out of their medications when a disaster is imminent or after it strikes.

61. Effects of MA Organization Responsibilities in Disasters and Emergencies

The proposed addition of section § 422.100(m) requires plan activities during disasters that are currently recommended in our guidance. Since plans are already cooperating with our recommendations we expect no impact as a result of this requirement. Additionally, we are requiring a dedicated Web page for disasters on plan Web sites. Since plans already have Web sites and technical staff supporting them, we expect minimal cost, if any, for the additional page. We are also requiring plans to annually notify enrollees about disaster preparation. Since plans, as required at § 422.111, already annually notify beneficiaries using the Evidence of Coverage template, we expect minimal cost, if any, for the additional notification about disasters.

62. Effects of the Technical Changes Regarding the Termination of a Contract, Contract Determination and Other Appeals, and Intermediate Sanctions and Civil Money Penalties Under Parts C and D

Sections III.E.13. and 14 this proposed rule include provisions making minor technical and clarifying changes. These changes include making language consistent, aligning titles and correcting references. These technical and clarifying changes will not result in additional burden to sponsors nor will they have a financial impact on sponsors.

63. Effects of Technical Change to the Restrictions on use of Information Under Part D

There is no impact associated with this provision as it is a technical change to regulation language to reflect the expansion, pursuant to section 6402(b)(1) of the Affordable Care Act, in the purposes for which HHS, its contractors, and the Attorney General, and Comptroller General may use information disclosed or obtained pursuant to section 1860D–15 of the Act.

TABLE 14—ESTIMATED [1] AGGREGATE COSTS AND SAVINGS TO THE HEALTH CARE SECTOR BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2019

| Provision | Regulation section(s) | Calendar year ($ in millions) | | | | | Total ($ in millions) CYs 2015–2019 |
|---|---|---|---|---|---|---|---|
| | | 2015 | 2016 | 2017 | 2018 | 2019 | |
| **Impacts to MA Organizations and Part D Sponsors** | | | | | | | |
| A.6. Changes to Audit and Inspection | § 422.503(d)(2), § 423.504(d)(2). | 8.9 | 8.9 | 8.9 | 8.9 | 8.9 | 44.5 |
| Total ($ in millions) | | 8.9 | 8.9 | 8.9 | 8.9 | 8.9 | 44.5 |
| **Federal Government (Medicare) Impacts** | | | | | | | |
| A.10. Enrollment Eligibility for Individuals Not Lawfully Present in the United States [2]. | § 422.1, § 422.50, AND § 422.74; § 423.1, § 423.30, and § 423.44. | −10 | −12 | −13 | −15 | −17 | −67 |
| A.14. Drug Categories or Classes of Clinical Concern and Exceptions [3]. | § 423.102(b)(2)(v)–(vi) | 0 | −30 | −50 | −220 | −420 | −720 |
| A.35. Eligibility of Enrollment for Incarcerated Individuals [4]. | § 422.74 | −73 | −90 | −108 | −129 | −152 | −552 |

TABLE 14—ESTIMATED [1] AGGREGATE COSTS AND SAVINGS TO THE HEALTH CARE SECTOR BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2019—Continued

| Provision | Regulation section(s) | Calendar year ($ in millions) | | | | | Total ($ in millions) CYs 2015–2019 |
|---|---|---|---|---|---|---|---|
| | | 2015 | 2016 | 2017 | 2018 | 2019 | |
| Total ($ in millions) | | −83 | −132 | −171 | −364 | −589 | −1,339 |

**Notes:**

[1] Estimates of costs and savings reflect scoring by the CMS, Office of the Actuary. Also, only provisions with savings or cost exceeding $1,000,000 are listed. Other provisions either have no expected savings or cost, or, have a savings or cost under $1,000,000. Details on these savings and cost may be found in the RIA narrative.

[2] Supporting 2012 lawful presence data provided by SSA.

[3] Projected savings are based upon full implementation of the criteria and do not reflect that changes for the antipsychotic class of drugs are deferred at this time.

[4] Supporting 2012 incarceration data provided by the SSA.

*D. Expected Benefits*

1. Drug Categories or Classes of Clinical Concerns and Exceptions (§ 423.102(b)(2)(v)–(vi)

Proposed codification of the categories or classes of clinical concern provisions would assist PBMs in applying the Part D plans and managing the Part D sponsor's benefit packages more efficiently.

2. Medication Therapy Management Program under Part D

We anticipate that many more beneficiaries will have access to MTM services and believe that the proposed changes will simplify the MTM criteria and minimize beneficiary confusion when choosing or transitioning between plans. Moreover, we believe the proposed changes would reduce disparity and allow more beneficiaries with drug therapy problems to receive MTM services. Similarly, we expect the proposed requirement that sponsors develop an effective strategy to ensure access to services for all MTM-eligible beneficiaries will help to ensure that beneficiaries in special populations receive focused targeting, outreach, or engagement for enrollment or participation in MTM.

*E. Alternatives Considered*

1. Separating the Annual Notice of Change from the Evidence of Coverage

We considered reverting back to requirements in place prior to the 2009 contract year, which allowed issuing EOCs as late as January 31 of the applicable contract year. We determined the EOC should be received by members before the effective date of their coverage for that contract year, beginning on January 1, in order for members to have full disclosure of plan rules prior to the beginning of the contract year.

2. Modifying the Agent/Broker Compensation Requirements

In the preamble we outlined a few alternative compensation schedules. Ultimately we determined that the best approach was a two tier payment schedule, incorporating an initial payment and a continuous renewal payment.

3. Medicare Coverage Gap Discount Program and Employer Group Waiver Plans

In the preamble we outlined the alternative approaches we considered in our efforts to make sure that the discounts were used to benefit enrollees. Ultimately we determined that the best approach would be to make sure that employer groups have the information needed to incorporate the payments into their benefit packages.

4. Prescription Drug Pricing Standards and Maximum Allowable Cost

No alternatives were considered.

5. Access to Covered Part D drugs (c) Use of Standardized Technology

No alternatives were considered.

6. Any Willing Pharmacy Standard Terms & Conditions

We considered the alternative of maintaining the current process where Part D plans can limit pharmacy access to preferred cost-sharing contracts. We have observed this in practice to be limiting market competition, creating a barrier to entry, and further, not producing the savings to the program that were initially anticipated.

7. Negotiated Prices

We did not identify any alternatives that both maintained consistent reporting among sponsors leading to comparable bids, and maximized price competition.

8. Preferred Cost Sharing

We considered whether a methodology that was based on lower average costs (or any other function of costs in the rest of the network) in return for preferred cost sharing would suffice to meet the statutory requirement. While such a methodology might technically meet the requirement not to increase CMS payments to plans, whether it did so or not would be dependent on the actual negotiated prices paid and could be determined only long after a coverage year had ended and complete the PDE data was available. We believe that to promote price competition, the relative levels of negotiated prices offered for preferred cost sharing and in the rest of the network should be transparent and verifiable at the point of sale, as well as to CMS oversight at any point prior to and during a coverage year. We were unable to identify any methodology other than our proposal to accomplish these goals. We solicit comments on alternative approaches to ensuring that the offering of preferred cost sharing does not increase CMS payments. We believe that any alternative methodology must be based solely on the level of negotiated prices and thus consistent with our proposal to amend that definition. We also solicit comments on whether we should also establish standards on how much lower drug costs should be in return for preferred cost sharing.

9. Transfer of TrOOP Between Part D Sponsors Due to Enrollment Changes During the Coverage Year

No alternative proposals were considered.

10. Part D Notice of Changes

We did not consider any alternatives for the proposed provision because it proposes to codify a longstanding policy.

11. Special Part D Access Rules During Disasters or Emergencies

We did not consider alternatives to requiring Part D sponsors to lift ''refill too soon'' (RTS) edits in the event of any imminent or occurring disaster or emergency that would hinder an enrollee's access to covered Part D drugs. It is important for the well-being and health of beneficiaries that they be able to obtain their medications after disasters strike. Furthermore, given the complexities of moving large numbers of people with different health conditions to safer locations, we also believed we had no alternative but to require Part D sponsors to relax RTS edits when a disaster is imminent and access to services might be jeopardized rather than waiting for it to strike.

12. Business Continuity for MA Organizations and Part D Sponsors

We did not consider any alternatives for the initial part of the provision found in §§ 422.504(o)(1) and 423.505(p)(1) that would, respectively, require MA organizations and Part D sponsors to develop and maintain business continuity plans. Creating such a plan is an accepted business practice and we would require MA organizations and Part D sponsors to address a standard list of areas; in short, we know of no other options.

In contrast, we considered other options when drafting proposed §§ 422.504(o)(2) and 423.505(p)(2), which would require the restoration of essential functions within 24 hours after failure. We considered requiring MA organizations and Part D sponsors to restore even more functions, but decided disruptions to business would presumably limit resources and that it was important to focus on only the most vital functions. We also considered paring down the list of essential functions, but found that we could not do so without jeopardizing the mandate of the Act—to ensure access to health care and covered Part D drugs through the provision of appropriate Medicare benefits. Benefit authorization, claim adjudications, and call center operations are all essential to providing appropriate Medicare coverage for beneficiaries both living inside and outside of areas hit by disasters and other disruptions.

Lastly, we considered the option of requiring restoration of essential functions to occur for a shorter or longer time period than 24 hours after failure proposed. We decided that 12 hours might present operational challenges for MA organizations and Part D sponsors; conversely, requiring beneficiaries to wait more than 24 hours to access their coverage and therefore health care and drug benefits, seemed to pose an undue risk to both their present and possibly future health and well-being.

13. Drug Categories or Classes of Clinical Concerns and Exceptions

The critical policy decision was how broadly or narrowly to establish criteria and exceptions to those criteria pursuant to Affordable Care Act provisions. Broad criteria might easily encompass many classes of drugs and significantly increase costs to the Part D program by eliminating the need for manufacturers to aggressively rebate their products for formulary placement. Only narrow criteria would limit the number of categories or classes of clinical concern receiving additional protections under the Affordable Care Act. Similarly, broad exceptions further limit the products within those categories or classes of clinical concern that would receive additional protection under the Affordable Care Act.

14. Medication Therapy Management Program (MTM) Under Part D

We considered leaving the maximum number of multiple chronic diseases a plan may require for targeted enrollment at three, but believed this threshold significantly limited the number of beneficiaries who qualified for MTM services and was inconsistent with literature concerning the relative risk of the combination of multiple disease states and the need for access to MTM interventions. Similarly, we considered other numbers of Part D drugs less than eight, but again believed these thresholds decreased access to MTM services, contributed to beneficiary confusion, and led to racial disparities in access to MTM services. We also considered other cost thresholds less than $3,000, for example, $900 or $1,200, which roughly coincide with cost thresholds achieved by taking 3 or 4 generic drugs, and we solicit stakeholder comment on where the threshold might alternatively be set.

Relative to the requirement for sponsors to establish effective strategies for reaching all MTM-eligible beneficiaries, we do not believe it is appropriate at this time to prescribe outreach activities for Part D sponsors to effectively reach diverse, special populations of their enrolled beneficiaries. Rather, we propose that sponsors develop an effective strategy to ensure access to MTM services for all MTM-eligible beneficiaries. We will continue to monitor the efficacy of such programs and the impact of any change to the requirements and will consider other options as may be necessary.

15. Requirement for Applicants or Their Contracted First Tier, Downstream, or Related Entities To Have Experience in the Part D Program Providing Key Part D Functions

Based on CMS' authority at section 1860D–12(b)(3)(D) of the SSA to adopt additional contract terms that are necessary and appropriate to administer the Part D program, we proposed at § 423.504(b)(8)(i) through (iii) that Part D organizations seeking a new Medicare contract must have arrangements in place such that either the applicant or a contracted entity that will be performing certain key Part D functions has at least one full benefit year of experience providing the function for another Part D plan sponsor. This proposal ensures that applicants take advantage of the abundant Part D industry expertise and experience that exists today in the development of their Part D program operations, rather than relying on technical assistance from CMS and having their inexperience place beneficiaries' access to prescription drugs at risk. We believe this provision will have a very minor savings impact on the federal budget, based on savings of time and effort (staff time and contracted auditor time and resources) that the government would spend on overseeing the disproportionate level of problems experienced by organizations operating Part D plans without prior Part D experience. For each inexperienced organization allowed into the program in the absence of this proposal, we would anticipate a savings of 1,000 staff hours at an average rate of $50 per hour, for a total of $50,000 in employee time, plus an additional savings of $200,000 in contractor dollars to conduct an emergency audit, for a total of $250,000. In the absence of this proposal, we would anticipate no more than two such inexperienced entities beginning Part D operations per year, for a total annual savings of $500,000.

The burden associated with this proposal on industry would be minimal, with a total estimated number of labor hours of 3.25 to submit information during the Part D application process. Using the same average hourly salary as previously mentioned, the total cost to Part D applicants would be $162.50. We do not believe there are any non-administrative costs to industry associated with this proposal, as Part D applicants are already required to have arrangements in place to perform the key Part D functions discussed in our proposal.

The main anticipated effect from this proposal is ensuring that only entities

with some experience with Part D in critically important functional areas are permitted to offer new Part D contracts, thus strengthening the Part D program by enhancing the qualification criteria. CMS considered the alternate proposal of requiring the prior Part D experience to be tied to specific quality outcomes. CMS rejected the alternative because we believed it added unnecessary complexity and burden to the process, and we believe a simple experience requirement is currently sufficient.

*F. Accounting Statement and Table*

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a0004/a-4/pdf*), in Table 15, we have prepared an accounting statement showing the classification of the expenditures, costs, and savings associated with the provisions of this proposed rule for CYs 2015 through 2019.

TABLE 15—ACCOUNTING STATEMENT: CLASSIFICATIONS OF ESTIMATED COSTS AND TRANSFERS FROM CALENDAR YEARS 2015 TO 2019

[$ in millions]

| Category | Transfers | | |
|---|---|---|---|
| | Discount rate | | Period covered |
| | 7% | 3% | |
| Annualized Monetized Transfers (Federal) | −$251.23 | −$260.49 | CYs 2015–2019. |
| Whom to Whom? | Federal Government, MA Organizations and Part D Sponsors | | |
| | Costs (all other provisions) | | |
| | Discount rate | | Period covered |
| | 7% | 3% | |
| Annualized Costs to MA Organizations and Part D Sponsors | $8.9 | $8.9 | CYs 2015–2019. |

**Note:** Monetized Figures in 2014 Dollars.

*G. Conclusion*

We estimate the savings to the federal government from implementing these provisions will be $83 million in CY 2015. The savings will increase annually. In CY 2019, the federal government savings from implementing these provisions will be $589 million. For the entire estimated period, CYs 2015 through 2019, we estimate the total federal government (Medicare) impact to result in savings of approximately $1.34 billion in 2014 dollars. The cost impact to MA organizations and Part D sponsors is estimated at $8.9 million annually during CYs 2015 through 2019. We note that these savings do not represent net social benefits because they consist of transfers of value from drug manufacturers, pharmacies, incarcerated individuals and individuals not lawfully present in the United States to the federal government, MA organizations, Part D sponsors and beneficiaries who continue in the programs.

**List of Subjects**

*42 CFR Part 409*

Health facilities and Medicare.

*42 CFR Part 417*

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, and Reporting and recordkeeping requirements.

*42 CFR Part 422*

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

*42 CFR Part 423*

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and record keeping requirements.

*42 CFR Part 424*

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and record keeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV as follows:

## PART 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 409.30 is amended by revising paragraph (b)(2)(ii) to read as follows:

**§ 409.30 Basic requirements.**

(b) * * *

(2) * * *

(ii) If, upon admission to the SNF, the beneficiary was enrolled in an M+C plan, as defined in § 422.4 of this chapter, offering the benefits described in § 422.102(a)(5) of this chapter, the beneficiary will be considered to have met the requirements described in paragraphs (a) and (b) of this section, and also in § 409.31(b)(2), for the duration of the SNF stay.

## PART 417—HEALTH MAINTENANCE ORGANIZATION, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 3. 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.

■ 4. Section 417.1 is amended by revising the definition of ''service area'' to read as follows:

**§ 417.1 Definitions.**

* * * * *

*Service area* means a geographic area, defined through zip codes, census tracts, or other geographic measurements, that is the area, as determined by CMS, within which the HMO furnishes basic and supplemental health services and makes them available and accessible to all its enrollees in accordance with § 417.106(b). Facilities in which individuals are incarcerated are not included in the geographic service area of an HMO or CMP plan.

* * * * *

■ 5. Section 417.2 is amended by revising paragraph (b) to read as follows:

**§ 417.2 Basis and scope.**

* * * * *

(b) Subparts G through R of this part set forth the rules for Medicare contracts with, and payment to, HMOs and competitive medical plans (CMPs) under section 1876 of the Act and 8 U.S.C. 1611.

* * * * *

**§ 417.420 [Amended].**

■ 6. In § 417.420, paragraph (a) is amended by removing the phrase ''Individuals who are entitled to'' and adding in its place the phrase ''Eligible individuals who are entitled to''.

■ 7. Section 417.422 is amended—

■ A. In the introductory text, by removing the phrase ''any individual who—'' and adding in its place the phrase ''any individual who meets all of the following:''

■ B. In paragraphs (a) through (e), by removing the '';'' and adding in its place ''.''.

■ C. In paragraph (f), by removing the ''; and'' and adding in its place ''.''.

■ D. Adding paragraph (h).

The addition reads as follows:

**§ 417.422 Eligibility to enroll in an HMO or CMP.**

* * * * *

(h) Is a United States citizen or qualified alien who is lawfully present in the United States as determined in 8 CFR 1.3.

■ 8. Section 417.460 is amended—

■ A. Revising paragraph (b)(2)(i).

■ B. In paragraph (b)(2)(iii), by removing ''; or'' and adding in its place '';''.

■ C. By removing the period at the end of (b)(2)(iv) and adding ''; or'' in its place.

■ D. By adding paragraph (b)(2)(v).

■ E. In paragraph (b)(3), by removing the cross-reference ''paragraphs (c) through (i)'' and adding in its place the cross-reference ''paragraphs (c) through (j)''.

■ F. By revising paragraph (c)(3).

■ G. In paragraph (c)(4), by removing the phrase ''non-payment of premiums.'' and adding in its place the phrase ''non-payment of premiums or other charges.''.

■ H. By adding new paragraphs (f)(1)(i)(A) through (C).

■ I. By adding paragraph (j).

The revisions and the additions read as follows:

**§ 417.460 Disenrollment of beneficiaries by an HMO or CMP.**

* * * * *

(b) * * *

(2) * * *

(i) Moves out of the HMO's or CMP's geographic area or is incarcerated.

* * * * *

(v) Loses qualified alien status or lawful presence in the United States.

* * * * *

(c) * * *

(3) *Good cause and reinstatement.* When an individual is disenrolled for failure to pay premiums or other charges imposed by the HMO or CMP for deductible and coinsurance amounts for which the enrollee is liable, CMS (or its designee) may reinstate enrollment in the plan, without interruption of coverage, if the individual shows good cause for failure to pay and pays all overdue premiums or other charges within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums or other charges was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

* * * * *

(f) * * *

(1) * * *

(i) * * *

(A) *Incarceration.* The HMO or CMP must disenroll an individual if the HMO or CMP establishes, on the basis of evidence acceptable to CMS, that the individual is incarcerated per § 417.1.

(B) *Notification by CMS of incarceration.* When CMS notifies an HMO or CMP of disenrollment due to an incarceration as per § 417.1, disenrollment is effective the first of the month following the start of incarceration, unless otherwise specified by CMS.

(C) *Exception.* The exception in paragraph (f)(2) of this section does not apply to individuals who are incarcerated.

* * * * *

(j) *Loss of qualified alien status.* Disenrollment is effective the first day of the month following the last month of lawful presence or qualified alien status in the United States.

## PART 422—MEDICARE ADVANTAGE PROGRAM

■ 9. 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).

■ 10. Section 422.1 is amended by revising paragraph (a) to read as follows:

**§ 422.1 Basis and scope.**

(a) *Basis.* This part is based on the indicated provisions of the following:

(1) The following provisions of the Act:

1128J(d)—Reporting and Returning of Overpayments.
1851—Eligibility, election, and enrollment.
1852—Benefits and beneficiary protections.
1853—Payments to Medicare Advantage (MA) organizations.
1854—Premiums.
1855—Organization, licensure, and solvency of MA organizations.
1856—Standards.
1857—Contract requirements.
1858—Special rules for MA Regional Plans.
1859—Definitions; enrollment restriction for certain MA plans.

(2) 8 U.S.C. 1611—Aliens who are not qualified aliens ineligible for Federal public benefits

* * * * *

■ 11. Section 422.2 is amended by—

■ A. Revising the definition of ''Attestation process''.

■ B. Removing the definition of ''Initial Validation Contractor (IVC)''.

■ C. Adding the definitions of ''Parent organization'' and ''RADV appeal process''.

■ D. Removing the definition of ''RADV payment error calculation appeal process''.

■ E. Revising the definition of ''Risk adjustment data validation (RADV) audit''.

■ F. Revising introductory text of the definition of ''Service area''.

■ G. Removing the definition of ''The one best medical record for the purposes of Medicare Advantage Risk Adjustment Validation (RADV)''.

The revisions and additions read as follows:

**§ 422.2 Definitions.**

* * * * *

*Attestation process* means a CMS-developed RADV audit-related process that is part of the medical record review process that enables MA organizations undergoing RADV audit to submit CMS-generated attestations for eligible medical records with missing or illegible signatures or credentials. The purpose of the CMS-generated attestations is to cure signature and credential issues. CMS-generated attestations do not provide an opportunity for a provider or supplier to replace a medical record or for a provider or supplier to attest that a beneficiary has the medical condition.

* * * * *

*Parent organization* means a legal entity that owns one or more other subsidiary legal entities.

* * * * *

*RADV appeal process* means an administrative process that enables MA organizations that have undergone RADV audit to appeal the Secretary's medical record review determinations and the Secretary's calculation of an MA organization's RADV payment error.

* * * * *

*Risk adjustment data validation (RADV) audit* means a payment audit of a MA organization administered by the Secretary that ensures the integrity and accuracy of risk adjustment payment data.

* * * * *

*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. Facilities in which individuals are incarcerated, with the exclusion of Institutions for Mental Disease, are not included in the service area of an MA plan. 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:

* * * * *

■ 12. Section 422.50 is amended—

■ A. In paragraph (a) introductory text, by removing the phrase ''if he or she—'' and adding in its place the phrase ''if he or she meets all of the following:''

■ B. In paragraphs (a)(1) and (4), by removing '';'' and adding in its place ''.''.

■ C. In paragraph (a)(5), by removing ''; and'' and adding in its place ''.''.

■ D. By adding paragraph (a)(7).

The addition reads as follows:

**§ 422.50 Eligibility to elect an MA plan.**

* * * * *

(a) * * *

(7) Is a United States citizen or qualified alien who is lawfully present in the United States as determined in 8 CFR 1.3.

* * * * *

■ 13. Section 422.60 is amended by redesignating paragraphs (g) introductory text through (g)(3) as paragraphs (g)(1) through (4), and by revising newly redesignated paragraph (g)(1) to read as follows:

**§ 422.60 Election process.**

* * * * *

(g) * * *

(1) *Passive enrollment by CMS.* CMS may implement passive enrollment procedures (as described in paragraph (g)(2) of this section) in any of the following situations:

(i) Immediate terminations as provided in § 422.510(a)(5).

(ii) Other situations in which CMS determines that remaining enrolled in a plan poses potential harm to the members.

(iii) Situations which meet all of the following criteria:

(A) A specialized MA plan for special needs individuals in which the individual is enrolled will no longer be offered following the end of the current calendar year,

(B) The individual is a—

(*1*) Special needs individual entitled to medical assistance under a Medicaid State plan, as defined in section 1859(b)(6)(B)(ii) of the Act and § 422.2; and

(*2*) Full-benefit dual eligible beneficiary, as defined in section 1935(c) of the Act.

(C) The passive enrollment is into a specialized MA plan for special needs individuals with a network and benefits that are substantially similar, as determined by CMS, to the non-renewing plan, and where the sponsoring organization also offers the Medicaid managed care organization in which the individual is also enrolled.

* * * * *

■ 14. Section 422.74 is amended by—

■ A. Adding paragraph (b)(2)(v).

■ B. Revising paragraphs (d)(1)(v) and (d)(4)(i)(A).

■ C. Adding paragraphs (d)(4)(v)and (d)(8).

The additions and revisions read as follows:

**§ 422.74 Disenrollment by the MA organization.**

* * * * *

(b) * * *

(2) * * *

(v) The individual loses qualified alien status or is no longer lawfully present in the United States.

* * * * *

(d) * * *

(1) * * *

(v) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failure to pay the plan premium, CMS (or its designee) may reinstate enrollment in the MA plan, without interruption of coverage, if the individual shows good cause for failure to pay within the initial grace period, and pays all overdue premiums within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums within the initial grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

* * * * *

(4) * * *

(i) * * *

(A) Out of the MA plan's service area or is incarcerated as specified in paragraph (d)(4)(v) of this section.

* * * * *

(v) *Incarceration.* (A) The MA organization must disenroll an individual if the MA organization establishes, on the basis of evidence acceptable to CMS, that the individual is incarcerated as specified § 422.2 or when notified of the incarceration by CMS as specified paragraph (d)(4)(v)(B) of this section.

(B) *Notification by CMS of incarceration.* When CMS notifies the MA organization of the disenrollment due to an incarceration as specified in § 422.2, disenrollment is effective the first of the month following the start of incarceration, unless otherwise specified by CMS.

* * * * *

(8) *Loss of qualified alien status.* Disenrollment is effective with the month following the last month of lawful presence or qualified alien status in the United States.

* * * * *

■ 15. Section 422.100 is amended by adding paragraph (m) to read as follows:

**§ 422.100 General requirements.**

* * * * *

(m) *Special requirements during a disaster or emergency.* (1) When a state of disaster is declared as described in paragraph (m)(2) of this section, an MA organization offering an MA plan must, until one of the conditions described in

paragraph (m)(3) of this section occurs, ensure access to benefits in the following manner:

(i) Cover Medicare Parts A and B services and supplemental Part C plan benefits furnished at non-contracted facilities subject to § 422.204(b)(3).

(ii) Waive, in full, requirements for gatekeeper referrals where applicable.

(iii) Provide the same cost-sharing for the enrollee had the service or benefit been furnished at a plan-contracted facility.

(iv) Make changes that benefit the enrollee effective immediately without the 30-day notification requirement at § 422.111(d)(3).

(2) *Declarations of disasters.* A declaration of disaster will identify the geographic area affected by the event and may be made as one of the following:

(i) Presidential declaration of a disaster or emergency under the either of the following:

(A) Stafford Act.

(B) National Emergencies Act.

(ii)(A) Secretarial declaration of a public health emergency under section 319 of the Public Health Service Act.

(B) If the President has declared a disaster as described in paragraph (m)(2)(i) or (2)(ii) of this section, then the Secretary may also authorize waivers or modifications under section 1135 of the Act.

(iii) Declaration by the Governor of a State or Protectorate.

(3) *End of the disaster.* The public health emergency or state of disaster ends when any of the following occur:

(i) The source that declared the public health emergency or state of disaster declares an end.

(ii) The CMS declares an end of the public health emergency or state of disaster.

(iii) Thirty days have elapsed since the declaration of the public health emergency or state of disaster and no end date was identified in paragraph (m)(3)(i) or (3)(ii) of this section.

(4) *MA plans unable to operate.* An MA plan that cannot resume normal operations by the end of the public health emergency or state of disaster must notify CMS.

(5) *Disclosure.* In addition to other requirements of annual disclosure under § 422.111, an organization must do all of the following:

(i) Indicate the terms and conditions of payment during the public health emergency or disaster for non-contracted providers furnishing benefits to plan enrollees residing in the state-of-disaster area.

(ii) Annually notify enrollees of the information listed in paragraphs (m)(1) through (3) and (m)(5) of this section.

(iii) Provide the information described in paragraphs (m)(1) through (3) and (m)(4)(i) of this section on its Web site.

**§ 422.101 [Amended]**

■ 16. Section 422.101 is amended by removing and reserving paragraph (c).

■ 17. Section 422.102 is amended by adding paragraph (a)(5) to read as follows:

**§ 422.102 Supplemental benefits.**

(a) * * *

(5) MA organizations may elect to furnish, as part of their Medicare covered benefits, coverage of post hospital SNF care as described in subparts C and D of this part, in the absence of the prior qualifying hospital stay that would otherwise be required for coverage of this care.

* * * * *

■ 18. Section 422.111 is amended by revising paragraphs (a)(3) and (d)(1) to read as follows:

**§ 422.111 Disclosure requirements.**

(a) * * *

(3) At the time of enrollment and at least annually thereafter by December 31 for the following contract year.

* * * * *

(d) * * *

(1) Submit the changes for CMS review under procedures of Subpart V of this part.

* * * * *

■ 19. Section 422.112 is amended by adding paragraph (b)(7) to read as follows:

**§ 422.112 Access to services.**

* * * * *

(b) * * *

(7) With respect to drugs for which payment as so prescribed and dispensed or administered to an individual may be available under Part A or Part B, or under Part D, MA–PD plans must coordinate all benefits administered by the plan and—

(i) Establish and maintain a process to ensure timely and accurate claims adjudication at the point-of-sale; and

(ii) Issue the determination and authorize or provide the benefit under Part A or Part B or as a benefit under Part D as expeditiously as the enrollee's health condition requires, in accordance with the requirements of part 422, subpart M and Part 423, subpart M, as appropriate, when a party requests a coverage determination.

* * * * *

■ 20. Section 422.113 is amended by revising paragraph (b)(1)(iii) introductory text to read as follows:

**§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.**

* * * * *

(b) * * *

(1) * * *

(iii) *Urgently needed services* means covered services that are not emergency services as defined in this section, provided when an enrollee is temporarily absent from the MA plan's service (or, if applicable, continuation) area (or provided when the enrollee is in the service or continuation area but the organization's provider network is temporarily unavailable or inaccessible) when the services are medically necessary and immediately required—

* * * * *

■ 21. Section 422.134 is added to subpart C to read as follows:

**§ 422.134 Reward and incentive programs.**

(a) *General rule.* The MA organization may create one or more programs consistent with the standards of this section that provide rewards and incentives to enrollees in connection with participation in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources.

(b) *Non-discrimination.* Reward and incentive programs—

(1) Must not discriminate against enrollees based on race, gender, chronic disease, institutionalization, frailty, health status or other impairments;

(2) Must be designed so that all enrollees are able to earn rewards; and

(3) Are subject to sanctions at § 422.752(a)(4).

(c) *Requirements.* (1) A rewards and incentives program must meet all of the following:

(i) Be offered in connection with completion of the entire service or activity.

(ii) Be offered to all eligible members without discrimination.

(iii) Have a monetary cap, as determined by CMS, of a value that may be expected to impact enrollee behavior but not exceed the value of the health related service or activity itself.

(iv) Otherwise comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil money penalty prohibiting inducements to beneficiaries.

(2) Reward and incentive items may not—

(i) Be offered in the form of cash or other monetary rebates; or

(ii) Be used to target potential enrollees.

(3) The MA organization must make information available to CMS upon request about the form and manner of any rewards and incentives programs it offers and any evaluations of the effectiveness of such programs.

■ 22. Section 422.152 is amended as follows:

■ A. Paragraph (a) introductory text is amended by:

■ i. Removing the phrase ''for each of those plans'' and adding in its place the phrase ''for each plan''.

■ .ii. Removing the phrase ''a plan must—'' and adding in its place the phrase ''a plan must do all of the following:''

■ B. By redesignating paragraphs (a)(1) through (3) as (a)(2) through (4), respectively.

■ C. By adding a new paragraph (a)(1).

■ D. In newly redesignated paragraph (a)(2), by removing the '';'' and adding in its place ''.''.

■ E. In newly redesignated paragraph (a)(3), by removing the ''; and'' and adding in its place ''.''.

■ F. By revising paragraphs (c), (g) introductory text, and (h).

The addition and revisions read as follows:

**§ 422.152 Quality improvement program.**

(a) * * *

(1) Create a quality improvement program plan that sufficiently outlines the elements of the plan's quality improvement program.

* * * * *

(c) *Chronic care improvement program requirements.* (1) Develop criteria for a chronic care improvement program. These criteria must include all of the following:

(i) Methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions that would benefit from participating in a chronic care improvement program.

(ii) Mechanisms for monitoring MA enrollees that are participating in the chronic improvement program and evaluating participant outcomes such as changes in health status.

(iii) Performance assessments that use quality indicators that are objective, clearly and unambiguously defined, and based on current clinical knowledge or research.

(iv) Systematic and ongoing follow-up on the effect of the program.

(2) The organization must report the status and results of each program to CMS as requested.

* * * * *

(g) *Special requirements for specialized MA plans for special needs individuals.* All special needs plans (SNPs) must be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. SNPs must submit their model of care (MOC), as defined under § 422.101(f), to CMS for NCQA evaluation and approval, in accordance with CMS guidance. In addition to the requirements under paragraphs (a) and (f) of this section, a SNP must conduct a quality improvement program that meets all of the following:

* * * * *

(h) *Requirements for MA private-fee-for-service plans and Medicare medical savings account plans.* MA PFFS and MSA plans are subject to the requirement that may not exceed the requirement specified in § 422.152(e).

**§ 422.300 [Amended]**

■ 23. Section 422.300 is amended by removing the phrase ''and 1858 of the Act.'' and adding in its place the phrase ''1858, and 1128J(d) of the Act.''

■ 24. Section 422.310 is amended by:

■ A. Redesignating the text of paragraph (e) as paragraph (e)(2) and adding new paragraph (e)(1) following current paragraph (e) subject heading.

■ B. Adding new paragraph (e)(1).

■ C. Revising paragraph (g)(2).

■ D. Adding paragraph (g)(3).

The additions and revision read as follows:

**§ 422.310 Risk adjustment data.**

* * * * *

(e) * * *

(1) Any medical record reviews conducted by an MA organization must be designed to determine the accuracy of diagnoses submitted under § 422.308(c) and § 422.310(g).

* * * * *

(g) * * *.

(2) After the payment year is completed, CMS recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary.

(i) Prior to calculation of final risk factors for a payment year, CMS allows a reconciliation process to account for risk adjustment data submitted after the March deadline until the final risk adjustment data submission deadline in the year following the payment year.

(ii) After the final risk adjustment data submission deadline, which is announced by CMS, an MA organization can submit data to correct overpayments but cannot submit diagnoses for additional payment.

(3) Submission of corrected risk adjustment data in accordance with overpayments after the final risk adjustment data submission deadline, as described in paragraph (g)(2) of this section, must be made as provided in § 422.326.

■ 25. Section 422.311 is amended as follows:

■ A. In paragraph (a), by removing the phrase ''CMS annually'' and adding in its place the phrase ''the Secretary annually''.

■ B. In paragraph (b)(2), by removing the phrase ''to CMS or its contractors'' and adding in its place the phrase ''to the Secretary''.

■ C. By removing paragraph (b)(3).

■ D. By revising paragraph (c).

The revision read as follows:

**§ 422.311 RADV audit dispute and appeal processes.**

* * * * *

(c) *RADV audit appeals.* (1) *Appeal rights.* MA organizations that do not agree with their RADV audit results may appeal.

(2) *Issues eligible for RADV appeals.* (i) *General rules.* MA organizations may appeal RADV medical record review determinations and the Secretary's RADV payment error calculation. In order to be eligible for RADV appeal, MA organizations must adhere to the following:

(A) Established RADV audit procedures and requirements.

(B) RADV appeals procedures and requirements.

(ii) *Failure to follow RADV rules.* Failure to follow the Secretary's RADV audit procedures and requirements and the Secretary's RADV appeals procedures and requirements will render the MA organization's request for appeal invalid.

(iii) *RADV appeal rules.* The MA organization's written request for medical record review determination appeal must specify the following:

(A) The audited HCC(s) that the Secretary identified as being in error.

(B) A justification in support of the audited HCC selected for appeal.

(iv) *Number of medical records eligible for appeal.* For each audited HCC, MA organizations may appeal one medical record that has undergone RADV review. If an attestation was submitted to cure a signature or credential-related error, the attestation may be included in the HCC appeal.

(v) *Selection of medical record for appeal.* The MA organization must select the medical record that undergoes appeal.

(vi) *Written request for RADV payment error calculation appeal.* The written request for RADV payment error calculation appeal must clearly specify the following:

(A) The MA organization's own RADV payment error calculation.

(B) Where the Secretary's RADV payment error calculation was erroneous.

(3) *Issues ineligible for RADV appeals.* (i) MA organizations' request for appeal may not include HCCs, medical records or other documents beyond the audited HCC, RADV-reviewed medical record, and any accompanying attestation that the MA organization chooses for appeal.

(ii) MA organizations may not appeal the Secretary's medical record review determination methodology or RADV payment error calculation methodology.

(iii) As part of the RADV payment error calculation appeal—MA organizations may not appeal RADV medical record review-related errors.

(iv) MA organizations may not appeal RADV errors that result from an MA organization's failure to submit a medical record.

(4) *Burden of proof.* The MA organization bears the burden of proof by a preponderance of the evidence in demonstrating that the Secretary's medical record review determination(s) or payment error calculation was incorrect.

(5) *Manner and timing of a request for RADV appeal.* (i) At the time the Secretary issues its RADV audit report, the Secretary notifies audited MA organizations of the following:

(A) That they may appeal RADV HCC errors that are eligible for medical record review determination appeal.

(B) That they may appeal the Secretary's RADV payment error calculation.

(ii) MA organizations have 30 days from date of issuance of the RADV audit report to file a written request with CMS for RADV appeal. This request for RADV appeal must specify one of the following:

(A) Whether the MA organization requests medical record review determination appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements.

(B) Whether the MA organization requests RADV payment error calculation appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements.

(C) Whether the MA organization requests both medical record review determination appeal and RADV payment error calculation appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements.

(iii) For MA organizations that appeal both medical record review determination appeal and RADV payment error calculation appeal:

(A) The Secretary adjudicates the request for RADV payment error calculation following conclusion of reconsideration of the MA organization's request for medical record review determination appeal.

(B) MA organizations may not appeal their RADV payment error calculation until appeals of RADV medical record review determinations filed by the MA organization have been completed and the decisions are final.

(6) *Reconsideration stage.* (i) *Written request for medical record review reconsideration.* A MA organization's written request for medical record review determination reconsideration must specify the following:

(A) The audited HCC that the Secretary identified as being in error that the MA organization wishes to appeal.

(B) A justification in support of the audited HCC chosen for appeal.

(ii) *Written request for payment error calculation.* The MA organization's written request for payment error calculation reconsideration—

(A) Must include the MA organization's own RADV payment error calculation that clearly specifies where the Secretary's RADV payment error calculation was erroneous; and

(B) May include additional documentary evidence pertaining to the calculation of the payment error that the MA organization wishes the reconsideration official to consider.

(iii) *Conduct of the reconsideration.* (A) For medical record review determination reconsideration, a medical record review professional who was not involved in the initial medical record review determination of the disputed audited HCCs does the following:

(*1*) Reviews the medical record and accompanying dispute justification.

(*2*) Reconsiders the initial audited medical record review determination.

(B) For payment error calculation reconsideration, CMS ensures that a third party not involved in the initial RADV payment error calculation does the following:

(*1*) Reviews the Secretary's RADV payment error calculation.

(*2*) Reviews the MA organization's RADV payment error calculation;

(*3*) Recalculates the payment error in accordance with CMS's RADV payment error calculation procedures.

(iv) *Effect of the reconsideration official's decision.* (A) The reconsideration official issues a written reconsideration decision to the MA organization.

(B) The reconsideration official's decision is final unless the MA organization disagrees with the reconsideration official's decision.

(C) If the MA organization disagrees with the reconsideration official's decision, they may request a hearing in accordance with paragraph (c)(8) of this section.

(7) *Hearing stage.* (i) *Errors eligible for hearing.* At the time the reconsideration official issues his or her reconsideration determination to the MA organization, the reconsideration official notifies the MA organization of any RADV HCC errors or payment error-calculations that are eligible for RADV hearing.

(ii) *General hearing rules.* A MA organization that requests a RADV hearing must do so in writing in accordance with procedures established by CMS.

(iii) *Written request for hearing.* The written request for a hearing must be filed with the Hearing Officer within 30 days of the date the MA organization receives the reconsideration officer's written reconsideration decision.

(A) If the MA organization appeals medical record review reconsideration determination, the written request for RADV hearing must—

(*1*) Include a copy of the written decision of the reconsideration official;

(*2*) Specify the audited HCCs that the reconsideration official confirmed as being in error; and

(*3*) Specify a justification why the MA organization disputes the reconsideration official's determination.

(B) If the MA organization appeals the RADV payment error calculation, the written request for RADV hearing must include the following:

(*1*) A copy of the written decision of the reconsideration official.

(*2*) The MA organization's own RADV payment error calculation that clearly specifies where the Secretary's payment error calculation was erroneous.

(iv) *Designation of hearing officer.* A hearing officer will conduct the RADV hearing.

(v) *Disqualification of the 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.

(D) If the hearing officer withdraws, another hearing officer conducts the hearing.

(E) 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 the Secretary.

(vi) *Hearing Officer review.* The hearing officer reviews the following:

(A) For medical record review determination appeal all of the following:

(*1*) The RADV-reviewed medical record and any accompanying attestation that the MA organization selected for review.

(*2*) The reconsideration official's written determination.

(*3*) The written brief submitted by the MA organization or the Secretary in response to the reconsideration official's determination.

(B) For payment error calculation appeal all of the following:

(*1*) A copy of the written decision of the reconsideration official that clearly specifies whether the Secretary's payment error calculation was erroneous.

(*2*) Briefs addressing the reconsideration decision.

(vii) *Hearing procedures.* (A) *Authority of the Hearing Officer.* The hearing officer has full power to make rules and establish procedures, consistent with the law, regulations, and the Secretary rulings. These powers include the authority to dismiss the appeal with prejudice and take any other action which the hearing officer considers appropriate, including for failure to comply with such rules and procedures.

(B) *The hearing is on the record.* (*1*) Except as specified in paragraph (c)(viii)(B)(*2*), the hearing officer is limited to the review of the record.

(*2*)(*i*) Subject to the hearing officer's full discretion, the parties may request a live or telephonic hearing regarding some or all of the disputed medical records.

(*ii*) The hearing officer may, on his or her own-motion, schedule a live or telephonic hearing.

(*3*) The record is comprised of the following:

(*i*) Documents described at paragraphs (c)(6)(iv) and (7)(vi) of this section.

(*ii*) Written briefs from the MA organization explaining why they believe the reconsideration official's determination was incorrect.

(*iii*) The Secretary's optional brief that responds to the MA organization's brief—

(*4*) The hearing officer neither receives testimony nor accepts any new evidence that is not part of the record.

(*5*) Either the MA organization or the Secretary may ask the hearing officer to rule on a motion for summary judgment.

(viii) *Hearing Officer decision.* The hearing officer decides whether to uphold or overturn the reconsideration official's decision, and sends a written determination to CMS and the MA organization, explaining the basis for the decision.

(ix) *Computations based on hearing decision.* (A) Once the hearing officer's decision is considered final pursuant to subsection (x), a third party not involved in the initial RADV payment error calculation recalculates the MA organization's RADV payment error and issues a new RADV audit report to the appellant MA organization and CMS.

(B) For MA organizations appealing the RADV error calculation only, a third party not involved in the initial RADV payment error calculation recalculates the MA organization's RADV payment error and issues a new RADV audit report to the appellant MA organization and CMS.

(x) *Effect of the Hearing Officer's decision.* The hearing officer's decision is final unless the decision is reversed or modified by the CMS Administrator.

(8) *CMS Administrator review stage.* (i) A request for CMS Administrator review must be made in writing and filed with the CMS Administrator.

(ii) CMS or a MA organization that has received a hearing officer's decision and requests review by the CMS Administrator must do so within 30 days of receipt of the hearing officer's decision.

(iii) After receiving a request for review, the CMS Administrator has the discretion to elect to review the hearing officer's decision or to decline to review the hearing officer's decision.

(iv) If the CMS Administrator elects to review the hearing decision—

(A) The CMS Administrator acknowledges the decision to review the hearing decision in writing and notifies CMS and the MA organization of their right to submit comments within 15 days of the date of the notification; and

(B) The CMS Administrator is limited to the review of the record. The record is comprised of the following:

(*1*) The record is comprised of documents described at paragraphs (c)(6)(iv), (7)(vii), and (7)(ix) of this section.

(*2*) The hearing record.

(*3*) Written arguments from the MA organization or CMS explaining why either or both parties believe the hearing officer's determination was correct or incorrect.

(C) The CMS Administrator reviews the record and determines whether the hearing officer's determination should be upheld, reversed, or modified.

(v) The CMS Administrator renders his or her final decision in writing to the parties within 60 days of acknowledging his or her decision to review the hearing officer's decision.

(vi) The decision of the hearing officer is final if the CMS Administrator—

(A) Declines to review the hearing officer's decision; or

(B) Does not make a decision within 60 days.

■ 26. Section 422.326 is added to subpart G to read as follows:

**§ 422.326 Reporting and returning of overpayments.**

(a) *Terminology.* For purposes of this section—

*Applicable reconciliation* occurs on the date of the annual final deadline for risk adjustment data submission described at § 422.310(g), which is announced by CMS each year.

*Funds* means any payment that an MA organization has received that is based on data submitted by the MA organization to CMS for payment purposes, including § 422.308(f) and § 422.310.

*Overpayment* means any funds that an MA organization has received or retained under title XVIII of the Act to which the MA organization, after applicable reconciliation, is not entitled under such title.

(b) *General rule.* If an MA organization has identified that it has received an overpayment, the MA organization must report and return that overpayment in the form and manner set forth in this section.

(c) *Identified overpayment.* The MA organization has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment. An MA organization must exercise reasonable diligence to determine the accuracy of information it receives that an overpayment may exist.

(d) *Reporting and returning of an overpayment.* An MA organization must report and return any overpayment it received no later than 60 days after the date on which it identified it received an overpayment.

(1) *Reporting.* An MA organization must notify CMS, of the amount and reason for the overpayment, using a notification process determined by CMS.

(2) *Returning.* An MA organization must return identified overpayments in a manner specified by CMS.

(3) *Enforcement.* Any overpayment retained by an MA organization after the 60-day deadline for reporting and returning is an obligation under 31 U.S.C. 3729(b)(3).

(e) *Look-back period.* An MA organization must report and return any overpayment identified for the 6 most recent completed payment years. Overpayments resulting from fraud are not subject to this limitation of the look-back period.

**§ 422.502 [Amended]**

■ 27. Section 422.502(b)(3) is amended by removing the phrase ''CMS may deny an application based on the applicant's'' and adding in its place the phrase ''CMS may deny an application for a new contract or service are expansion based on the applicant's''.

■ 28. Section 422.503 is amended by—

■ A. Adding paragraph (b)(4)(vi)(C)(*3*).

■ B. Adding and reserving paragraph (b)(4)(vi)(G)(4).

■ C. Revising paragraph (b)(4)(vi)(G)(*5*).

■ D. In paragraph (d)(2) introductory text, removing the phrase ''has the right to:'' and adding in its place the phrase ''has the right to timely do all of the following:''.

■ E. In paragraph (d)(2)(i), removing the ''; '' and adding in its place a ''.''.

■ F. In paragraph (d)(2)(ii), removing the ''; and'' and adding in its place a ''.''.

■ G. Adding paragraph (d)(2)(iv).

The revisions and additions are as follows:

**§ 422.503 General provisions.**

* * * * *

(b) * * *

(4) * * *

(vi) * * *

(C) * * *

(*3*) An MA organization must require all of its first tier, downstream and related entities to take the CMS training and accept the certificate of completion of the CMS training as satisfaction of this requirement. MA organizations are prohibited from developing and implementing their own training or providing supplemental training materials to fulfill this requirement.

* * * * *

(G) * * *

(*5*) Not accept, or share a corporate parent organization with an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

(d) * * *

(2) * * *

(iv) CMS may require that the MA organization hire an independent auditor to conduct full or partial program audits or to provide CMS with information to determine if deficiencies found during an audit or inspection have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

* * * * *

■ 29. Amend § 422.504 by:

■ A. Adding paragraphs (a)(3)(iv) and (a)(19).

■ B. Redesignating paragraph (i)(2)(ii) as (i)(2)(iii).

■ C. Adding new paragraph (i)(2)(ii) and paragraphs (1)(5) and (o).

**§ 422.504 Contract provisions.**

* * * * *

(a) * * *

(3) * * *

(iv) Such benefits and access in a manner that provides good quality health care demonstrated by scores of three or higher on CMS performance standards for patient outcomes, intermediate outcomes, process, patient experience, and patient access to care.

* * * * *

(19) That it will not submit a bid for the same type of MA plan that is non-renewed under § 522.506(b)(1)(iv) in the service area of the non-renewed plan for 2 years.

* * * * *

(i) * * *

(2) * * *

(ii) HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any records under (i)(2)(i) of this section directly from any first tier, downstream, or related entity.

* * * * *

(l) * * *

(5) *Certification of accuracy of data for overpayments.* The CEO, CFO, or COO must certify (based on best knowledge, information, and belief) that the information provided for purposes of reporting and returning of overpayments under § 422.326 is accurate, complete, and truthful.

* * * * *

(o) *Business continuity.* (1) The MA organization agrees to develop, maintain, and implement a business continuity plan containing policies and procedures to ensure the continuation of business operations during disruptions to business operations which would include natural or man-made disasters, system failures, emergencies, and other similar circumstances and the threat of such occurrences. To meet the requirement, the business continuity plan must, at a minimum, include the following:

(i) *Risk assessment.* Identify threats and vulnerabilities that might affect business operations.

(ii) *Mitigation strategy.* Design strategies to mitigate hazards. Identify essential functions in addition to those specified in paragraph (o)(2) of this section and prioritize the order in which to restore all other functions to normal operations. At a minimum, each MA organization must do the following:

(A) Identify specific events that will activate the business continuity plan.

(B) Develop a contingency plan to maintain, during any business disruption, the availability and, as applicable, confidentiality of communication systems and essential records in all forms (including electronic and paper copies). The contingency plan must do the following:

(*1*) Ensure that during any business disruption the following systems will operate continuously or, should they fail, be restored to operational capacity on a timely basis:

(*i*) Information technology (IT) systems including those supporting claims processing at point of service.

(*ii*) Provider and enrollee communication systems including telephone, Web site, and email.

(*2*) With respect to electronic protected health information, comply with the contingency plan requirements of the Health Insurance Portability and Accountability Act of 1996 Security Regulations at 45 CFR 160 and 164, Subparts A and C.

(C) Establish a chain of command.

(D) Establish a business communication plan that includes emergency capabilities and procedures to contact and communicate with the following:

(*1*) Employees.

(*2*) First tier, downstream, and related entities.

(*3*) Other third parties (including pharmacies, providers, suppliers, and government and emergency management officials).

(E) Establish employee and facility management plans to ensure that essential operations and job responsibilities can be assumed by other employees or moved to alternate sites as necessary.

(F) Establish a restoration plan including procedures to transition to normal operations.

(G) Comply with all applicable Federal, State, and local laws.

(iii) *Testing and revision.* On at least an annual basis, test and update the business operations continuity plan to ensure the following:

(A) That it can be implemented in emergency situations.

(B) That employees understand how it is to be executed.

(iv) *Training.* On at least an annual basis, educate all employees, including contract staff about the business

continuity plan and their own respective roles.

(v) *Records.* (A) Develop and maintain records documenting the elements of the business continuity plan described in paragraphs (o)(1)(i) through (iv) of this section.

(B) Make the information specified in paragraph (o)(1)(v)(A) of this section available to CMS upon request.

(2) *Restoration of essential functions.* Every MA organization must restore essential functions within 24 hours after any of the essential functions fail or otherwise stop functioning as usual. In addition to any essential functions that the MA organization identifies under paragraph (o)(1)(ii) of this section, for purposes of this paragraph (o)(2) of the section essential functions include, at a minimum, the following:

(i) Benefit authorization (if not waived), adjudication, and processing of health care claims for services furnished at a hospital, clinic, provider office or other place of service.

(ii) Operation of an enrollee exceptions and appeals process including coverage determinations.

(iii) Operation of call center customer services.

■ 30. Section 422.506 by revising paragraphs (a)(4) and (b)(1)(iv) to read as follows:

**§ 422.506 Nonrenewal of contract.**

(a) * * *

(4) If an MA organization does not renew a contract under this paragraph (a) of this section, CMS may deny an application for a new contract or a service area expansion from the MA organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS. This prohibition may apply regardless of the product type, contract type or service area of the previous contract.

* * * * *

(b) * * *

(1) * * *

(iv) The contract must be non-renewed as to an individual MA plan if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.

* * * * *

■ 31. Section 422.508 is amended by revising paragraphs (c) and (d) introductory text to read as follows:

**§ 422.508 Modification or termination of contract by mutual consent.**

* * * * *

(c) *Agreement to limit new MA applications.* As a condition of the consent to a mutual termination CMS requires, as a provision of the termination agreement, language prohibiting the MA organization from applying for new contracts or service area expansions for a period of 2 years, absent circumstances warranting special consideration. This prohibition may apply regardless of the product type, contract type or service area of the previous contract.

(d) *Prohibition against Part C program participation by organizations whose owners, directors, or management employees served in a similar capacity with another organization that mutually terminated its Medicare contract within the previous 2 years.* During the same 2-year period, CMS does not contract with an organization whose covered persons also served as covered persons for the mutually terminating sponsor. This prohibition may apply regardless of the product type, contract type or service area of the previous contract. A ''covered person'' as used in this paragraph means one of the following:

* * * * *

■ 32. Amend § 422.510 as follows;

■ A. By redesigating paragraphs (a)(4) through (15) as paragraphs (a)(4)(i) through (xii).

■ B. By adding new paragraph (a)(4) introductory text.

■ C. In newly redesignated paragraphs (a)(4)(ii), (v), (vi), and (viii) by removing the term ''fails'' and adding in its place the term ''failed''.

■ D. In newly redesignated paragraphs (a)(4)(iii), (iv), (vii), (ix), and (x), by removing the term ''Fails'' and adding in its place the term ''Failed''.

■ E. By revising newly redesignated paragraphs (a)(4)(xi) and (xii).

■ F. In paragraph (b)(1)(i), by removing the phrase ''90 days'' and adding in its place the phrase ''at least 45 calendar days''.

■ G. By revising paragraph (b)(1)(iii) and the heading for paragraph (b)(2).

■ H. In paragraph (b)(2)(i)(C), by removing the cross-reference ''(a)(4) of this section'' and adding in its place the cross reference ''(a)(4)(i) of this section''.

■ I. In paragraph (c)(2)(iii), by removing the cross reference ''(a)(4) of this section'' and adding in its place the cross reference ''(a)(4)(i) of this section''.

The additions and revisions read as follows:

**§ 422.510 Termination of Contract by CMS.**

* * * * *

(a) * * *

(3) * * *

(4) CMS may make a determination under paragraph (a)(1), (2), or (3) of this section if the MA organization has had one or more of the following occur:

* * * * *

(xi) Achieves a Part C summary plan rating of less than 3 stars for 3 consecutive contract years. Plan ratings issued by CMS before September 1, 2012, are not included in the calculation of the 3–year period.

(A) Holds a MA contract that does not include a Part D addendum and achieves a Part C summary plan rating of less than 3 stars for 3 consecutive contract years.

(B) Holds a MA contract that includes a Part D addendum and fails for three consecutive years to achieve both Part C and D summary ratings of 3 or more stars in the same year.

(xii) Has failed to report MLR data in a timely and accurate manner in accordance with § 422.2460 or that any MLR data required by this subpart is found to be materially incorrect or fraudulent.

* * * * *

(b) * * *

(1) * * *

(i) CMS notifies the MA organization in writing at least 45 calendar days before the intended date of the termination.

(ii) The MA organization notifies its Medicare enrollees of the termination by mail at least 30 calendar days before the effective date of the termination.

(iii) The MA organization notifies the general public of the termination at least 30 calendar days before the effective date of the termination by releasing a press statement to news media serving the affected community or county and posting the press statement prominently on the organization's Web site.

(2) Immediate termination of contract by CMS.

* * * * *

■ 33. Section 422.512 is amended by revising paragraph (e)(1) to read as follows:

**§ 422.512 Termination of contract by the MA organization.**

* * * * *

(e) * * *

(1) CMS may deny an application for a new contract or a service area expansion from an MA organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS. This prohibition may apply regardless of the contract type, product type, or service area of the previous contract.

* * * * *

■ 34. Amend § 422.566 by revising paragraphs (b) introductory text, and (b)(1) through (3) and adding paragraph (b)(6) to read as follows:

**§ 422.566 Organization determinations.**

* * * * *

(b) *Actions that are organization determinations.* The following actions by an MA organization are organization determinations:

(1) Any determination with respect to payment for temporarily out of the area renal dialysis services, emergency services, post-stabilization care, or urgently needed services.

(2) Any determination with respect to payment for any other health services furnished by a provider other than the MA organization that the enrollee believes—

(i) Are covered under Medicare; or

(ii) If not covered under Medicare, should have been furnished, arranged for, or reimbursed by the MA organization.

(3) Any determination by the MA organization not to provide or pay for services, in whole or in part, including the type, level or duration of services, that the enrollee believes should be furnished or arranged for by the MA organization.

* * * * *

(6) Any determination by the MA organization to provide or pay for an item or service, including the initial or continued provision of an item or service by a contract provider of the MA organization.

* * * * *

■ 35. Section 422.568 is amended by revising paragraph (b) to read as follows:

**§ 422.568 Standard timeframes and notice requirements for organization determinations.**

* * * * *

(b) *Timeframe for requests for service.* Except as provided in paragraph (b)(1) of this section, 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.

(1) *Extensions.* The MA organization may extend the timeframe by up to 14 calendar days if—

(i) The enrollee requests the extension;

(ii) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(iii) The extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest.

(2) *Notice of extension.* 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.

* * * * *

■ 36. Section 422.572 is amended by revising paragraph (b) to read as follows:

**§ 422.572 Timeframes and notice requirements for expedited organization determinations.**

* * * * *

(b) *Extensions.* (1) The MA organization may extend the 72-hour deadline by up to 14 calendar days if—

(i) The enrollee requests the extension;

(ii) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(iii) The extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest.

(2) *Notice of extension.* When the MA organization 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 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.

* * * * *

■ 37. Section 422.590 is amended as follows:

■ A. By revising paragraph (a)(1).

■ B. In paragraph (d)(1), by removing the cross reference ''(d)(2)'' and adding in its place the cross-reference ''(e)''.

■ C. By removing paragraph (d)(2).

■ D. By redesignating paragraphs (d)(3) through (5) as paragraphs (d)(2) through (4), respectively.

■ E. By redesignating paragraphs (e) through (g) as paragraphs (f) through (h), respectively;

■ F. By adding new paragraph (e).

The additions and revisions read as follows:

**§ 422.590 Timeframes and responsibility for reconsiderations.**

(a) * * *

(1) Except as provided in paragraph (e) of this section, if the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue the determination (and effectuate it in accordance with § 422.618(a)) 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 reconsideration.

* * * * *

(e) *Extensions.* (1) As described in paragraphs (e)(1)(i) through (e)(1)(iii) of this section, the MA organization may extend the standard or expedited reconsideration deadline by up to 14 calendar days if—

(i) The enrollee requests the extension; or

(ii) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(iii) The extension is justified due to extraordinary, exigent or other non-routine circumstances and is in the enrollee's interest.

(2) *Notice of extension.* When the MA organization 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 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.

* * * * *

**§ 422.618 [Amended]**

■ 38. In paragraph (a), removing the cross-reference ''§ 422.590(a)(1)'' and adding in its place the cross-reference ''§ 422.590(e)''.

**§ 422.619 [Amended]**

■ 39. In paragraph (a), removing the cross-reference ''§ 422.590(d)(2)'' and adding in its place the cross-reference ''§ 422.590(e)''.

■ 40. Amend § 422.641 by revising paragraphs (b) and (c) to read as follows:

**§ 422.641 Contract determinations.**

* * * * *

(b) A determination not to authorize a renewal of a contract with an MA organization in accordance with § 422.506(b).

(c) A determination to terminate a contract with an MA organization in accordance with § 422.510(a).

* * * * *

■ 41. Amend § 422.644 by revising paragraphs (a), (b)(1), and (c)(1) to read as follows:

**§ 422.644 Notice of contract determination.**

* * * * *

(a) When CMS makes a contract determination under § 422.641, it gives the MA organization written notice.

(b) * * *

(1) Reasons for the determination; and

* * * * *

(c) * * *

(1) *General rule.* Except as provided in (c)(2) of this section, CMS mails notice to the MA organization 45 calendar days before the anticipated effective date of the termination.

* * * * *

■ 42. Amend § 422.660 by revising paragraphs (a)(2), (a)(3), and (b)(4) to read as follows:

**§ 422.660 Right to a hearing, burden of proof, standard of proof, and standards of review.**

* * * * *

(a) * * *

(2) An MA organization whose contract has been terminated in accordance with § 422.510.

(3) An MA organization whose contract has not been renewed in accordance with § 422.506.

(b) * * *

(4) During a hearing to review the imposition of an intermediate sanction as described at § 422.750, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.752(a) and (b).

* * * * *

■ 43. Amend § 422.752 by adding paragraphs (a)(9) through (12) and revising paragraphs (c)(1) and (c)(2)(ii) to read as follows:

**§ 422.752 Basis for imposing intermediate sanctions and civil money penalties**

(a) * * *

(9) Except as provided under § 423.34 of this chapter, enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual.

(10) Transfers an individual enrolled under this part from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission.

(11) Fails to comply with marketing restrictions described in subpart V or applicable implementing guidance.

(12) Employs or contracts with any individual, agent, provider, supplier or entity who engages in the conduct described in paragraphs (a)(1) through (11) of this section.

* * * * *

(c) * * *

(1) *CMS.* In addition to, or in place of, any intermediate sanctions, CMS may impose civil money penalties in the amounts specified in the following:

(i) Section 422.760(b) for any of the determinations at § 422.510(a), except § 422.510(a)(4)(i).

(ii) Section 422.760(c) for any of the determinations at § 422.752(a) except § 422.752(a)(5).

(2) * * *

(ii) Determinations made under § 422.510(a)(4)(i).

■ 44. Amend § 422.756 by revising paragraphs (a)(2), (b)(4), and (d) to read as follows:

**§ 422.756 Procedures for imposing intermediate sanctions and civil money penalties.**

(a) * * *

(2) *Opportunity to respond.* CMS allows the MA organization 10 calendar days after receipt of the notice to provide a written rebuttal. CMS considers receipt of the notice as the day after the notice is sent by fax, email, or submitted for overnight mail.

(b) * * *

(4) The MA organization must follow the right to a hearing procedure as specified in subpart N of this part.

* * * * *

(d) *Non-renewal or termination by CMS.* In addition to or as an alternative to the sanctions described in § 422.750, CMS may—

(1) Decline to authorize the renewal of an organization's contract in accordance with § 422.506(b); or

(2) Terminate the contract in accordance with § 422.510.

* * * * *

■ 45. Amend 422.760 by revising paragraph (a)(3) and the heading of paragraph (b) and adding paragraph (c) to read as follows:

**§ 422.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.**

(a) * * *

(3) The adverse effect to enrollees which resulted or could have resulted from the conduct of MA organization;

(b) *Amount of penalty imposed by CMS.* * * *

* * * * *

(c) *Amount of penalty imposed by CMS or OIG.* CMS or the OIG may impose civil money penalties in the following amounts for a determination made under § 422.752(a):

(1) Civil money penalties of not more than $25,000 for each determination made.

(2) With respect to a determination made under § 422.752(a)(4) or (a)(5)(i), not more than $100,000 for each such determination, except with respect to a determination made under § 422.752(a)(5), an assessment of not more than the amount claimed by such plan or MA organization based upon the misrepresentation or falsified information involved.

(3) Plus with respect to a determination made under § 422.752(a)(2), double the excess amount charged in violation of such paragraph (and the excess amount charged must be deducted from the penalty and returned to the individual concerned).

(4) Plus with respect to a determination made under § 422.752(a)(4), $15,000 for each individual not enrolled as a result of the practice involved.

■ 46. Amend § 422.1016 by revising the first sentence of paragraph (b)(1) to read as follows:

**§ 422.1016 Filing of briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal.**

* * * * *

(b) * * *

(1) The other party will have 20 calendar days from the date of mailing or in person filing to submit any rebuttal statement or additional evidence. * * *

* * * * *

■ 47. Amend § 422.1020 by revising paragraph (a)(2) to read as follows:

**§ 422.1020 Request for hearing.**

(a) * * *

(2) The MA organization or its legal representative or other authorized official must file the request, in writing, to the appropriate Departmental Appeals Board office, with a copy to CMS, within 60 calendar days after receipt of the notice of initial determination, to request a hearing before an ALJ to appeal any determination by CMS to impose a civil money penalty.

* * * * *

■ 48. Amend § 422.2262 by adding paragraph (a)(2) to read as follows:

**§ 422.2262 Review and Distribution of marketing materials.**

(a) * * *

(2) If CMS does not approve or disapprove marketing materials within the specified review timeframe, the materials will be deemed approved. Deemed approved means that the MA organization may use the material.

* * * * *

**§ 422.2266 [Removed and Reserved]**

■ 49. Section 422.2266 is removed and reserved.

■ 50. Amend § 422.2274 by:

■ A. Revising the introductory text.

■ B. Redesignating paragraphs (a) through (f) as (b) through (g).

■ C. Adding new paragraph (a).

■ D. Revising newly redesignated paragraphs (b) through (d).

■ E. Adding paragraph (h).

The revisions and addition read as follows:

**§ 422.2274 Broker and agent requirements.**

If an MA organization uses agents and brokers to sell its Medicare plans, the following requirements in this section are applicable:

(a) *Definitions.* For purposes of this section, the following definitions are applicable:

*Compensation* (1) Includes monetary or non-monetary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to—

(i) Commissions;

(ii) Bonuses;

(iii) Gifts;

(iv) Prizes or Awards; or

(v) Referral or Finder fees.

(2) Does not include—

(i) Payment of fees to comply with State appointment laws, training, certification, and testing costs;

(ii) Reimbursement for mileage to, and from, appointments with beneficiaries; or

(iii) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

*Like plan type* means one of the following:

(1) PDP replaced with another PDP.

(2) MA or MA–PD replaced with another MA or MA–PD.

(3) Cost plan replaced with another cost plan.

*Unlike plan type* means one of the following:

(1) PDP replaced with a MA–PD or a MA–PD replaced with a PDP.

(2) PDP replaced with a cost plan or a cost plan replaced with a PDP.

(3) MA–PD replaced with a cost plan or a cost plan replaced with a MA–PD.

*Plan year* means the year beginning January 1 and ending December 31.

*Renewal year* means all years following the initial enrollment year in a like plan type.

(b) *Compensation rules.* A MA organization must compensate independent brokers and agents, if compensation is paid, only according to the following rules in this section.

(1) *Compensation amounts.* (i) For an initial year enrollment of a Medicare beneficiary into an MA plan, the compensation must be at or below the fair market value of such services, published annually as a cut-off amount by CMS.

(ii) For renewal years, compensation may be up to 35 percent of the current fair market value cut-off amounts published annually by CMS.

(2) *Aggregate compensation.* (i) An entity must not provide aggregate compensation to its agents or brokers greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan at any time.

(ii) An agent or broker must not receive aggregate compensation greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan type at any time.

(iii) The initial compensation is paid for replacements between unlike plan types.

(3) *Compensation payment and payment recovery.* (i) Compensation may only be paid for the enrollee's months of enrollment during a plan year.

(ii)(A) Subject to paragraph (b)(3)(iii) of this section, compensation payments may be made at one time for the entire current plan year or in installments throughout the year.

(B) Compensation may not be paid until January 1 of the compensation year and, if paid at all, must be paid in full by December 31 of the compensation year.

(iii) When a beneficiary disenrolls from an MA plan, compensation paid to agents and brokers must be recovered for those months of the plan year for which the beneficiary is not enrolled. For disenrollments occurring within the first 3 months, the entire compensation must be recovered when the disenrollment was the result of agent or broker behavior.

(4) *Compensation structure.* (i) The MA organization must establish a compensation structure for new and replacement enrollments and renewals effective in a given plan year. Compensation structures must be in place by the beginning of the plan marketing period, October 1.

(ii) Compensation structures must be available upon CMS request including for audits, investigations, and to resolve complaints.

(c) *Annual training.* The MA organization must ensure that all agents and brokers selling Medicare products are trained annually on the following:

(1) Medicare rules and regulations.

(2) Details specific to the plan products they intend to sell.

(d) *Annual testing.* It must ensure that all agents and brokers selling Medicare products are tested annually, to ensure the following:

(1) Appropriate knowledge and understanding of Medicare rules and regulations.

(2) Details specific to the plan products they intend to sell.

* * * * *

(h) *Finder's (referral) fees.* Finder's (referral) fees paid to all agents and brokers—

(1) May not exceed an amount CMS determines could reasonably be expected to affect enrollee behavior while not exceeding the value of the health-related service or activity itself; and

(2) Must be included in the total compensation not to exceed the fair market value for that calendar year.

## Subpart Y—[Reserved]

■ 51. Part 422 is amended by adding reserved subpart Y.

■ 52. Part 422 is amended by adding subpart Z to read as follows:

**Subpart Z—Part C Recovery Audit Contractor Appeals Process**

Sec.
422.2600 Payment appeals.
422.2605 Request for reconsideration.
422.2610 Hearing official review.
422.2615 Review by the Administrator.

## Subpart Z—Part C Recovery Audit Contractor Appeals Process

**§ 422.2600 Payment appeals.**

If the Part C RAC did not apply its stated payment methodology correctly, an MA organization may appeal the findings of the applied methodology. The payment methodology itself is not subject to appeal.

**§ 422.2605 Request for reconsideration.**

(a) *Time for filing a request.* The request for reconsideration must be filed with the designated independent reviewer within 60 calendar days from the date of the demand letter received by the MA organization.

(b) *Content of request.* (1) The request for reconsideration must be in writing and specify the findings or issues with which the MA organization disagrees.

(2) The MA organization must include with its request all supporting documentary evidence it wishes the independent reviewer to consider.

(i) This material must be submitted in the format requested by CMS.

(ii) Documentation, evidence, or substantiation submitted after the filing of the reconsideration request will not be considered.

(c) *CMS rebuttal.* CMS may file a rebuttal to the MA organization's reconsideration request.

(1) The rebuttal must be submitted within 30 calendar days of the review entity's notification to CMS that it has received the MA organization's reconsideration request.

(2) CMS sends its rebuttal to the MA organization at the same time it is submitted to the independent reviewer.

(d) *Review entity.* An independent reviewer conducts the reconsideration. The independent reviewer reviews the demand for repayment, the evidence and findings upon which it was based and any supporting documentation that the MA organization or CMS submitted in accordance with this section.

(e) *Notification of decision.* The independent reviewer informs the CMS and the MA organization of its decision in writing.

(f) *Effect of decision.* A reconsideration decision is final and binding unless the MA organization requests a hearing official review in accordance with § 422.2610.

(g) *Right to hearing official review.* An MA organization that is dissatisfied with the independent reviewer's reconsideration decision is entitled to a hearing official review as provided in § 422.2610.

**§ 422.2610 Hearing official review.**

(a) *Time for filing a request.* A MA organization must file with CMS a request for a hearing official review within 15 calendar days from the date of the independent reviewer's issuance of a reconsideration determination.

(b) *Content of the request.* (1) The request must be in writing and must specify the findings or issues in the reconsideration decision with which the MA organization disagrees and the reasons for the disagreements.

(2) The MA organization must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered.

(3) No new evidence may be submitted.

(4) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(c) *CMS rebuttal.* CMS may file a rebuttal to the MA organization's hearing official review request.

(1) The rebuttal must be submitted within 30 calendar days of the MA organization's submission of its hearing official review request.

(2) CMS sends its rebuttal to the MA organization at the same time it is submitted to the hearing official.

(d) *Conducting a review.* A CMS-designated hearing official conducts the hearing on the record.

(1) The hearing is not to be conducted live or via telephone unless the hearing official, in his or her sole discretion, requests a live or telephonic hearing.

(2) In all cases, the hearing official's review is limited to information that meets one or more of the following:

(i) The Part C RAC used in making its determinations.

(ii) The independent reviewer used in making its determinations.

(iii) The MA organization submits with its hearing request.

(iv) CMS submits in accordance with paragraph (c) of this section.

(3) Neither the MA organization nor CMS may submit new evidence.

(e) *Hearing official decision.* The CMS hearing official decides the case within 60 days and sends a written decision to the MA organization and CMS, explaining the basis for the decision.

(f) *Effect of hearing official decision.* The hearing official's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with § 422.2615.

**§ 422.2615 Review by the Administrator.**

(a) *Request for review by Administrator.* If an MA organization is dissatisfied with the hearing official's decision, it may request that the CMS Administrator review the decision.

(1) The request must be filed with the CMS Administrator within 15 calendar days of the date of the hearing official's decision.

(2) The request must provide evidence or reasons to substantiate the request.

(b) *Content of request.* The MA organization must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered.

(1) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(2) Neither the MA organization, nor CMS may submit new evidence.

(c) *Discretionary review.* After receiving a request for review, the CMS Administrator has the discretion to review the hearing official's decision in accordance with paragraph (e) of this section or to decline to review said decision.

(d) *Notification of decision whether to review.* The Administrator notifies the MA organization within 45 days of receiving the MA organization's hearing request of whether he or she intends to review the hearing official's decision.

(1) If the Administrator agrees to review the hearing official's decision, CMS may file a rebuttal statement within 30 days of the Administrator's notice to the plan that the request for review has been accepted. CMS sends its rebuttal statement to the plan at the same time it is submitted to the Administrator.

(2) If the CMS Administrator declines to review the hearing official's decision, the hearing official's decision is final and binding.

(e) *CMS Administrator's review.* If the CMS Administrator agrees to review the hearing official's decision, he or she determines, based upon this decision, the hearing record, and any arguments submitted by the MA organization or CMS in accordance with this section, whether the determination should be upheld, reversed, or modified. The Administrator furnishes a written decision, which is final and binding, to the MA organization and to CMS.

## PART 423—MEDICARE PROGRAM; MEDICARE PRESCRIPTION DRUG PROGRAM

■ 53. The authority citation for part 423 continues 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).

■ 54. Amend § 423.1 by adding new references in numerical order to paragraph (a)(1) and by adding paragraph (a)(3) to read as follows:

**§ 423.1 Basis and scope.**

(a) * * *

(1) * * *

1128J(d). Reporting and Returning of Overpayments.

* * * * *

1860D–14A. Medicare coverage gap discount program.

* * * * *

1860D–43. Condition for coverage of drugs under this part.

* * * * *

(3) Section 8 of the United States Code regarding aliens who are not qualified aliens ineligible for Federal public benefits.

* * * * *

■ 55. Section 423.10 is added to subpart A to read as follows:

**§ 423.10 Prohibition on intervention in negotiations with manufacturers.**

(a) *General rule.* CMS promotes fair private market competition in the market for Part D drugs.

(b) *No interference in negotiations.* (1) Except as necessary to enforce CMS requirements, CMS is not—

(i) A party to discussions between drug manufacturers and pharmacies or

between prescription drug manufacturers and Part D sponsors; nor

(ii) An arbiter of the meaning of or compliance with the terms and conditions of agreements reached between these parties.

(2) Nothing in paragraph (b)(1) of this section limits CMS's authority to—

(i) Require documentation of and access to all agreements referenced in paragraph (b)(1)(ii) of this section; or

(ii) Require inclusion of terms and conditions in such agreements when necessary to implement requirements under the Act.

(c) *No establishment of formulary drug product selection.* CMS does not determine the specific drug products to be included on Part D sponsor formularies or any tier placement of such products, except as necessary to comply with § 423.120(b)(1)(v) or § 423.272(b)(2).

(d) *No establishment of Part D drug price reimbursement methodologies.* (1) CMS does not establish specific drug product pricing standards (as defined in § 423.505(b)(21)) or the dollar amount of price concessions at any stage in the drug distribution channel for Part D drugs.

(2) Nothing in this section limits CMS authority to require full disclosure or uniform treatment and reporting of drug costs, prices, or price concessions consistent with rules established by CMS.

■ 56. Amend § 423.30 as follows:

■ A. In paragraph (a)(1) introductory text, by removing the phrase ''if he or she:'' and adding in its place the phrase ''if he or she does all of the following:''.

■ B. In paragraph (a)(1)(i), by removing ''; and'' and adding in its place ''.''.

■ C. By adding paragraph (a)(1)(iii).

The addition reads as follows:

**§ 423.30 Eligibility and enrollment.**

(a) * * *

(1) * * *

(iii) Is a United States citizen or qualified alien who is lawfully present in the United States as determined in 8 CFR 1.3.

* * * * *

**§ 423.44 [Amended]**

■ 57. Amend § 423.44 as follows:

■ A. By adding paragraph (b)(2)(vi).

■ B. In paragraph (d)(1)(vi), by removing the phrase ''CMS may reinstate'' and adding in its place the phrase ''CMS (or its designee) may reinstate''.

■ C. By adding paragraph (d)(8).

The additions read as follows:

**§ 423.44 Involuntary disenrollment from Part D coverage.**

* * * * *

(b) * * *

(2) * * *

(vi) The individual loses qualified alien status or is no longer lawfully present in the United States.

* * * * *

(d) * * *

(8) *Loss of qualified alien status.* Disenrollment is effective with the month following the last month of lawful presence or qualified alien status in the United States.

* * * * *

**§ 423.100 [Amended]**

■ 58. Amend § 423.100 as follows:

■ A. By revising the definition of ''Daily cost-sharing rate''.

■ B. By revising the definition of ''Negotiated prices''.

■ C. By removing the definition of ''Non-preferred pharmacy''.

■ D. In the definition of ''Part D drug''—

■ i. By revising paragraph (1) introductory text.

■ ii. By adding paragraph (1)(vii).

■ iii. In paragraph (2) introductory text, by removing the phrase ''Does not include—'' and adding in its place the phrase ''Does not include any of the following:''

■ iv. In paragraph (2)(i), by removing ''; and'' and adding in its place ''.''.

■ vi. By adding paragraph (2)(iii).

■ E. By adding the definition of ''Preferred cost sharing''.

■ F. By removing the definition of ''Preferred pharmacy''.

The additions and revisions read as follows:

**§ 423.100 Definitions.**

* * * * *

*Daily cost-sharing rate* means, as applicable, the established—

(1) Monthly copayment under the enrollee's Part D plan, divided by the number of days in the approved month's supply for the drug dispensed and rounded to the nearest cent; or

(2) Coinsurance percentage under the enrollee's Part D plan.

* * * * *

*Negotiated prices* means prices for covered Part D drugs that meet all of the following:

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug.

(2) Are inclusive of all price concessions and any other fees charged to network pharmacies; and

(3) Include any dispensing fees; but

(4) May exclude additional contingent amounts, such as incentive fees, only if these amounts increase prices and cannot be predicted in advance.

(5) May not be rebated back to the Part D sponsor (or other intermediary contracting organization) in full or in part.

* * * * *

*Part D drug* * * *

(1) Unless excluded under paragraph (2) of this definition, any of the following, or any FDA-approved combinations of the following, if used for a medically accepted indication (as defined in section 1860D–2(e)(4) of the Act).

* * * * *

(vii) A combination product approved and regulated by the FDA as a drug, vaccine, or biologic (or any approved combinations of these) described in paragraphs (i), (ii), (iii), or (v) of the Part D drug definition.

(2) Does not include any of the following:

* * * * *

(iii) Medical foods, defined as a food that is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation, and that are not regulated as drugs under section 505 of the Federal Food, Drug, and Cosmetic Act.

* * * * *

*Preferred cost sharing* means lower cost sharing for certain covered Part D drugs at certain network pharmacies offered in accordance with the requirements of § 423.120(a)(9).

* * * * *

■ 59. Amend 423.120 by:

■ A. Revising paragraphs (a)(3), (8), and (9).

■ B. Redesignating paragraphs (b)(1)(iv) through (x) as (b)(1)(v) through (xi), respectively.

■ C. Adding a new paragraph (b)(1)(iv).

■ D. Revising paragraphs (b)(2)(v), (vi)(B), and (C).

■ E. Adding new paragraphs (b)(2)(vi)(D) through (G) and (3)(vi).

■ F. Redesignating paragraphs (c)(5)(i) through (v) as paragraphs (c)(5)(i)(A) through (E), respectively.

■ G. Adding paragraph (c)(5)(i) introductory text.

■ H. In newly resdesignated paragraphs (c)(5)(i)(A) and (B), removing the cross-reference ''(c)(5)(iii) of this section'' and adding in its place the cross-reference ''(c)(5)(i)(C) of this section''

■ I. In newly redesignated paragraph (c)(5)(i)(D), removing the cross-reference

''(c)(5)(ii) and (iii) of this section'' and adding in its place the cross-reference ''(c)(5)(i)(B) and (C) of this section''.

■ J. Adding a new paragraph (c)(5)(ii).

■ K. Adding paragraph (c)(6).

The revisions and additions read as follows:

**§ 423.120 Access to covered Part D drugs.**

* * * * *

(a) * * *

(3) *Access to non-retail pharmacies.* A part D sponsor's contracted pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering home delivery via mail order and institutional pharmacies, provided the requirements of paragraph (a)(1) of this section are met. Sponsors that contract with mail order pharmacies, and pharmacies offering home delivery via mail order, must ensure that the pharmacies meet the following fulfillment standards:

(i) For prescriptions adjudicated and filled without requiring additional review, the time of shipment must not be more than 3 business days from order receipt by the mail order pharmacy.

(ii) For prescriptions requiring additional review before shipping, the time of shipment must not be more than 5 business days from order receipt by the mail order pharmacy.

* * * * *

(8) *Pharmacy network contracting requirements.* In establishing its contracted pharmacy network, a Part D sponsor offering qualified prescription drug coverage must comply with all of the following requirements:

(i) Must offer and publicly post standard terms and conditions for network participation for each type of pharmacy in the network, subject to paragraphs (a)(8)(ii) and (iii) of this section.

(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the Part D sponsor's contracted pharmacy network.

(iii) Must offer payment terms for every level of cost sharing offered under the sponsor's plans consistent with CMS limitations on the number and type of cost sharing levels (preferred, standard, extended day), and for every type of similarly situated retail pharmacy.

(iv) Must contract with any willing pharmacy able to meet one set of the terms and conditions offered by that plan for that type of pharmacy.

(9) *Preferred cost-sharing in network pharmacies.* A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a subset of network pharmacies, as long as such preferred cost sharing is offered in accordance with the requirements of § 423.120(a)(8) and for Part D drugs with consistently lower negotiated prices than the same Part D drugs when obtained in the rest of the pharmacy network.

* * * * *

(b) * * *

(1) * * *

(iv) Clearly articulates and documents processes to determine that the requirements under paragraphs (b)(1)(i) through (iii) of this section have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts.

* * * * *

(2) * * *

(v) Effective contract year 2015, except as provided in paragraph (b)(2)(vi) of this section, a Part D sponsor's formulary must include without restriction at point of sale all Part D drugs in a category or class that CMS has determined for a typical individual with a disease or condition treated by the drugs in the category or class meets the all of the following criteria:

(A) Hospitalization, persistent or significant disability or incapacity, or death will likely result if initial administration (including self-administration) of a drug in the category or class does not occur within 7 days of the date the prescription for the drug was presented to the pharmacy to be filled.

(B) More specific CMS formulary requirements will not suffice to meet the universe of clinical drug-and-disease-specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.

(vi) * * *

(B) Drug products that are primarily covered under Medicare Part A or B.

(C) Part D Compounds as described in § 423.120(d).

(D) Fixed combination dosage form prescription drugs other than antiretrovirals, including co-packaged drug products, as defined by 21 CFR 300.50.

(E) Certain types of Part D drugs, including the following:

(*1*) Multisource brands of the identical molecular structure.

(*2*) Extended-release products when the immediate-release product is included.

(*3*) Products that have the same active ingredient or moiety.

(*4*) Dosage forms that do not provide a unique route of administration (for example, tablets and capsules versus tablets and transdermals).

(F) Point-of-sale utilization management safety edits consistent with the FDA approved label.

(G) Prior authorization requirements used to verify a drug is being used for a medically accepted indication (as defined in § 423.100) or to verify a drug is not covered under Medicare Parts A or B as prescribed and dispensed or administered.

(3) * * *

(vi) A Part D sponsor must charge cost sharing for a temporary supply of drugs provided under its transition process such that the following conditions are met:

(A) For low-income subsidy (LIS) enrollees, a sponsor must not charge higher cost sharing for transition supplies than the statutory maximum copayment amounts.

(B) For non-LIS enrollees, a sponsor must charge—

(*1*) The same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non-formulary drugs approved through a formulary exception in accordance with § 423.578(b); and

(*2*) The same cost sharing for formulary drugs subject to utilization management edits provided during the transition that would apply once the utilization management criteria are met.

* * * * *

(c) * * *

(5)(i) Before January 1, 2015—

* * * * *

(ii) Beginning January 1, 2015—

(A) A Part D sponsor must deny or must require its PBM to deny a pharmacy claim for a Part D drug if an active and valid physician or eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) National Provider Identifier is not contained on the claim.

(B) A Part D sponsor must deny or require its PBM to deny a pharmacy claim for a Part D drug if the physician or eligible professional—

(*1*) Is not enrolled in the Medicare program in an approved status; and

(*2*) Does not have a valid opt-out affidavit on file with an A/B MAC.

(C) To receive payment for a drug, a beneficiary's request for reimbursement from a Part D sponsor must be for a Part D drug that was dispensed in accordance with a prescription written by a physician or, when permitted under applicable State law, other eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) who—

(*1*) Is identified by his or her legal name in the request; and

(*2*)(*i*) Is enrolled in Medicare in an approved status; or

(*ii*) Has a valid opt-out affidavit on file with an A/B MAC.

* * * * *

(6)(i) In order for a Part D sponsor to submit to CMS a prescription drug event record, the PDE must pertain to a claim for a Part D drug that was dispensed in accordance with a prescription written by a physician or, when permitted under applicable State law, an eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) who is either of the following:

(A) Is enrolled in Medicare in an approved status.

(B) Has a valid opt-out affidavit on file with an A/B MAC.

(ii) To receive payment for a drug, a beneficiary's request for reimbursement from a Part D sponsor must be for a Part D drug that was dispensed in accordance with a prescription written by a physician or, when permitted, other eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) who—

(A)(*1*) Is identified by his or her legal name in the request; and

(*2*) Is enrolled in Medicare in an approved status; or

(B) Has a valid opt-out affidavit on file with an A/B MAC.

(iii) A Part D sponsor must deny or must require its PBM to deny the following:

(A) A pharmacy claim for a drug, if the claim does not meet the requirements of paragraph (c)(6)(i) of this section.

(B) A request for reimbursement from a Medicare beneficiary for a drug, if the request does not meet the requirements of paragraph (c)(6)(ii) of this section.

* * * * *

■ 60. Section 423.126 is added to read as follows:

**§ 423.126 Special access rules during disasters or emergencies.**

(a) *Special access rules during disasters or emergencies.* A Part D sponsor must relax ''refill-too-soon'' (RTS) edits to allow an enrollee to obtain one early refill of each covered Part D drug he or she is taking in the event of an anticipated or actual disaster or emergency, as evidenced by a declaration of a disaster or emergency issued by an appropriate Federal, State, or local official, and it is reasonable to conclude that such disaster or emergency or preparation therefore would make it difficult for beneficiaries to obtain refills of their medications because the disaster or emergency or anticipation thereof has affected, or will affect, their ability to have timely access to their usual pharmacies.

(b) *Duration of relaxed edits.* A Part D sponsor must continue to relax the RTS edits as described in paragraph (a) of this section until the 30 days after the date of the triggering emergency or disaster declaration.

■ 61. Amend § 423.128 by revising paragraph (a)(3) and adding paragraph (g) to read as follows:

**§ 423.128 Dissemination of Part D information.**

* * * * *

(a) * * *

(3) At the time of enrollment, and at least annually thereafter by December 31 for the following contract year.

* * * * *

(g) *Changes in rules.* If a Part D sponsor intends to change its rules for a Part D plan, it must do all of the following:

(1) Submit the changes for CMS review under the procedures of Subpart V of this part.

(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 as defined in section 1860D–1(b)(1)(B) of the Act.

(3) Provide notice of all other changes in accordance with notice requirements as specified in Part 423.

■ 62. Amend § 423.153 by revising paragraphs (b)(4), (d)(1)(v), and (d)(2)(i) through (iii) to read as follows:

**§ 423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs)**

* * * * *

(b) * * *

(4)(i) *Daily cost sharing rate.* Subject to paragraph (b)(4)(ii) of this section, establishes a daily cost-sharing rate (as defined in § 423.100) and applies it to a prescription presented to a network pharmacy for a covered Part D drug that is dispensed for a supply less than 30 days, if the drug is in the form of a solid oral dose and may be dispensed for a supply less than 30 days under applicable law.

(ii) *Exceptions.* The requirements of paragraph (b)(4)(i) of this section do not apply to either of the following:

(A) Solid oral doses of antibiotics.

(B) Solid oral doses that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance.

(iii) *Cost-sharing*—(A) *Copayments.* In the case of a drug that would incur a copayment, the Part D sponsor must apply cost-sharing as calculated by multiplying the applicable daily cost-sharing rate by the days' supply actually dispensed when the beneficiary receives less than a 30 days' supply.

(B) *Coinsurance.* In the case of a drug that would incur a coinsurance percentage, the Part D sponsor must apply the coinsurance percentage for the drug to the days' supply actually dispensed.

* * * * *

(d) * * *

(1) * * *

(v) Must do both of the following:

(A) Have an outreach strategy designed to effectively engage at-risk beneficiaries enrolled in the plan.

(B) Enroll targeted beneficiaries using an opt-out method of enrollment only.

* * * * *

(2) * * *

(i) Have two or more chronic diseases. At least one of the chronic diseases must be one from the following list of core chronic diseases:

(A) Cardiovascular disease

(B) Diabetes.

(C) Dyslipidemia.

(D) Respiratory disease.

(E) Bone disease-arthritis.

(F) Mental health.

(G) Alzheimer's disease.

(H) End-stage renal disease.

(ii) Are taking two or more covered Part D drugs.

(iii) Are likely to incur annual costs for covered Part D drugs that are commensurate with the drug spending of beneficiaries with two or more chronic diseases that take two covered Part D drugs.

* * * * *

■ 62. Amend § 423.154 by:

■ A. Revising paragraphs (a)(2) and (c).

■ B. Removing paragraph (e).

■ D. Redesignating paragraph (f) as (e).

■ E. Adding a new paragraph (f).

The revisions and addition read as follows:

**§ 423.154 Appropriate dispensing of prescription drugs in long-term care facilities under PDPs and MA–PD plans.**

(a) * * *

(2) Collect and report information, in a form and manner specified by CMS, on the dispensing methodology used for each dispensing event described by paragraph (a)(1) of this section.

* * * * *

(c) *Waivers.* CMS waives the requirements under paragraph (a) of this section for any of the following:

(1) Pharmacies when they service intermediate care facilities for the mentally retarded (ICFs/IID) and

institutes for mental disease (IMDs) as defined in § 435.1010 of this chapter.

(2) I/T/U pharmacies (as defined in § 423.100).

(3)(i) Institutional pharmacies that—

(A) Subject to paragraph (c)(3)(iii) of this section, exclusively use a dispensing technique that returns all unused medications to stock for reuse;

(B) Issues full credit of the ingredient costs of unused medication to the Part D sponsor; and

(C) For drugs that cannot be returned to stock for reuse under applicable law use a dispensing methodology that results in the delivery of no more than a 14 days' supply of a drug at a time.

(ii) The waiver in paragraph (c)(3)(i) of this section does not apply to a pharmacy organization that is contracted to use this dispensing technique at some of its pharmacies, but only to the qualifying pharmacies themselves.

* * * * *

(f) *Prohibition on proration of dispensing fees.* A Part D sponsor must not, or must require its intermediary contracting organization not to, do the following:

(1) Not penalize long-term care facilities' choice of more efficient uniform dispensing techniques described in paragraph (a)(1)(ii) of this section by prorating dispensing fees based on days' supply or quantity dispensed.

(2) Ensure that any difference in payment methodology among long-term care pharmacies incentivizes more efficient dispensing techniques.

■ 64. Amend § 423.265 as follows:

■ A. By redesignating paragraph (b)(3) as (b)(4).

■ B. By adding a new paragraph (b)(3).

■ C. In newly redesignated paragraph (b)(4), by adding a paragraph heading.

The additions read as follows:

**§ 423.265 Submission of bids and related information.**

* * * * *

(b) * * *

(3) *Number of bids.* Starting with bids submitted during 2015 for plans to be offered during coverage year 2016, CMS will not accept more than two bids for a coverage year from a stand-alone PDP sponsor in each PDP region.

(4) *Declining a bid.* * * *

* * * * *

■ 65. Section 423.294 is added to subpart F to read as follows:

**§ 423.294 Collections of premiums and cost sharing.**

(a) *Refunds of incorrect collections*—(1) *Definitions.* As used in this section the following definitions are applicable:

*Amounts incorrectly collected.* (i) Means amounts that exceed the monthly beneficiary Part D premium limits under § 423.286 or exceed permissible cost-sharing amounts as specified § 423.104(d) through (f); 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.

*Other amounts due* means amounts due for covered Part D drugs that were—

(i) Accessed at an out-of-network pharmacy in accordance with the requirements at § 423.124; or

(ii) Initially denied but, upon appeal, found to be covered Part D drugs the enrollee was entitled to have provided by the Part D plan.

(2) *General rule.* A Part D plan must 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 within the timeframe specified at § 423.466(a).

(3) *Refund methods*—(i) *Lump-sum payment.* The Part D plan must use lump-sum payments for the following:

(A) Amounts incorrectly collected that were not collected as premiums.

(B) Other amounts due.

(C) All amounts due if the Part D plan is going out of business or terminating its Part D contract for a prescription drug plan(s).

(ii) *Premium adjustment, 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 Part D plan may refund by adjustment of future premiums or by a combination of premium adjustment and lump-sum payments.

(iii) *Refund when enrollee has died or cannot be located.* If an enrollee has died or cannot be located after reasonable effort, the Part D plan must make the refund in accordance with State law.

(4) If the Part D plan does not make the refund required under this section within the timeframe specified at § 423.466(a), the Part D plan may receive compliance notices from CMS or, depending on the significance of the non-compliance, be the subject of an intermediate sanction (for example, suspension of marketing and enrollment activities) in accordance with part 423, subpart O.

(b) *Retroactive collection of cost-sharing amounts*—(1) *General rule.* A Part D plan must make a reasonable effort to collect cost sharing from a beneficiary or to bill cost sharing to another appropriate party.

(2) *Timeframe.* Recovery efforts must be initiated in accordance with the timeframe specified at § 423.466(a).

(c) *Reduction or waiver of premiums and cost sharing*—(1) *General rule.* Part D plans, directly, or indirectly through related entities as defined at § 423.501, are prohibited from reducing or waiving the collection of enrollee premiums or cost sharing or both.

(2) *Failure to collect premiums and cost sharing.* Failure to collect premiums, collect cost sharing at the time the service is provided, or attempt to collect cost sharing from a beneficiary or to bill cost sharing to another appropriate party after the fact, is in violation of the uniform benefit provisions set forth in § 423.104(b).

■ 66. Amend § 423.308 by revising the definition of ''Actually paid'' to read as follows:

**§ 423.308 Definitions and terminology.**

* * * * *

*Actually paid* means that the costs must be actually incurred by the Part D sponsor and must be net of any direct or indirect remuneration (including discounts, incentive payments, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, 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 other than pharmacies (including manufacturers, enrollees, or any other person) that would serve to decrease (or increase) the costs incurred under the Part D plan.

(1) Direct and indirect remuneration includes discounts, incentive payments, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers or similar entities obtained by an intermediary contracting organization with which the Part D plan sponsor has contracted, regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the Part D plan sponsor and regardless of the terms of the contract between the plan sponsor and the intermediary contracting organization.

(2) Direct and indirect remuneration may include additional payments to pharmacies, such as for incentive payments, but may not include any other price concessions from pharmacies.

* * * * *

■ 67. Amend § 423.322 by revising paragraph (b) to read as follows:

**§ 423.322 Requirement for disclosure of information.**

* * * * *

(b) *Restrictions on use of information.* (1) 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 for the purposes of, and to the extent necessary—

(i) In carrying out this subpart, including, but not limited to, determination of payments, and payment-related oversight and program integrity activities.

(ii) In conducting oversight, evaluation, and enforcement under Title XVIII of the Act.

(2) The United States Attorney General and the Comptroller General of the United States may use the information disclosed or obtained in accordance with the provisions of this subpart for purposes of, and to the extent necessary in, carrying out health oversight activities.

(3) The restrictions described in paragraphs (b)(1) and (2) of this section do not limit either of the following:

(i) OIG's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

(ii) CMS' ability to use data regarding drug claims in accordance with section 1848(m) of the Act.

**§ 423.329 [Amended]**

■ 68. Amend § 423.329 (d)(1), by removing the phrase ''the amount described in § 423.782.'' and adding in its place the phrase ''the difference between the Part D cost-sharing for a non-low-income subsidy eligible beneficiary under the Part D plan and the statutory cost-sharing for a low-income subsidy eligible beneficiary.''

■ 69. Section 423.346 is amended by revising paragraphs (a) through (c) to read as follows:

**§ 423.346 Reopening.**

(a) CMS may reopen an initial 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) one time within 5 years after the date of the notice of the initial determination to the Part D sponsors.

(b) CMS may reopen the Coverage Gap Discount Reconciliation (as described at § 423.2320 (b), one time within 5 years after the date of the notice of the Coverage Gap Discount Reconciliation to the Part D sponsors.

(c) CMS does not reopen as a result of a change in legal interpretation or administrative ruling upon which the final determination was made.

* * * * *

■ 70. Amend § 423.350 as follows:

■ A. In paragraph (a)(1)(iii), by removing ''; or'' and adding in its place ''.''.

■ B. In paragraph (a)(1)(iv), by removing '').'' adding in its place ''.''.

■ C. By adding paragraph (a)(1)(v).

■ D. By revising paragraph (a)(2).

■ E. By adding paragraph (b)(1)(iv).

**§ 423.350 Payment appeals.**

(a) * * *

(1) * * *

(v) The reconciled coverage gap discount payment under § 423.2320(b).

(2) *Payment information not subject to appeal.* Payment information submitted to CMS under § 423.322 and reconciled under § 423.343 or submitted and reconciled under § 423.2320(b) is final and may not be appealed nor may the appeals process be used to submit new information after the submission of information necessary to determine retroactive adjustments and reconciliations.

(b) * * *

(1) * * *

(iv) For the Coverage Gap Discount Program, the date of the final reconciled payment under § 423.2320(b).

* * * * *

■ 71. Section 423.360 is added to subpart G to read as follows:

**§ 423.360 Reporting and returning of overpayments.**

(a) *Definitions.* For the purposes of this section the following definitions are applicable:

*Applicable reconciliation* means the later of either the annual deadline for submitting—

(i) PDE data for the annual Part D payment reconciliations referred to in § 423.343(c) and (d); or

(ii) Direct and indirect remuneration data.

*Funds* for purposes of this section, means any payment that a Part D sponsor has received that is based on data submitted by the Part D sponsor to CMS for payment purposes, including data submitted under § 423.329(b)(3), § 423.336(c)(1), § 423.343, and data provided for purposes of supporting allowable costs as defined in § 423.308 which includes data submitted to CMS regarding direct or indirect remuneration.

*Overpayment* means funds that a Part D sponsor has received or retained under title XVIII of the Act to which the Part D sponsor, after applicable reconciliation, is not entitled under such title.

(b) *General rule.* If a Part D sponsor has identified that it has received an overpayment, the Part D sponsor must report and return that overpayment in the form and manner set forth in this section.

(c) *Identified overpayment.* A Part D sponsor has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment. A Part D sponsor must exercise reasonable diligence to determine the accuracy of information it receives that an overpayment may exist.

(d) *Reporting and returning of an overpayment.* A Part D sponsor must report and return any overpayment it received no later than 60 days after the date on which it identified it received an overpayment.

(1) *Reporting.* A Part D sponsor must notify CMS of the amount and reason for the overpayment, using the notification process determined by CMS.

(2) *Returning.* A Part D sponsor must return identified overpayments in a manner specified by CMS.

(3) *Enforcement.* Any overpayment retained by a Part D sponsor after the 60-day deadline for reporting and returning is an obligation under 31 U.S.C. 3729(b)(3).

(e) *Look-back period.* A Part D sponsor must report and return any overpayment identified within the 6 most recent completed payment years. Overpayments resulting from fraud would not be subject to this limitation.

■ 72. Amend § 423.464 as follows:

■ A. In paragraph (f)(2)(i) introductory text, by removing the phrase ''a Part D plan must—'' and adding in its place ''a Part D plan must do all of the following:''.

■ B. In paragraph (f)(2)(i)(A), by removing ''; and'' and adding in its place ''.''.

■ C. By adding paragraph (f)(2)(i)(C). The addition reads as follows:

**§ 423.464 Coordination of benefits with other providers of prescription drug coverage.**

* * * * *

(f) * * *

(2) * * *

(i) * * *

(C) Report, accept and apply benefit accumulator data in a timeframe and manner determined by CMS.

* * * * *

**§ 423.466 [Amended]**

■ 73. Amend § 423.466(b) by removing the phrase ''a period not to exceed 3 years'' and adding in its place the phrase ''a period of 3 years''.

■ 74. Amend § 423.501 by a adding a definition for ''prescription drug pricing standard'' to read as follows:

**§ 423.501 Definitions.**

* * * * *

*Prescription drug pricing standard* means any methodology or formula for varying the pricing of a drug or drugs during the term of a pharmacy reimbursement contract that is based on the cost of a drug, which includes, but is not limited to, drug pricing references and amounts based on any of the following:

(1) Average wholesale price.
(2) Wholesale average cost.
(3) Average manufacturer price.
(4) Average sales price.
(5) Maximum allowable cost.
(6) Other cost, whether publicly available or not.

* * * * *

■ 75. Amend § 423.503 by revising paragraph (a)(1) and adding paragraphs (a)(3), (c)(4), and (d) to read as follows:

**§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.**

(a) * * *

(1) With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an entity's application solely on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits and an essential operations test.

* * * * *

(3) CMS may not approve an application when it would result in the applicant's parent organization, directly or through its subsidiaries, holding more than one PDP sponsor contract in the PDP Region for which the applicant is seeking qualification as a PDP sponsor. A parent organization is an entity that exercises a controlling interest in the applicant.

* * * * *

(c) * * *

(4) *Nullification of approval of application.* If CMS discovers through any means that an applicant is not qualified to contract based on information gained subsequent to application approval (for example, failure of an essential operations test, absence of required employees), CMS gives the applicant written notice indicating that the approval issued under § 423.503(c)(1) is nullified and the applicant no longer qualifies to contract as a Part D plan sponsor.

(i) This determination is not subject to the appeals provisions in subpart N of this part.

(ii) This provision only applies to applicants that have not previously entered into a Part D contract with CMS and neither it, nor another subsidiary of the applicant's parent organization, is offering Part D benefits during the current year.

(d) Withdrawal of application and bid in a previous year. An applicant that withdraws its application and corresponding bid after the release of the low income subsidy benchmark is not eligible to be approved as a Part D plan sponsor for the 2 succeeding annual contracting cycles.

■ 76. Amend § 423.504 as follows:

■ A. By adding paragraphs (b)(4)(vi)(C)(*4*) and (b)(8) through (10).

■ B. In paragraph (d)(2) introductory text, by removing the phrase ''has the right to—'' and adding in its place the phrase ''has the right to timely do all of the following:''.

■ C. In paragraph (d)(2)(i), by removing '';'' and adding in its place a ''.''.

■ D. In paragraph (d)(2)(ii), by removing ''; and'' and adding in its place a ''.''.

■ E. By adding paragraph (d)(2)(iv).

The additions read as follows:

**§ 423.504 General provisions.**

* * * * *

(b) * * *

(4) * * *

(vi) * * *

(C) * * *

(*4*) A Part D plan sponsor must require all of its first tier, downstream and related entities to take the CMS training and accept the certificate of completion of the CMS training as satisfaction of this requirement. Part D plan sponsors are prohibited from developing and implementing their own training or providing supplemental training materials to fulfill this requirement.

* * * * *

(8) If neither the applicant, nor its parent or another subsidiary of the same parent, holds a Part D sponsor contract that has been in effect for at least 1 year at the time it submits an application, the applicant must have arrangements in place such that the applicant and its contracted first tier, downstream, or related entities, in combination, have at least 1 full-benefit year of experience within the 2 years preceding the application submission performing at a minimum all of the following functions in support of the operation of another Part D contract:

(i) Authorization, adjudication, and processing of prescription drug claims at the point of sale.

(ii) Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers.

(iii) Operation of an enrollee appeals and grievance process.

(9) For organizations applying to offer stand-alone prescription drug plans, the organization, its parent, or a subsidiary of the organization or its parent, must have either of the following:

(i) For 2 continuous years immediately prior to submitting an application, actively offered health insurance or health benefits coverage, including prescription drug coverage, as a risk-bearing entity in at least one State.

(ii) For 5 continuous years immediately prior to submitting an application, actively managed prescription drug benefits for an organization that offers health insurance or health benefits coverage, including at a minimum, all of the services listed in paragraph (b)(8) of this section.

(10) Effective contract year 2015, pass an essential operations test prior to the start of the benefit year. This provision only applies to new sponsors that have not previously entered into a Part D contract with CMS when neither it, nor another subsidiary of the applicant's parent organization, is offering Part D benefits during the current year.

* * * * *

(d) * * *

(2) * * *

(iv) CMS may require that the Part D Plan sponsor hire an independent auditor to conduct full or partial program audits or to provide CMS with information to determine if deficiencies found during an audit or inspection have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

* * * * *

■ 77. Amend § 423.505 as follows:

■ A. By revising paragraphs (b)(18) and (21).

■ B. By adding paragraphs (b)(27) and (28).

■ C. In paragraph (f)(3)(v), by removing ''.'' and adding in its place ''.''.

■ D. In paragraph (f)(3)(vi), by removing ''; and'' and adding in its place ''.''.

■ E. By adding paragraph (f)(3)(viii).

■ F. In paragraph (i)(2)(i), by removing the phrase ''audit, evaluate and inspect'' and adding in its place ''audit, evaluate, collect, and inspect''.

■ G. By redesignating paragraph (i)(2)(ii) as paragraph (i)(2)(iii).
■ H. By adding a new paragraph (i)(2)(ii).
■ I. By revising paragraph (i)(3)(viii).
■ J. By adding paragraph (k)(7).
■ K. By adding a paragraph (m) subject heading.
■ L. By revising paragraphs (m)(1)(iii) introductory text, (m)(1)(iii)(A) and (B).
■ M. By removing paragraph (m)(1)(iii)(C).
■ N. By redesignating (m)(1)(iii)(D) as paragraph (m)(1)(iii)(C).
■ O. By revising newly redesignated (m)(1)(iii)(C)(*1*) and (3).
■ P. By revising paragraph (m)(3).
■ Q. By adding paragraph (p).

The revisions and additions read as follows:

**§ 423.505 Contract provisions.**

* * * * *

(b) * * *

(18) To agree to have standard contracts that meet the requirements described in § 423.120(a)(8) with reasonable and relevant terms and conditions of participation for each type of pharmacy in its network whereby any willing pharmacy may access all relevant contract(s) to participate as a network pharmacy.

* * *

(21)(i) Update any prescription drug pricing standard (as defined in § 423.501) based on the cost of the drug used for reimbursement of network pharmacies by the Part D sponsor on January 1 of each contract year and not less frequently than once every 7 days thereafter;

(ii) Indicate the source used for making any such updates; and

(iii) Disclose all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims, if the source for any prescription drug pricing standard is not publicly available.

* * * * *

(27) A Part D sponsor is required to administer a Part D Benefit that provides good quality health care demonstrated by scores of three or higher on CMS performance standards for patient outcomes, intermediate outcomes, process, patient experience, and patient access to care.

(28) Effective contract year 2015, pass an essential operations test prior to the start of the benefit year. This provision only applies to new sponsors that have not previously entered into a Part D contract with CMS and neither it, nor another subsidiary of the applicant's parent organization, is offering Part D benefits during the current year.

* * * * *

(f) * * *

(3) * * *

(viii) Supporting program integrity purposes, including coordination with the States.

* * * * *

(i) * * *

(2) * * *

(ii) HHS, the Comptroller General or their designees have the right to audit, evaluate, collect, and inspect any records under (i)(2)(i) directly from any first tier, downstream, or related entity.

* * * * *

(3) * * *

(viii) If applicable, provisions addressing the drug pricing standard requirements of § 423.505(b)(21).

* * * * *

(k) * * *

(7) *Certification of accuracy of data for overpayments.* The CEO, CFO, or COO must certify (based on best knowledge, information, and belief) that the information provided for purposes of reporting and returning of overpayments under § 423.360 is accurate, complete, and truthful.

* * * * *

(m) *Release of data.*

(1) * * *

(iii) Subject, in certain cases, to encryption of beneficiary identifiers and aggregation of cost data to protect beneficiary confidentiality and commercially sensitive data of Part D sponsors, in accordance with all of the following principles:

(A) Subject to the restrictions in this paragraph, all elements on the claim are available to HHS, other executive branch agencies, and the States.

(B) Cost data elements on the claim generally are aggregated for releases to other executive branch agencies, States, and external entities. Upon request, CMS excludes sales tax from the aggregation at the individual level if necessary for the project.

(C) * * *

(*1*) Beneficiary identifier elements on the claim generally are encrypted for release, except in limited circumstances, such as the following:

(*i*) If needed, in the case of release to other HHS entities, Congressional oversight agencies, non-HHS executive agencies and the States.

(*ii*) If needed to link to another dataset, in the case of release to external entities. Public disclosure of research results will not include beneficiary identifying information.

* * * * *

(3)(i) CMS must make available to Congressional support agencies (the Congressional Budget Office, the Government Accountability Office, the Medicare Payment Advisory Commission, and the Congressional Research Service when it is acting on behalf of a Congressional committee in accordance with 2 U.S.C. 166(d)(1)), all information collected under paragraph (f)(3) of this section for the purposes of conducting congressional oversight, monitoring, making recommendations, and analysis of the Medicare program.

(ii) The Congressional Research Service is considered an external entity when it is not acting on behalf of a Congressional committee in accordance with 2 U.S.C. 166(d)(1) for the purposes of paragraph (m)(1) of this section.

* * * * *

(p) *Business continuity.* (1) The Part D sponsor agrees to develop, maintain, and implement a business continuity plan containing policies and procedures to ensure the continuation of business operations during disruptions to business operations which would include natural or man-made disasters, system failures, emergencies, and other similar circumstances and the threat of such occurrences. To meet the requirement, the business continuity plan must, at a minimum, include the following:

(i) *Risk assessment.* Identify threats and vulnerabilities that might affect business operations.

(ii) *Mitigation strategy.* Design strategies to mitigate hazards. Identify essential functions in addition to those specified in paragraph (p)(2) of this section and prioritize the order in which to restore all other functions to normal operations. At a minimum, each Part D sponsor must do the following:

(A) Identify specific events that will activate the business continuity plan.

(B) Develop a contingency plan to maintain, during any business disruption, the availability and, as applicable, confidentiality of communication systems and essential records in all forms (including electronic and paper copies). The contingency plan must do the following:

(*1*) Ensure that during any business disruption the following systems will operate continuously or, should they fail, be restored to operational capacity on a timely basis:

(*i*) Information technology IT systems including those supporting claims processing at point of service.

(*ii*) Provider and enrollee communication systems including telephone, Web site, and email.

(*2*) With respect to electronic protected health information, comply with the contingency plan requirements of the Health Insurance Portability and Accountability Act of 1996 Security

Regulations at 45 CFR 160 and 164, Subparts A and C.

(C) Establish a chain of command.

(D) Establish a business communication plan that includes emergency capabilities and procedures to contact and communicate with the following:

(*1*) Employees.

(*2*) First tier, downstream, and related entities.

(*3*) Other third parties (including pharmacies, providers, suppliers, and government and emergency management officials).

(E) Establish employee and facility management plans to ensure that essential operations and job responsibilities can be assumed by other employees or moved to alternate sites as necessary or both.

(F) Establish a restoration plan including procedures to transition to normal operations.

(G) Comply with all applicable Federal, State, and local laws.

(iii) *Testing and revision.* On at least an annual basis, test and update the business operations continuity plan to ensure the following:

(A) That it can be implemented in emergency situations.

(B) That employees understand how it is to be executed.

(iv) *Training.* On at least an annual basis, educate all new and existing employees about the business continuity plan and their own respective roles.

(v) *Records.* (A) Develop and maintain records documenting the elements of the business continuity plan described in paragraph (p)(1)(i) through (p)(1)(iv) of this section.

(B) Make the information specified in paragraph (p)(1)(v)(A) of this section available to CMS upon request.

(2) *Restoration of essential functions.* Every Part D sponsor must restore essential functions within 24 hours after any of the essential functions fail or otherwise stop functioning as usual. In addition to any essential functions that the Part D sponsor identifies under paragraph (p)(1)(ii) of this section, for purposes of this paragraph (p)(2) of this section essential functions include at a minimum, the following:

(i) Benefit authorization (if not waived), adjudication, and processing of prescription drug claims at the point of sale.

(ii) Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers.

(iii) Provision of pharmacy technical assistance.

(iv) Operation of an enrollee exceptions and appeals process including coverage determinations.

(v) Operation of call center customer services.

■ 78. Amend § 423.509 as follows:

■ A. By redesignating paragraphs (a)(4) through (a)(14) as paragraphs (a)(4)(i) through (a)(4)(xi).

■ B. By adding paragraph (a)(4) introductory text.

■ C. In newly redesignated paragraphs (a)(4)(ii), (iv), (v) introductory text, (vi), and (vii), by removing the term ''fails'' and adding in its place the term ''failed''.

■ D. In newly redesignated paragraphs (a)(4)(iii), (viii), and (ix), by removing the term ''fails'' and adding in its place the term ''failed''.

■ E. By revising newly redesignated paragraphs (a)(4)(x) and (xi).

■ F. By adding paragraph (a)(4)(xii).

■ G. By revising paragraphs (b)(1)(i) through (iv) and (b)(2)(i)(C).

■ H. In paragraph (b)(2)(ii), by removing the phrase ''MA organization'' and adding in its place the phrase ''Part D plan sponsor''.

■ I. In paragraph (c)(2)(iii), by removing the cross-reference ''(a)(4) of this section'' and adding in its place the cross-reference ''(a)(4)(i) of this section''.

■ J. In paragraph (d), by removing the cross-reference ''§ 423.642'' and adding in its place the cross-reference ''subpart N of this part''.

The additions and revisions read as follows:

**§ 423.509 Termination of a contract by CMS.**

(a) * * *

(4) CMS may make a determination under paragraph (a)(1), (2) or (3) of this section if the Part D Plan sponsor has had one or more of the following occur:

* * * * *

(x) Achieves a Part D summary plan rating of less than 3 stars for 3 consecutive contract years. Plan ratings issued by CMS before September 1, 2012 are not included in the calculation of the 3-year period.

(xi)(A) Has failed to report MLR data in a timely and accurate manner in accordance with § 423.2460; or

(B) That any MLR data required by this subpart is found to be materially incorrect or fraudulent.

(xii) Failure of an essential operations test before the start of the benefit year by an organization that has entered into a Part D contract with CMS when neither it, nor another subsidiary of the organization's parent organization, is offering Part D benefits during the current year.

* * * * *

(b) * * *

(1) * * *

(i) CMS notifies the Part D plan sponsor in writing at least 45 calendar days before the intended date of the termination.

(ii) The Part D plan sponsor notifies its Medicare enrollees of the termination by mail at least 30 calendar days before the effective date of the termination.

(iii) The Part D plan sponsor notifies the general public of the termination at least 30 calendar days before the effective date of the termination by releasing a press statement to news media serving the affected community or county and posting the press statement prominently on the organization's Web site.

(iv) CMS notifies the general public of the termination no later than 30 calendar days after notifying the plan of CMS's decision to terminate the Part D plan sponsor's contract by releasing a press statement.

(2) * * *

(i) * * *

(C) The contract is being terminated based on the grounds specified in paragraphs (a)(4)(i) and (xii) of this section.

* * * * *

**§ 423.562 [Amended]**

■ 79. Amend § 423.562(a)(3) by removing the phrase ''request an exception if they disagree with the information provided by the pharmacist.'' and adding in its place the phrase ''request an exception.''.

**§ 423.642 [Amended]**

■ 80. Amend § 423.642(c)(1) by removing the phrase ''90 calendar days'' and adding in its place ''45 calendar days''.

**§ 423.650 [Amended]**

■ 81. Amend § 423.650 as follows:

■ A. In paragraph (a)(2), by removing the term ''under'' and adding in its place the phrase ''in accordance with''.

■ B. In paragraph (a)(4), by removing the cross-reference ''§ 423.752(a) and (b)'' and adding in its place the cross-reference ''§ 423.752(a) and (b)''.

■ 82. Amend § 423.752 as follows:

■ A. By adding paragraphs (a)(7) through (10).

■ B. By revising paragraph (c)(1).

■ C. In paragraph (c)(2)(ii), by removing the phrase ''pursuant to 423.509(a)(4)'' and adding in its place the phrase ''pursuant to § 422.510(a)(4)(i)''.

The additions and revision read as follows:

**§ 423.752 Basis for imposing intermediate sanctions and civil money penalties**

* * * * *

(a) * * *

(7) Except as provided under § 423.34, enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual.

(8) Transfers an individual enrolled under this part from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission.

(9) Fails to comply with marketing restrictions described in subpart V or applicable implementing guidance.

(10) Employs or contracts with any individual, agent, provider, supplier or entity who engages in the conduct described in paragraphs (a)(1) through (9) of this section.

* * * * *

(c) * * *

(1) *CMS.* In addition to, or in place of, any intermediate sanctions, CMS may impose civil money penalties in the amounts specified in either of the following:

(i) Section 423.760(b) for any of the determinations at § 423.509(a), except § 423.509(a)(4)(i).

(ii) Section 423.760(c) for any of the determinations in paragraph (a) of this section except § 422.752(a)(5).

* * * * *

■ 83. Amend § 423.756 as follows:

■ A. In paragraph (a)(2), by removing the phrase ''days from receipt'' and adding in its place ''days after receipt''.

■ B. In paragraph (b)(4), by removing the cross-reference ''§ 423.650 through § 423.662 of this part.'' and adding in its place ''Subpart N of this part.''.

■ C. In paragraph (c)(3)(ii) introductory text, by removing the phrase ''In instances where marketing or enrollment or both intermediate sanctions have been imposed,'' and adding in its place the phrase ''In instances where intermediate sanctions have been imposed,''.

■ D. Adding paragraph (c)(3)(ii)(C).

■ E. Revising paragraph (d).

The addition and revision read as follows:

**§ 423.756 Procedures for imposing intermediate sanctions and civil money penalties.**

* * * * *

(c) * * *

(3) * * *

(ii) * * *

(C) During the limited time period, sanctioned Part D plan sponsors under the benchmark that would normally participate in the annual and monthly auto enrollment process for enrollees receiving the low income subsidy will not be allowed to receive or process these types of enrollments.

(d) *Non-renewal or termination by CMS.* In addition to or as an alternative to the sanctions described in § 423.750, CMS may decline to authorize the renewal of an organization's contract in accordance with § 423.507(b), or terminate the contract in accordance with § 423.509.

* * * * *

■ 84. Amend § 423.760 as follows:

■ A. In paragraph (a) introductory text, by removing the phrase ''under 423.752(c)(1), CMS will consider as appropriate:'' and adding in its place the phrase ''under § 423.752(c)(1), CMS considers the following as appropriate:''.

■ B. In paragraphs (a)(1) and (2), by removing '';'' and adding in its place ''.''.

■ C. Revising paragraph (a)(3).

■ D. In paragraph (a)(4) by removing '';'' and adding in its place ''.''.

■ E. In paragraph (a)(5), by removing ''; and'' and adding in its place ''.''.

■ F. Adding paragraph (c).

The revision and addition read as follows:

**§ 423.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.**

(a) * * *

(3) The adverse effect to enrollees which resulted or could have resulted from the conduct of the Part D sponsor.

* * * * *

(c) *Amount of penalty imposed by CMS or OIG.* CMS or the OIG may impose civil money penalties in the following amounts for a determination made under § 423.752(a):

(1) Civil money penalties of not more than $25,000 for each determination made.

(2) With respect to a determination made under § 423.752(a)(4) or 423.752(a)(5)(i), not more than $100,000 for each such determination except with respect to a determination made under § 423.752(a)(5), an assessment of not more than the amount claimed by such plan or PDP sponsor based upon the misrepresentation or falsified information involved.

(3) Plus with respect to a determination made under § 423.752(a)(2), double the excess amount charged in violation of such paragraph (and the excess amount charged must be deducted from the penalty and returned to the individual concerned).

(4) Plus with respect to a determination made under § 423.752(a)(4), $15,000 for each individual not enrolled as a result of the practice involved.

■ 85. Amend § 423.882 by revising the definition of ''Actually paid'' to read as follows:

**§ 423.882 Definitions.**

* * * * *

*Actually paid* means that the costs must be actually incurred by the qualified retiree prescription drug plan and must be net of any direct or indirect remuneration (including discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any manufacturer or similar entity that would serve to decrease the costs incurred under the qualified retiree prescription drug plan.

* * * * *

■ 86. Amend § 423.1016 by revising the first sentence in paragraph (b)(1) to read as follows:

**§ 423.1016 Filing of briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal.**

* * * * *

(b) * * *

(1) The other party will have 20 calendar days from the date of mailing or in person filing to submit any rebuttal statement or additional evidence. * * *

* * * * *

■ 87. Amend § 423.1020 by revising paragraph (a)(2) to read as follows:

**§ 423.1020 Request for hearing.**

(a) * * *

(2) The Part D sponsor or its legal representative or other authorized official must file the request, in writing, to the appropriate Departmental Appeals Board office, with a copy to CMS, within 60 calendar days after receipt of the notice of initial determination, to request a hearing before an ALJ to appeal any determination by CMS to impose a civil money penalty.

* * * * *

■ 88. Amend § 423.2262 by adding paragraph (a)(2) to read as follows:

**§ 423.2262 Review and distribution of marketing materials.**

(a) * * *

(2) If CMS does not approve or does not disapprove marketing materials within the specified review timeframe, the materials are deemed approved and the Part D sponsor may use the material.

* * * * *

**§ 423.2266 [Removed and Reserved]**

■ 89. Section 423.2266 is removed and reserved.

■ 90. Amend § 423.2274 by:
■ A. Revising the introductory text.
■ B. Redesignating paragraphs (a) through (f) as (b) through (g).
■ C. Adding new paragraph (a).
■ D. Revising newly redesignated paragraphs (b) through (d).
■ E. Adding paragraph (h).

The revisions and additions read as follows:

**§ 423.2274 Broker and agent requirements.**

If a Part D sponsor uses agents and brokers to sell its Part D plans, the following requirements in this section are applicable.

(a) *Definitions.* For purposes of this section, the following definitions are applicable:

*Compensation* (1) Includes monetary or non-monetary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to—

(i) Commissions;

(ii) Bonuses;

(iii) Gifts;

(iv) Prizes or Awards; or

(v) Referral or Finder fees.

(2) Does not include—

(i) Payment of fees to comply with State appointment laws, training, certification, and testing costs;

(ii) Reimbursement for mileage to, and from, appointments with beneficiaries; or

(iii) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

*Like plan type* means one of the following:

(1) PDP replaced with another PDP.

(2) MA or MA–PD replaced with another MA or MA–PD.

(3) Cost plan replaced with another cost plan.

*Unlike plan type* means one of the following:

(1) PDP replaced with a MA–PD or a MA–PD replaced with a PDP

(2) PDP replaced with a cost plan or a cost plan replaced with a PDP

(3) MA–PD replaced with a cost plan or a cost plan replaced with a MA–PD

*Plan year* means the year beginning January 1 and ending December 31.

*Renewal year* means all years following the initial enrollment year in a like plan type.

(b) *Compensation rules.* An Part D sponsor must compensate independent brokers and agents, if compensation is paid, only according to the following rules in this section.

(1) *Compensation amounts.* (i) For an initial year enrollment of a Medicare beneficiary into a Part D plan, the compensation must be at or below the fair market value of such services, published annually as a cut-off amount by CMS.

(ii) For renewal years, compensation may be up to 35 percent of the current fair market value cut-off amounts published annually by CMS.

(2) *Aggregate compensation.* (i) An entity must not provide aggregate compensation to its agents or brokers greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan at any time.

(ii) An agent or broker must not receive aggregate compensation greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan type at any time.

(iii) The initial compensation is paid for replacements between unlike plan types.

(3) *Compensation payment and payment recovery.* (i) Compensation may only be paid for the enrollee's months of enrollment during a plan year.

(ii)(A) Subject to paragraph (b)(3)(iii) of this section, compensation payments may be made at one time for the entire current plan year or in installments throughout the year.

(B) Compensation may not be paid until January 1 of the compensation year and, if paid at all, must be paid in full by December 31 of the compensation year.

(iii) When a beneficiary disenrolls from an MA plan, compensation paid to agents and brokers must be recovered for those months of the plan year for which the beneficiary is not enrolled. For disenrollments occurring within the first 3 months, the entire compensation must be recovered when the disenrollment was the result of agent or broker behavior.

(4) *Compensation structure.* (i) A Part D sponsor must establish a compensation structure for new and replacement enrollments and renewals effective in a given plan year. Compensation structures must be in place by the beginning of the plan marketing period, October 1.

(ii) Compensation structures must be available upon CMS request including for audits, investigations, and to resolve complaints.

(c) *Annual training.* The Part D sponsor must ensure that all agents and brokers selling Medicare products are trained annually on the following:

(1) Medicare rules and regulations.

(2) Details specific to the plan products they intend to sell.

(d) *Annual testing.* The Part D sponsor must ensure that all agents and brokers selling Medicare products are tested annually, to ensure the following:

(1) Appropriate knowledge and understanding of Medicare rules and regulations.

(2) Details specific to the plan products they intend to sell.

* * * * *

(h) *Finder's (referral) fees.* Finder's (referral) fees paid to all agents and brokers—

(1) May not exceed an amount CMS determines could reasonably be expected to affect enrollee behavior while not exceeding the value of the health-related service or activity itself; and

(2) Must be included in the total compensation not to exceed the fair market value for that calendar year.

■ 91. Amend § 423.2320 by adding paragraph (c) to read as follows:

**§ 423.2320 Payment processes for Part D sponsors.**

* * * * *

(c) In the event that a manufacturer declares bankruptcy, as described in Title 11 of the United States Code and, as a result of the bankruptcy, does not pay the quarterly invoices described in § 423.2315(b)(10) by the time of the Coverage Gap Discount Reconciliation described in paragraph (b) of this section, CMS adjusts the Coverage Gap Discount Reconciliation amount of each of the affected Part D sponsors to account for the total unpaid quarterly invoiced amount owed to each of the Part D sponsors in the contract year being reconciled.

■ 92. Amend § 423.2325 by adding paragraph (h) to read as follows:

**§ 423.2325 Provision of applicable discounts.**

* * * * *

(h) *Treatment of employer group waiver plans.* (1) Beginning 2014, Part D sponsors offering employer group waiver plans must provide applicable discounts to employer group waiver plan enrollees as determined consistent with the defined standard benefit.

(2)(i) Part D sponsors offering employer group waiver plans must report to each employer or union group client projected and actual aggregate manufacturer payments attributable to the EGWPs enrollees, at least annually or upon request.

(ii) CMS may request documentation that notice as described in paragraph (h)(2)(i) of this section has been provided by the Part D sponsor and received by the employer or union group.

## Subpart Y [Reserved]

■ 93. Part 423 is amended by adding reserved subpart Y.

■ 94. Part 423 is amended by adding subpart Z to read as follows:

### Subpart Z—Recovery Audit Contractor Part C Appeals Process

Sec.
423.2600 Payment appeals.
423.2605 Request for reconsideration.
423.2610 Hearing official review.
423.2615 Review by the Administrator.

## Subpart Z—Recovery Audit Contractor Part C Appeals Process

### § 423.2600 Payment appeals.

If the Part D RAC did not apply its stated payment methodology correctly, a Part D plan sponsor may appeal the findings of the applied methodology. The payment methodology itself is not subject to appeal.

### § 423.2605 Request for reconsideration.

(a) *Time for filing a request.* The request for reconsideration must be filed with the designated independent reviewer within 60 calendar days from the date of the demand letter received by the Part D plan sponsor.

(b) *Content of request.* (1) The request for reconsideration must be in writing and specify the findings or issues with which the Part D plan sponsor disagrees.

(2) The Part D plan sponsor must include with its request all supporting documentary evidence it wishes the independent reviewer to consider.

(i) This material must be submitted in the format requested by CMS.

(ii) Documentation, evidence, or substantiation submitted after the filing of the reconsideration request will not be considered.

(c) *CMS Rebuttal.* CMS may file a rebuttal to the Part D plan sponsor's reconsideration request.

(1) The rebuttal must be submitted within 30 calendar days of the review entity's notification to CMS that it has received the Part D plan sponsor's reconsideration request.

(2) CMS sends its rebuttal to the Part D plan sponsor at the same time it is submitted to the independent reviewer.

(d) *Review entity.* An independent reviewer conducts the reconsideration. The independent reviewer reviews the demand for repayment, the evidence and findings upon which it was based, and any evidence that the Part D plan sponsor or CMS submitted in accordance with this section.

(e) *Notification of decision.* The independent reviewer informs CMS and the Part D plan sponsor of its decision in writing.

(f) *Effect of decision.* A reconsideration decision is final and binding unless the Part D plan sponsor requests a hearing official review in accordance with § 423.2610.

(g) *Right to hearing official review.* A Part D plan sponsor that is dissatisfied with the independent reviewer's reconsideration decision is entitled to a hearing official review as provided in § 423.2610.

### § 423.2610 Hearing official review.

(a) *Time for filing a request.* A Part D plan sponsor must file with CMS a request for a hearing official review within 15 calendar days from the date of the independent reviewer's issuance of a determination.

(b) *Content of the request.* (1) The request must be in writing and must provide evidence or reasons or both to substantiate the request.

(2) The Part D plan sponsor must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered.

(3) No new evidence may be submitted.

(4) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(c) *CMS rebuttal.* CMS may file a rebuttal to the Part D plan sponsor's hearing official review request.

(1) The rebuttal must be submitted within 30 calendar days of the Part D plan sponsor's submission of its hearing official review request.

(2) CMS sends its rebuttal to the Part D plan sponsor at the same time it is submitted to the hearing official.

(d) *Conducting a review.* A CMS-designated hearing official conducts the hearing on the record.

(1) The hearing is not to be conducted live or via telephone unless the hearing official, in his or her sole discretion, requests a live or telephonic hearing.

(2) In all cases, the hearing official's review is limited to information that meets one or more of the following:

(i) The Part D RAC used in making its determinations.

(ii) The independent reviewer used in making its determinations.

(iii) The Part D plan sponsor submits with its hearing request.

(iv) CMS submits in accordance with paragraph (c) of this section.

(3) Neither the Part D plan sponsor nor CMS may submit new evidence.

(e) *Hearing official decision.* The CMS hearing official decides the case within 60 days and sends a written decision to the Part D plan sponsor and CMS, explaining the basis for the decision.

(f) *Effect of hearing official decision.* The hearing official's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with § 423.2610.

### § 423.2615 Review by the Administrator.

(a) *Request for review by Administrator.* If a Part D plan sponsor is dissatisfied with the hearing official's decision, it may request that the CMS Administrator review the decision.

(1) The request must be filed with the CMS Administrator within 15 calendar days of the date of the hearing official's decision.

(2) The request must provide evidence or reasons to substantiate the request.

(b) *Content of request.* The Part D plan sponsor must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered.

(1) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(2) Neither the Part D plan sponsor nor CMS may submit new evidence.

(c) *Discretionary review.* After receiving a request for review, the CMS Administrator has the discretion to review the hearing official's decision in accordance with paragraph (e) of this section or to decline to review said decision.

(d) *Notification of decision whether to review.* The CMS Administrator notifies the Part D plan sponsor within 45 days of receiving the Part D plan sponsor's hearing request of whether he or she intends to review the hearing official's decision. If the Administrator agrees to review the hearing official's decision, CMS may file a rebuttal statement within 30 days of the Administrator's notice to the plan sponsor that the request for review has been accepted. CMS sends its rebuttal statement to the plan sponsor at the same time it is submitted to the Administrator. If the CMS Administrator declines to review the hearing official's decision, the hearing official's decision is final and binding.

(e) *Administrator review.* If the CMS Administrator agrees to review the hearing official's decision, he or she determines, based upon this decision, the hearing record, and any arguments submitted by the Part D plan sponsor or CMS in accordance with this section, whether the determination should be upheld, reversed, or modified. The CMS Administrator furnishes a written decision, which is final and binding, to the Part D plan sponsor and to CMS.

## PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 95. The authority citation for part 424 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 96. Amend § 424.530 by adding paragraph (a)(11) to read as follows:

### § 424.530 Denial of enrollment in the Medicare program.

(a) * * *

(11) *Prescribing authority.* (i) A physician or eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration to dispense a controlled substance is currently suspended or revoked; or

(ii) The applicable licensing or administrative body for any State in which a physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs, and such suspension or revocation is in effect on the date physician or eligible professional submits his or her enrollment application to the Medicare contractor.

* * * * *

■ 97. Amend § 424.535 by revising the section heading and adding paragraphs (a)(13) and (14) to read as follows:

### § 424.535 Revocation of enrollment in the Medicare program.

(a) * * *

(13) *Prescribing authority.* (i) The physician or eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration is suspended or revoked; or

(ii) The applicable licensing or administrative body for any state in which the physician or eligible professional practices suspends or revokes the physician or eligible professional's ability to prescribe drugs.

(14) *Improper prescribing practices.* CMS determines that the physician or eligible professional has a pattern or practice of prescribing Part D drugs that falls into one of the following categories:

(i) The pattern or practice is abusive and represents a threat to the health and safety of Medicare beneficiaries. In making this determination, CMS considers the following factors:

(A) Whether there are diagnoses to support the indications for which the drugs were prescribed.

(B) Whether there are instances when the necessary evaluation of the patient for whom the drug was prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit).

(C) Whether the physician or eligible professional has prescribed controlled substances in excessive dosages that are linked to patient overdoses.

(D) The number and type(s) of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the State or States in which he or she practices, and the reason(s) for the action(s).

(E) Whether the physician or eligible professional has any history of ''final adverse actions'' (as that term is defined in § 424.502).

(F) The number and type(s) of malpractice suits that have been filed against the physician or eligible professional related to prescribing that have resulted in a final judgment against the physician or eligible professional or in which the physician or non-physician practitioner has paid a settlement to the plaintiff(s) (to the extent this can be determined).

(G) Whether any State Medicaid program or any other public or private health insurance program has restricted, suspended, revoked, or terminated the physician or eligible professional's ability to prescribe medications, and the reason(s) for any such restriction, suspension, revocation, or termination.

(H) Any other relevant information provided to CMS.

(ii) The pattern or practice of prescribing fails to meet Medicare requirements. In making this determination, CMS considers the following factors:

(A) Whether the physician or eligible professional has a pattern or practice of prescribing without valid prescribing authority.

(B) Whether the physician or eligible professional has a pattern or practice of prescribing for controlled substances outside the scope of the prescriber's DEA registration.

(C) Whether the physician or eligible professional has a pattern or practice of prescribing drugs for indications that were not medically accepted—that is, for indications neither approved by the FDA nor medically accepted under section 1860D–2(e)(4) of the Act— and whether there is evidence that the physician or eligible professional acted in reckless disregard for the health and safety of the patient.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 21, 2013.

**Marilyn Tavenner,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: December 11, 2013.

**Kathleen Sebelius,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2013–31497 Filed 1–6–14; 4:15 pm]

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**H.R. 623/P.L. 113–68**
Alaska Native Tribal Health Consortium Land Transfer Act (Dec. 26, 2013; 127 Stat. 1205)

**H.R. 767/P.L. 113–69**
To amend the Energy Policy Act of 2005 to modify the Pilot Project offices of the Federal Permit Streamlining Pilot Project. (Dec. 26, 2013; 127 Stat. 1207)

**H.R. 2319/P.L. 113–70**
Native American Veterans' Memorial Amendments Act of 2013 (Dec. 26, 2013; 127 Stat. 1208)

**H.R. 3343/P.L. 113–71**
To amend the District of Columbia Home Rule Act to clarify the rules regarding the determination of the compensation of the Chief Financial Officer of the District of Columbia. (Dec. 26, 2013; 127 Stat. 1209)

**H.R. 3487/P.L. 113–72**
To amend the Federal Election Campaign Act to extend through 2018 the authority of the Federal Election Commission to impose civil money penalties on the basis of a schedule of penalties established and published by the Commission, to expand such authority to certain other violations, and for other purposes. (Dec. 26, 2013; 127 Stat. 1210)

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