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WHAT: Free public briefings (approximately 3 hours) to present:

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2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
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WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, May 10, 2011
9 a.m.-12:30 p.m.

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

RESERVATIONS: (202) 741-6008



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Federal Register

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Doc. AMS–NOP–10–0048; NOP–10–05]

National Organic Program: Notice of Final Guidance for Accredited Certifying Agents and Certified Operations

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of availability of final guidance.

SUMMARY: The National Organic Program (NOP) is announcing the availability of four final guidance documents intended for use by accredited certifying agents and certified operations. The four final guidance documents are entitled as follows: “Compost and Vermicompost in Organic Crop Production (NOP 5021); Wild Crop Harvesting (NOP 5022); “Commingling and Contamination Prevention in Organic Production and Handling (NOP 5025); and “The Use of Chlorine Materials in Organic Production and Handling (NOP 5026)”. These final guidance documents are intended to inform the public of NOP’s current thinking on these topics. These final guidance documents are now available from the NOP through “The Program Handbook: Guidance and Instructions for Accredited Certifying Agents (ACAs) and Certified Operations”. The current edition of the Program Handbook is available online at <http://www.ams.usda.gov/NopProgramHandbook>, or in print upon request.

DATES: The final guidance documents announced by this notice are effective on May 9, 2011.

FOR FURTHER INFORMATION CONTACT: Melissa Bailey, Ph.D., Director, Standards Division, National Organic

Program, USDA–AMS–NOP, 1400 Independence Ave., SW., Room 2646–So., Ag Stop 0268, Washington, DC 20250, E-mail: Melissa.bailey@ams.usda.gov; Telephone: (202) 720–3252; Fax: (202) 205–7808.

SUPPLEMENTARY INFORMATION:

I. Background

On October 13, 2010, the National Organic Program (NOP) published in the **Federal Register** a notice of availability with request for public comment on five draft guidance documents (75 FR 62693). The topics covered in the draft documents addressed recommendations issued by the National Organic Standards Board (NOSB) and the USDA Office of Inspector General (OIG) in a March 2010 audit report of the NOP. The five draft guidance topics included compost and vermicompost, wild crop harvesting, outdoor access for poultry, commingling and contamination prevention, and the use of chlorine materials. The five draft guidances can be viewed on-line at <http://www.ams.usda.gov/NopDraftGuidance>. The 60-day comment period closed on December 13, 2010.

The NOP received a total of 69 individual comments and 22,096 form letter responses on the five draft guidance documents. “NOP Notice 11–7” provides a complete discussion of the comments received and the rationale behind any changes made to the guidance documents as well as any changes proposed, but not made to the guidance documents. “NOP Notice 11–7” can be found at <http://www.ams.usda.gov/NOPCorrespondance>.

Based upon the comments received, the NOP revised and is publishing four of the five guidance documents as final: “NOP 5021—Compost and Vermicompost in Organic Crop Production”; “NOP 5022—Wild Crop Harvesting”; “NOP 5025—Commingling and Contamination Prevention in Organic Production and Handling”; and “NOP 5026—The Use of Chlorine Materials in Organic Production and Handling”. Based upon the comments received, the NOP is not finalizing the draft guidance, “NOP 5024—Outdoor Access for Poultry”. The NOP intends to initiate a separate rulemaking on the outdoor access requirements for poultry in 2011.

The four final guidance documents are now available from the NOP through “The Program Handbook: Guidance and Instructions for Accredited Certifying Agents (ACAs) and Certified Operations”. This Handbook provides those who own, manage, or certify organic operations with guidance and instructions that can assist them in complying with the NOP regulations. The current edition of the Program Handbook is available online at <http://www.ams.usda.gov/NopProgramHandbook>.

II. Significance of Guidance

These final guidance documents are being issued in accordance with the Office of Management and Budget (OMB) Bulletin on Agency Good Guidance Practices (GGPs) (January 25, 2007, 72 FR 3432–3440). The purpose of GGPs is to ensure that program guidance documents are developed with adequate public participation, are readily available to the public, and are not applied as binding requirements. Final guidance represents the NOP’s current thinking on these topics. It does not create or confer any rights for, or on, any person and does not operate to bind the NOP or the public. Guidance documents are intended to provide a uniform method for operations to comply that can reduce the burden of developing their own methods and simplify audits and inspections. Alternative approaches that can demonstrate compliance with the Organic Foods Production Act (OFPA), as amended (7 U.S.C. 6501–6522), and its implementing regulations are also acceptable. As with any alternative compliance approach, the NOP strongly encourages industry to discuss alternative approaches with the NOP before implementing them to avoid unnecessary or wasteful expenditures of resources and to ensure the proposed alternative approach complies with the Act and its implementing regulations.

III. Electronic Access

Persons with access to Internet may obtain a copy of final guidance in the “Program Handbook” along with the “NOP Notice 11–7” at NOP’s Web site at <http://www.ams.usda.gov/nop>.

Dated: May 2, 2011.

Rayne Pegg,

Administrator, Agricultural Marketing Service.

[FR Doc. 2011-11115 Filed 5-5-11; 8:45 am]

BILLING CODE 3410-02-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9525]

RIN 1545-BG98

Modifications to Treatment of Aircraft and Vessel Leasing Income

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations addressing the treatment of certain income and assets related to the leasing of aircraft or vessels in foreign commerce. The regulations reflect statutory changes made by the American Jobs Creation Act of 2004. In general, the regulations will affect United States shareholders of controlled foreign corporations that derive income from the leasing of aircraft or vessels in foreign commerce and U.S. persons that transfer property subject to these leases to a foreign corporation.

DATES: *Effective Date:* These regulations are effective on May 6, 2011.

Applicability Dates: For dates of applicability, see §§ 1.367(a)-2(e)(2), 1.367(a)-4(i), 1.367(a)-5(f)(3)(ii), 1.954-2(i) and 1.956-2(e).

FOR FURTHER INFORMATION CONTACT: Concerning the final regulations under section 367, Ronald M. Gootzeit at (202) 622-3860; concerning the final regulations under section 954 or 956, Kristine A. Crabtree at (202) 622-3840; (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

In General

This document contains amendments to 26 CFR Part 1 under sections 367, 954 and 956 of the Internal Revenue Code (Code). Final and temporary regulations (TD 9406, 73 FR 38113) (the temporary regulations) and a cross-reference notice of proposed rulemaking (REG-138355-07, 73 FR 38162) were published in the **Federal Register** on July 3, 2008 (the proposed regulations). On July 29, 2008, corrections to the final regulations (73 FR 43863) were published in the

Federal Register. No public hearing was requested or held with respect to the proposed regulations. After consideration of the comments received, the proposed regulations are adopted, as amended by this Treasury decision.

Explanation of Provisions

Section 415(a) of the American Jobs Creation Act of 2004, Public Law 108-357 (118 Stat. 1418) (Jobs Act), repealed section 954(a)(4) and (f), the foreign base company shipping income provisions of subpart F. As a result of the repeal of these provisions, rents derived from leasing an aircraft or vessel in foreign commerce are included in subpart F income only if the rents are described in another category of subpart F income, such as foreign personal holding company income (FPHCI) as defined in section 954(c). Rents are generally included in FPHCI under section 954(c)(1)(A), subject to certain exceptions. One such exception is for rents received from unrelated persons and derived in the active conduct of a trade or business. See section 954(c)(2)(A).

For this purpose, rents derived by a controlled foreign corporation (CFC) are considered derived in the active conduct of a trade or business in certain circumstances, including circumstances whereby the rents are derived as a result of the performance of marketing functions by the lessor CFC with respect to the leased property (the marketing exception). § 1.954-2(c)(1)(iv). Specifically, a lessor satisfies the marketing exception if the lessor, through its own officers or staff of employees located in a foreign country, maintains and operates an organization in the foreign country that is regularly engaged in the business of marketing, or of marketing and servicing, the leased property and that is substantial in relation to the amount of rents derived from leasing the property. For this purpose, whether an organization in a foreign country is substantial in relation to the amount of rents is determined based on all facts and circumstances; however, such an organization will be considered substantial if active leasing expenses equal or exceed 25 percent of the adjusted leasing profit (as defined in § 1.954-2(c)(2)(iv)). § 1.954-2T(c)(2)(ii).

The Jobs Act amended section 954(c)(2)(A) to expand the marketing exception with respect to rents derived from leasing an aircraft or vessel in foreign commerce. In particular, section 954(c)(2)(A) now provides that “rents derived from leasing an aircraft or vessel in foreign commerce shall not fail to be treated as derived in the active conduct of a trade or business if, as determined

under regulations prescribed by the Secretary, the active leasing expenses are not less than 10 percent of the profit on the lease.” In addition, the legislative history to this provision states that the Secretary of the Treasury will make “conforming changes to existing regulations, including guidance that aircraft or vessel leasing activity that satisfies the requirements of section 954(c)(2)(A) shall also satisfy the requirements for avoiding income inclusion under section 956 and section 367(a).” H.R. Conf. Rep. No. 755, 108th Cong., 2d Sess. 402 (2004).

On July 3, 2008, the Treasury Department and the IRS published the proposed regulations providing guidance with respect to the treatment of certain income and assets related to the leasing of aircraft or vessels in foreign commerce under sections 367, 954, and 956 of the Code in light of the Jobs Act changes. These final regulations adopt the proposed regulations with the modifications described herein.

Section 954 Regulations

Under current regulations, to satisfy the marketing exception, the lessor must, among other things, maintain an organization that is regularly engaged in the business of marketing, or of marketing and servicing, the leased property and that is “substantial in relation to the rents derived.” § 1.954-2(c)(1)(iv). The proposed regulations added a new marketing safe harbor for purposes of determining whether an organization is substantial in relation to rents derived from leasing aircraft or vessels (including component parts, such as engines, that are leased separately from an aircraft or vessel) in foreign commerce. This safe harbor provides that an organization will be considered substantial for purposes of § 1.954-2(c)(1)(iv) if active leasing expenses equal or exceed 10 percent of the adjusted leasing profit. For this purpose, the rules in the current regulations for computing active leasing expense and adjusted leasing profit continue to apply. The proposed regulations also included a definition of when an aircraft or vessel is leased in foreign commerce, including defining when property is used predominantly outside the United States, that is consistent with the legislative history to the Jobs Act. See H.R. Rep. No. 108-548, pt. 1, at 210 (2004); H.R. Conf. Rep. No. 108-755, at 402 (2004). Finally, the proposed regulations also clarified that rents derived from certain finance leases and acquired leases are eligible for the active rents exclusion.

One commentator expressed concern that § 1.954–2T(c)(2)(vii), which addresses finance leases, could be interpreted to limit the application of the marketing exception solely to finance leases. In response to this comment, the final regulations clarify that the marketing exception can apply to both operating leases and finance leases.

The same commentator also suggested that, for purposes of applying § 1.954–2T(c)(2)(vi), the regulations should clarify that “remarketing functions” include remarketing for purposes of selling the leased property. The final regulations adopt this change.

In addition to these changes, the final regulations clarify that an aircraft or vessel is considered to be leased in foreign commerce if it is used in foreign commerce, and is used predominantly outside the United States. Finally, the language of § 1.954–2T(c)(3) *Example 6* has been modified to make it consistent with the other examples in § 1.954–2(c)(3).

Section 956 Regulations

Section 956(c)(1)(A) provides that the term *United States property* (“U.S. property”) generally includes tangible property located in the United States. Section 956(c)(2) provides exceptions to the general definition of U.S. property, including any aircraft, railroad rolling stock, vessel, motor vehicle, or container used in the transportation of persons or property in foreign commerce and used predominantly outside the United States. See section 956(c)(2)(D). Prior to issuance of the temporary regulations, § 1.956–2(b)(1)(vi) provided that, as a general rule, such transportation property will be considered to be used predominantly outside the United States if 70 percent or more of the miles traversed (during the taxable year at the close of which a determination is made under section 956(a)(2)) in the use of such property are traversed outside the United States or if such property is located outside the United States 70 percent of the time during such taxable year.

In Notice 2006–48 (2006–1 CB 922) the IRS and Treasury Department announced that regulations would be issued providing that an aircraft or vessel used in the transportation of persons or property in foreign commerce is excluded from U.S. property under § 1.956–2(b)(1)(vi) if rents derived from leasing such aircraft or vessel are excluded from FPHCI under section 954(c)(2)(A) and such property is considered to be used predominantly outside the United States under § 1.954–2(b)(1)(vi), determined by

substituting “more than 50 percent” for the phrases “70 percent or more” and “70 percent.” The proposed regulations amended § 1.956–2(b)(1)(vi) to provide that an aircraft or vessel is excluded from U.S. property if rents derived from leasing such aircraft or vessel are excluded from FPHCI under section 954(c)(2)(A) but inadvertently omitted the language from Notice 2006–48 concerning its use in the transportation of persons or property in foreign commerce and its predominant use outside the United States. Consistent with section 956(c)(2)(D), the legislative history of section 954(c)(2)(A), and Notice 2006–48, the final regulations modify the proposed regulations to clarify that an aircraft or vessel is excepted from the definition of U.S. property under section 956(c)(2)(D) only if the aircraft or vessel is leased in foreign commerce as that term is defined in § 1.954–2(c)(2)(v), and the rents from the aircraft or vessel qualify for the exception to FPHCI under section 954(c)(2)(A). See § 601.601(d)(2).

No comments were received and no changes other than the change described herein have been made to the section 956 provisions of the proposed regulations.

Section 367 Regulations

No written comments were received and no changes have been made to the section 367 provisions of the proposed regulations.

Request for Comments

The Treasury Department and IRS continue to study and request comments on how to determine whether an aircraft or vessel is used predominantly outside the United States during a particular month for purposes of calculating depreciation recapture under section 367. Until further guidance is issued, taxpayers may continue to use any reasonable method to make this determination.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. Ch. 6) does not apply. Pursuant to section 7805(f) of the Code, this regulation has been submitted to the Chief Counsel for Advocacy of the Small Business

Administration for comment on its impact on small business.

Drafting Information

The principal authors of these regulations are Ronald M. Gootzeit and Kristine A. Crabtree, Office of Associate Chief Counsel (International). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

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

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

■ **Par. 2.** Section 1.367(a)–2 is added to read as follows:

§ 1.367(a)–2 Exception for transfers of property for use in the active conduct of a trade or business.

(a) through (d) [Reserved]. For further guidance, see § 1.367(a)–2T(a) through (d).

(e) *Special rules for certain transfers occurring on or after May 2, 2006—*
(1) *General rule.* Whether a trade or business that produces rents or royalties is actively conducted shall be determined under the principles of section 954(c)(2)(A) and the regulations thereunder (but without regard to whether the rents or royalties are received from an unrelated party). See § 1.954–2(c) and (d).

(2) *Effective/applicability date.* The rules of this paragraph (e) apply to transfers occurring on or after May 2, 2006. However, if the transferor makes the election to apply the provisions of § 1.367(a)–4(c)(3) for transfers occurring on or after October 22, 2004, then paragraph (e)(1) of this section will also apply to the transfers occurring on or after October 22, 2004.

■ **Par. 3.** Section 1.367(a)–2T is amended by removing and reserving paragraph (e) to read as follows:

§ 1.367(a)–2T Exception for transfers of property for the use in the active conduct of a trade or business (temporary).

* * * * *

(e) [Reserved]. For further guidance see § 1.367(a)–2(e).

■ **Par. 4.** Section 1.367(a)–4 is added to read as follows:

§ 1.367(a)–4 Special rules applicable to specified transfers of property.

(a) through (c)(2) [Reserved]. For further guidance, see § 1.367(a)–4T(a) through (c)(2).

(3) *Aircraft and vessels leased in foreign commerce.* For purposes of satisfying § 1.367–4T(c)(1), aircraft or vessels, including component parts such as engines leased separately from aircraft or vessels, transferred to a foreign corporation and leased to other persons by the foreign corporation shall be considered to be transferred for use in the active conduct of a trade or business if—

(i) The employees of the foreign corporation perform substantial managerial and operational activities of leasing aircraft or vessels outside the United States; and

(ii) The leased tangible personal property is predominantly used outside the United States, as determined under § 1.954–2(c)(2)(v).

(d) through (h) [Reserved]. For further guidance, see § 1.367–4T(d) through (h).

(i) *Effective/applicability date.* The rules of paragraph (c)(3) of this section apply for transfers of property occurring on or after May 2, 2006. Transferors may elect to apply these provisions to transfers occurring on or after October 22, 2004, by citing the provisions of paragraph (c)(3) of this section in the documentation for such transfers required by § 1.6038B–1T(c)(4)(i) and (iv).

■ **Par. 5.** Section 1.367(a)–4T is amended by removing and reserving paragraphs (c)(3) and (i) to read as follows:

§ 1.367(a)–4T Special rules applicable to specified transfers of property (temporary).

* * * * *

(c) * * *

(3) [Reserved]. For further guidance see § 1.367(a)–4(c)(3).

* * * * *

(i) [Reserved]. For further guidance see § 1.367(a)–4(i).

■ **Par. 6.** Section § 1.367(a)–5 is added to read as follows:

§ 1.367(a)–5 Property subject to section 367(a)(1) regardless of use in a trade or business.

(a) through (f)(2) [Reserved]. For further guidance, see § 1.367(a)–5T(a) through (f)(2).

(3)(i) With respect to vessels and aircraft, including their component parts, that will be leased by the transferee to third persons, the transferee satisfies the conditions set forth in § 1.367(a)–4(c)(3).

(ii) *Effective/applicability date.* The rules of this paragraph (f)(3) apply to

transfers of property occurring on or after May 2, 2006. If the transferor makes the election to apply the provisions of § 1.367(a)–4(c)(3) to transfers occurring on or after October 22, 2004, then paragraph (f)(3)(i) of this section will also apply to transfers affected by that election.

■ **Par. 7.** Section § 1.367(a)–5T is amended by removing and reserving paragraph (f)(3) to read as follows:

§ 1.367(a)–5T Property subject to section 367(a)(1) regardless of use in trade or business (temporary).

* * * * *

(f) * * *

(3) [Reserved]. For further guidance see § 1.367(a)–5(f)(3).

■ **Par. 8.** Section 1.954–2 is amended by revising paragraphs (c)(2)(ii), (c)(2)(v), (c)(2)(vi), (c)(2)(vii), and (c)(3) *Example 6* and paragraph (i) to read as follows:

§ 1.954–2 Foreign personal holding company income.

* * * * *

(c) * * *

(2) * * *

(ii) *Substantiality of foreign organization.* For purposes of paragraph (c)(1)(iv) of this section, whether an organization in a foreign country is substantial in relation to the amount of rents is determined based on all facts and circumstances. However, such an organization will be considered substantial in relation to the amount of rents if active leasing expenses, as defined in paragraph (c)(2)(iii) of this section, equal or exceed 25 percent of the adjusted leasing profit, as defined in paragraph (c)(2)(iv) of this section. In addition, for purposes of aircraft or vessels leased in foreign commerce, an organization will be considered substantial if active leasing expenses, as defined in paragraph (c)(2)(iii) of this section, equal or exceed 10 percent of the adjusted leasing profit, as defined in paragraph (c)(2)(iv) of this section. For purposes of paragraphs (c)(1)(iv) and (c)(2) of this section and § 1.956–2(b)(1)(vi), the term *aircraft or vessels* includes component parts, such as engines that are leased separately from an aircraft or vessel.

* * * * *

(v) *Leased in foreign commerce.* For purposes of paragraphs (c)(1)(iv) and (c)(2)(ii) of this section, an aircraft or vessel is considered to be leased in foreign commerce if the aircraft or vessel is used in foreign commerce and is used predominantly outside the United States. An aircraft or vessel is considered to be used in foreign commerce if it is used for the transportation of property or passengers

between a port (or airport) in the United States and a port (or airport) in a foreign country or between foreign ports (or airports). An aircraft or vessel will be considered to be used predominantly outside the United States if more than 50 percent of the miles traversed during the taxable year in the use of the aircraft or vessel are traversed outside the United States or if the aircraft or vessel is located outside the United States more than 50 percent of the time during the taxable year.

(vi) *Leases acquired by the CFC lessor.*

Except as provided in this paragraph (c)(2)(vi), the exception in paragraph (c)(1)(iv) of this section will also apply to rents from leases acquired from any person, if following the acquisition the lessor performs active and substantial management, operational, and remarketing (including remarketing for purposes of re-leasing or selling the property) functions with respect to the leased property. However, if any person is claiming a benefit with respect to an acquired lease pursuant to section 921 or 114 of the Internal Revenue Code or section 101(d) of the American Jobs Creation Act of 2004, (Pub. L. 108–357 (118 Stat. 1418) (2004)), the rents from such lease, notwithstanding paragraphs (b)(6) and (c) of this section, are ineligible for the exception in section 954(c)(2)(A).

(vii) *Marketing of leases.* Paragraph (c)(1)(iv) of this section can apply whether a lessor is engaged in the marketing of leases as a form of financing or is engaged in marketing the property as such, and regardless of whether the lease is classified as a finance lease or an operating lease for financial accounting purposes, so long as such lease is treated as a lease for Federal income tax purposes.

(3) * * *

Example 6. The facts are the same as in *Example 2*, except that controlled foreign corporation D purchases aircraft which it leases to others. If Corporation D incurs active leasing expenses, as defined in paragraph (c)(2)(iii) of this section, equal to or in excess of 10 percent of its adjusted leasing profit, as defined in paragraph (c)(2)(iv) of this section, the organization maintained and operated by Corporation D in country X is substantial in relation to the amount of rents Corporation D receives from leasing the aircraft. Therefore, under paragraph (c)(1)(iv) of this section, such rents are derived in the active conduct of a trade or business for purposes of section 954(c)(2)(A). If a particular aircraft subject to lease was not leased by the lessee corporation in foreign commerce, for example, because 50 percent or less of the miles during the taxable year were traversed outside the United States and the aircraft was located in the United States for 50 percent or more of the taxable year, Corporation D is not prevented from

otherwise showing that it actively carries on a trade or business with regard to the rents derived from that aircraft under paragraph (c)(2)(ii) of this section, based on its facts and circumstances or a showing that active leasing expenses equal or exceed 25 percent of the adjusted leasing profit.

* * * * *

(i) *Effective/applicability date.* The last two sentences of paragraph (c)(2)(ii), and paragraphs (c)(2)(v) through (vii) and (c)(3) *Example 6* of this section apply to taxable years of controlled foreign corporations beginning on or after May 2, 2006, and for taxable years of United States shareholders with or within which such taxable years of the controlled foreign corporations end. Taxpayers may elect to apply the last two sentences of paragraph (c)(2)(ii) and paragraphs (c)(2)(v) through (vii) to taxable years of controlled foreign corporations beginning after December 31, 2004, and for taxable years of United States shareholders with or within which such taxable years of the controlled foreign corporations end. If an election is made to apply § 1.956–2(b)(1)(vi) to taxable years beginning after December 31, 2004, then the election must also be made for paragraphs (c)(2)(ii) and (c)(2)(v) through (vii) of this section.

§ 1.954–2T [Removed].

■ **Par. 9.** Section 1.954–2T is removed.

■ **Par. 10.** Section 1.956–2 is amended by revising paragraphs (b)(1)(vi) and (e) to read as follows:

§ 1.956–2 Definition of United States property.

* * * * *

(b)* * *

(1)* * *

(vi) Any aircraft, railroad rolling stock, vessel, motor vehicle, or container used in the transportation of persons or property in foreign commerce and used predominantly outside the United States. Whether transportation property described in this paragraph (b)(1)(vi) is used in foreign commerce and predominantly outside the United States is to be determined from all the facts and circumstances of each case. As a general rule, such transportation property will be considered to be used predominantly outside the United States if 70 percent or more of the miles traversed (during the taxable year at the close of which a determination is made under section 956(a)(2)) in the use of such property are traversed outside the United States or if such property is located outside the United States 70 percent of the time during such taxable year.

Notwithstanding the above, an aircraft

or vessel, including component parts, is excluded from United States property if the aircraft or vessel is leased in foreign commerce (as the term is defined in § 1.954–2(c)(2)(v)) and rents derived from leasing such aircraft or vessel are excluded from foreign personal holding company income under section 954(c)(2)(A).

* * * * *

(e) *Effective/applicability date.* The last sentence of paragraph (b)(1)(vi) of this section applies to taxable years of controlled foreign corporations beginning on or after May 2, 2006, and for taxable years of United States shareholders with or within which such taxable years of the controlled foreign corporations end. Taxpayers may elect to apply the rule of the last sentence of paragraph (b)(1)(vi) of this section to taxable years of controlled foreign corporations beginning after December 31, 2004, and for taxable years of United States shareholders with or within which such taxable years of the controlled foreign corporations end. If an election is made to apply the last two sentences of § 1.954–2(c)(2)(ii) and § 1.954–2(c)(2)(v) through (vii) to taxable years of a controlled foreign corporation beginning after December 31, 2004, then the election must also be made for the last sentence of paragraph (b)(1)(vi) of this section.

■ **Par. 11.** Section 1.956–2T is amended by removing and reserving paragraphs (b)(1)(vi) and (e) to read as follows:

§ 1.956–2T Definition of United States property (temporary).

* * * * *

(b)* * *

(1)* * *

(vi) [Reserved]. For further guidance see § 1.956–2(b)(1)(vi).

* * * * *

(e) [Reserved]. For further guidance see § 1.956–2(e).

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

Approved: March 30, 2011.

Michael Mundaca,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2011–11164 Filed 5–5–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–0317]

Drawbridge Operation Regulation; Sacramento River, Sacramento, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eleventh Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Tower Drawbridge across Sacramento River, mile 59.0, at Sacramento, CA. The deviation is necessary to allow the community to participate in the Hope Foundation walk event. This deviation allows the bridge to remain in the closed-to-navigation position during the event.

DATES: This deviation is effective from 8 a.m. to 11 a.m. on May 29, 2011.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of the docket USCG–2011–0317 and are available online by going to <http://www.regulations.gov>, inserting USCG–2011–0317 in the “Keyword” box and then clicking “Search”. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District; telephone 510–437–3516, e-mail David.H.Sulouff@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The California Department of Transportation has requested a temporary change to the operation of the Tower Drawbridge, mile 59.0, over Sacramento River, at Sacramento, CA. The drawbridge navigation span provides a vertical clearance of 30 feet above Mean High Water in the closed-to-navigation position. The draw opens on signal from May 1 through October 31 from 6 a.m. to 10 p.m. and from November 1 through April 30 from 9 a.m. to 5 p.m.

At all other times the draw shall open on signal if at least four hours notice is given, as required by 33 CFR 117.189(a). Navigation on the waterway is commercial and recreational.

The drawspan will be secured in the closed-to-navigation position from 8 a.m. through 11 a.m. on May 29, 2011 to allow the community to participate in the Hope Foundation walk event. This temporary deviation has been coordinated with waterway users. There are no scheduled river boat cruises or anticipated levee maintenance during this deviation period. No objections to the proposed temporary deviation were raised.

Vessels that can transit the bridge, while in the closed-to-navigation position, may continue to do so at any time. In case of emergencies the draw can open with 15 minutes advance notice.

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

Dated: Apr 22, 2011.

D.H. Sulouff,

District Bridge Chief, Eleventh Coast Guard District.

[FR Doc. 2011-11058 Filed 5-5-11; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2011-0314]

RIN 1625-AA09

Drawbridge Operation Regulations; Hood Canal, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Thirteenth Coast Guard District has issued a temporary deviation from the regulation governing the operation of the Hood Canal floating drawbridge near Port Gamble, Washington to test an operational change and seek public comment regarding that change in order to evaluate the need for a permanent change. The deviation establishes a restricted period from 3 p.m. to 6 p.m. every day of the week from 3 p.m. May 27, 2011 through 6 p.m. on September 30, 2011.

DATES: This rule is effective from 3 p.m. May 27, 2011 through 6 p.m. on September 30, 2011. Comments and related material must be received by the Coast Guard on November 30, 2011.

ADDRESSES: You may submit comments identified by docket number USCG-2011-0314 using any one of the following methods:

(1) Federal Rulemaking 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.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or e-mail Commander Daryl Peloquin, Chief, Waterways Management Branch, 13th Coast Guard District; telephone 206-220-7273, e-mail daryl.r.peloquin@uscg.mil. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

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.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG-2011-0314), 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 (<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 via [http://](http://www.regulations.gov)

www.regulations.gov, it will be considered as having been 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 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>, click on "submit a comment" box, which will then become highlighted in blue. In the "Keyword" box insert "USCG-2011-0314", click "Search", and then click on the balloon shape in the "Actions" column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based upon your comments.

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>, click on the "read comments" box, which will then become highlighted in blue. In the "Keyword" box insert "USCG-2011-0314" and click "Search." Click the "Open Docket Folder" in the "Actions" column. 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. We have an agreement with the Department of Transportation to use the Docket Management Facility.

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).

Public Meeting

We do not now plan to hold a public meeting, but you may submit a request for one using four methods specified under **ADDRESSES**. Please explain why one 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**.

Basis and Purpose

Senator Phil Rockefeller and Representative Christine Rolfes of the Washington State Legislature have requested that the operating regulations of the Hood Canal Bridge be changed in order to try to provide some relief to road traffic on State Routes 3 and 104. Traffic queues south of the eastern end of the bridge can be long during and after openings of the drawspan. The stopped road traffic on this two-lane highway blocks access to intersecting streets along the queue.

The operating regulations currently in effect for the bridge are found at 33 CFR 117.1045. These state that the bridge shall open on signal if at least one hour notice is provided and that the draw shall be opened horizontally for three hundred feet unless the maximum opening of 600 feet is requested. The current regulations remain in effect except for the establishment of the restricted period.

Navigation on the waterway consists of commercial tugs with tows, recreational vessels of various sizes, commercial fishing vessels, and U.S. naval vessels with escort vessels including those of the U.S. Coast Guard.

This change will not affect naval vessels or vessels in service to the Navy. Unlike many other restricted or closed periods in effect for certain drawbridges, this restriction will not guarantee the complete absence of interruptions to vehicular traffic in the designated hours. At best it would diminish openings without eliminating them entirely during the affected hours. Approximately, one half of all openings of the Hood Canal draw are for the passage of Navy ships, submarines, and other vessels in service to the Navy. The movement of vessels for national security purposes or emergencies cannot be impeded by drawbridge operating regulations.

Recreational vessels too tall to pass under the fixed spans of the bridge generally ply Hood Canal seasonally. Most of this taller recreational traffic occurs from June through September. These are the only months subject to this test deviation.

The openings for the full width of this floating drawspan are much slower than

for a typical bascule type of draw. While some openings and closings have been completed within 20 minutes or less, others have lasted far longer than 30 minutes increasing traffic queues on the road. Traffic has generally exceeded 1200 vehicles per hour throughout the week from 9 a.m. to 6 p.m. However, peak traffic loads are not discernable for the morning hours as for the afternoon hours. Draw openings can occur at any time and do. A further difficulty is that this variability makes it difficult to match waterway traffic to peak road travel times.

For example in June 2010 draw records show that the Hood Canal Bridge opened a total of 29 times including one movement that was for testing the draw. Of these 16 were for pleasure craft and the rest were for military vessels. There were only five days with more than one opening per day. July 2010 was busier than June. In July 43 openings occurred. Five of these were operational tests. It opened 22 times for pleasure craft, twice for commercial vessels and 19 times for the Navy.

For the hours affected by these test deviation, in July 2010 there were 5 openings for the Navy, 2 for sailboats, and one for a tug with tow.

The Coast Guard will evaluate public comments from this Test Deviation as well as draw records and road traffic data after the end of the test period. We may seek to make this change permanent for the following year or modify it via a Notice of Proposed Rulemaking, or maintain the current regulations based on the effectiveness of this test for both navigation and road traffic.

From 3 p.m. to 6 p.m. every day from 3 p.m. on May 27 through 6 p.m. on September 30, 2011, the draw need not open for vessels other than those of the U.S. Navy or vessels attending the missions of the U.S. Navy. The established regulations found at 33 CFR 117.1045 remain in effect with that exception.

This test deviation is authorized under 33 CFR 117.35. In accordance with 33 CFR 117.35(e), the Hood Canal Bridge will return to its regular operations at the end of the designated time period.

Dated: April 25, 2011.

G.T. Blore,

Rear Admiral, U.S. Coast Guard, Commander, Thirteenth Coast Guard District.

[FR Doc. 2011-11059 Filed 5-5-11; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2011-0297]

RIN 1625-AA00

Safety Zone; Repair of High Voltage Transmission Lines to Logan International Airport, Saugus River, Saugus, MA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the Saugus River, Lynn, Massachusetts, within the Captain of the Port (COTP) Boston Zone to allow for repair of high voltage transmission lines to Logan Airport. This safety zone is required to provide for the safety of life on navigable waters during the repair of high voltage transmission lines. Entering into, transiting through, mooring or anchoring within this zone is prohibited unless authorized by the COTP.

DATES: This rule is effective from 9 a.m. on May 7, 2011, to 9 a.m. on May 9, 2011. The regulation will be enforced from 9 a.m. to 2 p.m. daily on May 7, 2011, and May 8, 2011.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2011-0297 and are available online by going to <http://www.regulations.gov>, inserting USCG-2011-0297 in the "Keyword" box, and then clicking "Search." This material is also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail MST1 David Labadie of the Waterways Management Division, U.S. Coast Guard Sector Boston; telephone 617-223-3010, e-mail david.j.labadie@uscg.mil. If you have questions on viewing material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On January 26, 2011, we published a notice of proposed rulemaking (NPRM) entitled, *Safety Zone; Repair of High Voltage Transmission Lines to Logan International Airport, Saugus River, Saugus, Massachusetts*, in the **Federal Register** (76 FR 4575–4577). We received no comments on the proposed rule. No public meeting was requested, and none was held.

On April 8, 2011, we published a final rule (FR) of the same in the **Federal Register** (76 FR 19698–19701). In the final rule, the safety zone has an effective date beginning on May 9, 2011. Based on limited equipment availability, the repair date schedule has since been moved up to May 7, 2011 and May 8, 2011.

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because sufficient information regarding the change of the repair date was not received in time to publish a NPRM followed by a final rule before the effective date, thus making the publication of a NPRM impractical. Immediate action is necessary to provide for the safety of life on navigable waters during the repair of high voltage transmission lines.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register** because the safety zone as currently published, will not be in effect until after the completion of the repair operations for which the safety zone is required. The timeline for this rule is based on the limited availability of equipment needed to complete the repairs. Because of the vital importance of the repairs to Logan Airport, and the safety zone necessary to complete those repairs, delaying this rule would be contrary to public interest.

Background and Purpose

This rule is necessary to ensure the safety of vessels and workers from the hazards associated with work related to repairs of high voltage transmission

lines over navigable waters. This temporary safety zone will be in effect during the repair of the high voltage transmission lines that feed Logan Airport. The safety zone will be enforced immediately before, during and after the start of the repairs. National Grid, the transmission line repair company has specified the repairs will take place on May 7, 2011 and May 8, 2011, to begin each day at 9 a.m. and end at 2 p.m.

The COTP will also inform the public using a variety of means, including Local Notice to Mariners and Broadcast Notice to Mariners.

All persons and vessels shall comply with the instructions of the COTP Boston or the designated on-scene representative. Entering into, transiting through, mooring or anchoring within the safety zone is prohibited unless authorized by the COTP Boston or the designated on scene representative. The COTP or the designated on scene representative may be contacted via VHF Channel 16 or by telephone at (617) 223–5750.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

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

The Coast Guard determined that this rule is not a significant regulatory action for the following reasons: The safety zone will be of limited duration, is located in a waterway that has no deep draft commercial traffic and is designed to avoid, to the extent possible, fishing and recreational boating traffic routes. Persons and vessels may still enter, transit through, anchor in, or remain within the regulated area if they obtain permission from the COTP or the designated representative.

Small Entities

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities.

The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

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

This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to enter, transit through, moor or anchor in a portion of the Saugus River during a 48 hour enforcement period related to repairs of high voltage transmission lines to Logan Airport.

This rule will not have a significant economic impact on a substantial number of small entities for the following reasons: National Grid intends to make repairs to the high voltage transmission lines running to Logan Airport during a 48 hour period between the hours of 9 a.m. and 2 p.m. daily. This time window will allow the local lobster fishing fleet to transit to the fishing grounds and return home at night with only minor inconvenience. The local harbor masters have notified their tenants in advance of the intended repairs, thus allowing Saugus River users to plan accordingly. Vessel traffic will be allowed to pass through the zone prior to 9 a.m. and after 2 p.m. and if necessary through the zone if they first obtain permission from the COTP. Before the effective period, we will issue maritime advisories widely available to users of the river.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact MST1 David Labadie at the telephone number or e-mail address indicated under the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The

Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

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

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

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

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

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human

environment. This rule is categorically excluded, under figure 2-1, paragraph (34)(g), of the Instruction. This rule involves the establishment of a safety zone. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05-1(g), 6.04-1, 6.04-6, and 160.5; Pub. L. 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T01-0297 to read as follows:

§ 165.T01-0297 Safety Zone; Repair of High Voltage Transmission Lines to Logan International Airport; Saugus River, Saugus, MA.

(a) *General.* A temporary safety zone is established for repair of high voltage transmission lines to Logan International Airport; Saugus River, Saugus, MA:

(1) *Location.* All waters of the Saugus River, from surface to bottom, within a 250-yard radius of position 42°26'42" N; 070°58'14" W.

(2) *Effective Period.* This rule is effective from 9 a.m. on May 7, 2011 to 9 a.m. on May 9, 2011.

(3) *Enforcement Period.* This rule will be enforced from 9 a.m. to 2 p.m. daily on May 7, 2011 and May 8, 2011.

(b) *Regulations.* (1) In accordance with the general regulations in Section 165.23 of this part, entry into, transiting or anchoring within this regulated area is prohibited unless authorized by the Captain of the Port (COTP) Boston, or his designated on-scene representative.

(2) The "on-scene representative" of the COTP Boston is any Coast Guard commissioned, warrant, or petty officer who has been designated by the COTP Boston to act on his behalf. The on-scene representative will be aboard either a Coast Guard or Coast Guard Auxiliary vessel. The COTP or the designated on-scene representative may be contacted by telephone at 617-223-5750 or on VHF Channel 16.

(3) Persons and vessels desiring to enter, transit through, anchor in, or

remain within the regulated area may request permission from the COTP or the designated representative by contacting Sector Boston by telephone at 617-223-5750 or VHF radio channel 16.

Dated: April 22, 2011.

John N. Healey,

Captain, U.S. Coast Guard, Captain of the Port Boston.

[FR Doc. 2011-11057 Filed 5-5-11; 8:45 am]

BILLING CODE 9110-04-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2009-0686; FRL-8865-4]

RIN 2070-AB27

Multi-Walled Carbon Nanotubes; Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for the chemical substance identified generically as multi-walled carbon nanotubes (MWCNT) which was the subject of premanufacture notice (PMN) P-08-199. This action requires persons who intend to manufacture, import, or process the chemical substance for a use that is designated as a significant new use by this final rule to notify EPA at least 90 days before commencing that activity. EPA believes that this action is necessary because the chemical substance may be hazardous to human health. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

DATES: This final rule is effective June 6, 2011.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPPT-2009-0686. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are

available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Jim Alwood, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; *telephone number:* (202) 564-8974; *e-mail address:* alwood.jim@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; *telephone number:* (202) 554-1404; *e-mail address:* TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

You may be potentially affected by this action if you manufacture, import, process, or use the chemical substance which is the subject of this final rule. Potentially affected entities may include, but are not limited to:

- Manufacturers, importers, or processors of the subject chemical substance (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

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 in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in § 721.5. 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**.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. For importers of the chemical substance subject to this SNUR, those requirements include the SNUR. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export the chemical substance that is the subject of this final rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

II. Background

A. What action is the agency taking?

EPA is finalizing a SNUR under TSCA section 5(a)(2) for the chemical substance identified generically (due to confidentiality claims) as multi-walled carbon nanotubes (PMN P-08-199). This action requires persons who intend to manufacture, import, or process the subject chemical substance for an activity that is designated as a significant new use by this final rule to notify EPA at least 90 days before commencing that activity.

Previously, in the **Federal Register** issue of February 3, 2010 (75 FR 5546) (FRL-8796-7), EPA issued a proposed SNUR on the chemical substance. On July 28, 2010 (75 FR 44198) (FRL-8828-3), in order to address public comment and add information to the docket, EPA reopened the comment period for 30 days. In response to comments on the basis for the SNUR, EPA developed a revised summary document entitled "Summary of EPA's Current Assessments of Health and Environmental Effects of Carbon Nanotubes," that specifies EPA's current hazard concerns as supported by available information and data. The docket for the proposed SNUR on this chemical substance is found under docket ID number EPA-HQ-OPPT-2009-0686. That docket includes information considered by the Agency in developing this final rule, including comments on the rule and the

aforementioned summary document. More information on the chemical substance subject to this final rule can be found in the proposed SNUR.

EPA received several comments on the proposed rule. A full discussion of EPA's response to these comments is included in Unit V. of this document. Taking into consideration these comments, EPA is issuing a final rule on this chemical substance that:

1. Retains the proposed workplace protection and specific use provisions as significant new uses.

2. Adds exclusions from applicability of the SNUR uses identified as ongoing.

3. Identifies those forms of the subject PMN substance which are exempt from the provisions of the SNUR. These exemptions apply to quantities of the PMN substance:

- After they have been completely reacted (cured);
- Incorporated or embedded into a polymer matrix that itself has been reacted (cured);

or,

- Embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing.

B. What is the agency's authority for taking this action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use. Persons who must report are described in § 721.5.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule. Provisions relating to user fees appear at 40 CFR part 700.

According to § 721.1(c), persons subject to these SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and

5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated in Customs and Border Patrol regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. For importers of a chemical substance subject to a final SNUR those requirements include the SNUR. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance identified in a final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611 (b)) (see § 721.20) and must comply with the export notification requirements in 40 CFR part 707, subpart D.

III. Rationale and Objectives of the Rule

A. Rationale

As discussed in the proposed rule, EPA identified concerns for lung effects, immunotoxicity, and mutagenicity from exposure to the PMN substance during its review of the chemical substance, which was the subject of P-08-199. These concerns were based on test data on analogous respirable, poorly soluble particulates and on other carbon nanotubes (CNTs). EPA determined that the PMN substance met the decisional criteria at § 721.170.

B. Objectives

EPA is issuing this final SNUR for a specific chemical substance that has undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this final rule:

- EPA will receive notice of any person's intent to manufacture, import, or process a listed chemical substance for the described significant new use before that activity begins.
- EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, importing, or

processing a listed chemical substance for the described significant new use.

- EPA will be able to regulate prospective manufacture, import, or processing of a listed chemical substance, before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Inventory. Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on-line at <http://www.epa.gov/opptintr/newchems/pubs/invntory.htm>.

IV. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the MWCNT subject to this final SNUR, EPA considered relevant information— included in the docket and discussed further in Unit V. of this document— about the toxicity of the chemical substance, likely human exposures and environmental releases associated with possible uses, taking into consideration the four bulleted TSCA section 5(a)(2) factors listed in this unit, and the regulations at § 721.170 for issuing a SNUR after receipt of a PMN.

For the MWCNT described in P-08-199, EPA believes that certain changes from the use scenario described in the PMN could result in increased exposures. EPA has determined that activities being designated as a "significant new use" in this rule satisfy the two requirements stipulated in § 721.170(c)(2), i.e., these significant new use activities, "(i) are different from those described in the premanufacture

notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified" for the PMN substance.

V. Response to Comments on Proposed SNUR on Multi-Walled Carbon Nanotubes

EPA received public comments on the proposed SNUR for the MWCNT which was the subject of PMN P-08-199. A discussion of the comments received and the Agency's responses follows.

Comment 1: One commenter requested that should EPA require testing, it should consider high-throughput methods that have been specifically designed for nanomaterials in order to reduce reliance on animal based testing, and so that testing does not become an unreasonable or unattainable burden for manufacturers as not to violate section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The commenter also requested that, in addition to relying on early characterization of nanomaterials using *in vitro* methods as outlined in EPA's *Nanomaterial Testing Strategy*, EPA apply integrated testing strategies (ITS) to assess the toxicological risk of nanomaterials.

Response: EPA identified recommended testing in the preamble of the proposed SNUR. Any manufacturers, importers, or processors who intend to conduct testing or submit a SNUN are encouraged to contact EPA to avoid duplicative testing, to identify alternative testing, and to discuss protocols for any testing to be conducted. EPA recognizes the value of high-throughput methods for nanomaterials. When contacted by a manufacturer, importer, or processor who intends to conduct testing or requiring testing by a SNUN submitter, EPA will consider this and other alternatives identified by the commenter.

Comment 2: One commenter asked EPA to include language in the SNUR that clarifies the exempt status of its laboratory in particular and research laboratories in general to SNUR requirements.

Response: The general SNUR requirements of 40 CFR part 721, subpart A, apply to this SNUR. The requirements in § 721.45(b) exempts a person from the notification requirements of this SNUR when they manufacture, import, or process small quantities of the substance subject to the SNUR solely for research and

development in accordance with the conditions in § 721.47.

Comment 3: One commenter supported the use of respiratory equipment to prevent exposures and another commenter supported timely issuance of the SNUR.

Response: EPA is issuing the final rule to include respiratory protection when workers are reasonably likely to be exposed.

Comment 4: One commenter noted that the proposed SNUR for the MWCNT, which was the subject of P-08-199, did not contain a no-release-to-water restriction and that other consent orders and SNURs for carbon nanotubes do contain a no-release-to-water restriction. The commenter stated that this difference was inappropriate and that it should not be allowed to persist.

Response: The PMN submitter identified a release to water in the PMN for this substance and EPA did not act to restrict the activity under TSCA section 5(e). Because the release to water is an ongoing use, EPA is unable to issue a SNUR that includes a no release to water provision.

Comment 5: The PMN submitter commented that significant new uses must not be ongoing and should be consistent with the existing uses identified in its comments. The PMN submitter also outlined its understanding of how the rule would apply in practice to particular existing uses and requested that the Agency clarify that understanding.

Response: After reviewing the PMN and the PMN submitter's outline of how the SNUR would apply in practice to its existing uses, EPA confirms that the significant new uses in this rule are not ongoing and that the commenter's outline of how the rule would apply to existing uses is correct. However, in its March 5, 2010, comments on the proposed SNUR, the PMN submitter identified specific use(s) other than as an additive/filler for polymer composites and support media for industrial catalysts. The company claimed these specific uses as CBI. As described in the proposed SNUR, persons who begin, after the date of the proposed rule, commercial manufacture, import, or processing of the MWCNT that was the subject of P-08-199 for a use preliminarily designated as a "significant new use" in the proposed rule must cease any such activity before the effective date of the rule if and when finalized. After the final SNUR is effective, any person intending to manufacture, import, or process the substance for a use other than as an additive/filler for polymer composites and support media for industrial

catalysts must submit a SNUN (in accordance with the requirements of 40 CFR part 721, subpart A) at least 90 days before commencing such use.

Comment 6: The PMN submitter asked EPA to clarify the meaning of uses as described in the PMN. The uses described in the PMN were additive/filler for polymer composites and support media for industrial catalysts. The PMN submitter asked whether notification would be required for each specific polymer composite or for different equipment used to manufacture or process the PMN substance.

Response: If a manufacturer or processor is using the PMN substance as either an additive/filler for polymer composites, or support media for industrial catalysts, they may change processes to include new equipment or new polymer composites. If there is any question as to whether a specific use or application is not the use described in the PMN, a manufacturer or processor may contact EPA or submit a SNUN.

Comment 7: The PMN submitter commented that there should be an exemption for bound forms of the PMN substance when the SNUR would not apply, for example, when the PMN substance is embedded or incorporated into plastic resin pellets.

Response: EPA agrees that, consistent with other SNURs and consent orders for CNTs, (e.g., the MWCNT which was the subject of PMN P-08-177), and the existing uses of the PMN substance, there should be an exemption from the final SNUR requirements once the PMN substance has been fixed to a substrate or encapsulated within a plastic or other polymer matrix. The Agency has included language in the final SNUR to exempt from SNUR requirements persons that manufacture, import, or process the PMN substance when the substance has been incorporated or embedded into a polymer matrix that itself has been reacted (cured) or embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing.

Comment 8: The PMN submitter asked EPA to specify the identity of the PMN substance specifically in relation to other MWCNTs, explaining how EPA is describing the PMN substance as a unique chemical type.

Response: Because of a lack of established nomenclature for CNTs, EPA has allowed PMN submitters to represent their CNTs using a generic name such as carbon nanotube (CNT), multi-walled carbon nanotube (MWCNT), or single-walled carbon nanotube (SWCNT) while submitting a

detailed description of the CNT using specific structural characteristics. All submitters of new chemical notices for CNTs, including the submitter for the MWCNT described in P-08-199, have claimed those specific structural characteristics as CBI. EPA is publishing the generic chemical name along with the PMN number to identify that a distinct chemical substance was the subject of the PMN without revealing the confidential chemical identity of the PMN substance. Confidentiality claims preclude a more detailed description of the identity of this MWCNT.

Manufacturers may submit a *bona fide* intent to manufacture or import under § 720.25 to determine whether a specific CNT is on the TSCA Inventory.

Comment 9: The PMN submitter commented on the document entitled, "Material Characterization of Carbon Nanotubes for Molecular Identity (MI) Determination & Nomenclature" (docket ID number EPA-HQ-OPPT-2009-0686-0015), that identifies a list of chemical structural features, chemical particle properties, and manufacturing methods that may be important for making carbon nanotube molecular identity determinations and naming them for TSCA purposes. The PMN submitter stated it was difficult to comment on the document, as the record does not identify either its particular provenance, or how the Agency is using, or plans to use it. The commenter also noted that many of the features may be impractical to observe, measure, or characterize with any consistency or statistical certainty, and others may be altered simply by the act of measuring. The commenter stated that several of the criteria refer only to properties of a CNT material (i.e., a collection of molecules rather than a single molecule), then asserted that these characteristics may be relevant to management considerations, but they are not relevant to defining molecular identity for TSCA purposes.

Response: EPA does not agree that these characteristics are not relevant to defining the molecular identity of a CNT. As noted in the response to "Comment 8," because of a lack of established nomenclature for CNTs, EPA is currently representing CNTs using a generic chemical name along with the PMN number to identify them as distinct chemical substances. EPA included this list of physical features that may be important to demonstrate that it is considering additional characteristics when reviewing and identifying CNTs. EPA has used a wide variety of characteristics to identify chemical substances of unknown or variable composition, complex reaction

products, and biological materials (UVCB) for TSCA purposes. As noted by the commenter, some of these characteristics may not be suitable for unambiguously determining molecular identity. As EPA learns more about the structures of CNTs, it will develop a set of characteristics to systematically identify CNTs.

Comment 10: A commenter noted that recent signed and draft consent orders for other CNTs contain additional updated hazard assessment information for both health and environmental concerns. The commenter suggested this language should be referenced in the final SNUR so that all of EPA's concerns are described in a similar manner for all SNURs pertaining to CNTs. The PMN submitter stated that while EPA did place data in the public docket supporting the finding at § 721.170(b)(3)(ii) from inhalation exposure, there is no data in the public docket supporting the finding from dermal exposures.

Response: EPA is continually refining and adding to its risk assessment and risk management approaches, especially for new chemical substances such as CNTs that have limited available hazard, exposure, and fate data. Recent consent orders for CNTs cite additional data which was not referenced in the proposed SNUR for this PMN substance. EPA placed in the public docket a document entitled, "Summary of EPA's Current Assessment of Health and Environmental Effects of Carbon Nanotubes" (docket ID number EPA-HQ-OPPT-2009-0686-0016), in support of the health effects findings and significant new use designations made in the proposed rule. This document identifies those references available at the time of assessment of the chemical substance in this final rule. EPA also reopened the comment period on July 28, 2010 (75 FR 44198), to allow interested parties to comment on the additional information that was the basis for the SNUR.

Comment 11: EPA missed the 270-day deadline so it should use the procedure and analysis otherwise required by 5(a)(2) of TSCA.

Response: A schedule for issuing SNURs with various types of rulemaking, including proposed rules, interim rules, and direct final rules is included at § 721.170(e)(1). The schedule states that EPA will issue the SNUR within 270 days of receipt of the notice of commencement under § 720.102 for any substance for which the notice of commencement was received on or after October 10, 1989. The schedule is not mandatory, and rulemaking is not contingent on meeting

this schedule. Although EPA did not issue the rule within the time period set out in the schedule, the Agency remains able to do so by any rulemaking procedure compatible with the Administrative Procedure Act (APA). EPA believes the procedures followed in developing this rule are consistent with the requirements in TSCA section 5(a)(2) and the APA.

Comment 12: The PMN submitter expressed concerns with respect to the cited inhalation (or simulated inhalation) studies. The commenter questioned the validity of the studies as several of the cited studies exist only as abstracts of unpublished presentations. The commenter stated there is no assessment of the doses involved in these studies, or the studies underlying the poorly soluble particles chemical categories report. The commenter also noted a Bayer Material Science study for carbon nanotubes and detailed results of the inhalation studies that have been recently published in the peer-reviewed journals, *Inhalation Toxicology*, *Toxicological Sciences* and *Toxicology* that EPA should take into account in connection with the rulemaking. Finally, the commenter states that EPA does not explain how these studies satisfy the regulatory concern criteria on which EPA relies.

Response: EPA has found that the substance meets the decisional criteria in § 721.170(b)(3)(ii). The decisional criteria state that: The substance may cause serious chronic effects, serious acute effects, or developmentally toxic effects under reasonably anticipated conditions of exposure because the substance is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another chemical substance that has been shown by valid test data to cause serious chronic effects, serious acute effects, or developmentally toxic effects in humans or in at least one species of laboratory animal at dose levels that could be of concern under reasonably anticipated conditions of exposure. EPA is not required to conduct a quantitative risk assessment or establish safe dose levels. EPA must only establish that effects could occur under reasonably anticipated conditions of exposure. The papers referenced in the docket, the Bayer Material Science study and other data cited by the PMN submitter, and data that is the basis for the poorly soluble respirable particulates category, demonstrate the potential chronic pulmonary and cardiovascular effects (including pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity, and cardiovascular

toxicity) of carbon nanotubes, including the PMN substance, at various dose levels. EPA considered this information in the review of the MWCNT described in PMN P-08-199, and concluded that the specified significant new uses of the PMN substance could result in inhalation exposures at levels where health effects were observed in the papers referenced in the docket. All of the papers referenced in the docket are publicly available peer reviewed scientific journals and publications.

Comment 13: The PMN submitter stated that the company supports minimizing dermal and inhalation exposures to the extent reasonably practicable on a voluntary basis, and that controls should be used where warranted, but they should not be required to prevent particular exposures for which the Agency has no reasoned basis to believe may cause significant effects. The commenter asserted that the materials in the public docket only address the potential direct and indirect effects of inhalation exposures. Further, in summary, the commenter stated that the proposal appears to lack any reasoned basis for the particular dermal controls proposed in the SNUR and does not appear to meet the decisional criteria in § 721.170(b)(3)(ii) as the basis for establishing controls. The commenter stated that one cannot assess the basis and extent for the Agency's concern, making it impossible to comment on whether the suggested controls are reasonably tailored to those concerns.

Response: EPA believes it has demonstrated that the subject substance meets the decisional criteria in § 721.170(b)(3)(ii), including the significant new use of manufacturing, importing, or processing of the PMN substance without dermal protection where workers are reasonably likely to be exposed. As noted in the response to "Comment 12," EPA has established that CNTs, including the PMN substance, may cause pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity, and cardiovascular toxicity. The "Summary of EPA's Current Assessment of Health and Environmental Effects of Carbon Nanotubes" (docket ID number EPA-HQ-OPPT-2009-0686-0016) states that "absorption is expected to be poor for all routes" which includes dermal exposure. This suggests that some dermal absorption could occur. EPA considered this information in the review of the MWCNT described in PMN P-08-199, and concluded that the specified significant new uses of the PMN substance could also result in dermal exposures at levels where health

effects were observed in the papers referenced in the docket.

VI. Applicability of Rule to Uses Occurring Before Effective Date of the Final Rule

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376), EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of the proposed SNUR rather than as of the effective date of the final rule. If uses begun after publication were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements because a person could defeat the SNUR by initiating the proposed significant new use before the rule became effective, and then argue that the use was ongoing before the effective date of the final rule.

Any person who began commercial manufacture, import, or processing of the MWCNT described in PMN P-08-199 for any of the significant new uses designated in the proposed SNUR after the date of publication of the proposed SNUR must stop that activity before the effective date of this final rule. Persons who ceased those activities will have to meet all SNUR notice requirements and wait until the end of the notification review period, including all extensions, before engaging in any activities designated as significant new uses. If, however, persons who began manufacture, import, or processing of the chemical substance between the date of publication of the proposed SNUR and the effective date of this final SNUR meet the conditions of advance compliance as codified at § 721.45(h), those persons would be considered to have met the final SNUR requirements for those activities.

VII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require the development of any particular test data before submission of a SNUN. There are two exceptions:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).
2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)). In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see § 720.50).

However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. In this case, EPA recommends persons, before performing any testing, to consult with the Agency pertaining to protocol selection.

The recommended testing specified in Unit IV. of the proposed rule may not be the only means of addressing the potential risks of the chemical substance. However, SNUNs submitted without any test data may increase the likelihood that EPA will respond by taking action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests prior to submitting a SNUN.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substance.
- Potential benefits of the chemical substance.
- Information on risks posed by the chemical substance compared to risks posed by potential substitutes.

VIII. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in § 720.50. SNUNs must be on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in §§ 721.25 and 720.40. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

IX. Economic Analysis

EPA evaluated the potential costs of establishing SNUN requirements for potential manufacturers, importers, and processors of the chemical substance subject to this final rule. The Agency's complete Economic Analysis is available in the docket under docket ID number EPA-HQ-OPPT-2009-0686.

X. Statutory and Executive Order Reviews

A. Executive Order 12866

This final rule establishes a SNUR for a chemical substance that was the

subject of a PMN. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this final rule. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington,

DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of this SNUR will not have a significant adverse economic impact on a substantial number of small entities. The rationale supporting this conclusion is discussed in this unit. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a "significant new use." Because these uses are "new," based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of over 1,400 SNURs, the Agency receives on average only 5 notices per year. Of those SNUNs submitted from 2006-2008, only one appears to be from a small entity. In addition, the estimated reporting cost for submission of a SNUN (see Unit VIII.) is minimal regardless of the size of the firm. Therefore, EPA believes that the potential economic impacts of complying with this SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL-5597-1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this final rule. As such, EPA has determined that this final rule does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the

requirements of sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4).

E. Executive Order 13132

This action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This final rule does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This final rule does not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), do not apply to this final rule.

G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This action is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

In addition, since this action does not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects*40 CFR Part 9*

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: April 29, 2011.

Wendy C. Hamnett,

Director, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR parts 9 and 721 are amended as follows:

PART 9—[AMENDED]

- 1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

- 2. The table in § 9.1 is amended by adding the following section in numerical order under the undesignated center heading “Significant New Uses of Chemical Substances” to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation

OMB control No.

* * * * *

Significant New Uses of Chemical Substances

* * * * *

721.10183 2070–0012

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PART 721—[AMENDED]

- 3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

- 4. Add § 721.10183 to subpart E to read as follows:

§ 721.10183 Multi-walled carbon nanotubes (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as multi-walled carbon nanotubes (PMN P–08–199) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the chemical substance after it has been completely reacted (cured), incorporated or embedded into a polymer matrix that itself has been reacted (cured), or embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(4), (a)(5) (National Institute for Occupational Safety and Health (NIOSH)-approved full-face respirators with N100 cartridges), (a)(6)(i), and (c).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (additive/filler for polymer composites and support media for industrial catalysts).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this chemical substance.

(2) *Limitations or revocation of certain notification requirements.* The

provisions of § 721.185 apply to this section.

[FR Doc. 2011–11127 Filed 5–5–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[EPA–R09–OAR–2011–0302; FRL–9292–6]

Revisions to the California State Implementation Plan, Northern Sonoma County Air Pollution Control District (NSCAPCD) and Mendocino County Air Quality Management District (MCAQMD)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve revisions to the Northern Sonoma County Air Pollution Control District (NSCAPCD) and Mendocino County Air Quality Management District (MCAQMD) portions of the California State Implementation Plan (SIP). Both districts are required under Part C of title I of the Clean Air Act (CAA) to adopt and implement SIP-approved Prevention of Significant Deterioration (PSD) permit programs. These revisions update the definitions used in the districts’ PSD permit programs.

DATES: This rule is effective on July 5, 2011 without further notice, unless EPA receives adverse comments by June 6, 2011. If we receive such comments, we will publish a timely withdrawal in the **Federal Register** to notify the public that this direct final rule will not take effect.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2011–0302, by one of the following methods:

1. *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions.

2. *E-mail:* R9airpermits@epa.gov.

3. *Mail or deliver:* Gerardo Rios (Air-3), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected

should be clearly identified as such and should not be submitted through <http://www.regulations.gov> or e-mail. <http://www.regulations.gov> is an “anonymous access” system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: EPA has established a docket for this action under EPA–R09–OAR–2011–0302. Generally, documents in the docket for this action are available

electronically at <http://www.regulations.gov> or in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed at <http://www.regulations.gov>, some information may be publicly available only at the hard copy location (e.g., copyrighted material, large maps, multi-volume reports) and some may not be available in either location (e.g., confidential business information (CBI)). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Laura Yannayon, EPA Region IX, (415) 972–3534, yannayon.laura@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document, “we,” “us,” and “our” refer to EPA.

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I. The State’s Submittal

A. What rules did the State submit?

Table 1 lists the rules we are approving with the dates that they were adopted by the local air agencies and submitted by the California Air Resources Board.

TABLE 1—SUBMITTED RULES

| Local agency | Rule No. | Rule title | Date adopted | Date submitted |
|---------------|----------|-------------------|--------------|----------------|
| NSCAPCD | 130 | Definitions | 12/14/10 | 02/28/11 |
| MCAQMD | 130 | Definitions | 02/15/11 | 02/28/11 |

On March 22, 2011, EPA determined that the submittal for both NSCAPCD’s and MCAQMD’s Rule 130 met the completeness criteria in 40 CFR Part 51 Appendix V, which must be met before formal EPA review.

B. Are there other versions of these rules?

We approved earlier versions of Rule 130 for both districts into the SIP. For NSCAPCD and MCAQMD, Rule 130 was last approved into the SIP on February 9, 1999 and July 31, 1998, respectively (See 64 FR 6223 and 63 FR 40830). There are no other pending submittals of these rules.

C. What is the purpose of the submitted rules and rule revisions?

Part C of title I of the Clean Air Act (CAA) requires that the SIP for any area designated as attainment or unclassifiable for a National Ambient Air Quality Standard (NAAQS) contain a Prevention of Significant Deterioration (PSD) permit program. Both the NSCAPCD and MCAQMD are currently designated as attainment or unclassifiable for all NAAQS, and are therefore required to adopt and implement a SIP-approved PSD permit program.

Both NSCAPCD’s and MCAQMD’s Rule 130, Definitions, define various terms used throughout the District’s regulations. In particular, Rule 130

provides definitions of several key terms related to the PSD program. Both districts’ submitted revisions to Rule 130, Definitions, are being evaluated together because both the existing SIP rules and proposed revisions are very similar. In each case, the District has revised Rule 130 to provide new and revised definitions in order to ensure consistency with CAA requirements for PSD programs.

II. EPA’s Evaluation and Action

A. How is EPA evaluating the rules?

Since the submitted rules only consist of definitions, our evaluation focuses on whether the definitions are either identical or equivalent to EPA’s definitions found in 40 CFR 51.100 and 51.166, and 40 CFR part 50.

Section 110(l) of the Act prohibits EPA from approving any revision of a SIP that would interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable requirement of the Act.

Section 193 of the Act, which was added by the Clean Air Act Amendments of 1990, only applies to control requirements in nonattainment areas. Neither the NSCAPCD nor MCAQMD are designated nonattainment for any NAAQS; therefore Section 193 does not apply to this rulemaking action.

B. Do the rules meet the evaluation criteria?

The new and revised definitions contained in both districts’ submitted versions of Rule 130 are consistent with the applicable definitions of these terms in 40 CFR 51.100 and 51.166, and 40 CFR part 50. EPA’s approval of these rules will strengthen the SIP by adding and updating terms that establish applicability and evaluation criteria for pollutants subject to the PSD program. The rules do not interfere with attainment and reasonable further progress or any other applicable requirement of the Act, and thus are approvable under Section 110(l) of the Act. EPA’s technical support document (TSD) has more information about these rules and the revisions.

C. Public Comment and Final Action

As authorized in section 110(k)(3) of the Act, EPA is fully approving the submitted rules because we believe they fulfill all applicable requirements. We do not think anyone will object to this approval, so we are finalizing it without proposing it in advance. However, in the Proposed Rules section of this **Federal Register**, we are simultaneously proposing approval of the same submitted rules. If we receive adverse comments by June 6, 2011, we will publish a timely withdrawal in the **Federal Register** to notify the public

that the direct final approval will not take effect and we will address the comments in a subsequent final action based on the proposal. If we do not receive timely adverse comments, the direct final approval will be effective without further notice on July 5, 2011. This will incorporate these rules into the federally enforceable SIP.

Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

III. Statutory and Executive Order Reviews

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

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

application of those requirements would be inconsistent with the Clean Air Act; and

- Does not provide EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 5, 2011. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

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

Dated: March 31, 2011.

Jared Blumenfeld,

Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart F—California

- 2. Section 52.220 is amended by adding paragraph (c)(385) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *
(385) New and amended regulations for the following APCDs were submitted on February 28, 2011.

(i) Incorporation by Reference.

(A) Mendocino County Air Quality Management District.

(1) Rule 130, "Definitions," amended February 15, 2011.

(B) Northern Sonoma County Air Pollution Control District.

(1) Rule 130, "Definitions," amended December 14, 2010.

[FR Doc. 2011-11038 Filed 5-4-11; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2009-0194; FRL-8872-3]

Metarhizium anisopliae Strain F52; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of *Metarhizium anisopliae* strain F52 in or on all food commodities when applied as an insecticide, miticide, or ixodicide and used in accordance with good agricultural practices. Novozymes Biologicals, Inc. submitted a petition to

EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Metarhizium anisopliae* strain F52 under the FFDCA.

DATES: This regulation is effective May 6, 2011. Objections and requests for hearings must be received on or before July 5, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2009-0194. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8097; e-mail address: bacchus.shanaz@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

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

- Pesticide manufacturing (NAICS code 32532).

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 in this unit could also be affected. The North American Industrial Classification System (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 person listed under **FOR FURTHER INFORMATION CONTACT**.

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

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at <http://www.gpoaccess.gov/ecfr>. To access the harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2009-0194 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before July 5, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2009-0194, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of April 8, 2009 (74 FR 15969) (FRL-8407-6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 8F7508) by Novozymes Biologicals, Inc., 5400 Corporate Circle, Salem, VA 24153. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Metarhizium anisopliae* strain F52. This notice referenced a summary of the petition prepared by the petitioner, Novozymes Biologicals, Inc., which is available in the docket, via <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

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

exposure to the pesticide chemical residue. * * *” Additionally, section 408(b)(2)(D) of FFDCA requires that EPA consider “available information concerning the cumulative effects of [a particular pesticide’s] residues and other substances that have a common mechanism of toxicity.”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and has considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

A. Overview of *Metarhizium Anisopliae* Strain F52

Metarhizium anisopliae strain F52 (called MetF52), a deuteromycetous and entomopathogenic fungus that is found worldwide, infects numerous insect (primarily Coleoptera of the families Elateridae and Curculionidae), mite, and tick species that are contacted by it. Once spores of *Metarhizium anisopliae* strain F52 attach to the surface of the target pest, they germinate, grow, penetrate the target pest’s exoskeleton, continue to grow in the target pest, and eventually cause death. Susceptible insects, mites, or ticks that come into contact with other insects, mites, or ticks that have been infected with *Metarhizium anisopliae* strain F52 also become infected with the fungus, thus continuing this microbe’s pesticidal effect.

Given this distinct capability and efficiency in controlling various insects, mites, and ticks, *Metarhizium anisopliae* strain F52 is currently recognized as the active ingredient in several microbial pesticide products, which were conditionally registered under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) in June 2003 to Earth BioSciences, Inc. Since the registration of these pesticide products in 2003, they have been labeled specifically for non-food applications in urban and suburban (residential) areas to control

various insects (e.g., thrips and root weevils), mites, and ticks. In 2006, the *Metarhizium anisopliae* strain F52-containing registrations were transferred from Earth BioSciences, Inc. to Novozymes Biologicals, Inc. (TAE-001 Technical Bioinsecticide, EPA Reg. No. 70127-7; Taenure Granular Bioinsecticide, EPA Reg. No. 70127-8; Tick-EX G, EPA Reg. No. 70127-9; Tick-EX EC, EPA Reg. No. 70127-10).

After maintaining the registrations with non-food uses for several years, Novozymes Biologicals, Inc. has now petitioned EPA to establish an exemption from the requirement of a tolerance for residues of *Metarhizium anisopliae* strain F52 in or on all food commodities. Accordingly, EPA has reevaluated an assessment of the mammalian toxicology data that were submitted prior to 2003 to support the initial applications for *Metarhizium anisopliae* strain F52 pesticide products. The overall conclusions from these data are described in Unit III.B., while more in-depth synopses of the study results can be found in a 2001 risk assessment, the 2003 *Metarhizium anisopliae* strain F52 Biopesticides Registration Action Document (BRAD), and the 2011 Addendum to the *Metarhizium anisopliae* strain F52 BRAD provided as references in Unit IX. (Refs. 1, 2, and 3).

B. Microbial Pesticide Toxicology Data Requirements

All mammalian toxicology data requirements supporting the request for an exemption from the requirement of a tolerance for residues of *Metarhizium anisopliae* strain F52 in or on all food commodities have been fulfilled with acceptable studies.

1. *Acute oral toxicity and pathogenicity—rat* (Harmonized Guideline 885.3050; Master Record Identification Number (MRID No.) 448447-09). An acceptable acute oral toxicity and pathogenicity study demonstrated that *Metarhizium anisopliae* strain F52 was not toxic and/or pathogenic to rats when dosed at approximately 1.04×10^8 colony-forming units (cfu)/animal.

2. *Acute dermal toxicity—rabbit* (Harmonized Guideline 885.3100; MRID No. 448447-10). An acceptable acute dermal toxicity study demonstrated that *Metarhizium anisopliae* strain F52 was not toxic to rabbits when dosed at $3.63\text{--}4.42 \times 10^{10}$ cfu/animal (median lethal dose (LD₅₀) > 2,000 milligrams per kilogram (mg/kg); Toxicity Category III).

3. *Acute pulmonary toxicity and pathogenicity—rat* (Harmonized Guideline 885.3150; MRID No. 448447-11). An acceptable acute pulmonary

toxicity and pathogenicity study demonstrated that *Metarhizium anisopliae* strain F52 was not toxic and/or pathogenic to rats when dosed intratracheally at approximately 1.17×10^8 cfu/animal.

4. *Acute injection toxicity and pathogenicity—rat* (Harmonized Guideline 885.3200; MRID No. 448447-12). An acceptable acute injection toxicity and pathogenicity study demonstrated that *Metarhizium anisopliae* strain F52 was not toxic and/or pathogenic to rats when dosed intraperitoneally at approximately 1×10^7 cfu/animal.

5. *Acute eye irritation—rabbit* (Harmonized Guideline 870.2400; MRID No. 448447-13). An acceptable acute eye irritation study demonstrated that *Metarhizium anisopliae* strain F52 was moderately irritating (i.e., the test substance caused corneal opacity, iritis, and conjunctival irritation with resolution by day 4) to rabbits when dosed at 6.3×10^8 cfu/eye/animal (Toxicity Category III).

6. *Dermal sensitization—guinea pig* (Harmonized Guideline 870.2600; MRID No. 448447-15). An acceptable dermal sensitization study demonstrated that *Metarhizium anisopliae* strain F52 was not a dermal sensitizer to guinea pigs when induced and challenged at 2.37×10^9 cfu.

7. *Hypersensitivity incidents* (Harmonized Guideline 885.3400; MRID No. 448447-14). No hypersensitivity incidents involving *Metarhizium anisopliae* strain F52 and occurring during fermentation, processing, formulation, research, or application have been reported to EPA.

IV. Aggregate Exposure

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

Dietary exposure to this microbial pesticide may occur (more likely through food than drinking water), but the lack of acute oral toxicity, infectivity, and/or pathogenicity, as exhibited in a toxicology test on rats presented in Unit III.B., supports the establishment of a tolerance exemption for residues of *Metarhizium anisopliae* strain F52.

1. *Food*. Exposure to this microbial active ingredient through food is expected to be minimal. When applied in accordance with good agricultural practices, *Metarhizium anisopliae* strain F52, a known pathogen of various insects, mites, and ticks, is unlikely to persist on plants. Any spores on plants due to pesticide application would presumably decrease over time, similar to other fungal entomopathogens and microbial pest control agents, because of environmental factors such as rainfall, ultraviolet radiation, and temperature (Refs. 4 and 5). For example, several studies, designed to evaluate the susceptibility of *Metarhizium* spores to sunlight, showed that ultraviolet radiation (UV-A and UV-B) quickly causes inactivation of these spores, both with and without the use of substances intended to act as sunscreens (Ref. 6). In the unlikely event that the applied fungus grew on the edible portions of treated crops, the results of the toxicology testing demonstrated that no toxicity, infectivity, and/or pathogenicity in treated animals occurred, even when dosed with high levels of *Metarhizium anisopliae* strain F52 by the oral route of exposure (see additional discussion in Unit III.B.). In conclusion, there are no concerns for *Metarhizium anisopliae* strain F52 exposure through food.

2. *Drinking water exposure*. Much like dietary exposure, drinking water exposure is expected to be negligible, albeit for slightly different reasons. Given the terrestrial use sites, the application methods with reduced chance for offsite movement of *Metarhizium anisopliae* strain F52 (e.g., soil incorporation), and low application rates, it is not likely that use of *Metarhizium anisopliae* strain F52 products, when good agricultural practices are followed, will result in significant increase in fungal spore exposure in drinking water. With regard to percolation through the soil, Zimmerman (2007) suggests that *Metarhizium anisopliae* is a typical soil-borne fungus as it has mostly been isolated from the upper soil layer. Further, Zimmerman (2007) also goes on to describe field tests in which many sprayed *Metarhizium anisopliae* spores were found in upper layers of loamy soil and humus, thereby supporting the soil adhesion theory and the absence of significant spore percolation down to ground water. In the unlikely event of exposure to *Metarhizium anisopliae* strain F52 spores through drinking water, the results of the oral toxicology testing, as described in Unit III.B., demonstrated that no toxicity,

infectivity, and/or pathogenicity in treated animals occurred. As was concluded for food exposure, there are no concerns for *Metarhizium anisopliae* strain F52 exposure through drinking water.

B. Other Non-Occupational Exposure

Deuteromycetous fungi, such as *Metarhizium anisopliae* strain F52, are naturally occurring and found worldwide. As a pesticidal active ingredient, *Metarhizium anisopliae* strain F52 has historically been applied in residential areas. Because of the use patterns and low application rates, there will not likely be a significant increase in exposure over the background levels of *Metarhizium anisopliae* strain F52 in these residential areas. Furthermore, there is no evidence of any concern for inhalation or dermal toxicity at exposure levels several orders of magnitude higher than would be expected to be encountered by a typical residential end user (see Unit III.B.). Finally, given that this deuteromycetous fungi affects only certain species of insects, mites, and ticks, and that no recognized relationships exist between the *Metarhizium* genus and any pathogen of humans and animals, no adverse effects to humans from inhalation or dermal exposure to this widespread fungus have been reported or are anticipated.

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

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

EPA has not found *Metarhizium anisopliae* strain F52 to share a common mechanism of toxicity with any other substances, and *Metarhizium anisopliae* strain F52 does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that *Metarhizium anisopliae* strain F52 does not have a common mechanism of toxicity with other substances. Following from this, therefore, EPA concludes that there are no cumulative effects associated with *Metarhizium anisopliae* strain F52 that need to be considered. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at <http://www.epa.gov/pesticides/cumulative>.

VI. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of exposure (safety), which are often referred to as uncertainty factors, are incorporated into EPA risk assessments, either directly, or through the use of a margin of exposure analysis, or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk.

Based on the acute toxicity and pathogenicity data discussed in Unit III.B., as well as use of *Metarhizium anisopliae* strain F52 as a microbial pesticide for approximately eight years without reported adverse effects to humans, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of *Metarhizium anisopliae* strain F52. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has arrived at this conclusion because the data and information available on *Metarhizium anisopliae* strain F52 do not demonstrate toxic, pathogenic, and/or infective potential to mammals. Thus, there are no threshold effects of concern and, as a result, an additional margin of safety is not necessary.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever

possible, consistent with U.S. food safety standards and agricultural practices. In this context, EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for *Metarhizium anisopliae* strain F52.

VIII. Conclusions

EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Metarhizium anisopliae* strain F52. Therefore, an exemption is established for residues of *Metarhizium anisopliae* strain F52 in or on all food commodities when applied as an insecticide, miticide, or ixodicide and used in accordance with good agricultural practices.

IX. References

1. U.S. EPA. 2011. Addendum to *Metarhizium anisopliae* strain F52 Biopesticides Registration Action Document dated March 2011 (available as "Supporting & Related Materials" within docket ID number EPA-HQ-OPP-2010-0081 at <http://www.regulations.gov>).
2. U.S. EPA. 2003. *Metarhizium anisopliae* strain F52 Biopesticides Registration Action Document.
3. U.S. EPA. 2001. Review of Toxicology Data for *Metarhizium anisopliae* F52 in Support of a Section Three Registration for *Metarhizium anisopliae* F52 from Taensa, Inc., Fairfield, CT. Memorandum from C.A. Wozniak, PhD and J.L. Kough, PhD to L. Cole dated December 11, 2001 (available as "Supporting & Related Materials" within docket ID number EPA-HQ-OPP-2010-0081 at <http://www.regulations.gov>).
4. Jaronski ST. 2010. Ecological factors in the inundative use of fungal entomopathogens. *Biocontrol* 55:159–185.
5. U.S. EPA. 1996. Microbial Pesticide Test Guidelines—Background for Residue Analysis of Microbial Pest Control Agents (OPPTS 885.2000). Available from: http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series885.htm.
6. Zimmermann G. 2007. Review of safety of the entomopathogenic fungus

Metarhizium anisopliae. *Biocontrol Sci Techn* 17(9):879–920.

X. Statutory and Executive Order Reviews

This final rule establishes a tolerance exemption under section 408(d) of FFDCA in response to a petition submitted to EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, EPA has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, EPA has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), do not apply to this final rule. In addition, this final

rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

This action does not involve any technical standards that would require EPA consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: April 28, 2011.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

- 2. Section 180.1303 is added to subpart D to read as follows:

§ 180.1303 *Metarhizium anisopliae* strain F52; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Metarhizium anisopliae* strain F52 in or on all food commodities when applied as an insecticide, miticide, or ixodicide and used in accordance with good agricultural practices.

[FR Doc. 2011–11030 Filed 5–5–11; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION**47 CFR Parts 0 and 20****[WT Docket No. 05–265; FCC 11–52]****Reexamination of Roaming Obligations of Commercial Mobile Radio Service Providers and Other Providers of Mobile Data Services****AGENCY:** Federal Communications Commission.**ACTION:** Final rule.

SUMMARY: In this document, the Federal Communications Commission (FCC) adopts a rule that requires facilities-based providers of commercial mobile data services to offer data roaming arrangements to other such providers on commercially reasonable terms and conditions, subject to certain limitations, thereby advancing the Commission's goal of ensuring that all Americans have access to competitive broadband mobile data services.

DATES: Effective June 6, 2011, except for § 20.12(e)(2) which contains information collection requirements that have not been approved by the Office of Management and Budget (OMB). The Commission will publish a document in the **Federal Register** announcing the effective date of this amendment.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Second Report and Order in WT Docket No. 05–265; FCC 11–52, adopted April 7, 2011, and released on April 7, 2011. The full text of the Second Report and Order is available for public inspection and copying during business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. It also may be purchased from the Commission's duplicating contractor at Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554; the contractor's Web site, <http://www.bcpweb.com>; or by calling (800) 378–3160, facsimile (202) 488–5563, or e-mail FCC@BCPIWEB.com. Copies of the public notice also may be obtained via the Commission's Electronic

Comment Filing System (ECFS) by entering the docket number WT Docket No. 05–265. Additionally, the complete item is available on the Federal Communications Commission's Web site at <http://www.fcc.gov>.

Synopsis of the Second Report and Order**I. Introduction**

1. In this Second Report and Order (Second R&O), the Commission promotes consumer access to nationwide mobile broadband service by adopting a rule that requires facilities-based providers of commercial mobile data services to offer data roaming arrangements to other such providers on commercially reasonable terms and conditions, subject to certain limitations. Widespread availability of data roaming capability will allow consumers with mobile data plans to remain connected when they travel outside their own provider's network coverage areas by using another provider's network, and thus promote connectivity for and nationwide access to mobile data services such as e-mail and wireless broadband Internet access. The rule the Commission adopts today also serves the public interest by promoting investment in and deployment of mobile broadband networks, consistent with the recommendations of the National Broadband Plan. The deployment of mobile data networks is essential to achieve the goal of making broadband connectivity available everywhere in the United States, and the availability of data roaming will help ensure the viability of new wireless data network deployments and thus promote the development of competitive facilities-based service offerings for the benefit of consumers. Today's actions will therefore advance the Commission's goal of ensuring that all Americans have access to competitive broadband mobile data services.

2. The Commission adopts the data roaming rule based on its authority under the Act, including several provisions of Title III, which provides the Commission with authority to manage spectrum and establish and modify license and spectrum usage conditions in the public interest. This rule will apply to all facilities-based providers of commercial mobile data services regardless of whether these entities are also providers of commercial mobile radio service (CMRS). To resolve disputes arising pursuant to the rule the Commission adopts here, the Commission provides that parties may file a petition for declaratory ruling

under Section 1.2 of the Commission's rules or file a formal or informal complaint under the rule established herein depending on the circumstances specific to each dispute. Also, in order to facilitate the negotiation of data roaming arrangements, the Commission provides guidance on factors that the Commission could consider when evaluating any data roaming disputes that might be brought before the agency.

II. Discussion**A. The Public Interest in a Data Roaming Rule**

3. After carefully considering the arguments in the record, the Commission concludes that it will serve the public interest to adopt a data roaming rule. Specifically, the Commission requires providers of commercial mobile data services to offer data roaming arrangements on commercially reasonable terms and conditions, subject to specified limitations as set forth below, pursuant to the Commission's authority under the Communications Act. The Commission concludes that adopting a roaming rule tailored for mobile data services will best promote consumer access to seamless mobile data coverage nationwide, appropriately balance the incentives for new entrants and incumbent providers to invest in and deploy advanced networks across the country, and foster competition among multiple providers in the industry, consistent with the National Broadband Plan. Broadband deployment is a key priority for the Commission, and the deployment of commercial mobile data networks will be essential to achieve the goal of making broadband connectivity available everywhere in the United States. As discussed above, the Commission's determination to adopt a commercial mobile data roaming rule is supported by the overwhelming majority of commenters and evidence in the record.

4. Commercial mobile data services provided over advanced mobile broadband technologies have become an increasingly significant part of the lives of American consumers and the shape of the mobile industry. Mobile data services increasingly are used for a variety of both personal and business purposes, including back-up communications during emergencies and for accessibility. Data traffic has risen sharply over the past few years as a result of the increased adoption of smartphones combined with increased data consumption per device. The Commission's data roaming rule will maximize consumers' ability to use and

benefit from wireless broadband data services wherever they are by enhancing the ability of all facilities-based providers, including small and regional providers, to provide nearly nationwide data coverage through roaming arrangements.

5. As data services increasingly become the focus of the mobile wireless services, consumers increasingly expect their providers to offer competitive broadband data services, and the availability of data roaming arrangements can be critical to providers remaining competitive in the mobile services marketplace. The Commission agrees that the availability of roaming capabilities is and will continue to be a critical component to enable consumers to have a competitive choice of facilities-based providers offering nationwide access to commercial mobile data services. As more and more consumers use mobile devices to access a wide array of both personal and business services, they have become more reliant on their devices. These consumers expect to be able to have access to the full range of services available on their devices wherever they go. Providers with local or regional service areas need roaming arrangements to offer nationwide coverage, and there may be areas where building another network may be economically infeasible or unrealistic. Even where providers have invested in and built out broadband networks in a regional service territory, a service provider's inability to offer roaming easily can deter customers from subscribing. For example, Cincinnati Bell represents that "[d]ue to the limited availability of nationwide roaming partners for 3G and 4G services, [it] is seeing a steady defection of its customers to the national carriers even though Cincinnati Bell offers a superior network in its operating area." Availability of such roaming arrangements also may be particularly important for consumers in rural areas—where mobile data services may be solely available from small rural providers. According to BendBroadband, its mobile broadband product is "not commercially viable for most consumers primarily because we cannot offer mobility outside of our service area, due to our inability to secure reasonable rates and terms for data roaming." A data roaming requirement will therefore help to ensure that, as consumers become increasingly reliant on wireless devices, continuity of spectrum-based services is preserved across networks and geographic regions.

6. The Commission also concludes that the data roaming rule that the Commission adopts today will encourage investment in and deployment of broadband networks by multiple service providers, including large nationwide providers, regional providers, and small providers. Given that mobile broadband networks, particularly "fourth-generation" networks, are still at an early stage of development, significant network investment and deployment will also be critical to nationwide broadband access and for the promotion of competitive choice in broadband services. This data roaming rule will promote mobile broadband network deployment, investment, and competition, consistent with the goals of the National Broadband Plan, by helping to ensure the viability of new data network deployments.

7. The Commission is persuaded by the evidence that roaming arrangements help encourage investment by ensuring that providers wanting to invest in their networks can offer subscribers a competitive level of mobile network coverage. Roaming arrangements can help provide greater assurance to service providers that, if they make the investment to expand or upgrade their facilities, they will be able to offer competitive service options to their customers through a combination of local or regional facilities-based service and roaming arrangements. Sprint and T-Mobile state that data roaming arrangements will allow service providers to compete more effectively and thus greater certainty in access to such arrangements will give them "the resources and the confidence to continue to invest in their businesses, including in the construction of new network infrastructure." SouthernLINC explains that "when carriers are considering whether to invest in the deployment of new technologies and services, the availability of data roaming assures the carriers that they will be able to meet customers' expectations of seamless connectivity for these services. This in turn provides carriers with the certainty they need to move forward with these much-needed investments." NTELOS reports that its roaming agreement with Sprint led to its ability to upgrade virtually its entire network to EV-DO Revision A. Clearwire asserts that a data roaming obligation supports long-term facilities-based entry into new markets, and that once providers enter into new markets they will continue to build out networks to contain business costs associated with roaming. Further, as argued by several commenters

representing rural providers—Blooston Rural Carriers, OPASTCO and NTCA, RCA, and RTG—the lack of roaming for commercial mobile wireless services may deter providers from investing in broadband at the exact time such investment is sorely needed. The Chief Financial Officer of regional provider Cellular South, for example, states that "investment banks and other sources of investment capital are likely to make the judgment that a small rural or regional carrier that cannot obtain data roaming agreements with the large national carriers will find it more difficult to attract and retain customers" and that "[s]uch a judgment would lead to the withholding of investment capital which, in turn, would hamstring the carrier's efforts to deploy advanced broadband infrastructure." MetroPCS contends that in order to ensure that smaller, rural and mid-tier carriers invest now in LTE, they need to know that they will have access to LTE roaming once they have upgraded.

8. The availability of roaming arrangements can also provide additional incentives to enter a market by allowing network providers without a presence in an area a competitive level of local coverage during the early period of investment and buildout. The Commission finds that encouraging new entry and local or regional deployments serves the public interest, given that such network deployments, particularly when these deployments are coupled with roaming availability beyond the network service area, would provide consumers with greater competitive choices in mobile broadband. Previously, the Commission found that lack of roaming can constitute a significant hurdle to new competition and can delay or deter entry into a market because a provider seeking to provide service in a new geographic area, without the ability to supplement its networks with roaming and whose initial facilities would necessarily be limited, would be required to compete with incumbents that had been developing and expanding their networks for many years.

9. The record in this proceeding supports these findings. Bright House Networks, for example, contends that a data roaming requirement would remove a barrier to entry and a Senior Vice President of the company states that such a requirement would be key to Bright House investing more. T-Mobile notes that the ability to roam has enabled the company to "build a facilities-based footprint over time as its customer base grows," and asserts that a roaming rule will enable it to "invest in new facilities in smaller markets that

would not be economical to build out unless T-Mobile could use roaming to serve the adjacent more sparsely populated areas,” and thus promote rural investment. In addition, according to US Cellular, new wireless providers entering the wireless marketplace today face far more daunting prospects than did their predecessors of decades ago unless they can offer their customers both voice and data roaming on a seamless nationwide basis. SkyTerra (now LightSquared) states that the absence of a data roaming obligation can discourage service providers from entering the market and building upon existing networks. SkyTerra further states that without a data roaming obligation, its potential customers would likely be discouraged from purchasing terrestrial-based services from SkyTerra, especially in the initial stages of SkyTerra’s network build out.

10. Accordingly, the Commission finds that availability of roaming arrangements helps provide consumers with greater competitive choices in mobile broadband by encouraging investment and network deployments and ensuring that providers wanting to invest in their networks or to enter into a new market can offer subscribers a competitive level of mobile network coverage and service. By removing barriers to customer acquisition by providers in smaller or remote areas, the rule the Commission adopts today will encourage greater use of spectrum and additional sustainable investment in broadband networks serving these areas.

11. The Commission finds the roaming rule that the Commission adopts, discussed in greater detail below, also will provide incentives for host providers to invest and deploy advanced data networks, and avoid potential disincentives for those providers to invest. The Commission agrees with AT&T and Verizon Wireless that there are pro-competitive benefits that flow from providers differentiating themselves on the basis of coverage in their licensed service areas, including in rural and remote areas. The Commission finds that the terms and scope of the roaming rule that the Commission adopts will protect these benefits, maintain incentives for host providers to invest and deploy advanced data networks, and avoid potential disincentives for those providers to invest. First, host providers will be paid for providing data roaming service, and the Commission adopts a general requirement of commercial reasonableness for all roaming terms and conditions, including rates, rather than a more specific prescriptive regulation of rates requested by some

commenters. This will give host providers appropriate discretion in the structure and level of such rates that they offer. As the Commission found in the *Order on Reconsideration*, “the relatively high price of roaming compared to providing facilities-based service will often be sufficient to counterbalance the incentive to ‘piggy back’ on another carrier’s network.” The Commission notes that the pro-investment incentives that providers will have as a consequence of the high cost of roaming are reflected in the terms and conditions offered by mobile data service providers, which commonly include authorizing termination of service or other actions if a subscriber’s roaming on other networks becomes too large a part of the subscriber’s service use. At a minimum, these roaming limitations demonstrate that providers are unlikely to rely on roaming arrangements in place of network deployment as the primary source of their service provision, nor will such arrangements lead to reduced investment by requesting providers.

12. Finally, as discussed more fully below, the Commission provides that, if providers bring disputes to the Commission, the Commission will take into account factors including the impact on buildout incentives and the extent and nature of providers’ existing build-out in determining the commercial reasonableness of proffered terms. As the Commission has concluded before, a case-by-case determination of commercial reasonableness in the event of a dispute preserves incentives to invest and protects consumers by facilitating their access to nationwide service.

13. The data roaming rule the Commission adopts today also adequately addresses AT&T’s argument that a data roaming requirement would weaken host providers’ investment incentives by leaving them with “no control” over the terms under which they will carry roaming traffic and thus unable to manage the additional network congestion caused by such traffic. Under the Commission’s data roaming rule, providers will have the ability to negotiate commercially reasonable measures to safeguard the quality of service against network congestion that may result from roaming traffic or to prevent harm to the network. This rule also includes the ability to offer individualized, commercially reasonable terms, including rates, and to evaluate a number of factors on a case-by-case basis in determining commercial reasonableness. The Commission finds that this approach strikes the best

balance between concerns over the potential for congestion or other harms from roaming traffic and the significant benefits that data roaming arrangements can provide to consumers.

14. The Commission rejects arguments by AT&T and Verizon Wireless that a data roaming rule is unnecessary because data roaming agreements are occurring without regulation. The Commission finds that providers have encountered significant difficulties obtaining data roaming arrangements on advanced “3G” data networks, particularly from the major nationwide providers. For example, Cellular South states that after constructing its own EVDO facilities in some portions of its service area, its requests for data roaming on large carriers’ compatible networks were “rebuffed” for over a year. OPASTCO and NTCA state that “rural wireless carriers’ attempts to enter into negotiations with the nationwide wireless providers for data roaming agreements are many times rejected out of hand, with a citation to the lack of a data roaming requirement in the Commission’s rules” and that “[t]his trend has increased as the mobile wireless industry has begun to transition to 3G wireless services.”

15. The Commission observes that AT&T has largely refused to negotiate domestic 3G roaming arrangements until recently, even though it launched its 3G service in 2005 and was providing coverage to 275 major metropolitan areas in May 2008. For example, RTG has stated that “collectively, its members have not been able to enter into 3G data roaming agreements with AT&T.” In addition, according to RCA, AT&T indicated “recently” that “it will not negotiate any 3G data roaming agreements unless it helps to fill-in its nationwide coverage map.” AT&T itself stated in its Reply Comments filed July 12, 2010 that it had just “begun to offer 3G roaming arrangements * * *.” In mid-November, 2010, it stated that it was “actively negotiating” several domestic 3G agreements but did not indicate that it had entered into any such agreements. On March 24, 2011, AT&T filed an ex parte with the Commission indicating that it had entered into a domestic HSPA+ roaming agreement, with Mosaic Telecommunications—apparently, its first roaming agreement for data service above 2.5G.

16. Commenters also assert difficulties reaching agreements with Verizon Wireless. Cox Communications states that obtaining an initial response to a request to negotiate a roaming agreement with Verizon Wireless

required nearly four months and that negotiations over the terms of Verizon Wireless's requirement for a nondisclosure agreement consumed another four months; and thus, actual negotiations over terms and conditions of a roaming agreement did not even begin for eight months after Cox's initial request. RTG and RCA assert that Verizon Wireless has "told numerous RTG members that it will not enter into EV-DO (3G) roaming agreements in areas where it already has 3G coverage," and therefore is not open to 3G roaming agreements for customers of smaller providers that serve areas where Verizon Wireless has its own network coverage. Although Verizon Wireless indicates that it currently has a number of EV-DO roaming arrangements with other providers (including with several providers that it asserts are members of RCA), it had only nine EV-DO roaming agreements as of April, 2010 even though its EV-DO network has been in operation since October of 2003 and as of June 2007, covered more than 210 million pops with EV-DO Rev. A. The Commission notes again the importance of roaming to consumers in rural areas, where mobile data services may be solely available from small rural providers, and therefore the past difficulties of rural providers in obtaining data roaming presents a serious concern.

17. The Commission is also concerned that the recent successes by some providers in obtaining 3G data roaming agreements or offers may have been the result of large providers seeking to defuse an issue under active Commission consideration and may not accurately reflect the ability of requesting providers to obtain data roaming arrangements in the future if the Commission were to decide not to adopt any data roaming rules. For example, although the Commission determined in 2007 that CMRS providers were not entitled to voice roaming within their own licensed service areas (the "home roaming" exclusion) in part because it contemplated that providers would negotiate home roaming agreements, the Commission concluded in the *Order on Reconsideration* that "the adoption of an automatic roaming obligation with a home roaming exclusion appears to have significantly reduced the incentive to make home roaming available, and will lead to a reduction in the availability of home roaming arrangements over time." Consolidation in the mobile wireless industry has reduced the number of potential roaming partners for some of the

smaller, regional and rural providers. In addition, this consolidation may have simultaneously reduced the incentives of the largest two providers to enter into such arrangements by reducing their need for reciprocal roaming. The Commission also notes that AT&T and Verizon Wireless are only now deploying "fourth-generation" Long Term Evolution networks. Based on the record before it, the Commission finds it likely that these providers will not be willing to offer roaming arrangements that cover these networks any time in the near future, except in very limited circumstances. The Commission agrees with many of the commenters that, given the coverage of these nationwide providers, there is a serious risk they might halt the negotiations of roaming on their advanced mobile data networks altogether in the future in the absence of Commission oversight, harming competition and consumers. Given these developments in the mobile services marketplace, and in light of past difficulties that providers have experienced obtaining data roaming arrangements, the Commission finds that adopting a balanced, flexible requirement will help to promote the availability of data roaming in the future. The Commission notes that the Commission intends to closely monitor further development of the commercial mobile broadband data marketplace and stand ready to take additional action if necessary to help ensure that the Commission's goals in this proceeding are achieved.

18. In sum, the Commission concludes that there are substantial benefits that will be derived from adoption of the data roaming rule set forth herein, and that these benefits substantially outweigh the minimal costs associated with the rule. The Commission reaches this conclusion even though it is not possible to quantify with precision the benefits and costs based on the information the Commission has before it, and even though many of the benefits are not subject to quantification. Adoption of the rule, which is designed to promote access to nationwide mobile broadband service and enhance incentives for providers to invest in deployment of broadband facilities, is necessary to help ensure that the benefits of mobile broadband services will be more fully realized. Absent such a rule, there will be a significant risk that fewer consumers would have nationwide access to competitive mobile broadband services, and that even voice roaming will ultimately be rolled back as voice becomes a data application.

19. The benefits of adopting the proposed data roaming obligation are substantial. The rule promotes the availability of commercially reasonable data roaming arrangements that might not otherwise be available. Consistent with the record comments submitted by providers of all sizes serving a large portion of consumers throughout all parts of this country, millions of American consumers who otherwise might not have full access to mobile broadband services will benefit from adoption of the rule.

20. Furthermore, the Commission finds that the rule will promote significant investment in facilities-based broadband networks throughout the country. As discussed above, several providers state that a data roaming obligation is necessary to provide an acceptable level of risk for the investment in data capabilities for their network, as it increases their chances of being able to offer their subscribers the nationwide coverage needed for a viable product offering. Based on the information in the record, the Commission expects that there could be billions of dollars of additional investment in upgraded facilities and/or expanded coverage, providing consumers with substantial benefits while also creating thousands of jobs.

21. With the added investment and deployment of broadband services by multiple providers, additional benefits will result from increased competition. As discussed above, several commenters have stated that a data roaming obligation is necessary for them to provide competitive services, and enables them to upgrade existing services or build out facilities-based coverage in new markets. The benefits of competition include likely lower prices for such services, which will result in direct consumer surplus as well as greater utilization of broadband data services. In addition, less expensive mobile broadband services increase the availability of these services to consumers, which in turn creates incentives for edge providers to develop innovative new services that use this capability. Although the benefits cannot be calculated with precision, a rough estimate is that the benefits from the increased competition would be in the billions of dollars per year.

22. By comparison with the benefits of adopting a data roaming rule that promotes the availability of data roaming arrangements, the Commission finds that the potential costs of adopting the rule that requires providers to offer data roaming arrangements on

commercial reasonable terms and conditions are small.

23. As discussed above, the two major opponents of a data roaming obligation—Verizon Wireless and AT&T—assert that adoption of such an obligation could discourage investment by providers, particularly in rural areas, which in turn would reduce mobile broadband availability and utilization. The rule adopted in this Order, however, allows host providers to control the terms and conditions of proffered data roaming arrangements, within a general requirement of commercial reasonableness. For the reasons stated above, the Commission concludes that such terms would preserve providers' incentive to invest in their networks. Indeed, neither AT&T nor Verizon state that they would invest less under a roaming obligation and therefore do not expect the roaming rule to reduce the investment of host networks.

24. Another potential cost is the possibility that requesting providers will substitute roaming for investment in coverage and accordingly under-invest in deploying new infrastructure. Again, however, the Commission's rule obligates the host provider only to offer data roaming on commercially reasonable terms and conditions. As discussed above, such a standard will provide the requesting provider with sufficient incentive to invest in facilities, except where doing so would be economically infeasible or unrealistic regardless of the availability of roaming agreements. Further, the Commission provides that the data roaming obligation does not create mandatory resale obligations.

25. An additional potential cost could result from harm to the host provider's network that might result from congestion or technical problems. To enable a host provider to safeguard its quality of service against network congestion, the order expressly provides that host providers are permitted to negotiate commercially reasonable measures to safeguard against network congestion that might result from data roaming traffic. The host provider thus would have the flexibility to account for the additional traffic roaming would generate, and therefore avoid harmful congestion. Similarly, the rule expressly provides that it is reasonable for a provider not to offer a data roaming arrangement to a requesting provider that is not technologically compatible, or where it is not technically feasible to provide roaming for the particular data service for which roaming is requested, or where any changes to the host provider's network required to

accommodate roaming are not economically reasonable.

26. Thus, the Commission concludes that there are substantial benefits that will be derived from adoption of the data roaming rule set forth herein, and that these benefits substantially outweigh the minimal costs associated with the rule.

B. Scope and Requirements of the Data Roaming Rule

27. As discussed above, the Commission concludes that the public interest would be served by adopting a data roaming rule. The Commission will require that facilities-based providers of commercial mobile data services offer data roaming arrangements to other such providers on commercially reasonable terms and conditions, subject to certain limitations specified below. The Commission determines that the data roaming rule the Commission adopts should apply to all facilities-based providers of commercial mobile data services. In establishing this rule, the Commission seeks to balance various competing interests, and the Commission finds that it is appropriate to specify certain grounds on which, under the rule adopted today, providers of commercial mobile data services can reasonably refuse to offer a data roaming arrangement. The Commission also clarifies that under the data roaming rule adopted herein, providers of commercial mobile data roaming services are permitted to negotiate commercially reasonable measures to safeguard quality of service against network congestion that may result from roaming traffic or to prevent harm to their networks. The Commission discusses the rule and limitations and the standard of commercial reasonableness in more detail below.

28. *Covered Entities.* Consistent with the comments addressing the scope of covered entities, the Commission determines that the data roaming requirement should apply to all facilities-based providers of commercial mobile data services. For purposes of data roaming, the Commission defines a "commercial mobile data service" as any mobile data service that is not interconnected with the public switched network but is (1) provided for profit; and (2) available to the public or to such classes of eligible users as to be effectively available to the public. The scope of the current roaming obligation in Section 20.12 covers the CMRS providers' provision of mobile voice and data services that are interconnected with the public switched network, as well as their provision of text messaging and push-to-talk services. The rule

adopted herein will complement the current roaming obligation in Section 20.12 and cover mobile services that fall outside the scope of that obligation. Under the Commission's decision today, as long as a provider provides mobile data services that are for profit and available to the public or to such classes of eligible users as to be effectively available to the public, it will be covered by the rule adopted herein regardless of whether the provider also provides any CMRS and without regard to the mobile technology it is utilizing to provide services. Thus, the scope includes MSS/ATC providers that offer commercial mobile data services that meet these requirements. In addition, the data roaming rule adopted herein covers all facilities-based providers of commercial mobile data services, including those constructing network facilities to offer service on a wholesale basis. Further, providers of commercial mobile data services are covered without regard to the devices used to access or receive their services. This approach is supported by those parties in the record that commented on this issue, will help to achieve technological neutrality in the data roaming obligation, and will ensure that the rule the Commission adopts is adequate in the face of rapid changes in commercial mobile technology and the commercial mobile ecosystem overall.

29. *Application of the Commercial Mobile Data Roaming Rule.* The rule the Commission adopts today requires all facilities-based providers of commercial mobile data services to offer data roaming arrangements to other such providers on commercially reasonable terms and conditions. As noted above, the Commission concludes that this rule serves the public interest by promoting connectivity for and nationwide access to mobile data services and by promoting investment in and deployment of mobile broadband networks, among other benefits. When a request for data roaming negotiations is made, as a part of the duty of providers to offer data roaming arrangements on commercially reasonable terms and conditions, a would-be host provider has a duty to respond promptly to the request and avoid actions that unduly delay or stonewall the course of negotiations regarding that request. The Commission will determine whether the terms and conditions of a proffered data roaming arrangement are commercially reasonable on a case-by-case basis, taking into consideration the totality of the circumstances.

30. The duty to offer data roaming arrangements on commercially reasonable terms and conditions is

subject to certain limitations. In particular: (1) Providers may negotiate the terms of their roaming arrangements on an individualized basis; (2) it is reasonable for a provider not to offer a data roaming arrangement to a requesting provider that is not technologically compatible; (3) it is reasonable for a provider not to offer a data roaming arrangement where it is not technically feasible to provide roaming for the particular data service for which roaming is requested and any changes to the host provider's network necessary to accommodate roaming for such data service are not economically reasonable; and (4) it is reasonable for a provider to condition the effectiveness of a data roaming arrangement on the requesting provider's provision of mobile data service to its own subscribers using a generation of wireless technology comparable to the technology on which the requesting provider seeks to roam.

31. The Commission concludes that it serves the public interest to include these limitations in recognition of the particular technical and policy issues that arise with respect to the provision of data services. As discussed above, the Commission recognizes that the commercial mobile broadband data marketplace, particularly 4G deployment, is still in a critical early stage. It encompasses many different services offered in conjunction with many different devices employing wide-ranging technologies and exacting varying network demands. In light of that continuing evolution, the Commission finds that the scope the Commission establishes for the roaming rule is sufficiently flexible to apply to a wide range of ever changing technologies and commercial contexts, and should afford parties negotiating commercial mobile data services roaming agreements a solid framework within which to arrange their negotiations and ultimately reach agreement on commercially reasonable terms. Below, the Commission further discusses and clarifies each of these limitations in turn.

32. First, providers may negotiate the terms of their roaming arrangements on an individualized basis. In other words, providers may offer data roaming arrangements on commercially reasonable terms and conditions tailored to individualized circumstances without having to hold themselves out to serve all comers indiscriminately on the same or standardized terms. Conduct that unreasonably restrains trade, however, is not commercially reasonable. As discussed below, the Commission may consider a range of

individualized factors in addressing disputes over the commercial reasonableness of the terms and conditions of the proffered data roaming arrangements. Giving providers flexibility to negotiate the terms of their roaming arrangements on an individualized basis ensures that the data roaming rule best serves the Commission's public interest goals discussed herein, and the boundaries of the rule are narrowly tailored to execute the Commission's spectrum management duties under the Act.

33. Second, it is commercially reasonable for providers not to offer a data roaming arrangement to a requesting provider that is not technologically compatible. The Commission clarifies, however, that technological compatibility does not necessarily require the same air interface in the network infrastructure of the two providers. Technological compatibility can be achieved by using mobile equipment that can communicate with the host provider's network. For example, requesting providers that operate on different bands or technologies than the host might achieve technological compatibility by providing subscribers with multi-band and multi-mode user devices.

34. Even if providers are technologically compatible, however, roaming for a particular service may not be feasible for other technical reasons. Accordingly, it is also commercially reasonable for a provider to refuse to enter into a data roaming arrangement for a particular data service where it is not technically feasible to provide roaming for such service and where any changes to its network that are necessary to accommodate such data roaming are economically unreasonable. With regard to these grounds for reasonably refusing to enter into a roaming arrangement, the Commission disagrees with commenters that they are too vague or would be too open to interpretation by providers seeking to delay or deny roaming access. As noted above, identical conditions already apply to requests for push-to-talk and text-messaging roaming arrangements. Further, the Commission finds that these grounds will offer parties negotiating roaming agreements reasonable flexibility to negotiate terms without, for example, unduly hampering a host provider with the burden of either adopting technologies which it has not already adopted in order to accommodate the requesting provider's technology or undertaking economically unreasonable changes to its network.

35. Finally, the Commission provides that it is commercially reasonable for a provider to condition the effectiveness of a roaming arrangement on the requesting provider's provision of mobile data service using a generation of wireless technology comparable to the technology on which the requesting provider seeks to roam. The Commission notes that as with technological compatibility, this does not mean that the requesting provider must have exactly the same air interface as the host provider. Rather, this focuses on capabilities, including data rates, of the generation of mobile wireless technology that is being used to provide services to subscribers. Permitting a service provider to condition the effectiveness of a roaming arrangement in this circumstance provides additional incentives for the requesting provider to invest in and upgrade its network to offer advanced services to its subscribers and ensures that the requesting provider is not merely reselling the host provider's services. This limitation prevents providers, for example, from only building a 2G network, providing their customers with 3G capable handsets, and then relying on roaming arrangements to provide nationwide 3G coverage, and thus reasonably addresses concerns raised by AT&T. To prevent undue delay in negotiations, the Commission clarifies that a host provider may not decline to enter into a roaming agreement with a requesting provider on the grounds that the requesting provider is not actually providing service at the time of the request for negotiations, but may tie the effectiveness of the agreement to the requesting provider offering the underlying service to its subscribers with a generation of wireless technology comparable to the technology on which it would roam. The Commission finds that incorporating this limitation as part of the scope of the data roaming rule is in the public interest and critical to ensuring facilities are deployed, helping to alleviate concerns about providers merely reselling commercial mobile data services on other networks. While the Commission agrees that providers have many different legitimate business and technological reasons for rolling out services in certain markets and not in others, the Commission finds that requiring, at a minimum, the underlying service to be offered by the requesting provider with a generation of wireless technology comparable to the technology on which it seeks to roam best balances competing interests of affording data roaming while also encouraging facilities-based service.

36. This limitation is also consistent with the Commission's previous roaming decisions where the Commission has consistently limited roaming obligations to provisioning of certain services on technologically compatible networks. The limitation on covered services coupled with the technologically compatible networks requirement was sufficient to ensure that the generations of wireless technologies used were comparable. The commercial mobile data services marketplace, however, encompasses a broad array of generations of wireless technology and many different applications—many of which may require different technical considerations and offer different data speeds. Some of these also may be more competitively attractive than others. The Commission seeks to encourage facilities-based offerings of advanced mobile data services by providers and usage of data roaming arrangements to supplement such offerings. Accordingly, it serves the public interest to focus on capabilities, including data rates, of the generation of mobile wireless technology that is being used to provide services to subscribers.

37. The Commission declines to adopt certain other requirements proposed by AT&T, which suggests that, in order to preserve the proper incentives for investment, the Commission establish an "equal network" rule that would limit data roaming to only providers that use the same radio technologies and air interfaces and that have substantial networks of their own. For the reasons discussed above, the Commission concludes, contrary to AT&T's argument, that providers will not have heightened incentives under the rule adopted here to scale back their own deployments and "free-ride" on the superior investments of others.

38. The Commission finds it is unnecessary to adopt a requirement of identical interfaces. The Commission requires that the air interfaces be comparable in terms of capabilities, which should achieve the same benefits as a requirement of identical interfaces while providing greater technological flexibility in the rule. Further, the Commission agrees with Leap and RCA that adopting a "substantial network" requirement could be problematic. An inability to negotiate a roaming arrangement before making a substantial build out could deter new entrants and small, rural, and mid-sized providers from investing in broadband at the exact time such investment is sorely needed. The Commission are concerned that a "substantial network" requirement could hamper or dampen facilities-based

build-out in rural areas by unduly limiting the role of roaming in network buildout. The Commission also disagrees with AT&T that, absent this requirement, providers will have heightened incentives to scale back their own deployments and "free-ride" on the superior investments of others. As discussed above, the relatively high price of roaming compared to providing facilities-based service will often be sufficient to counterbalance the incentive to scale back deployments in favor of relying on another provider's network. Further, although the Commission does not find that lack of "substantial" networks deployments is categorically a commercially reasonable ground for declining to enter into a roaming arrangement, the Commission may consider the extent and nature of providers' build-out as one of the relevant factors in determining whether the proposed terms and conditions of a particular data roaming arrangement are commercially reasonable.

39. *Reasonable safeguards against congestion.* With respect to any issues concerning network capacity, network integrity, or network security, the Commission notes that under the rule that the Commission is adopting providers of commercial mobile data services are free to negotiate commercially reasonable measures to safeguard quality of service against network congestion that may result from roaming traffic or to prevent harm to their networks. The Commission expects any measures, methods, or practices to manage the roaming traffic to be part of the roaming terms and conditions offered by the host providers in their roaming arrangements given that once providers enter into a data roaming arrangement, the arrangement will govern the terms under which roaming is provided. Any issues arising in connection with the negotiation of these measures will be resolved in accordance with the dispute resolution procedures the Commission adopts in this Order. The Commission notes that reasonable measures to safeguard against network congestion from roaming traffic are supported by a number of commenters, and are already a feature of many commercially negotiated roaming arrangements. The Commission cautions, however, that host providers may not engage in stonewalling behavior or refuse to negotiate because of concerns over the impact of roaming traffic on network congestion.

40. The Commission declines to further detail the specific measures that may be adopted to safeguard subscriber quality of service, as proposed by AT&T.

As discussed herein, the commercial mobile data services marketplace encompasses an array of generations of wireless technology and many different services—many of which may require different technical considerations in resolving network congestion. Providers should have significant flexibility to negotiate safeguards subject to commercial reasonableness, and a dispute over the reasonableness of any particular measure can be addressed under the dispute resolution procedures, on a case-by-case basis based on the totality of circumstances. The Commission does not agree with AT&T that its approach will lead to "constant second-guessing" by the Commission.

41. The Commission also declines to specify, as suggested by Clearwire, that data roaming be limited to "best efforts access" to the host provider's network. The Commission does not see the benefit in prohibiting parties from negotiating other access terms in their roaming arrangement.

42. Host providers of commercial mobile data roaming services also are authorized to negotiate commercially reasonable measures to ensure that data roaming does not compromise the security and integrity of their networks. The Commission is aware of the risks network operators face from harmful devices on their networks and note that the Commission has previously considered the need for providers to protect their networks when it adopted open platform provisions for the 700 MHz Band C Block. It would also be appropriate for providers of commercial mobile data roaming service to take reasonable measures to ensure that network performance will not be significantly degraded.

43. We emphasize again that we intend to closely monitor further development of the commercial mobile broadband data marketplace and stand ready to take additional action if necessary to help ensure that our goals in this proceeding are achieved.

C. Legal Authority

44. The Commission finds that the Commission has the authority to require facilities-based providers of commercial mobile data services to offer data roaming arrangements to other such providers on commercially reasonable terms and conditions. As discussed above, the Commission finds that the rule the Commission adopts today serves the public interest by promoting connectivity for, and nationwide access to, mobile broadband. By promoting consumer access to advanced wireless services, the data roaming rule will

enhance the unique social and economic benefits that a mobile service provides. The data roaming rule will also serve the public interest by promoting competition and investment in and deployment of mobile broadband services. Broadband deployment is a key priority for the Commission, and the deployment of mobile data networks will be essential to achieve the goal of making broadband connectivity available everywhere in the United States. As noted earlier, mobile broadband networks, particularly “fourth-generation” networks, are still at an early stage of deployment. Both nationwide and non-nationwide providers have obtained licenses, including AWS and 700 MHz spectrum licenses, which will be used to provide innovative wireless data services to consumers. The Commission finds that the availability of data roaming will help ensure the viability of new data network deployments and promote the development of competitive service offerings for the benefit of consumers.

45. The Commission’s authority under Title III allows it to adopt requirements to serve these public interest objectives. Spectrum is a public resource, and Title III of the Act provides the Commission with broad authority to manage spectrum, including allocating and assigning radio spectrum for spectrum based services and modifying spectrum usage conditions in the public interest. The Commission is charged with maintaining control “over all the channels of radio transmission” in the United States. Section 301 states that “[i]t is the purpose of this Act, among other things, to maintain the control of the United States over all the channels of radio transmission; and to provide for the use of such channels, but not the ownership thereof, by persons for limited periods of time, under licenses granted by Federal authority, and no such license shall be construed to create any right, beyond the terms, conditions, and periods of the license.” The issuance of a Commission license does not convey any ownership or property interests in the spectrum and does not provide the licensee with any rights that can override the Commission’s proper exercise of its regulatory power over the spectrum. Section 316 authorizes the Commission to adopt new conditions on existing licenses if it determines that such action “will promote the public interest, convenience, and necessity.” Further, the Commission may utilize its rulemaking powers to modify licenses when a new policy is based upon the general characteristics of an industry. Section 303 provides the Commission

with authority to establish operational obligations for licensees that further the goals and requirements of the Act if the obligations are in the “public convenience, interest, or necessity” and not inconsistent with other provisions of law. Section 303 also authorizes the Commission, subject to what the “public interest, convenience, or necessity requires,” to “[p]rescribe the nature of the service to be rendered by each class of licensed stations and each station within any class.”

46. The Commission finds that these provisions establish its authority to adopt rules facilitating roaming with respect to commercial mobile data services. Specifically, the Commission finds that it is within its authority to manage spectrum and to impose conditions on licensees where necessary to promote the public interest, convenience, and necessity to adopt data roaming rules. As discussed above, the Commission finds that the data roaming rule the Commission adopts today serves the public interest by facilitating consumer access to ubiquitous mobile broadband service. As more and more consumers use mobile devices to access a wide array of both personal and business services, they have become more reliant on their devices. These consumers expect to be able to have access to the full range of services available on their devices wherever they go. By promoting connectivity for, and ubiquitous access to, mobile broadband, the rule the Commission adopts today supports consumer expectations and helps ensure that consumers are able to fully utilize and benefit from the availability of wireless broadband data services.

47. As discussed earlier, the data roaming rule the Commission adopts today also supports the Commission’s goal of encouraging investment and innovation and the efficient use of spectrum. The Commission agrees with commenters that adopting a data roaming rule will encourage service providers to invest in and upgrade their networks to be able to compete with other providers and control their costs. By encouraging build-out and deployment of advanced data services, the rule the Commission adopts today helps ensure that spectrum is being put to its best and most efficient use. Data roaming also furthers the goals under Section 706(a) and (b) of the Telecommunications Act of 1996, including encouraging new deployment of advanced services to all Americans by promoting competition and by removing barriers to infrastructure investment, including the barriers to new entrants. The Commission

estimated that more than 10 million Americans live in rural census blocks with two or fewer mobile service providers. Data roaming will encourage service providers to invest in and upgrade their networks and to deploy advanced mobile services ubiquitously, including in rural areas.

48. The Commission disagrees with AT&T and Verizon Wireless’s argument that the Commission lacks authority to impose data roaming rules because data roaming is a private mobile radio service, as defined in section 332 of the Act and thus any common carrier regulation of data roaming is prohibited under the terms of the statute. Section 332(c)(2) provides that “a person engaged in the provision of a service that is a private mobile service shall not * * * be treated as a common carrier for any purpose * * *.” AT&T and Verizon Wireless argue that Section 332(c)(2) prohibits the Commission from imposing any roaming obligation for provisioning of commercial mobile data services that do not interconnect with the public switched networks because non-interconnected commercial mobile data services are not CMRS but private mobile radio service (PMRS). AT&T argues that roaming obligations clearly amount to common carrier obligations and that, under the Supreme Court’s decision in *FCC v. Midwest Video Corporation (Midwest Video II)*, such regulations are prohibited. In *Midwest Video II*, the Supreme Court found that obligations requiring cable television systems to allocate channels for educational, government, public, and leased access users had “relegated cable systems, *pro tanto*, to common-carrier status.” The Court noted that the rules required operators to make these channels available on a first-come non-discriminatory basis, prohibited cable operators from influencing the content of access programming, and also put limits on charges for access. The Court found that this “common carrier status” violated the Act’s prohibition against deeming broadcasters to be common carriers, because at the time, cable regulations rested on the FCC’s authority to regulate broadcasting. AT&T argues that requiring carriers to offer data roaming “on reasonable request, on reasonable terms and rates, and free from unreasonable discrimination” would similarly treat such providers as common carriers in violation of the prohibition against common carrier treatment in the definition of “private mobile service.”

49. Contrary to the arguments of AT&T and Verizon Wireless, to adopt a data roaming rule as discussed herein, the Commission does not need to

determine that a mobile service should be classified as CMRS. Section 332 does not bar the Commission from establishing spectrum usage conditions based upon its Title III authority. As discussed above, Title III generally provides the Commission with authority to regulate “radio communications” and “transmission of energy by radio.”

Among other provisions, Title III gives the Commission the authority to classify radio stations. It also establishes the basic licensing scheme for radio stations, allowing the Commission to grant, revoke, or modify licenses. The Commission has imposed operating conditions on licensees regardless of the type of service they provide.

50. In this Order, the Commission imposes an obligation with limitations on facilities-based providers of commercial mobile data services to offer data roaming arrangements to other facilities-based providers of commercial mobile data services on an individualized case-by-case basis, subject to a standard of commercial reasonableness as well as certain specified limitations set forth herein. Imposing such a requirement is consistent with the Commission’s authority to impose certain operating conditions on any spectrum authorization holders, including private mobile radio licensees, if it serves the public interest. The data roaming rule will complement the current roaming rules applicable to interconnected services, improve efficiency of spectrum use, encourage competition and increase sharing opportunities between private mobile services and other services. In particular, the Commission finds that the rule the Commission adopts today is consistent with the requirements of sections 332(a)(2)–(4) of the Act. Sections 332(a)(2)–(4) provide that, in managing the spectrum made available for use by private mobile services, the Commission shall consider whether its actions will: improve the efficiency of spectrum use and reduce the regulatory burden upon spectrum users, based upon sound engineering principles, user operational requirements, and marketplace demands; encourage competition and provide services to the largest feasible number of users; or increase interservice sharing opportunities between private mobile services and other services. The Commission finds that, by promoting competition, investment, and new entry while facilitating consumer access to ubiquitous mobile broadband service, the rule the Commission adopts today will serve these objectives.

51. The Commission also finds that the data roaming rules we adopt do not

amount to treating mobile data service providers as “common carriers” under the Act. As AT&T and Verizon Wireless recognize, a “*sine qua non*” of common carrier treatment is “the undertaking to carry for all people indifferently. The extent of the obligation the Commission imposes today is to offer, in certain circumstances, individually negotiated data roaming arrangements with commercially reasonable terms and conditions. The rule the Commission adopts will allow individualized service agreements and will not require providers to serve all comers indifferently on the same terms and conditions. Providers can negotiate different terms and conditions on an individualized basis, including prices, with different parties. The commercial reasonableness of terms offered to a particular provider may depend on numerous individualized factors, including the level of competitive harm in a given market and the benefits to consumers; the extent and nature of the requesting provider’s build-out; whether the requesting provider is seeking roaming for an area where it is already providing facilities-based service; and the impact of granting the request on the incentives for either provider to invest in facilities and coverage, services, and service quality. In addition, providers may reasonably choose not to offer a roaming arrangement to a requesting provider that is not technologically compatible or refuse to enter into a roaming arrangement where it is not technically feasible to provide roaming for the service for which it is requested. A provider is not required to make changes to its network that are economically unreasonable, and it is reasonable for a provider to condition the effectiveness of a roaming arrangement on the requesting provider’s provision of mobile data service to its own subscribers using a generation of wireless technology comparable to the technology on which the requesting provider seeks to roam. Providers of commercial mobile data services also are free to negotiate commercially reasonable measures to safeguard quality of service against network congestion that may result from roaming traffic or to prevent harm to their networks. In addition, the rule the Commission adopts does not impose any form of common carriage rate regulation or obligation on providers of mobile data services to publicly disclose the rates, terms, and conditions of their roaming agreements. Under the agreements to which negotiations may lead, providers will have flexibility with regard to roaming charges, subject to a

general requirement of commercial reasonableness. Further, actual provisioning of data roaming under those arrangements and any practices in connection with such arrangements will be subject to individually negotiated contractual provisions, unlike a common carrier obligation under Sections 201 and 202 of the Act which covers all charges and practices in connection with such services. In view of these boundaries, the Commission finds that the rule the Commission adopts today to execute its spectrum management duties under the Act does not subject a spectrum-based commercial mobile data service provider to Title II nor does it treat these providers as common carriers with respect to their regulatory status and obligations.

52. *Imposition of the Data Roaming Rule under Title III does not amount to Regulatory Taking.* Verizon Wireless argues that imposing data roaming obligations amounts to a physical and regulatory taking. Verizon Wireless claims that data roaming is a physical taking of wireless carriers’ property rights in their network infrastructure by authorizing third parties to occupy the physical space available on carrier networks at will. Verizon Wireless also claims that data roaming would constitute a regulatory taking because it would interfere with licensees’ reasonable expectations not to have common carrier regulations imposed on information services. The Commission disagrees. Under Section 304 of the Communications Act, the issuance of an FCC license does not provide the licensee with any rights that can override the Commission’s proper exercise of its regulatory power over the spectrum: “[n]o station license shall be granted by the Commission until the applicant therefore shall have waived any claim to the use of any particular frequency or of the electromagnetic spectrum as against the regulatory power of the United States because of the previous use of the same, whether by license or otherwise.” Further, under the data roaming rule, the host provider will be compensated for service it provides consistent with the commercially reasonable terms it negotiates in the roaming agreement. There can be no taking if that compensation is “just.” It does not appear to be possible that compensation could be “unjust” if it is commercially reasonable. Commercially reasonable terms may also include measures that allow the host provider to safeguard the quality of service and allow measures to

prevent harm to the host provider's network.

53. *Commission's Title II Authority.* Several commenters argue that data roaming is a telecommunications service under Title II. MetroPCS, for example, asserts that the transmission service provided by a third-party wireless roaming carrier (the Roaming Partner) to facilitate data roaming is only telecommunications and that the transmission provided by the Roaming Partner is functionally equivalent to the telecommunications services provided for voice roaming. MetroPCS asserts that "the separate, severable, non-integrated transmission service provided by a third-party wireless Roaming Partner is properly viewed as purely a transmission service that qualifies under long-standing Commission precedent as 'telecommunications' and as a 'telecommunications service.'" Leap argues that the Commission can act pursuant to its Title II authority, stating that "the Commission could define data roaming as a telecommunications service because during data roaming, the host carrier is providing pure data transmission to another carrier." The Commission finds that the Commission need not decide whether data roaming services provisioned in this manner are or are not telecommunications services. In any case, the Commission imposes the data roaming rule described herein based on its authority under Title III.

D. Dispute Resolution

54. To the extent that a complaint proceeding is an appropriate procedural vehicle to resolve a particular dispute arising out of the negotiation of a data roaming arrangement, the Commission finds that it is in the public interest to establish a complaint process similar to the complaint process available under the current roaming obligations. Specifically, to ensure consistent Commission processes for resolving all voice and data roaming disputes where a complaint is the appropriate procedural vehicle, the Commission will use the procedural complaint processes established in the Commission's Part 1, Subpart E rules for data roaming to the extent discussed herein. Disputes will be resolved based on the totality of the circumstances. The remedy of damages will not be available for data roaming complaints.

55. Parties may file a formal or informal complaint under the Commission's Part I, Subpart E rules or file a petition for declaratory ruling under Section 1.2 of the Commission's rules to resolve any disputes arising out of the data roaming rule adopted herein. These procedural mechanisms are

currently available for resolving voice roaming disputes, and the Commission finds that it is in the public interest to ensure a consistent Commission process for resolving both voice and data roaming complaints. Moreover, some roaming disputes will involve both data and voice and are likely to have factual issues common to both types of roaming. The approach the Commission is taking allows, but does not require, a party to bring a single proceeding to address such a dispute, rather than having to bifurcate the matter and initiate two separate proceedings under two different sets of procedures. This, in turn, will be more efficient for the parties involved, as well as for the Commission, and should result in faster resolution of such disputes.

56. With respect to remedies, the Commission excludes provisions applicable to damages in this context. The Commission notes that the remedy of damages after hearing on a complaint is specifically provided for in Section 209 of the Communications Act and applicable to claims arising out of Section 208 complaints. This means that if a complaint alleges violations with respect to both voice and data roaming, damages potentially are available as a remedy for only the portion of the complaint that deals with roaming obligations arising out of Sections 201, 202, and 208 of the Act.

57. When roaming-related complaints or petitions for declaratory ruling are filed, the Commission intends to address them expeditiously. Further, the Commission notes that the Accelerated Docket procedures, including pre-complaint mediation, will be available to data roaming complaints. Several commenters requested use of the Commission's Accelerated Docket procedures to resolve all roaming complaints. Although all roaming complaints will not automatically be placed on the Accelerated Docket, an affected provider can seek consideration of its complaint under the Commission's Accelerated Docket rules and procedures where appropriate.

58. The Commission notes that the duty to offer data roaming arrangements on commercially reasonable terms and conditions will allow greater flexibility and variation in terms and conditions, as parties will negotiate their rights and obligations under the agreements. The Commission expects providers to include any material practices regarding provisioning of roaming in the agreement (e.g., any practice to manage roaming traffic in times of congestion) because many disputes arising out of provisioning of roaming will be subject to the roaming contract provisions and

generally applicable laws. To provide parties with additional certainty regarding rights and obligations and to facilitate timely resolution of disputes, the Commission provides the following clarifications and guidance.

59. During ongoing negotiations, parties can seek Commission dispute resolution—including a determination whether the host provider has met its duty. The Commission will consider claims regarding the commercial reasonableness of the negotiations, providers' conduct, and the terms and conditions of the proffered data roaming arrangement. With respect to claims regarding the commercial reasonableness of the proffered terms and conditions, including prices, the Commission staff may, in resolving such claims, require both parties to provide to the Commission their best and final offers (final offers) that were presented during the negotiation. For example, if negotiations fail to produce a mutually acceptable set of terms and conditions, including rates, the Commission staff may require parties to submit on a confidential basis their final offers, including price, in the form of a proposed data roaming contract. These submissions would enable Commission staff, if it so chose, to resolve a particular roaming dispute in which a violation of Commission rules is found by ordering the parties to enter into a data roaming agreement pursuant to the terms of the complainant's commercially reasonable final offer or to otherwise rely on the submitted offers in determining an appropriate remedy. In cases where no violation of Commission rules is found, the complainant would be free, but not obligated, to enter into a roaming agreement on the proffered terms of the would-be host. The Commission staff also could order the parties to resume negotiations. The Commission staff's determination of the appropriate steps in resolving a particular dispute would depend in part of an assessment of the actions of both the host provider and the requesting provider.

60. With respect to disputes filed before reaching an agreement regarding the commercial reasonableness of a would-be host provider's proffered terms and conditions, the Commission finds that it is in the public interest to provide a possible avenue for the requesting provider to obtain data roaming service on an interim basis during the pendency of the dispute. Accordingly, in a case where a requesting provider disputes the commercial reasonableness of a roaming arrangement offered by a would-be host and none of the limitations is

applicable, the Commission staff may, if requested and in appropriate circumstances, order the host provider to provide data roaming on its proffered terms, during the pendency of the dispute, subject to possible true-up once the roaming agreement is in place. Similarly, if the Commission staff chooses to require submission of final offers as discussed above, in appropriate circumstances the Commission staff could order the host provider to provide data roaming in accordance with its final offer, subject to possible true-up. The ability to obtain data roaming service on an interim basis during the pendency of the dispute would enable the requesting provider's subscribers to obtain data roaming coverage without undue delay while the Commission staff considers the dispute. Alternatively, the parties may agree prior to the filing of the dispute to an interim roaming arrangement that will govern during the pendency of the dispute. Further, in the event a would-be host provider violates its duty by actions that unduly delay or stonewall the course of negotiations, the Commission stands ready to move expeditiously with fines, forfeitures, and other appropriate remedies, which should reduce any incentives to delay data roaming negotiations.

61. After the parties have entered into a data roaming agreement, the terms of the agreement generally will govern the data roaming rights and obligations of the parties, and disputes relating to performance, validity, or interpretation of the agreement will be subject to review in court under the relevant contract law, with certain exceptions. For instance, parties may bring before the Commission a claim that a host provider's conduct during negotiations violated the federal duty to offer a data roaming arrangement with commercially reasonable terms and conditions. In addition, the requesting provider may show that a host provider engaged in undue delay, or negotiated without any intent to perform. Further, the Commission provides that a requesting provider could file a complaint or petition for declaratory ruling regarding the commercial reasonableness of the agreed terms and conditions to the extent such claims are based on new information that the requesting provider reasonably did not know prior to signing the agreement. Because the standard of commercial reasonableness is one that we expect to accommodate a variety of terms and conditions in data roaming, and to discourage frivolous claims regarding the reasonableness of the terms and conditions in a signed agreement, the

Commission will presume in such cases that the terms of a signed agreement meet the reasonableness standard and will require a party challenging the reasonableness of any term in the agreement to rebut that presumption.

62. The Commission further clarifies that the Enforcement Bureau has delegated authority to resolve complaints arising out of the data roaming rule. The Commission notes that the Wireless Telecommunications Bureau has delegated authority to resolve other disputes with respect to the data roaming rule adopted herein. The Commission also notes that whether or not the appropriate procedural vehicle is a complaint under Section 20.12(e) or a petition for declaratory ruling under Section 1.2 may vary depending on the circumstances of each case. If a dispute arises regarding data roaming, parties are encouraged to contact Commission staff for procedural guidance and for negotiations using the Commission's informal dispute resolution processes.

63. Some commenters propose other measures for resolving data roaming disputes or roaming disputes in general, such as mandatory mediation or arbitration. Although the Commission is not adopting any such mandatory processes, the Commission notes that providers are free to negotiate and mutually agree to other processes, such as third party mediation or arbitration, as a means to resolve the roaming dispute.

64. A few commenters propose that the Commission adopts a time limit for roaming negotiations to limit the opportunity for host carriers to delay in negotiating roaming agreements. The Commission declines to adopt a specific time limit because some data roaming negotiations may be more complex or fact-intensive than others and are likely to require more time. A single time limit for all negotiations would not be appropriate in such cases. As part of the requirement to offer a data roaming arrangement, the Commission expects parties to proceed with such negotiations in a timely manner and to avoid stonewalling behavior or undue delays. If a provider involved in a data roaming negotiation believes that another provider is delaying the negotiation unduly, it may ask the Commission to set a time limit for that particular negotiation. The Commission will consider such requests on a case-by-case basis.

65. *Determination of Commercial Reasonableness.* The Commission will assess whether a particular data roaming offering includes commercially reasonable terms and conditions or

whether a provider's conduct during negotiations, including its refusal to offer data roaming, is commercially reasonable, on a case-by-case basis, taking into consideration the totality of the circumstances. As discussed above, providers can negotiate different terms and conditions, including prices, with different parties, where differences in terms and conditions reasonably reflect actual differences in particular cases. Further, providers of commercial mobile data services can negotiate commercially reasonable measures to safeguard quality of service against network congestion that may result from data roaming traffic or to prevent harm to their networks. Conduct that unreasonably restrains trade, however, is not commercially reasonable.

66. In the interconnected services context, the Commission listed factors it will take into account in resolving roaming disputes that are brought before it. Some parties have asked the Commission to use these factors, or others, in resolving disputes that arise with respect to data roaming. These factors relate to public interest benefits and costs of a data roaming arrangement offered in a particular case, including the impact on investment, competition, and consumer welfare and whether a particular data roaming offering is commercially reasonable. The Commission finds it is therefore appropriate to take them into account, as listed below, and to the extent relevant in the data roaming context. The Commission emphasizes that each case will be decided based on the totality of the circumstances. With that in mind, the Commission clarifies that, to guide it in determining the reasonableness of the negotiations, providers' conduct, and the terms and conditions of the proffered data roaming arrangements, including the prices, the Commission may consider the following factors, as well as others:

- Whether the host provider has responded to the request for negotiation, whether it has engaged in a persistent pattern of stonewalling behavior, and the length of time since the initial request;
- Whether the terms and conditions offered by the host provider are so unreasonable as to be tantamount to a refusal to offer a data roaming arrangement;
- Whether the parties have any roaming arrangements with each other, including roaming for interconnected services such as voice, and the terms of such arrangements;
- Whether the providers involved have had previous data roaming arrangements with similar terms;

- The level of competitive harm in a given market and the benefits to consumers;
- The extent and nature of providers' build-out;
- Significant economic factors, such as whether building another network in the geographic area may be economically infeasible or unrealistic, and the impact of any "head-start" advantages;
- Whether the requesting provider is seeking data roaming for an area where it is already providing facilities-based service;
- The impact of the terms and conditions on the incentives for either provider to invest in facilities and coverage, services, and service quality;
- Whether there are other options for securing a data roaming arrangement in the areas subject to negotiations and whether alternative data roaming partners are available;
- Events or circumstances beyond either provider's control that impact either the provision of data roaming or the need for data roaming in the proposed area(s) of coverage;
- The propagation characteristics of the spectrum licensed to the providers;
- Whether a host provider's decision not to offer a data roaming arrangement is reasonably based on the fact that the providers are not technologically compatible;
- Whether a host provider's decision not to enter into a roaming arrangement is reasonably based on the fact that roaming is not technically feasible for the service for which it is requested;
- Whether a host provider's decision not to enter into a roaming arrangement is reasonably based on the fact that changes to the host network necessary to accommodate the request are not economically reasonable;
- Whether a host provider's decision not to make a roaming arrangement effective was reasonably based on the fact that the requesting provider's provision of mobile data service to its own subscribers has not been done with a generation of wireless technology comparable to the technology on which the requesting provider seeks to roam;
- Other special or extenuating circumstances.

67. The Commission emphasizes that these factors are not exclusive or exhaustive and that providers may argue that the Commission should consider other relevant factors in determining the commercial reasonableness of the negotiations, providers' conduct, and the terms and conditions of the proffered data roaming arrangements, including the prices. In addition, in making this determination the

Commission also will consider all relevant precedents and decisions by the Commission.

E. Other Issues

68. *Advertising.* In the *Second Further Notice*, the Commission sought comment on whether it should "clarify that a carrier that obtains automatic roaming from another carrier does not have a right to advertise that it offers its subscribers roaming on a particular host carrier's network absent a voluntary agreement of the host carrier" and whether such measure would help to "prevent free riding on the value of the host carrier's brand name recognition and service quality reputation." The Commission now clarifies that it does not intend the rule it adopts today to be construed as permitting a provider that obtains roaming from another provider to use the trade name of a host provider when it advertises extended coverage due to roaming, unless the parties to the roaming agreement agree otherwise. Although Cellular South argues any such restrictions are not necessary or appropriate, the Commission agrees with AT&T that providers can make significant capital and marketing investments with respect to differentiating the quality and brand image of their networks from competitors. Also, the Commission is concerned that construing the rule the Commission adopts as allowing a roaming provider to engage in unauthorized use of a competitor's brand name recognition and/or service quality reputation as a means of differentiating the roaming provider's own service may indeed encourage the use of roaming as *de facto* resale. The Commission has previously stated with regard to automatic roaming for voice and data services for CMRS providers that "automatic roaming obligations can not be used as a backdoor way to create *de facto* mandatory resale obligations or virtual reseller networks." As requested, the Commission also further clarifies that the Commission does not intend the data roaming rule it establishes in this order to disturb any provider's existing right, under applicable law, to advertise the geographic reach of their services, as extended by roaming agreements, and to use data roaming to expand their advertised service area, where under applicable law there is no unauthorized use of a competitor's brand name and/or image associated with such advertising.

69. *Spectrum Sharing.* In the *Second Further Notice*, the Commission sought comment on what other actions might be appropriate to address spectrum capacity needs that may arise out of data

roaming or to help ensure that spectrum is utilized to the fullest extent possible, including, for example, whether facilitating spectrum sharing arrangements between a host provider and a requesting provider would be helpful or appropriate. After review of the record, the Commission finds there is an insufficient basis to make a determination on spectrum sharing in the context of data roaming services at this time. The one comment addressing the issue does so briefly in a footnote and provides no detail on how such a requirement would be implemented. Given the very limited record on this option, the Commission finds that requiring spectrum sharing arrangements as a condition for commercial mobile data services roaming arrangements is not warranted at this time.

III. Procedural Matters

A. Final Regulatory Flexibility Analysis

1. As required by the Regulatory Flexibility Act of 1980, as amended (the "RFA"),¹ an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the Order on Reconsideration and Second Further Notice of Proposed Rulemaking in WT Docket No. 05-265.² The Commission sought written public comment on the proposals in the Second Further Notice, including comment on the IRFA. The comments received are discussed below. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.³

1. Need for, and Objectives of, the Proposed Rules

2. In the *Second Further Notice* that the Commission adopted in conjunction with the *Order on Reconsideration* in 2010, the Commission sought to refresh and further develop the record by requesting additional comment on whether to extend roaming obligations to mobile data services, including mobile broadband Internet access, that are provided without interconnection to the public switched telephone network.⁴ The objective of the rule

¹ See 5 U.S.C. 603. The RFA, see 5 U.S.C. 601-612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Public Law 104-121, Title II, 110 Stat. 857 (1996).

² Reexamination of Roaming Obligations of Commercial Mobile Radio Service Providers and Other Providers of Mobile Data Services, WT Docket No. 05-265, *Order on Reconsideration and Second Further Notice of Proposed Rulemaking*, 25 FCC Rcd 4181 (2010).

³ See 5 U.S.C. 604.

⁴ The Commission had received several proposals concerning data roaming in response to the *Further Notice*, including a request by SpectrumCo that the Commission reconsider its decision to limit the

adopted is to require providers of commercial mobile data services to offer data roaming arrangements on commercially reasonable terms and conditions, pursuant to the Commission's authority under the Communications Act. In addition, the Commission also clarifies that providers of commercial mobile data roaming services are permitted to negotiate commercially reasonable measures to safeguard quality of service against network congestion that may result from roaming traffic or to prevent harm to their networks.

3. This rule will apply to all facilities-based providers of commercial mobile data services regardless of whether these entities are also providers of commercial mobile radio service (CMRS).⁵ For purposes of data roaming, the Commission defines a "commercial mobile data service" as any mobile data service that is not interconnected with the public switched network but is (1) provided for profit; and (2) available to the public or to such classes of eligible users as to be effectively available to the public.

4. Below, the Commission describes the duty of providers of commercial mobile data services to offer data roaming arrangements on commercially reasonable terms and conditions subject to certain limitations. When a request for data roaming negotiations is made, as a part of the duty of providers to offer data roaming arrangements on commercially reasonable terms and conditions, a would-be host provider has a duty to respond promptly to the request and avoid actions that unduly delay or stonewall the course of negotiations regarding that request. The Commission will determine whether the terms and conditions of a proffered data roaming arrangement are commercially reasonable on a case-by-case basis,

taking into consideration the totality of the circumstances. The duty to offer data roaming arrangements on commercially reasonable terms and conditions is subject to certain limitations. In particular: (1) Providers may negotiate the terms of their roaming arrangements on an individualized basis; (2) it is reasonable for a provider not to offer a data roaming arrangement to a requesting provider that is not technologically compatible; (3) it is reasonable for a provider not to offer a data roaming arrangement where it is not technically feasible to provide roaming for the particular data service for which roaming is requested and any changes to the host provider's network necessary to accommodate roaming for such data service are not economically reasonable; and (4) it is reasonable for a provider to condition the effectiveness of a data roaming arrangement on the requesting provider's provision of mobile data service to its own subscribers using a generation of wireless technology comparable to the technology on which the requesting provider seeks to roam.⁶

2. Legal Basis

5. The authority for the actions taken in this Second Report and Order is contained in Sections 1, 4(i), 4(j), 301, 303, 304, 309, 316, and 332 of the Communications Act of 1934, as amended, and Section 706 of the Telecommunications Act of 1996, as amended, 47 U.S.C. 151, 154(i), 154(j), 301, 303, 304, 309, 316, 332, and 1302.

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

6. The RFA directs agencies to provide a description of, and, where feasible, an estimate of, the number of small entities that may be affected by the proposed rules, if adopted. The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction."⁷ In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act.⁸ A "small business

concern" is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA).⁹

7. In the following paragraphs, the Commission further describes and estimates the number of small entity licensees that may be affected by the rules the Commission proposes in this Second Report and Order. This rule will apply to all facilities-based providers of commercial mobile data services regardless of whether these entities are also providers of commercial mobile radio service (CMRS).

8. This FRFA analyzes the number of small entities affected on a service-by-service basis. When identifying small entities that could be affected by the Commission's new rules, this FRFA provides information that describes auction results, including the number of small entities that were winning bidders. However, the number of winning bidders that qualify as small businesses at the close of an auction does not necessarily reflect the total number of small entities currently in a particular service. The Commission does not generally require that licensees later provide business size information, except in the context of an assignment or a transfer of control application that involves unjust enrichment issues.

9. *Wireless Telecommunications Carriers (except Satellite)*. Since 2007, the Census Bureau has placed wireless firms within this new, broad, economic census category.¹⁰ Prior to that time, such firms were within the now-superseded categories of "Paging" and "Cellular and Other Wireless Telecommunications."¹¹ Under the present and prior categories, the SBA has deemed a wireless business to be small if it has 1,500 or fewer employees.¹² For the category of

automatic roaming obligation only to services that use the public switched network. See *Second Further Notice*, 25 FCC Rcd at 4212–13 ¶ 63. The Commission noted that issues in SpectrumCo's petition for reconsideration were being addressed in the *Second Further Notice*. *Id.* at 4185 ¶ 9.

⁵ For purposes of this proceeding, "commercial mobile data service" is defined as any mobile data service that is not interconnected with the public switched network but is (1) provided for profit; and (2) available to the public or to such classes of eligible users as to be effectively available to the public. 47 CFR 20.12. The current roaming obligation in Section 20.12 applies to CMRS carriers' provision of mobile voice and data services that are interconnected with the public switched network, as well as their provision of text messaging and push-to-talk services. The data roaming rule adopted herein will cover mobile services that fall outside the scope of the current automatic roaming obligation if provided for profit; and available to the public or to such classes of eligible users as to be effectively available to the public.

⁶ In other words, a provider offering service only through, for example, a 1xRTT or GPRS/EDGE network, would not be able to rely on the data roaming obligation for this service to obtain roaming on a later generation EV-DO or UMTS/HSPA network until it starts offering the later generation service.

⁷ 5 U.S.C. 601(6).

⁸ 5 U.S.C. 601(3) (incorporating by reference the definition of "small-business concern" in the Small Business Act, 15 U.S.C. 632). Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies "unless an agency, after consultation with

the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the *Federal Register*."

⁹ 15 U.S.C. 632.

¹⁰ U.S. Census Bureau, 2007 NAICS Definitions, "Wireless Communications Carriers (Except Satellite)", NAICS code 517210"; <http://www.census.gov/naics/2007/def/ND517210.HTM#N517210>.

¹¹ U.S. Census Bureau, 2002 NAICS Definitions, "517211 Paging"; <http://www.census.gov/epcd/naics02/def/NDEF517.HTM>; U.S. Census Bureau, 2002 NAICS Definitions, "517212 Cellular and Other Wireless Telecommunications"; <http://www.census.gov/epcd/naics02/def/NDEF517.HTM>.

¹² 13 CFR 121.201, NAICS code 517210 (2007 NAICS). The now-superseded, pre-2007 CFR citations were 13 CFR 121.201, NAICS codes 517211 and 517212 (referring to the 2002 NAICS).

Wireless Telecommunications, Carriers (except Satellite), Census data for 2007, which supersede data contained in the 2002 Census, show that there were 1,383 firms that operated that year.¹³ Of those 1,383, 1,368 had fewer than 100 employees, and 15 firms had more than 100 employees. Thus under this category and the associated small business size standard, the majority of firms can be considered small. Similarly, according to Commission data, 413 carriers reported that they were engaged in the provision of wireless telephony, including cellular service, Personal Communications Service (PCS), and Specialized Mobile Radio (SMR) Telephony services.¹⁴ Of these, an estimated 261 have 1,500 or fewer employees and 152 have more than 1,500 employees.¹⁵ Consequently, the Commission estimates that approximately half or more of these firms can be considered small. Thus, using available data, we estimate that the majority of wireless firms can be considered small.

10. *Broadband Personal Communications Service.* The broadband personal communications services (PCS) spectrum is divided into six frequency blocks designated A through F, and the Commission has held auctions for each block. The Commission initially defined a “small business” for C- and F-Block licenses as an entity that has average gross revenues of \$40 million or less in the three previous calendar years.¹⁶ For F-Block licenses, an additional small business size standard for “very small business” was added and is defined as an entity that, together with its affiliates, has average gross revenues of not more than \$15 million for the preceding three calendar years.¹⁷ These small business size standards, in the context of broadband PCS auctions, have been approved by the SBA.¹⁸ No small businesses within the SBA-approved small business size standards bid

successfully for licenses in Blocks A and B. There were 90 winning bidders that claimed small business status in the first two C-Block auctions. A total of 93 bidders that claimed small business status won approximately 40 percent of the 1,479 licenses in the first auction for the D, E, and F Blocks.¹⁹ On April 15, 1999, the Commission completed the re-auction of 347 C-, D-, E-, and F-Block licenses in Auction No. 22.²⁰ Of the 57 winning bidders in that auction, 48 claimed small business status and won 277 licenses.

11. On January 26, 2001, the Commission completed the auction of 422 C and F Block Broadband PCS licenses in Auction No. 35. Of the 35 winning bidders in that auction, 29 claimed small business status.²¹ Subsequent events concerning Auction 35, including judicial and agency determinations, resulted in a total of 163 C and F Block licenses being available for grant. On February 15, 2005, the Commission completed an auction of 242 C-, D-, E-, and F-Block licenses in Auction No. 58. Of the 24 winning bidders in that auction, 16 claimed small business status and won 156 licenses.²² On May 21, 2007, the Commission completed an auction of 33 licenses in the A, C, and F Blocks in Auction No. 71.²³ Of the 12 winning bidders in that auction, five claimed small business status and won 18 licenses.²⁴ On August 20, 2008, the Commission completed the auction of 20 C-, D-, E-, and F-Block Broadband PCS licenses in Auction No. 78.²⁵ Of the eight winning bidders for Broadband PCS licenses in that auction, six claimed small business status and won 14 licenses.²⁶

¹⁹ See *Broadband PCS, D, E and F Block Auction Closes*, Public Notice, Doc. No. 89838 (rel. Jan. 14, 1997).

²⁰ See *C, D, E, and F Block Broadband PCS Auction Closes*, Public Notice, 14 FCC Rcd 6688 (WTB 1999). Before Auction No. 22, the Commission established a very small standard for the C Block to match the standard used for F Block. *Amendment of the Commission's Rules Regarding Installment Payment Financing for Personal Communications Services (PCS) Licensees*, WT Docket No. 97–82, *Fourth Report and Order*, 13 FCC Rcd 15743, 15768, para. 46 (1998).

²¹ See *C and F Block Broadband PCS Auction Closes; Winning Bidders Announced*, Public Notice, 16 FCC Rcd 2339 (2001).

²² See *Broadband PCS Spectrum Auction Closes; Winning Bidders Announced for Auction No. 58*, Public Notice, 20 FCC Rcd 3703 (2005).

²³ See *Auction of Broadband PCS Spectrum Licenses Closes; Winning Bidders Announced for Auction No. 71*, Public Notice, 22 FCC Rcd 9247 (2007).

²⁴ *Id.*

²⁵ See *Auction of AWS–1 and Broadband PCS Licenses Closes; Winning Bidders Announced for Auction 78*, Public Notice, 23 FCC Rcd 12749 (WTB 2008).

²⁶ *Id.*

12. *Narrowband Personal Communications Service.* In 1994, the Commission conducted an auction for Narrowband PCS licenses. A second auction was also conducted later in 1994. For purposes of the first two Narrowband PCS auctions, “small businesses” were entities with average gross revenues for the prior three calendar years of \$40 million or less.²⁷ Through these auctions, the Commission awarded a total of 41 licenses, 11 of which were obtained by four small businesses.²⁸ To ensure meaningful participation by small business entities in future auctions, the Commission adopted a two-tiered small business size standard in the Narrowband PCS Second Report and Order.²⁹ A “small business” is an entity that, together with affiliates and controlling interests, has average gross revenues for the three preceding years of not more than \$40 million.³⁰ A “very small business” is an entity that, together with affiliates and controlling interests, has average gross revenues for the three preceding years of not more than \$15 million.³¹ The SBA has approved these small business size standards.³² A third auction was conducted in 2001. Here, five bidders won 317 (Metropolitan Trading Areas and nationwide) licenses.³³ Three of these claimed status as a small or very small entity and won 311 licenses.

13. *Specialized Mobile Radio.* The Commission awards “small entity” bidding credits in auctions for Specialized Mobile Radio (SMR) geographic area licenses in the 800 MHz and 900 MHz bands to firms that had revenues of no more than \$15 million in each of the three previous calendar

²⁷ Implementation of Section 309(j) of the Communications Act—Competitive Bidding Narrowband PCS, *Third Memorandum Opinion and Order and Further Notice of Proposed Rulemaking*, 10 FCC Rcd 175, 196 ¶ 46 (1994).

²⁸ See “Announcing the High Bidders in the Auction of ten Nationwide Narrowband PCS Licenses, Winning Bids Total \$617,006,674,” *Public Notice*, PNWL 94–004 (rel. Aug. 2, 1994); “Announcing the High Bidders in the Auction of 30 Regional Narrowband PCS Licenses; Winning Bids Total \$490,901,787,” *Public Notice*, PNWL 94–27 (rel. Nov. 9, 1994).

²⁹ Amendment of the Commission's Rules to Establish New Personal Communications Services, Narrowband PCS, *Second Report and Order and Second Further Notice of Proposed Rule Making*, 15 FCC Rcd 10456, 10476 ¶ 40 (2000).

³⁰ *Id.*

³¹ *Id.*

³² See Letter to Amy Zoslov, Chief, Auctions and Industry Analysis Division, Wireless Telecommunications Bureau, Federal Communications Commission, from Aida Alvarez, Administrator, Small Business Administration, dated December 2, 1998.

³³ See “Narrowband PCS Auction Closes,” *Public Notice*, 16 FCC Rcd 18663 (WTB 2001).

¹³ U.S. Census Bureau, 2007 Economic Census, Sector 51, 2007 NAICS code 517210 (rel. Oct. 20, 2009), http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-ds_name=EC0700A1&-skip=700&-ds_name=EC0751SSSZ5&-lang=en.

¹⁴ See *Trends in Telephone Service* at Table 5.3.

¹⁵ *See id.*

¹⁶ See *Amendment of Parts 20 and 24 of the Commission's Rules—Broadband PCS Competitive Bidding and the Commercial Mobile Radio Service Spectrum Cap; Amendment of the Commission's Cellular/PCS Cross-Ownership Rule*, WT Docket No. 96–59, GN Docket No. 90–314, Report and Order, 11 FCC Rcd 7824, 7850–52, paras. 57–60 (1996) (“*PCS Report and Order*”); see also 47 CFR 24.720(b).

¹⁷ See *PCS Report and Order*, 11 FCC Rcd at 7852, para. 60.

¹⁸ See Alvarez Letter 1998.

years.³⁴ The Commission awards “very small entity” bidding credits to firms that had revenues of no more than \$3 million in each of the three previous calendar years.³⁵ The SBA has approved these small business size standards for the 900 MHz Service.³⁶ The Commission has held auctions for geographic area licenses in the 800 MHz and 900 MHz bands. The 900 MHz SMR was completed in 1996. Sixty bidders claiming that they qualified as small businesses under the \$15 million size standard won 263 geographic area licenses in the 900 MHz SMR band. The 800 MHz SMR auction for the upper 200 channels was conducted in 1997. Ten bidders claiming that they qualified as small businesses under the \$15 million size standard won 38 geographic area licenses for the upper 200 channels in the 800 MHz SMR band.³⁷ A second auction for the 800 MHz band was conducted in 2002 and included 23 BEA licenses. One bidder claiming small business status won five licenses.³⁸

14. The auction of the 1,050 800 MHz SMR geographic area licenses for the General Category channels was conducted in 2000. Eleven bidders won 108 geographic area licenses for the General Category channels in the 800 MHz SMR band qualified as small businesses under the \$15 million size standard.³⁹ In an auction completed in 2000, a total of 2,800 Economic Area licenses in the lower 80 channels of the 800 MHz SMR service were awarded.⁴⁰ Of the 22 winning bidders, 19 claimed “small business” status and won 129 licenses. Thus, combining all three auctions, 40 winning bidders for geographic licenses in the 800 MHz SMR band claimed status as small business.

15. In addition, there are numerous incumbent site-by-site SMR licensees and licensees with extended implementation authorizations in the

800 and 900 MHz bands. The Commission does not know how many firms provide 800 MHz or 900 MHz geographic area SMR pursuant to extended implementation authorizations, nor how many of these providers have annual revenues of no more than \$15 million. One firm has over \$15 million in revenues. In addition, the Commission does not know how many of these firms have 1500 or fewer employees.⁴¹ The Commission assumes, for purposes of this analysis, that all of the remaining existing extended implementation authorizations are held by small entities, as that small business size standard is approved by the SBA.

16. *AWS Services (1710–1755 MHz and 2110–2155 MHz bands (AWS–1); 1915–1920 MHz, 1995–2000 MHz, 2020–2025 MHz and 2175–2180 MHz bands (AWS–2); 2155–2175 MHz band (AWS–3)).* For the AWS–1 bands, the Commission has defined a “small business” as an entity with average annual gross revenues for the preceding three years not exceeding \$40 million, and a “very small business” as an entity with average annual gross revenues for the preceding three years not exceeding \$15 million.⁴² In 2006, the Commission conducted its first auction of AWS–1 licenses.⁴³ In that initial AWS–1 auction, 31 winning bidders identified themselves as very small businesses.⁴⁴ Twenty-six of the winning bidders identified themselves as small businesses.⁴⁵ In a subsequent 2008 auction, the Commission offered 35 AWS–1 licenses.⁴⁶ Four winning bidders identified themselves as very small businesses, and three of the winning bidders identified themselves as a small business.⁴⁷ For AWS–2 and

AWS–3, although the Commission does not know for certain which entities are likely to apply for these frequencies, the Commission notes that the AWS–1 bands are comparable to those used for cellular service and personal communications service. The Commission has not yet adopted size standards for the AWS–2 or AWS–3 bands but has proposed to treat both AWS–2 and AWS–3 similarly to broadband PCS service and AWS–1 service due to the comparable capital requirements and other factors, such as issues involved in relocating incumbents and developing markets, technologies, and services.⁴⁸

17. *Rural Radiotelephone Service.* The Commission has not adopted a size standard for small businesses specific to the Rural Radiotelephone Service.⁴⁹ A significant subset of the Rural Radiotelephone Service is the Basic Exchange Telephone Radio System (“BETRS”).⁵⁰ In the present context, the Commission will use the SBA’s small business size standard applicable to Wireless Telecommunications Carriers (except Satellite), *i.e.*, an entity employing no more than 1,500 persons.⁵¹ There are approximately 1,000 licensees in the Rural Radiotelephone Service, and the Commission estimates that there are 1,000 or fewer small entity licensees in the Rural Radiotelephone Service that may be affected by the rules and policies adopted herein.

18. *Wireless Communications Services.* This service can be used for fixed, mobile, radiolocation, and digital audio broadcasting satellite uses in the 2305–2320 MHz and 2345–2360 MHz bands. The Commission defined “small business” for the wireless communications services (WCS) auction as an entity with average gross revenues of \$40 million for each of the three preceding years, and a “very small business” as an entity with average gross revenues of \$15 million for each of the

⁴¹ See generally 13 CFR 121.201, NAICS code 517210.

⁴² See Service Rules for Advanced Wireless Services in the 1.7 GHz and 2.1 GHz Bands, *Report and Order*, 18 FCC Rcd 25,162, App. B (2003), modified by Service Rules for Advanced Wireless Services in the 1.7 GHz and 2.1 GHz Bands, *Order on Reconsideration*, 20 FCC Rcd 14,058, App. C (2005).

⁴³ See “Auction of Advanced Wireless Services Licenses Scheduled for June 29, 2006; Notice and Filing Requirements, Minimum Opening Bids, Upfront Payments and Other Procedures for Auction No. 66,” AU Docket No. 06–30, *Public Notice*, 21 FCC Rcd 4562 (2006) (“*Auction 66 Procedures Public Notice*”).

⁴⁴ See “Auction of Advanced Wireless Services Licenses Closes; Winning Bidders Announced for Auction No. 66,” *Public Notice*, 21 FCC Rcd 10,521 (2006) (“*Auction 66 Closing Public Notice*”).

⁴⁵ See *id.*

⁴⁶ See *AWS–1 and Broadband PCS Procedures Public Notice*, 23 FCC Rcd at 7499. Auction 78 also included an auction of broadband PCS licenses.

⁴⁷ See “Auction of AWS–1 and Broadband PCS Licenses Closes, Winning Bidders Announced for Auction 78, Down Payments Due September 9,

2008, FCC Forms 601 and 602 Due September 9, 2008, Final Payments Due September 23, 2008, Ten-Day Petition to Deny Period,” *Public Notice*, 23 FCC Rcd 12,749 (2008).

⁴⁸ Service Rules for Advanced Wireless Services in the 1915–1920 MHz, 1995–2000 MHz, 2020–2025 MHz and 2175–2180 MHz Bands et al., *Notice of Proposed Rulemaking*, 19 FCC Rcd 19,263, App. B (2005); Service Rules for Advanced Wireless Services in the 2155–2175 MHz Band, *Notice of Proposed Rulemaking*, 22 FCC Rcd 17,035, App. B (2007); Service Rules for Advanced Wireless Services in the 2155–2175 MHz Band, *Further Notice of Proposed Rulemaking*, 23 FCC Rcd 9859, App. B (2008).

⁴⁹ The service is defined in § 22.99 of the Commission’s Rules, 47 CFR 22.99.

⁵⁰ BETRS is defined in §§ 22.757 and 22.759 of the Commission’s Rules, 47 CFR 22.757 and 22.759.

⁵¹ 13 CFR 121.201, NAICS code 517210.

³⁴ 47 CFR 90.814(b)(1).

³⁵ *Id.*

³⁶ See Letter to Thomas Sugrue, Chief, Wireless Telecommunications Bureau, Federal Communications Commission, from Aida Alvarez, Administrator, Small Business Administration, dated August 10, 1999.

³⁷ See “Correction to Public Notice DA 96–586 ‘FCC Announces Winning Bidders in the Auction of 1020 Licenses to Provide 900 MHz SMR in Major Trading Areas,’” *Public Notice*, 18 FCC Rcd 18367 (WTB 1996).

³⁸ See “Multi-Radio Service Auction Closes,” *Public Notice*, 17 FCC Rcd 1446 (WTB 2002).

³⁹ See “800 MHz Specialized Mobile Radio (SMR) Service General Category (851–854 MHz) and Upper Band (861–865 MHz) Auction Closes; Winning Bidders Announced,” *Public Notice*, 15 FCC Rcd 17162 (2000).

⁴⁰ See, “800 MHz SMR Service Lower 80 Channels Auction Closes; Winning Bidders Announced,” *Public Notice*, 16 FCC Rcd 1736 (2000).

three preceding years.⁵² The SBA has approved these definitions.⁵³ The Commission auctioned geographic area licenses in the WCS service. In the auction, which commenced on April 15, 1997 and closed on April 25, 1997, there were seven bidders that won 31 licenses that qualified as very small business entities, and one bidder that won one license that qualified as a small business entity.

19. *220 MHz Radio Service—Phase I Licensees.* The 220 MHz service has both Phase I and Phase II licenses. Phase I licensing was conducted by lotteries in 1992 and 1993. There are approximately 1,515 such non-nationwide licensees and four nationwide licensees currently authorized to operate in the 220 MHz band. The Commission has not developed a small business size standard for small entities specifically applicable to such incumbent 220 MHz Phase I licensees. To estimate the number of such licensees that are small businesses, the Commission applies the small business size standard under the SBA rules applicable. The SBA has deemed a wireless business to be small if it has 1,500 or fewer employees.⁵⁴ For this service, the SBA uses the category of Wireless Telecommunications Carriers (except Satellite). Census data for 2007, which supersede data contained in the 2002 Census, show that there were 1,383 firms that operated that year.⁵⁵ Of those 1,383, 1,368 had fewer than 100 employees, and 15 firms had more than 100 employees. Thus under this category and the associated small business size standard, the majority of firms can be considered small.

20. *220 MHz Radio Service—Phase II Licensees.* The 220 MHz service has both Phase I and Phase II licenses. The Phase II 220 MHz service is a new service, and is subject to spectrum auctions. In the *220 MHz Third Report and Order*, the Commission adopted a small business size standard for defining “small” and “very small”

businesses for purposes of determining their eligibility for special provisions such as bidding credits and installment payments.⁵⁶ This small business standard indicates that a “small business” is an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding \$15 million for the preceding three years.⁵⁷ A “very small business” is defined as an entity that, together with its affiliates and controlling principals, has average gross revenues that do not exceed \$3 million for the preceding three years.⁵⁸ The SBA has approved these small size standards.⁵⁹ Auctions of Phase II licenses commenced on and closed in 1998.⁶⁰ In the first auction, 908 licenses were auctioned in three different-sized geographic areas: Three nationwide licenses, 30 Regional Economic Area Group (EAG) Licenses, and 875 Economic Area (EA) Licenses. Of the 908 licenses auctioned, 693 were sold.⁶¹ Thirty-nine small businesses won 373 licenses in the first 220 MHz auction. A second auction included 225 licenses: 216 EA licenses and 9 EAG licenses. Fourteen companies claiming small business status won 158 licenses.⁶² A third auction included four licenses: 2 BEA licenses and 2 EAG licenses in the 220 MHz Service. No small or very small business won any of these licenses.⁶³ In 2007, the Commission conducted a fourth auction of the 220 MHz licenses.⁶⁴ Bidding credits were offered to small businesses. A bidder with attributed average annual gross revenues that exceeded \$3 million and did not exceed \$15 million for the preceding three years (“small business”) received a 25 percent discount on its winning bid. A bidder with attributed

average annual gross revenues that did not exceed \$3 million for the preceding three years received a 35 percent discount on its winning bid (“very small business”). Auction 72, which offered 94 Phase II 220 MHz Service licenses, concluded in 2007.⁶⁵ In this auction, five winning bidders won a total of 76 licenses. Two winning bidders identified themselves as very small businesses won 56 of the 76 licenses. One of the winning bidders that identified themselves as a small business won 5 of the 76 licenses won.

21. *700 MHz Guard Band Licenses.* In the *700 MHz Guard Band Order*, the Commission adopted size standards for “small businesses” and “very small businesses” for purposes of determining their eligibility for special provisions such as bidding credits and installment payments.⁶⁶ A small business in this service is an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding \$40 million for the preceding three years.⁶⁷ Additionally, a “very small business” is an entity that, together with its affiliates and controlling principals, has average gross revenues that are not more than \$15 million for the preceding three years.⁶⁸ SBA approval of these definitions is not required.⁶⁹ In 2000, the Commission

⁶⁵ See “Auction of Phase II 220 MHz Service Spectrum Licenses Closes, Winning Bidders Announced for Auction 72, Down Payments due July 18, 2007, FCC Forms 601 and 602 due July 18, 2007, Final Payments due August 1, 2007, Ten-Day Petition to Deny Period, *Public Notice*, 22 FCC Rcd 11573 (2007).

⁶⁶ Service Rules for the 746–764 MHz Bands, and Revisions to Part 27 of the Commission’s Rules, *Second Report and Order*, 15 FCC Rcd 5299 (2000). Service rules were amended in 2007, but no changes were made to small business size categories. See Service Rules for the 698–746, 747–762 and 777–792 MHz Bands, WT Docket No. 06–150, Revision of the Commission’s Rules to Ensure Compatibility with Enhanced 911 Emergency Calling Systems, CC Docket No. 94–102, Section 68.4(a) of the Commission’s Rules Governing Hearing Aid-Compatible Telephones, WT Docket No. 01–309, Biennial Regulatory Review—Amendment of Parts 1, 22, 24, 27, and 90 to Streamline and Harmonize Various Rules Affecting Wireless Radio Services, WT Docket 03–264, Former Nextel Communications, Inc. Upper 700 MHz Guard Band Licenses and Revisions to Part 27 of the Commission’s Rules, WT Docket No. 06–169, Implementing a Nationwide, Broadband, Interoperable Public Safety Network in the 700 MHz Band, PS Docket No. 06–229, Development of Operational, Technical and Spectrum Requirements for Meeting Federal, State and Local Public Safety Communications Requirements Through the Year 2010, WT Docket No. 96–86, *Report and Order and Further Notice of Proposed Rulemaking*, 22 FCC Rcd 8064 (2007).

⁶⁷ *Id.* at 5343 ¶ 108.

⁶⁸ *Id.*

⁶⁹ *Id.* at 5343 ¶ 108 n.246 (for the 746–764 MHz and 776–704 MHz bands, the Commission is exempt from 15 U.S.C. 632, which requires Federal agencies to obtain Small Business Administration

⁵² Amendment of the Commission’s Rules to Establish Part 27, the Wireless Communications Service (WCS), *Report and Order*, 12 FCC Rcd 10785, 10879 ¶ 194 (1997).

⁵³ See Letter to Amy Zoslov, Chief, Auctions and Industry Analysis Division, Wireless Telecommunications Bureau, Federal Communications Commission, from Aida Alvarez, Administrator, Small Business Administration, dated December 2, 1998.

⁵⁴ 13 CFR 121.201, NAICS code 517210 (2007 NAICS). The now-superseded, pre-2007 CFR citations were 13 CFR 121.201, NAICS codes 517211 and 517212 (referring to the 2002 NAICS).

⁵⁵ U.S. Census Bureau, 2007 Economic Census, Sector 51, 2007 NAICS code 517210 (rel. Oct. 20, 2009), http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-fds_name=EC0700A1&-skip=700&-ds_name=EC0751SSSZ5&-lang=en.

⁵⁶ Amendment of Part 90 of the Commission’s Rules to Provide For the Use of the 220–222 MHz Band by the Private Land Mobile Radio Service, *Third Report and Order*, 12 FCC Rcd 10943, 11068–70 ¶¶ 291–295 (1997).

⁵⁷ *Id.* at 11068 ¶ 291.

⁵⁸ *Id.*

⁵⁹ See Letter to Daniel Phythyon, Chief, Wireless Telecommunications Bureau, Federal Communications Commission, from Aida Alvarez, Administrator, Small Business Administration, dated January 6, 1998 (*Alvarez to Phythyon Letter 1998*).

⁶⁰ See generally “220 MHz Service Auction Closes,” *Public Notice*, 14 FCC Rcd 605 (WTB 1998).

⁶¹ See “FCC Announces It is Prepared to Grant 654 Phase II 220 MHz Licenses After Final Payment is Made,” *Public Notice*, 14 FCC Rcd 1085 (WTB 1999).

⁶² See “Phase II 220 MHz Service Spectrum Auction Closes,” *Public Notice*, 14 FCC Rcd 11218 (WTB 1999).

⁶³ See “Multi-Radio Service Auction Closes,” *Public Notice*, 17 FCC Rcd 1446 (WTB 2002).

⁶⁴ See “Auction of Phase II 220 MHz Service Spectrum Scheduled for June 20, 2007, Notice and Filing Requirements, Minimum Opening Bids, Upfront Payments and Other Procedures for Auction 72,” *Public Notice*, 22 FCC Rcd 3404 (2007).

conducted an auction of 52 Major Economic Area ("MEA") licenses.⁷⁰ Of the 104 licenses auctioned, 96 licenses were sold to nine bidders. Five of these bidders were small businesses that won a total of 26 licenses. A second auction of 700 MHz Guard Band licenses commenced and closed in 2001. All eight of the licenses auctioned were sold to three bidders. One of these bidders was a small business that won a total of two licenses.⁷¹

22. *Upper 700 MHz Band Licenses.* In the 700 MHz *Second Report and Order*, the Commission revised its rules regarding Upper 700 MHz licenses.⁷² On January 24, 2008, the Commission commenced Auction 73 in which several licenses in the Upper 700 MHz band were available for licensing: 12 Regional Economic Area Grouping licenses in the C Block, and one nationwide license in the D Block.⁷³ The auction concluded on March 18, 2008, with 3 winning bidders claiming very small business status (those with attributable average annual gross revenues that do not exceed \$15 million for the preceding three years) and winning five licenses.

23. *Lower 700 MHz Band Licenses.* The Commission previously adopted criteria for defining three groups of small businesses for purposes of determining their eligibility for special provisions such as bidding credits.⁷⁴ The Commission defined a "small business" as an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding \$40 million for the preceding three years.⁷⁵ A "very small business" is defined as an entity that, together with its affiliates and controlling principals, has average gross revenues that are not more than \$15 million for the preceding three years.⁷⁶ Additionally, the lower 700 MHz Service had a third category of small business status for Metropolitan/Rural Service Area (MSA/RSA) licenses—"entrepreneur"—which is defined as an entity that, together with

its affiliates and controlling principals, has average gross revenues that are not more than \$3 million for the preceding three years.⁷⁷ The SBA approved these small size standards.⁷⁸ An auction of 740 licenses (one license in each of the 734 MSAs/RSAs and one license in each of the six Economic Area Groupings (EAGs)) was conducted in 2002. Of the 740 licenses available for auction, 484 licenses were won by 102 winning bidders. Seventy-two of the winning bidders claimed small business, very small business or entrepreneur status and won licenses.⁷⁹ A second auction commenced on May 28, 2003, closed on June 13, 2003, and included 256 licenses.⁸⁰ Seventeen winning bidders claimed small or very small business status, and nine winning bidders claimed entrepreneur status.⁸¹ In 2005, the Commission completed an auction of 5 licenses in the Lower 700 MHz band. All three winning bidders claimed small business status.

24. In 2007, the Commission reexamined its rules governing the 700 MHz band in the 700 MHz *Second Report and Order*.⁸² An auction of A, B and E block 700 MHz licenses was held in 2008.⁸³ Twenty winning bidders claimed small business status (those with attributable average annual gross revenues that exceed \$15 million and do not exceed \$40 million for the preceding three years). Thirty three winning bidders claimed very small business status (those with attributable average annual gross revenues that do not exceed \$15 million for the preceding three years).

25. *Wireless Telephony.* Wireless telephony includes cellular, personal communications services, and specialized mobile radio telephony carriers. As noted, the SBA has developed a small business size standard for Wireless Telecommunications Carriers (except Satellite).⁸⁴ Under the SBA small business size standard, a business is small if it has 1,500 or fewer employees.⁸⁵ According to *Trends in Telephone Service* data, 413 carriers reported that they were engaged in

wireless telephony.⁸⁶ Of these, an estimated 261 have 1,500 or fewer employees and 152 have more than 1,500 employees.⁸⁷ Therefore, more than half of these entities can be considered small.

26. *Air-Ground Radiotelephone Service.* The Commission has previously used the SBA's small business definition applicable to Wireless Telecommunications Carriers (except Satellite), *i.e.*, an entity employing no more than 1,500 persons.⁸⁸ There are approximately 100 licensees in the Air-Ground Radiotelephone Service, and under that definition, the Commission estimates that almost all of them qualify as small entities under the SBA definition. For purposes of assigning Air-Ground Radiotelephone Service licenses through competitive bidding, the Commission has defined "small business" as an entity that, together with controlling interests and affiliates, has average annual gross revenues for the preceding three years not exceeding \$40 million.⁸⁹ A "very small business" is defined as an entity that, together with controlling interests and affiliates, has average annual gross revenues for the preceding three years not exceeding \$15 million.⁹⁰ These definitions were approved by the SBA.⁹¹ In 2006, the Commission completed an auction of nationwide commercial Air-Ground Radiotelephone Service licenses in the 800 MHz band (Auction 65). Later in 2006, the auction closed with two winning bidders winning two Air-Ground Radiotelephone Services licenses. Neither of the winning bidders claimed small business status.

27. *Aviation and Marine Radio Services.* Small businesses in the aviation and marine radio services use a very high frequency (VHF) marine or aircraft radio and, as appropriate, an emergency position-indicating radio beacon (and/or radar) or an emergency locator transmitter. The Commission has not developed a small business size

approval before adopting small business size standards).

⁷⁰ See "700 MHz Guard Bands Auction Closes: Winning Bidders Announced," *Public Notice*, 15 FCC Rcd 18026 (2000).

⁷¹ See "700 MHz Guard Bands Auction Closes: Winning Bidders Announced," *Public Notice*, 16 FCC Rcd 4590 (WTB 2001).

⁷² 700 MHz *Second Report and Order*, 22 FCC Rcd 15289.

⁷³ See Auction of 700 MHz Band Licenses Closes, *Public Notice*, 23 FCC Rcd 4572 (WTB 2008).

⁷⁴ See Reallocation and Service Rules for the 698–746 MHz Spectrum Band (Television Channels 52–59), *Report and Order*, 17 FCC Rcd 1022 (2002) ("Channels 52–59 *Report and Order*").

⁷⁵ See *id.*, 17 FCC Rcd at 1087–88 ¶ 172.

⁷⁶ See *id.*

⁷⁷ See *id.*, 17 FCC Rcd at 1088 ¶ 173.

⁷⁸ See Alvarez Letter 1998.

⁷⁹ See Lower 700 MHz Band Auction Closes, *Public Notice*, 17 FCC Rcd 17,272 (2002).

⁸⁰ See Lower 700 MHz Band Auction Closes, *Public Notice*, 18 FCC Rcd 11,873 (2003).

⁸¹ See *id.*

⁸² 700 MHz *Second Report and Order*, *Second Report and Order*, 22 FCC Rcd 15,289, 15,359 n.434 (2007).

⁸³ See Auction of 700 MHz Band Licenses Closes, *Public Notice*, 23 FCC Rcd 4572 (2008).

⁸⁴ 13 CFR 121.201, NAICS code 517210.

⁸⁵ *Id.*

⁸⁶ *Trends in Telephone Service*, tbl. 5.3.

⁸⁷ *Id.*

⁸⁸ 13 CFR 121.201, NAICS codes 517210.

⁸⁹ Amendment of Part 22 of the Commission's Rules to Benefit the Consumers of Air-Ground Telecommunications Services, Biennial Regulatory Review—Amendment of Parts 1, 22, and 90 of the Commission's Rules, Amendment of Parts 1 and 22 of the Commission's Rules to Adopt Competitive Bidding Rules for Commercial and General Aviation Air-Ground Radiotelephone Service, WT Docket Nos. 03–103, 05–42, *Order on Reconsideration and Report and Order*, 20 FCC Rcd 19663, 19677–83 ¶¶ 28–42 (2005).

⁹⁰ *Id.*

⁹¹ See Letter from Hector V. Barreto, Administrator, SBA, to Gary D. Michaels, Deputy Chief, Auctions and Spectrum Access Division, Wireless Telecommunications Bureau, FCC (filed Sept. 19, 2005).

standard specifically applicable to these small businesses. For purposes of this analysis, the Commission uses the SBA small business size standard for the category Wireless Telecommunications Carriers (except satellite),” which is 1,500 or fewer employees.⁹² Census data for 2007, which supersede data contained in the 2002 Census, show that there were 1,383 firms that operated that year.⁹³ Of those 1,383, 1,368 had fewer than 100 employees, and 15 firms had more than 100 employees. Thus under this category and the associated small business size standard, the majority of firms can be considered small. Additionally, the Commission notes that most applicants for recreational licenses in this category of wireless service are individuals. Approximately 581,000 ship station licensees and 131,000 aircraft station licensees operate domestically and are not subject to the radio carriage requirements of any statute or treaty. For purposes of our evaluations in this analysis, the Commission estimates that there are up to approximately 712,000 licensees that are small businesses (or individuals) under the SBA standard. In addition, between December 3, 1998 and December 14, 1998, the Commission held an auction of 42 VHF Public Coast licenses in the 157.1875–157.4500 MHz (ship transmit) and 161.775–162.0125 MHz (coast transmit) bands. For purposes of the auction, the Commission defined a “small” business as an entity that, together with controlling interests and affiliates, has average gross revenues for the preceding three years not to exceed \$15 million dollars. In addition, a “very small” business is one that, together with controlling interests and affiliates, has average gross revenues for the preceding three years not to exceed \$3 million dollars.⁹⁴ There are approximately 10,672 licensees in the Marine Coast Service, and the Commission estimates that almost all of them qualify as “small” businesses under the above special small business size standards.

28. Fixed Microwave Services.

Microwave services include common carrier,⁹⁵ private-operational fixed,⁹⁶

and broadcast auxiliary radio services.⁹⁷ They also include the Local Multipoint Distribution Service (LMDS),⁹⁸ the Digital Electronic Message Service (DEMS),⁹⁹ and the 24 GHz Service,¹⁰⁰ where licensees can choose between common carrier and non-common carrier status.¹⁰¹ The Commission has not yet defined a small business with respect to microwave services. For purposes of the IRFA, the Commission will use the SBA’s definition applicable to Wireless Telecommunications Carriers (except satellite)—i.e., an entity with no more than 1,500 persons is considered small.¹⁰² For the category of Wireless Telecommunications Carriers (except Satellite), Census data for 2007, which supersede data contained in the 2002 Census, show that there were 1,383 firms that operated that year.¹⁰³ Of those 1,383, 1,368 had fewer than 100 employees, and 15 firms had more than 100 employees. Thus under this category and the associated small business size standard, the majority of firms can be considered small. The Commission notes that the number of firms does not necessarily track the number of licensees. The Commission estimates that virtually all of the Fixed Microwave licensees (excluding broadcast auxiliary licensees) would qualify as small entities under the SBA definition.

29. *Local Multipoint Distribution Service.* Local Multipoint Distribution Service (LMDS) is a fixed broadband point-to-multipoint microwave service that provides for two-way video telecommunications.¹⁰⁴ In the 1998 and 1999 LMDS auctions,¹⁰⁵ the

⁹⁷ Auxiliary Microwave Service is governed by Part 74 of Title 47 of the Commission’s Rules. See 47 CFR Part 74. Available to licensees of broadcast stations and to broadcast and cable network entities, broadcast auxiliary microwave stations are used for relaying broadcast television signals from the studio to the transmitter, or between two points such as a main studio and an auxiliary studio. The service also includes mobile TV pickups, which relay signals from a remote location back to the studio.

⁹⁸ See 47 CFR Part 101, Subpart L.

⁹⁹ See 47 CFR Part 101, Subpart G.

¹⁰⁰ See *id.*

¹⁰¹ See 47 CFR 101.533, 101.1017.

¹⁰² 13 CFR 121.201, NAICS code 517210.

¹⁰³ U.S. Census Bureau, 2007 Economic Census, Sector 51, 2007 NAICS code 517210 (rel. Oct. 20, 2009), http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-fds_name=EC0700A1&-skip=700&-ds_name=EC0751SSSZ5&-lang=en.

¹⁰⁴ See Local Multipoint Distribution Service, Second Report and Order, 12 FCC Rcd 12545 (1997).

¹⁰⁵ The Commission has held two LMDS auctions: Auction 17 and Auction 23. Auction No. 17, the first LMDS auction, began on February 18, 1998, and closed on March 25, 1998. (104 bidders won 864 licenses.) Auction No. 23, the LMDS re-auction,

Commission defined a small business as an entity that has annual average gross revenues of less than \$40 million in the previous three calendar years.¹⁰⁶ Moreover, the Commission added an additional classification for a “very small business,” which was defined as an entity that had annual average gross revenues of less than \$15 million in the previous three calendar years.¹⁰⁷ These definitions of “small business” and “very small business” in the context of the LMDS auctions have been approved by the SBA.¹⁰⁸ In the first LMDS auction, 104 bidders won 864 licenses. Of the 104 auction winners, 93 claimed status as small or very small businesses. In the LMDS re-auction, 40 bidders won 161 licenses. Based on this information, the Commission believes that the number of small LMDS licenses will include the 93 winning bidders in the first auction and the 40 winning bidders in the re-auction, for a total of 133 small entity LMDS providers as defined by the SBA and the Commission’s auction rules.

30. *Offshore Radiotelephone Service.* This service operates on several UHF television broadcast channels that are not used for television broadcasting in the coastal areas of states bordering the Gulf of Mexico.¹⁰⁹ There are presently approximately 55 licensees in this service. The Commission is unable to estimate at this time the number of licensees that would qualify as small under the SBA’s small business size standard for the category of Wireless Telecommunications Carriers (except Satellite). Under that standard¹¹⁰ a business is small if it has 1,500 or fewer employees.¹¹¹ Census data for 2007, which supersede data contained in the 2002 Census, show that there were 1,383 firms that operated that year.¹¹² Of those 1,383, 1,368 had fewer than 100 employees, and 15 firms had more than 100 employees. Thus under this category and the associated small business size standard, the majority of firms can be considered small.

31. *39 GHz Service.* The Commission created a special small business size

began on April 27, 1999, and closed on May 12, 1999. (40 bidders won 161 licenses.)

¹⁰⁶ See LMDS Order, 12 FCC Rcd at 12545.

¹⁰⁷ *Id.*

¹⁰⁸ See Letter to Daniel Phythyon, Chief, Wireless Telecommunications Bureau (FCC) from A. Alvarez, Administrator, SBA (January 6, 1998).

¹⁰⁹ This service is governed by Subpart I of Part 22 of the Commission’s Rules. See 47 CFR 22.1001–22.1037.

¹¹⁰ 13 CFR 121.201, NAICS code 517210.

¹¹¹ *Id.*

¹¹² U.S. Census Bureau, 2007 Economic Census, Sector 51, 2007 NAICS code 517210 (rel. Oct. 20, 2009), http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-fds_name=EC0700A1&-skip=700&-ds_name=EC0751SSSZ5&-lang=en.

⁹² 13 CFR 121.201, NAICS code 517210.

⁹³ U.S. Census Bureau, 2007 Economic Census, Sector 51, 2007 NAICS code 517210 (rel. Oct. 20, 2009), http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-fds_name=EC0700A1&-skip=700&-ds_name=EC0751SSSZ5&-lang=en.

⁹⁴ Amendment of the Commission’s Rules Concerning Maritime Communications, PR Docket No. 92–257, Third Report and Order and Memorandum Opinion and Order, 13 FCC Rcd 19853 (1998).

⁹⁵ See 47 CFR Part 101, Subparts C and I.

⁹⁶ See 47 CFR Part 101, Subparts C and H.

standard for 39 GHz licenses—an entity that has average gross revenues of \$40 million or less in the three previous calendar years.¹¹³ An additional size standard for “very small business” is: an entity that, together with affiliates, has average gross revenues of not more than \$15 million for the preceding three calendar years.¹¹⁴ The SBA has approved these small business size standards.¹¹⁵ The auction of the 2,173 39 GHz licenses began and closed in 2000. The 18 bidders who claimed small business status won 849 licenses.

32. *218–219 MHz Service.* The first auction of 218–219 MHz spectrum resulted in 170 entities winning licenses for 594 Metropolitan Statistical Area (MSA) licenses. Of the 594 licenses, 557 were won by entities qualifying as a small business. For that auction, the small business size standard was an entity that, together with its affiliates, has no more than a \$6 million net worth and, after federal income taxes (excluding any carry over losses), has no more than \$2 million in annual profits each year for the previous two years.¹¹⁶ In the *218–219 MHz Report and Order and Memorandum Opinion and Order*, the Commission established a small business size standard for a “small business” as an entity that, together with its affiliates and persons or entities that hold interests in such an entity and their affiliates, has average annual gross revenues not to exceed \$15 million for the preceding three years.¹¹⁷ A “very small business” is defined as an entity that, together with its affiliates and persons or entities that hold interests in such an entity and its affiliates, has average annual gross revenues not to exceed \$3 million for the preceding three years.¹¹⁸ The SBA has approved of these definitions.¹¹⁹ These size standards will be used in future auctions of 218–219 MHz spectrum.

33. *Incumbent 24 GHz Licensees.* This analysis may affect incumbent licensees who were relocated to the 24 GHz band

from the 18 GHz band, and applicants who wish to provide services in the 24 GHz band. For this service, the Commission uses the SBA small business size standard for the category “Wireless Telecommunications Carriers (except satellite),” which is 1,500 or fewer employees.¹²⁰ To gauge small business prevalence for these cable services we must, however, use the most current census data. Census data for 2007, which supersede data contained in the 2002 Census, show that there were 1,383 firms that operated that year.¹²¹ Of those 1,383, 1,368 had fewer than 100 employees, and 15 firms had more than 100 employees. Thus under this category and the associated small business size standard, the majority of firms can be considered small. The Commission notes that the Census’ use of the classifications “firms” does not track the number of “licenses”. The Commission believes that there are only two licensees in the 24 GHz band that were relocated from the 18 GHz band, Teligent¹²² and TRW, Inc. It is the Commission’s understanding that Teligent and its related companies have less than 1,500 employees, though this may change in the future. TRW is not a small entity. Thus, only one incumbent licensee in the 24 GHz band is a small business entity.

34. *Future 24 GHz Licensees.* With respect to new applicants in the 24 GHz band, the small business size standard for “small business” is an entity that, together with controlling interests and affiliates, has average annual gross revenues for the three preceding years not in excess of \$15 million.¹²³ “Very small business” in the 24 GHz band is an entity that, together with controlling interests and affiliates, has average gross revenues not exceeding \$3 million for the preceding three years.¹²⁴ The SBA has approved these small business size

standards.¹²⁵ These size standards will apply to the future auction, if held.

35. *1670–1675 MHz Services.* This service can be used for fixed and mobile uses, except aeronautical mobile.¹²⁶ An auction for one license in the 1670–1675 MHz band was conducted in 2003. The winning bidder was not a small entity.

36. *3650–3700 MHz Band.* In March 2005, the Commission released a *Report and Order and Memorandum Opinion and Order* that provides for nationwide, non-exclusive licensing of terrestrial operations, utilizing contention-based technologies, in the 3650 MHz band (i.e., 3650–3700 MHz).¹²⁷ As of April 2010, more than 1270 licenses have been granted and more than 7433 sites have been registered. The Commission has not developed a definition of small entities applicable to 3650–3700 MHz band nationwide, non-exclusive licensees. However, the Commission estimates that the majority of these licensees are Internet Access Service Providers (ISPs) and that most of those licensees are small businesses.

37. *Internet Service Providers.* The 2007 Economic Census places these firms, whose services might include voice over Internet protocol (VoIP), in either of two categories, depending on whether the service is provided over the provider’s own telecommunications facilities (e.g., cable and DSL ISPs), or over client-supplied telecommunications connections (e.g., dial-up ISPs). The former are within the category of Wired Telecommunications Carriers,¹²⁸ which has an SBA small business size standard of 1,500 or fewer employees.¹²⁹ These are also labeled “broadband.” The latter are within the category of All Other Telecommunications,¹³⁰ which has a size standard of annual receipts of \$25 million or less.¹³¹ These are labeled non-broadband.

38. The most current Economic Census data for all such firms are 2007 data, which are detailed specifically for

¹¹³ See Amendment of the Commission’s Rules Regarding the 37.0–38.6 GHz and 38.6–40.0 GHz Bands, ET Docket No. 95–183, *Report and Order*, 63 FR 6079 (Feb. 6, 1998).

¹¹⁴ *Id.*

¹¹⁵ See Letter to Kathleen O’Brien Ham, Chief, Auctions and Industry Analysis Division, Wireless Telecommunications Bureau, FCC, from Aida Alvarez, Administrator, SBA (Feb. 4, 1998).

¹¹⁶ *Implementation of Section 309(j) of the Communications Act—Competitive Bidding*, PP Docket No. 93–253, Fourth Report and Order, 9 FCC Rcd 2330 (1994).

¹¹⁷ *Amendment of Part 95 of the Commission’s Rules to Provide Regulatory Flexibility in the 218–219 MHz Service*, WT Docket No. 98–169, Report and Order and Memorandum Opinion and Order, 15 FCC Rcd 1497 (1999).

¹¹⁸ *Id.*

¹¹⁹ See Alvarez to Phythyon Letter 1998.

¹²⁰ 13 CFR 121.201, NAICS code 517210.

¹²¹ U.S. Census Bureau, 2007 Economic Census, Sector 51, 2007 NAICS code 517210 (rel. Oct. 20, 2009), http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-fds_name=EC0700A1&-skip=700&-ds_name=EC0751SSZ5&-lang=en.

¹²² Teligent acquired the DEMS licenses of FirstMark, the only licensee other than TRW in the 24 GHz band whose license has been modified to require relocation to the 24 GHz band.

¹²³ *Amendments to Parts 1, 2, 87 and 101 of the Commission’s Rules to License Fixed Services at 24 GHz*, WT Docket No. 99–327, Report and Order, 15 FCC Rcd 16934, 16967 at para. 77 (2000); see also 47 CFR 101.538(a)(2).

¹²⁴ *Amendments to Parts 1, 2, 87 and 101 of the Commission’s Rules to License Fixed Services at 24 GHz*, WT Docket No. 99–327, Report and Order, 15 FCC Rcd 16934, 16967 at para. 77 (2000); see also 47 CFR 101.538(a)(1).

¹²⁵ See Letter to Margaret W. Wiener, Deputy Chief, Auctions and Industry Analysis Division, Wireless Telecommunications Bureau, FCC, from Gary M. Jackson, Assistant Administrator, SBA (July 28, 2000).

¹²⁶ 47 CFR 2.106; see generally 47 CFR 27.1–70.

¹²⁷ The service is defined in section 90.1301 *et seq.* of the Commission’s Rules, 47 CFR 90.1301 *et seq.*

¹²⁸ U.S. Census Bureau, 2007 NAICS Definitions, “517110 Wired Telecommunications Carriers”; <http://www.census.gov/naics/2007/def/ND517110.HTM#N517110>.

¹²⁹ 13 CFR 121.201, NAICS code 517110.

¹³⁰ U.S. Census Bureau, 2007 NAICS Definitions, “517919 All Other Telecommunications”; <http://www.census.gov/naics/2007/def/ND517919.HTM#N517919>.

¹³¹ 13 CFR 121.201, NAICS code 517919 (updated for inflation in 2008).

ISPs within the categories above. For the first category, the data show that 396 firms operated for the entire year, of which 159 had nine or fewer employees.¹³² For the second category, the data show that 1,682 firms operated for the entire year.¹³³ Of those, 1,675 had annual receipts below \$25 million per year, and an additional two had receipts of between \$25 million and \$49,999,999. Consequently, the Commission estimates that the majority of ISP firms are small entities.

39. *Satellite Telecommunications Providers.* Two economic census categories address the satellite industry. The first category has a small business size standard of \$15 million or less in average annual receipts, under SBA rules.¹³⁴ The second has a size standard of \$25 million or less in annual receipts.¹³⁵

40. The category of Satellite Telecommunications “comprises establishments primarily engaged in providing telecommunications services to other establishments in the telecommunications and broadcasting industries by forwarding and receiving communications signals via a system of satellites or reselling satellite telecommunications.”¹³⁶ Census Bureau data for 2007 show that 512 Satellite Telecommunications firms that operated for that entire year.¹³⁷ Of this total, 464 firms had annual receipts of under \$10 million, and 18 firms had receipts of \$10 million to \$24,999,999.¹³⁸ Consequently, the Commission estimates that the majority of Satellite Telecommunications firms are small entities that might be affected by its action.

41. The second category, *i.e.* “All Other Telecommunications” comprises “establishments primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes

establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems. Establishments providing Internet services or voice over Internet protocol (VoIP) services via client-supplied telecommunications connections are also included in this industry.”¹³⁹ For this category, Census Bureau data for 2007 show that there were a total of 2,383 firms that operated for the entire year.¹⁴⁰ Of this total, 2,347 firms had annual receipts of under \$25 million and 12 firms had annual receipts of \$25 million to \$49,999,999.¹⁴¹ Consequently, the Commission estimates that the majority of All Other Telecommunications firms are small entities that might be affected by its action.

42. *Part 15 Device Manufacturers.* The Commission has not developed a definition of small applicable to unlicensed communications devices manufacturers. Therefore the Commission will utilize the SBA definition applicable to Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing. The Census Bureau defines this category as follows: This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless equipment. Examples of products made by these establishments are: transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment.”¹⁴² The SBA has developed a small business size standard for Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, which is all firms having 750 or fewer employees.¹⁴³ The U.S. Census data for 2007 indicate that in that year there were 939 active establishments, of which 912 had less than 500 hundred employees and of which 27 had 500 employees or

more.¹⁴⁴ Accordingly, the Commission concludes that the majority of businesses in this category were small.

43. *Telephone Apparatus Manufacturing.* This industry comprises establishments primarily engaged in manufacturing wire telephone and data communications equipment. These products may be standalone or board-level components of a larger system. Examples of products made by these establishments are central office switching equipment, cordless telephones (except cellular), PBX equipment, telephones, telephone answering machines, LAN modems, multi-user modems, and other data communications equipment, such as bridges, routers, and gateways.¹⁴⁵ The SBA has developed a small business size standard for Telephone Apparatus Manufacturing, which is all such firms having fewer than 1,000 employees.¹⁴⁶ U.S. Census data for 2007 indicate that there were 398 establishments that were operational during that year. Of that 398, 393 had less than 100 employees and 5 had 1,000 employees or more.¹⁴⁷ Accordingly, the Commission concludes that the majority of businesses in this category were small.

44. *Other Communications Equipment Manufacturing.* This industry comprises establishments primarily engaged in manufacturing communications equipment (except telephone apparatus, and radio and television broadcast, and wireless communications equipment).¹⁴⁸ The SBA has developed a small business size standard for Other Communications Equipment Manufacturing, which is all such firms having fewer than 750 employees.¹⁴⁹ U.S. Census data for 2007 indicate that there were 452 establishments that were operational in this category of manufacturing during that year. Of that 452, 452 had fewer than 1,000 employees. None had more than 100 employees.¹⁵⁰ Accordingly, the

¹³² U.S. Census Bureau, 2007 Economic Census, Subject Series: Information, “Establishment and Firm Size,” NAICS code 5171103 (released Nov. 19, 2010) (employment size). The data show only two categories within the whole: the categories for 1–4 employees and for 5–9 employees.

¹³³ U.S. Census Bureau, 2007 Economic Census, Subject Series: Information, “Establishment and Firm Size,” NAICS code 5179191 (released Nov. 19, 2010) (receipts size).

¹³⁴ 13 CFR 121.201, NAICS code 517410.

¹³⁵ 13 CFR 121.201, NAICS code 517919.

¹³⁶ U.S. Census Bureau, 2007 NAICS Definitions, “517410 Satellite Telecommunications.”

¹³⁷ See http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-skip=900&-ds_name=EC0751SSSZ4&-lang=en.

¹³⁸ http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-skip=900&-ds_name=EC0751SSSZ4&-lang=en.

¹³⁹ <http://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=517919&search=2007%20NAICS%20Search>.

¹⁴⁰ U.S. Cens http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-skip=900&-ds_name=EC0751SSSZ4&-lang=en.

¹⁴¹ http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-skip=900&-ds_name=EC0751SSSZ4&-lang=en.

¹⁴² <http://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=334220&search=2007%20NAICS%20Search>.

¹⁴³ NAICS Code 334220, 13 CFR 121.201 (Effective August 8, 2008 to November 4, 2011).

¹⁴⁴ http://factfinder.census.gov/servlet/IBQTable?_bm=y&-ds_name=EC0731SG3&-ib_type=NAICS2007&-NAICS2007=334220.

¹⁴⁵ <http://www.census.gov/cgi-bin/sssd/naics/naicsrch>.

¹⁴⁶ NAICS CODE 334210, 13 CFR 121.201 (Effective August 8, 2008 to November 4, 2011).

¹⁴⁷ http://factfinder.census.gov/servlet/IBQTable?_bm=y&-ds_name=EC0731SG3&-ib_type=NAICS2007&-NAICS2007=334210.

¹⁴⁸ <http://www.census.gov/naics/2007/def/ND334290.HTM>.

¹⁴⁹ NAICS CODE 334290, 13 CFR 121.201 (Effective August 8, 2008 to November 4, 2011).

¹⁵⁰ http://factfinder.census.gov/servlet/IBQTable?_bm=y&-ds_name=EC0731SG3&-ib_type=NAICS2007&-NAICS2007=334290.

Commission concludes that all of the businesses in this category were small.

4. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

45. The compliance requirement is that facilities-based providers of commercial mobile data services are required to offer data roaming arrangements to other such providers on commercially reasonable terms and conditions.

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

46. The RFA requires an agency to describe any significant alternatives that it has considered in developing its approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.¹⁵¹

47. The adoption of a data roaming rule will benefit small providers in many ways. The record in this proceeding shows that, among other things, many small providers have had difficulty negotiating data roaming agreements with nationwide providers on commercially reasonable terms. The data roaming rule will benefit small providers by helping them to maintain their ability to compete with the major national providers, and ensuring that consumers of such small providers have access to data services when they travel outside of their provider's network coverage. Additionally, the data roaming will help to encourage investment by ensuring that small providers wanting to invest in their networks or expand their coverage into new areas can offer subscribers a competitive level of coverage during the early period of investment and buildout.

48. With respect to data roaming disputes, the Commission establishes a complaint process similar to the complaint process available under the current roaming obligations for interconnected voice and data services. Under the dispute resolution procedures established, providers, including small providers, may file a complaint or file a petition for declaratory ruling to

resolve any disputes arising out of the data roaming rule adopted. Additionally, although all data roaming complaints will not automatically be placed on the Accelerated Docket, an affected small provider can seek consideration of its complaint under the Commission's Accelerated Docket rules and procedures where appropriate. Furthermore, during ongoing negotiations for data roaming, parties (including small providers) can seek Commission dispute resolution for claims such as, for example, those regarding the commercial reasonableness of the negotiations, providers' conduct, and the terms and conditions of the proffered data roaming arrangement. With respect to claims regarding the commercial reasonableness of the proffered terms and conditions, including prices, the Commission staff may, in resolving such claims, require both parties to provide to the Commission their best and final offers (final offers). This dispute resolution mechanism offers small providers an avenue to have disputes resolved in the event the parties are not able to agree on terms.

49. In light of the benefits described above that small providers will likely receive as a result of the adoption of the data roaming rule, and the extensive and uniform record support from small providers for a data roaming rule consistent with the Commission's approach, the Commission does not address any significant alternatives considered in developing that approach.

6. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

50. None.

B. Final Paperwork Reduction Act Analysis

70. This document contains modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104-13. It will be submitted to the Office of Management and Budget (OMB) for review under Section 3507(d) of the PRA. OMB, the general public, and other Federal agencies are invited to comment on the modified information collection requirements contained in this proceeding. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, see 44 U.S.C. 3506(c)(4), the Commission seeks specific comment on how the Commission might "further reduce the information collection burden for small business concerns with fewer than 25 employees."

71. In this present document, the Commission has assessed the effects of using the procedural complaint processes established in the Commission's Part 1, Subpart E rules, including applicable filing and discovery procedures, to govern the process for data roaming complaints, and find that this will ensure that voice and data roaming complaints are resolved under a consistent Commission process, which will reduce the regulatory burden of understanding and using these processes, and will allow a party to bring a single proceeding to address a roaming dispute that involves both voice and data services. This will, in turn, be more efficient for providers and result in faster resolution of such disputes.

C. Congressional Review Act

72. The Commission will send a copy of this Second Report and Order to Congress and the Government Accountability Office, pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).

D. Accessible Formats

73. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an e-mail to fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice) or 202-418-0432 (TTY).

IV. Ordering Clauses

74. Accordingly, *it is ordered*, pursuant to the authority contained in Sections 1, 4(i), 4(j), 301, 303, 304, 309, 316, and 332 of the Communications Act of 1934, as amended, and Section 706 of the Telecommunications Act of 1996, as amended, 47 U.S.C. 151, 154(i), 154(j), 301, 303, 304, 309, 316, 332, and 1302, that this *second report and order* in WT Docket No. 05-265 *is hereby adopted*.

75. *It is further ordered* that Parts 0 and 20 of the Commission's rules, 47 CFR Parts 0 and 20, are *Amended* as set forth in Appendix A, and such rule amendments shall be effective 30 days after the date of publication of the text thereof in the **Federal Register**, except for § 20.12(e)(2), which contains an information collection that is subject to OMB approval.

76. *It is further ordered* that § 20.12(e)(2) and the information collection contained in this Second Report and Order *will become effective* following approval by the Office of Management and Budget. The Commission will publish a document at

¹⁵¹ See 5 U.S.C. 603(c).

a later date establishing the effective date.

77. *It is further ordered* that, pursuant to Section 5(c) of the Communications Act of 1934, as amended, 47 U.S.C. 155(c), the Enforcement Bureau and the Wireless Telecommunications Bureau are granted delegated authority to resolve any disputes arising out of the data roaming rule, as set forth in this *second report and order* and the rules in Appendix A.

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

79. *It is further ordered* that the Commission *shall send* a copy of this *second report and order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).

List of Subjects

47 CFR Part 0

Organization and functions
(Government agencies).

47 CFR Part 20

Communications common carriers.
Federal Communications Commission.

Bulah P. Wheeler,
Deputy Manager.

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR parts 0 and 20 as follows:

PART 0—COMMISSION ORGANIZATION

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

Authority: Secs. 5, 48 Stat. 1068, as amended; 47 U.S.C. 155.

■ 2. Amend § 0.111 by revising paragraph (a)(11) introductory text (note remains unchanged) to read as follows:

§ 0.111 Functions of Bureau.

(a) * * *

(11) Resolves other complaints against Title III licensees and permittees, including complaints under § 20.12(e) of this chapter.

* * * * *

PART 20—COMMERCIAL MOBILE SERVICES

■ 3. The authority citation for part 20 is revised to read as follows:

Authority: 47 U.S.C. 154, 160, 201, 251–254, 301, 303, 316, and 332 unless otherwise noted. Section 20.12 is also issued under 47 U.S.C. 1302.

■ 4. Revise the heading to part 20 to read as set forth above.

■ 5. Amend § 20.3 by adding the definition “commercial mobile data service” in alphabetical order to read as follows:

§ 20.3 Definitions.

* * * * *

Commercial mobile data service. (1) Any mobile data service that is not interconnected with the public switched network and is:

- (i) Provided for profit; and
- (ii) Available to the public or to such classes of eligible users as to be effectively available to the public.

(2) Commercial mobile data service includes services provided by Mobile Satellite Services and Ancillary Terrestrial Component providers to the extent the services provided meet this definition.

* * * * *

■ 6. Amend § 20.12 by adding paragraphs (a)(3) and (e) to read as follows:

§ 20.12 Resale and roaming.

(a) * * *

(3) *Scope of Offering Roaming Arrangements for Commercial Mobile Data Services.* Paragraph (e) of this section is applicable to all facilities-based providers of commercial mobile data services.

* * * * *

(e) *Offering Roaming Arrangements for Commercial Mobile Data Services.*

(1) A facilities-based provider of commercial mobile data services is required to offer roaming arrangements to other such providers on commercially reasonable terms and conditions, subject to the following limitations:

(i) Providers may negotiate the terms of their roaming arrangements on an individualized basis;

(ii) It is reasonable for a provider not to offer a data roaming arrangement to a requesting provider that is not technologically compatible;

(iii) It is reasonable for a provider not to offer a data roaming arrangement where it is not technically feasible to provide roaming for the particular data service for which roaming is requested and any changes to the host provider's network necessary to accommodate roaming for such data service are not economically reasonable;

(iv) It is reasonable for a provider to condition the effectiveness of a roaming arrangement on the requesting

provider's provision of mobile data service to its own subscribers using a generation of wireless technology comparable to the technology on which the requesting provider seeks to roam.

(2) A party alleging a violation of this section may file a formal or informal complaint pursuant to the procedures in §§ 1.716 through 1.718, 1.720, 1.721, and 1.723 through 1.735 of this chapter, which sections are incorporated herein. For purposes of § 20.12(e), references to a “carrier” or “common carrier” in the formal and informal complaint procedures incorporated herein will mean a provider of commercial mobile data services. The Commission will resolve such disputes on a case-by-case basis, taking into consideration the totality of the circumstances presented in each case. The remedy of damages shall not be available in connection with any complaint alleging a violation of this section. Whether the appropriate procedural vehicle for a dispute is a complaint under this paragraph or a petition for declaratory ruling under § 1.2 of this chapter may vary depending on the circumstances of each case.

[FR Doc. 2011–10223 Filed 5–5–11; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 19

[FAC 2005–50; FAR Case 2011–004; Docket 2011–0004; Sequence 1]

RIN 9000–AL88

Federal Acquisition Regulation; Socioeconomic Program Parity

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to the interim rule which published in the **Federal Register** of Wednesday, March 16, 2011 (76 FR 14568). The regulations implement section 1347 of the “Small Business Jobs Act of 2010.”

DATES: Effective on May 6, 2011.

FOR FURTHER INFORMATION CONTACT: Mr. Karlos Morgan, Procurement Analyst, at (202) 501–2364. Please cite FAC 2005–50; FAR Case 2011–004.

SUPPLEMENTARY INFORMATION:**Background**

Section 1347 of the Small Business Jobs Act of 2010, clarifies the contracting officer's ability to use discretion when determining whether an acquisition will be restricted to small businesses participating in the 8(a), HUBZone, or Service-disabled veteran-owned (SDVOSB) programs. There is no order of priority among small businesses in the 8(a) Business Development program, the HUBZone program, or the SDVOSB program.

Need for Correction

As published, the regulations contain a technical error in the promulgated rule.

List of Subjects in 48 CFR Part 19

Government procurement.

Accordingly, 48 CFR part 19 is corrected by making the following correcting amendment:

PART 19—SMALL BUSINESS PROGRAMS

■ 1. The authority citation for 48 CFR part 19 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

■ 2. Amend section 19.502–2 by revising paragraph (b) to read as follows:

19.502–2 Total small business set-asides.

* * * * *

(b) Before setting aside an acquisition under this paragraph, refer to 19.203(c). The contracting officer shall set aside any acquisition over \$150,000 for small business participation when there is a reasonable expectation that:

(1) Offers will be obtained from at least two responsible small business concerns offering the products of different small business concerns (see paragraph (c) of this section); and

(2) Award will be made at fair market prices. Total small business set-asides shall not be made unless such a

reasonable expectation exists (see 19.502–3 as to partial set-asides). Although past acquisition history of an item or similar items is always important, it is not the only factor to be considered in determining whether a reasonable expectation exists. In making R&D small business set-asides, there must also be a reasonable expectation of obtaining from small businesses the best scientific and technological sources consistent with the demands of the proposed acquisition for the best mix of cost, performances, and schedules.

* * * * *

Dated: May 3, 2011.

Millisa Gary,

Acting Director, Office of Governmentwide Acquisition Policy.

[FR Doc. 2011–11117 Filed 5–5–11; 8:45 am]

BILLING CODE 6820–EP–P

Proposed Rules

Federal Register

Vol. 76, No. 88

Friday, May 6, 2011

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 54 and 62

[Doc. No. AMS-LS-11-0039]

Request for Extension and Revision of a Currently Approved Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this document announces the Agricultural Marketing Service's (AMS) intention to request approval, from the Office of Management and Budget, for an extension of and revision to the currently approved information collection 7 CFR part 54 Meats, Prepared Meats, and Meat Products (Grading, Certification, and Standards) and 7 CFR part 62 Quality Systems Verification Program (QSVP).

DATES: Comments on this document must be received by July 5, 2011 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit comments concerning this information collection document. Comments should be submitted online at <http://www.regulations.gov> or sent to James Riva, Chief, Audit, Review and Compliance Branch, Livestock and Seed Program, Agricultural Marketing Service, U.S. Department of Agriculture, 100 Riverside Parkway, Suite 101, Fredericksburg, Virginia, 22406, or by facsimile to (202) 690-1038. All comments should reference the docket number (AMS-LS-11-0039), the date, and the page number of this issue of the **Federal Register**. All comments received will be posted without change, including any personal information provided, online at <http://www.regulations.gov> and will be made available for public inspection at the

above physical address during regular business hours.

FOR FURTHER INFORMATION CONTACT:

James Riva at the above physical address, by telephone (540) 361-2740, or by e-mail at James.Riva@ams.usda.gov.

SUPPLEMENTARY INFORMATION:

Title: 7 CFR part 54 Meats, Prepared Meats, and Meat Products (Grading, Certification, and Standards) and 7 CFR part 62 Quality Systems Verification Program (QSVP).

OMB Number: 0581-0124.

Expiration Date of Approval: December 31, 2011.

Type of Request: Extension and revision of a currently approved information collection.

Abstract: The Agricultural Marketing Act of 1946, (7 U.S.C. 1621 *et seq.*) as amended, authorizes the Secretary of Agriculture to provide consumers with voluntary Federal meat grading and certification services that facilitate the marketing of meat and meat products. This is accomplished by providing meat and meat products that are uniform in quality. The Meat Grading and Certification (MGC) Branch provides these services under the authority of 7 CFR Part 54—Meats, Prepared Meats, and Meat Products (Grading, Certification, and Standards).

Due to the voluntary nature of grading and certification services, 7 CFR part 54 contains provisions for the collection of fees from users of MGC Branch services that nearly as possible are equal to the cost of providing requested services. Applicants (individual or businesses with financial interest in the product) may request services through either submission of Form LS-313, "Application for Service," or Form LS-315, "Application for Commitment Grading or Certification Service."

Also, under the authority of the 1946 Act, the Audit, Review, and Compliance (ARC) Branch conducts verification audits of the production process in accordance with procedures that are contained in 7 CFR Part 62—Quality Systems Verification Program (QSVP). QSVP is a collection of voluntary, audit-based, user-fee funded programs that allow applicants to have program documentation and program processes assessed by AMS auditor(s) and other U.S. Department of Agriculture (USDA) officials. QSVP are user-fee programs

based on the approved hourly rate established under 7 CFR part 62.

Applicants (individual or business with financial interest in the product) may request verification services through the submission of Form-313 "Application for Service." In addition to the application for service, applicant would have to develop a technical proposal documenting their quality management system.

Congress did not specifically authorize this information collection, but as a user-fee service, completion and submission of Form LS-313 or Form LS-315 serve as a legal agreement and assures payment for services provided.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 7 minutes per response.

Respondents: Livestock and meat industry or other for-profit businesses.

Estimated Number of Respondents: 83 respondents.

Estimated Total Annual Responses: 11,588 responses.

Estimated Number of Responses per Respondent: 140 responses.

Estimated Total Annual Burden on Respondents: 1,423 hours.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this document will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Dated: April 29, 2011.

David R. Shipman,
Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2011-11048 Filed 5-5-11; 8:45 am]

BILLING CODE 3410-02-P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[Docket No. PRM-50-96; NRC-2011-0069]

Petition for Rulemaking Submitted by Thomas Popik

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; receipt and request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is publishing for public comment a notice of receipt for a petition for rulemaking (PRM), dated March 14, 2011, which was filed with the NRC by Thomas Popik. The petition was docketed by the NRC on March 15, 2011, and has been assigned Docket No. PRM-50-96. The petition requests that the NRC amend its regulations regarding the domestic licensing of special nuclear material to require production and utilization facilities licensed by the NRC to assure long-term cooling and unattended water makeup of spent fuel pools.

DATES: Submit comments by July 20, 2011. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: Please include Docket ID NRC-2011-0069 in the subject line of your comments. For instructions on submitting comments and accessing documents related to this action, see "Submitting Comments and Accessing Information" in the **SUPPLEMENTARY INFORMATION** section of this document. You may submit comments by any one of the following methods:

- **Federal rulemaking Web site:** Go to <http://www.regulations.gov> and search for documents filed under Docket ID NRC-2011-0069. Address questions about NRC dockets to Carol Gallagher, telephone: 301-492-3668; e-mail: Carol.Gallagher@nrc.gov.

- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attn: Rulemakings and Adjudications Staff.

- **E-mail comments to:** Rulemaking.Comments@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301-415-1677.

- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852 between 7:30 a.m. and 4:15 p.m. during Federal workdays (telephone: 301-415-1677).

- **Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

FOR FURTHER INFORMATION CONTACT:

Cindy Bladey, Chief, Rules, Announcements, and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-492-3667, toll free: 800-368-5642, e-mail: Cindy.Bladey@nrc.gov.

SUPPLEMENTARY INFORMATION:

Submitting Comments and Accessing Information

Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site, <http://www.regulations.gov>. 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.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

You can access publicly available documents related to this document using the following methods:

- **NRC's Public Document Room (PDR):** The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** Publicly available documents created or received at the NRC are available electronically in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. From this page, the public can gain entry into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS Accession Nos. for this document and the incoming petition are ML110830730 and ML110750145, respectively.

- **Federal Rulemaking Web site:** Public comments and supporting materials related to this petition for

rulemaking can be found at <http://www.regulations.gov> by searching on Docket ID NRC-2011-0069.

Petitioner

The NRC received a petition for rulemaking on March 14, 2011 (PRM-50-96). The petition was submitted by Mr. Thomas Popik on behalf of the Foundation for Resilient Societies (the Foundation). The petition states that the Foundation is an association within the U.S. with an interest in citizens' health and safety, and an interest [in ensuring] that large U.S. land areas do not become contaminated with nuclear radiation and, therefore, uninhabitable for hundreds of years. The NRC was unable to confirm the existence of the Foundation.¹ The NRC requires in 10 CFR 2.802(c)(2) that each petition for rulemaking "[s]tate clearly and concisely petitioner's grounds for an interest in the action requested." The NRC has consistently interpreted this as requiring that the petitioner accurately identify itself, in part so that the NRC is able to evaluate the accuracy and weight to be given to any representations made by the petitioner in its petition. In light of the NRC's inability to confirm the Foundation as an actual organization, the NRC is treating Mr. Popik as the petitioner.²

Background

Grounds for Action Requested

The petitioner is requesting that the NRC amend its regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50 to address concerns about the effects of long-term commercial grid outage on spent fuel pool cooling and water makeup. The petitioner states that "in the event of a long-term loss of

¹ The original e-mail and petition submitted by Mr. Popik did not include any contact information for Mr. Popik or a mailing address for the Foundation. In response to an NRC inquiry, Mr. Popik provided a Nashua, New Hampshire mailing address for the Foundation (ML111080495). The NRC identified a Web site for the Foundation, which contains a news release on the petition, and a pdf file of the petition. The Web site provides no information describing the Foundation, its purpose or objectives, or the organizational structure of the Foundation. The only Foundation contact provided on the Web site is Mr. Popik. The NRC's search of the web did not disclose any information on the activities of the Foundation other than news articles about the Foundation's petition. The NRC was unable to identify the Foundation in a State of New Hampshire database of businesses and organizations registered in New Hampshire.

² If the NRC receives additional information sufficient to establish the Foundation as an entity independent of Mr. Popik, then the NRC will re-characterize the petitioner of PRM-50-96 as the Foundation, rather than Mr. Popik. Notice of any action in this regard will be placed on the <http://www.regulations.gov> Web site for this petition, and in the **Federal Register** notice of the NRC's resolution of PRM-50-96.

commercial grid power extending beyond a month, it is likely that water in spent fuel pools would heat up and boil off, fuel rods would become uncovered by water, zirconium cladding would catch fire, and large amounts of dangerous radionuclides would be released into the atmosphere.”

The petitioner states that “a primary rationale for this proposed amendment is a recently documented vulnerability of the North American power grids to severe space weather which could cause multiple-year power outages.” In addition, the petitioner states that “a government-sponsored study of second-order effects of commercial grid failure on petrochemical fuel and food supplies shows that any assumption of outside assistance to nuclear power plants, including resupply of diesel fuel and food, may not be valid.” The risks to the North American commercial grids from space weather and geomagnetic disturbance, and the effects of a commercial outage on the petrochemical fuel resupply and food and water supply are discussed in the petition.

The petition also expresses the petitioner's views on: (1) The necessity for the Department of Homeland Security to include in its National Security Guidelines a scenario for severe space weather and geomagnetic disturbance and the associated long-term and widespread commercial grid outage; (2) the August 1988 Oak Ridge National Laboratory (ORNL) and NRC Report ORNL/NRC/LTR-98/12, “Evaluation of the Reliability for the Offsite Power Supply as a Contributor to the Risk of Nuclear Plants”; (3) the regulatory actions after the 2003 northeastern blackout; (4) the necessity for the North American Electric Reliability Council to publish a reliability standard for geomagnetic disturbance; and (5) the role of other Government agencies in protecting “public health and safety in regard to geomagnetic disturbance.”

In addition, the petitioner discusses the NRC's probabilistic risk assessment (PRA) in NUREG-1738, “Technical Study of Spent Fuel Pool Accident Risk at Decommissioning Nuclear Power Plants,” February 2001, and proposes a “PRA to more precisely gauge the probability of zirconium fires at spent fuel pools due to geomagnetic disturbance and resulting long-term Loss of Outside Power (LOOP).” The petitioner stated that the purpose of the PRA is “to show that an amendment to the CFR is required.”

The Petition

The petitioner requests that the NRC amend its regulations in 10 CFR Part 50

to require licensees to provide reliable emergency systems to assure long-term cooling and water makeup for spent fuel pools using only onsite power sources. Specifically, the petitioner proposes amending 10 CFR Part 50 to require that the emergency systems be able to operate for a period of 2 years without human operator intervention and without offsite fuel resupply and that backup power systems for spent fuel pools be electrically isolated from other plant electrical systems during normal and emergency operation. In addition, the petitioner requests the NRC revise its requirements to state if weather-dependent power sources are used, sufficient water or power storage must be provided to maintain continual cooling during weather conditions which may temporarily constrict power generation.

Dated at Rockville, Maryland, this 2nd day of May 2011.

For the Nuclear Regulatory Commission.
Annette L. Vietti-Cook,
Secretary of the Commission.

[FR Doc. 2011-11112 Filed 5-5-11; 8:45 am]

BILLING CODE 7590-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R09-OAR-2011-0302; FRL-9292-5]

Revisions to the California State Implementation Plan, Northern Sonoma County Air Pollution Control District (NSCAPCD) and Mendocino County Air Quality Management District (MCAQMD)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the Northern Sonoma County Air Pollution Control District (NSCAPCD) and Mendocino County Air Quality Management District (MCAQMD) portions of the California State Implementation Plan (SIP). Both districts are required under Part C of title I of the Clean Air Act (CAA) to adopt and implement SIP-approved Prevention of Significant Deterioration (PSD) permit programs. These proposed revisions update the definitions used in the districts' PSD permit programs.

DATES: Any comments on this proposal must arrive by June 6, 2011.

ADDRESSES: Submit comments, identified by docket number EPA-R09-OAR-2011-0302, by one of the following methods:

1. *Federal eRulemaking Portal:* www.regulations.gov. Follow the on-line instructions.

2. *E-mail:* R9airpermits@epa.gov

3. *Mail or deliver:* Gerardo Rios (Air-3), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105-3901.

Instructions: All comments 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through <http://www.regulations.gov> or e-mail. <http://www.regulations.gov> is an “anonymous access” system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: EPA has established a docket for this action under EPA-R09-OAR-2011-0302. Generally, documents in the docket for this action are available electronically at <http://www.regulations.gov> or in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed at <http://www.regulations.gov>, some information may be publicly available only at the hard copy location (e.g., copyrighted material, large maps, multi-volume reports) and some may not be available in either location (e.g., confidential business information (CBI)). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Laura Yannayon, EPA Region IX, (415) 972-3534, yannayon.laura@epa.gov.

SUPPLEMENTARY INFORMATION: This proposal addresses the following local rules: Northern Sonoma County Air Pollution Control District (NSCAPCD) Rule 130—Definitions and Mendocino County Air Quality Management District (MCAQMD) Rule 130—Definitions. In

the Rules and Regulations section of this **Federal Register**, we are approving these local rules in a direct final action without prior proposal because we believe these SIP revisions are not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in subsequent action based on this proposed rule. Please note that if we receive adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

We do not plan to open a second comment period, so anyone interested in commenting should do so at this time. If we do not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

Dated: March 31, 2011.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2011-11035 Filed 5-5-11; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2010-0630; FRL-8871-7]

RIN 2070-AJ71

Elemental Mercury Used in Barometers, Manometers, Hygrometers/Psychrometers; Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for elemental mercury for use in barometers, manometers, and hygrometers/psychrometers. This action would require persons who intend to manufacture (including import) or process elemental mercury for an activity that is designated as a significant new use by this proposed rule to notify EPA at least 90 days before commencing that activity. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs. Not included in this proposed SNUR is mercury use in barometers, manometers, and hygrometers/psychrometers when

they are in service as of the publication date of this proposed rule and mercury use in portable battery-powered motor-aspirated psychrometers that contain fewer than seven grams of elemental mercury because they are currently manufactured. For this proposed rule, the general SNUR exemption for persons that import or process chemical substances as part of an article at § 721.45(f) would not apply.

DATES: Comments must be received on or before July 5, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2010-0630, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA-HQ-OPPT-2010-0630. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2010-0630. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line 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 www.regulations.gov or e-mail. The www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other

contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. 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 electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Sue Slotnick, National Program Chemicals Division (7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 556-1973; e-mail address: slotnick.sue@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (defined by statute to include import) or process elemental mercury used in barometers, manometers, or hygrometers/

psychrometers. Potentially affected entities may include, but are not limited to:

- Manufacturers of instruments and related products for measuring, displaying, and controlling industrial process variables (NAICS code 334513).

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 in this unit could also be affected. The North American Industrial Classification System (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**.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after June 6, 2011 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D. Note that as of January 1, 2013, the Mercury Export Ban Act of 2008 prohibits the export of elemental mercury from the United States (see TSCA section 12(c) (15 U.S.C. 2611(c))).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a

copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What action is the agency taking?

This proposed SNUR would require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of elemental mercury for any of the following significant new uses: Barometers, manometers, and hygrometers/psychrometers. Not included in this proposed rule are barometers, manometers, and hygrometers/psychrometers when they are in service as of the publication date of this proposed rule. Also not included in this proposal is the ongoing use of mercury in the manufacture, import, or processing of portable battery-powered motor-aspirated psychrometers that contain fewer than seven grams of elemental mercury because they are currently manufactured. Sphygmomanometers and other “devices” as defined under section 201 of the Federal Food, Drug, and Cosmetics Act (FFDCA) would not be affected by this proposed rule when manufactured, imported, or processed for use as a device (see TSCA

3(2)(B)(vi)). Finally, manometers used in the natural gas industry would not be affected by this proposed rule because they were included in a previous SNUR (75 FR 42330, July 21, 2010) (FRL–8832–2).

B. What is the agency’s authority for taking this action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering “all relevant factors including:

- The projected volume of manufacturing and processing of a chemical substance,
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.”

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)). As described in Unit II.C., the general SNUR provisions are found at 40 CFR part 721, subpart A.

C. Applicability of General Provisions

General provisions for SNURs appear under 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule. However, 40 CFR 721.45(f) would not apply to this proposed SNUR. As a result, persons subject to the provisions of this proposed rule would not be exempt from significant new use reporting if they import or process elemental mercury as part of an article (see § 721.5). Conversely, the exemption from notification requirements for exported articles (see § 707.60(b)) would remain in force. Thus, persons who export elemental mercury as part of an

article would not be required to provide export notification.

Provisions relating to user fees appear at 40 CFR part 700. According to 40 CFR 721.1(c), persons subject to SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of Premanufacture Notices (PMNs) under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, the Agency may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities on which it has received the SNUN. If EPA does not take action, the Agency is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

Persons who export or intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. Persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, codified at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Such persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B.

III. Summary of Proposed Rule

A. Overview of Mercury and Mercury Uses

1. *Mercury.* This proposed rule applies to elemental mercury (CAS No. 7439-97-6), which is a naturally occurring element. Because of its unique properties (*e.g.*, exists as a liquid at room temperature and forms amalgams with many metals), elemental mercury has been used in many industrial processes and consumer products. In addition to its useful characteristics, mercury also is known to cause adverse health effects in humans and wildlife. These effects can vary depending on the form of mercury to which a person or animal is exposed, as well as the magnitude, duration, and frequency of exposure.

The most prevalent human and wildlife exposure to mercury results from ingesting fish contaminated with methylmercury. Methylmercury is an

organo-metallic compound that is formed via the conversion of elemental or inorganic mercury compounds by certain microorganisms and other natural processes. For example, elemental mercury may evaporate and be emitted into the atmosphere. Atmospheric mercury can then be deposited directly into water bodies or watersheds, where it can be washed into surface waters via overland run-off. Once deposited in sediments, certain microorganisms and other natural processes can convert elemental mercury into methylmercury. Methylmercury bioaccumulates, which means that it is taken up and concentrated in the tissues of aquatic, mammalian, avian, and other wildlife. Methylmercury is a highly toxic substance; a number of adverse health effects associated with exposure to it have been identified in humans and in animal studies. Most extensive are the data on neurotoxicity, particularly in developing organisms. Fetuses, infants, and young children generally are more sensitive to methylmercury's neurological effects than adults.

In 2004, EPA and the Food and Drug Administration (FDA) issued a national consumption advisory concerning mercury in fish. The advisory contains recommended limits on the amount of certain types of fish and shellfish that pregnant women and young children can safely consume. By 2005, all fifty states had issued fish consumption advisories for fish from certain water bodies known to be contaminated by methylmercury <http://www.epa.gov/mercury/advisories.htm>.

In addition to methylmercury, exposure to elemental mercury can also pose health risks. Elemental mercury primarily causes health effects when it is breathed as a vapor that can be absorbed through the lungs. These exposures can occur when elemental mercury is spilled or products that contain elemental mercury break, resulting in release of mercury to the air, particularly in warm or poorly-ventilated indoor spaces.

For a more detailed summary of background information (*e.g.*, chemistry, environmental fate, exposure pathways, and health and environmental effects), as well as references pertaining to elemental mercury that EPA considered before proposing this rule, please refer to EPA's proposed SNUR for mercury switches in motor vehicles, issued in the **Federal Register** of July 11, 2006 (71 FR 39035) (FRL-7733-9), or in the docket for the 2006 proposal under docket identification number EPA-HQ-OPPT-2005-0036. All documents in the docket are listed in the docket's index,

which is available at <http://www.regulations.gov>.

2. *Mercury uses.* Elemental mercury has been used in thousands of products and applications. Over the past two decades, there has been a dramatic drop in elemental mercury use by industries in the United States. In response to increased concerns about exposure to anthropogenic sources of mercury in the environment and also because of the availability of suitable mercury-free products, Federal and State governments have made efforts to limit the use of elemental mercury in certain products. Various states have banned or restricted the manufacture or sale of products containing mercury. While this is not the rationale for this proposed rule, it does indicate that the transition to cost-effective non-mercury containing alternatives is already established (see <http://www.epa.gov/epawaste/hazard/tsd/mercury/laws.htm>).

On October 5, 2007, EPA issued a final SNUR for elemental mercury used in convenience light switches, anti-lock braking system switches, and active ride control system switches in certain motor vehicles (72 FR 56903, October 5, 2007) (FRL-8110-5). EPA promulgated another SNUR for flow meters, natural gas manometers, and pyrometers on July 21, 2010 (75 FR 42330). For more information on EPA activities on mercury in products and other areas, see <http://www.epa.gov/hg>.

In the past, elemental mercury was used in the manufacture of barometers, manometers, and hygrometers/psychrometers. The latest information available to EPA indicates that the manufacture (including import) of these mercury-containing articles has ceased (with the exception of one psychrometer as described at Unit III.A.5.). EPA also has found that all three products subject to the proposed SNUR currently have effective and economically feasible substitutes (Ref. 1). EPA requests comments on whether elemental mercury continues to be used in manufacturing (including importing into the U.S.) barometers, manometers, or hygrometers/psychrometers. EPA also requests comment on whether elemental mercury is being used in the remanufacturing of any of these articles that remain in use.

3. *Barometers containing elemental mercury.* Barometers are instruments which measure atmospheric pressure. Mercury barometers were manufactured as a long cylindrical tube, typically closed at one end, with a mercury-filled reservoir at the base. The weight of mercury created a vacuum at the top of the tube, and the mercury adjusted until the pressure inside the reservoir equaled

the atmospheric pressure. Rising mercury indicated increasing air pressure while dropping mercury indicated decreasing air pressure. Historically, mercury barometers were used in applications where measuring and monitoring changes in air pressure are important, such as weather stations, airports, and ships. Additional uses include scientific demonstration in schools and non-mercury device calibration. A mercury barometer contains between 400 and 620 grams of mercury (Ref. 1).

Alternatives to mercury-containing barometers include aneroid, electronic, and other liquid-based (water or eco-celli) barometers. At least eight states have banned the sale of mercury-containing barometers. EPA found sufficient information to conclude that mercury-containing barometers are no longer manufactured in or imported into the U.S. (Ref. 1).

4. *Manometers containing elemental mercury.* A manometer is an instrument used to measure pressure of gases or liquids. Mercury-containing manometers were manufactured for use in sectors such as dairy farms, heating ventilation and air conditioning/plumbing installation and repair, auto/motorcycle industry, laboratories; and in general industrial uses. The amount of mercury used in a single manometer ranged between approximately 30 grams and 525 grams (Ref. 1).

Alternatives to mercury manometers include hydrostatic gauges using mercury-free liquid, aneroid manometers, needle-bourdon gauges, and digital manometers. At least five states have banned the sale of mercury-containing manometers, and four additional states have banned the sale of mercury-containing dairy manometers (Ref. 1). EPA found sufficient information to conclude that mercury-containing manometers are no longer manufactured in or imported into the U.S. (Ref. 1).

5. *Hygrometers/psychrometers containing elemental mercury.* Hygrometers are instruments used to measure relative humidity (*i.e.*, the moisture content of the air). Psychrometers, which are the most common type of hygrometer, use two mercury-added thermometers, one with a wetted base, and one with a dry base. Hygrometers and psychrometers function similarly; however, they are used in different applications. Historically, mercury-containing hygrometers were used for cigar and tobacco humidors, or in residential settings, while mercury-containing psychrometers were used by atmospheric scientists and weather

enthusiasts. The amount of mercury in a single hygrometer or psychrometer was between three and seven grams.

There are two types of alternatives to mercury-added hygrometers that are readily available and widely used: Spirit-filled devices, which use methyl alcohol or citrus oil thermometers and provide results with comparable accuracy to mercury-added thermometers; and digital devices, which use electronic sensors to measure humidity changes and, when calibrated properly, provide results that are as accurate as mercury devices.

Seven states have banned the sale and distribution of mercury-containing hygrometers and psychrometers and three additional states have general phase-outs of mercury-added products. EPA found sufficient information to conclude that only one type of mercury-containing hygrometer/psychrometer is manufactured in or imported into the U.S. That one type is a portable battery-powered motor-aspirated psychrometer containing fewer than seven grams of elemental mercury (Ref. 1).

6. *Potential exposure and release.* The typical lifecycle of barometers, manometers, and hygrometers/psychrometers includes several stages: Manufacture, distribution in commerce, use, and waste management (landfilling or recycling). At any point in the lifecycle, there is potential for mercury to be released as liquid or vapor. Workers and others can be exposed to the mercury and it can be released into water, air, or onto land as the mercury is transported, stored, and handled during manufacturing. While the barometers, manometers, and hygrometers/psychrometers are in use, the mercury can vaporize or spill due to breakage during transport, installation, maintenance, refilling, or repair. Other opportunities for release can occur at the end of the lifecycle of barometers, manometers, and hygrometers/psychrometers as these devices are removed from equipment and facilities and handled during waste management.

B. Proposed Action

EPA is proposing to designate as significant new uses the use of elemental mercury in barometers, manometers, and hygrometers/psychrometers. However, use of elemental mercury in these articles when they are in service as of the publication date of this proposed rule would not be covered as a significant new use under this proposed SNUR. Also, use of mercury in portable battery-powered motor-aspirated psychrometers that contain fewer than seven grams of mercury is an ongoing use and therefore

would not be covered by this SNUR. Due to EPA's concern about use of mercury in products, the Agency may take other action to facilitate the evaluation or control of ongoing uses, as appropriate. For the portable battery-powered motor-aspirated psychrometers that contain fewer than seven grams of mercury, EPA is considering whether risk management or other actions would be appropriate. Use of mercury in manometers used in the natural gas industry would not be affected by this proposed SNUR because they are included in a previous SNUR (75 FR 42330, July 21, 2010). Proposed definitions of barometer, manometer, hygrometer and psychrometer can be found in § 721.10068 of the regulatory text in this proposed rule.

This action would amend § 721.10068 and require persons who intend to manufacture or process elemental mercury for a use designated by this proposed rule as a significant new use to notify EPA at least 90 days before commencing the manufacturing or processing of elemental mercury for such significant new use. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

For this SNUR, EPA is proposing not to include the general "article" exemption at § 721.45(f). Thus, persons importing or processing elemental mercury (including when part of an article) for a significant new use would be subject to the notification requirements of § 721.25. EPA proposes not to include this exemption because barometers, manometers, and hygrometers/psychrometers are articles, and a primary concern associated with this SNUR is potential exposures associated with the lifecycle of these uses. Further, it is possible to reclaim elemental mercury from certain articles, which could be used to produce barometers, manometers, or hygrometers/psychrometers. EPA notes that, in accordance with TSCA section 12(a) and § 721.45(g), persons who manufacture or process elemental mercury solely for export would be exempt from the notification requirements of § 721.25, if when distributing the substance in commerce, it is labeled in accordance with TSCA section 12(a)(1)(B). Further, EPA notes that the exemption from the TSCA section 12(b) notification requirements for exported articles (see § 707.60(b)) would remain in force. Thus, persons who export elemental mercury as part of an article would not be required to provide export notification.

EPA believes elemental mercury is no longer used to manufacture barometers, manometers, and hygrometers/psychrometers (with one exception as discussed), but some of these articles may remain in service in the U.S. The ongoing use of such articles, including some maintenance and servicing activities, falls outside of the scope of this significant new use rule. Thus, the manufacturing and processing of elemental mercury for use in these articles, provided they are in service as of the publication date of this proposed rule, would not be covered by the rule. For example, if an article that is in service as of the publication date of this proposed rule is removed from service for maintenance or servicing, including the addition of new mercury, and then placed back into service, any manufacturing or processing of mercury associated with that maintenance or servicing would not be covered by the rule. Otherwise, the addition of new mercury to these existing articles after the effective date of this proposed rule could potentially trigger a significant new use notice under this proposed rule (e.g., if it involved processing of the mercury), which is not EPA's intent.

IV. Significant New Use Determination

A. Rationale

As summarized in Unit III.A., EPA has concerns regarding the environmental fate and the exposure pathways of elemental mercury that lead to the presence of methylmercury in fish and the consumption of mercury-contaminated fish by humans and wildlife. EPA is encouraged by the general discontinuation of the use of elemental mercury in the manufacturing of barometers, manometers, and hygrometers/psychrometers. However, EPA is concerned that the manufacturing or processing of elemental mercury for the proposed significant new uses could be reinitiated in the future. Accordingly, EPA wants the opportunity to evaluate and control, where appropriate, activities associated with those uses, if such manufacturing or remanufacturing were to occur again. The required notification provided by a SNUN would provide EPA with the opportunity to evaluate activities associated with a significant new use and an opportunity to protect against unreasonable risks, if any, from exposure to mercury.

Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to propose a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or

potential risk associated with that use. Rather, the Agency's action is based on EPA's determination that if the use begins or resumes, it may present a risk that EPA should evaluate under TSCA before the manufacturing or processing for that use begins. Since the new use does not currently exist, deferring a detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the use, the notice to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use.

B. Objectives

Based on the considerations in Unit IV.A., EPA has the following objectives with regard to the significant new uses that are designated in this proposed rule:

1. EPA would receive notice of any person's intent to manufacture or process elemental mercury for any of the described significant new uses before that activity begins.
2. EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing of elemental mercury for any of the described significant new uses.
3. EPA would be able to regulate prospective manufacturers or processors of elemental mercury before the described significant new uses of the chemical substance occur, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6 or 7.

C. Relevant Factors Considered for This SNUR

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors (see further detail at Unit II.B.).

EPA has preliminarily determined that manufacturing or processing of elemental mercury for use in barometers, manometers, or hygrometers/psychrometers is a significant new use. This determination is based on the following factor in TSCA section 5(a)(2): "The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance." Increased exposure to mercury is significant because of the adverse health effects described at Unit III.A.1. The latest information available to EPA indicates that there is no ongoing use of elemental mercury in the manufacture or remanufacture of

barometers, manometers, hygrometers, and all but one type of psychrometer. Resumption of these uses of elemental mercury could increase the magnitude and duration of exposure to workers and the surrounding environment at facilities of all types involved in the lifecycle of the products, as described in greater detail in Unit III.A.6. Increase in releases could contribute additional mercury to the atmosphere for long-range transport. Resumption of these uses could also result in exposures to workers who had not previously worked in these facilities when elemental mercury was commonly used, as well as exposures to workers who are not currently being exposed to mercury in the manufacture of barometers, manometers, or hygrometers/psychrometers. Increases in mercury releases could lead to increases in mercury concentrations in the environment and reduction in overall ecosystem and human health from consumption of mercury-contaminated fish.

EPA believes that any of these renewed uses of elemental mercury would increase the magnitude and duration of exposure to humans and the environment over that which would otherwise exist. Thus, EPA has preliminarily determined that any manufacturing or processing of elemental mercury for use in barometers, manometers, or hygrometers/psychrometers is a significant new use, except for mercury use in barometers, manometers, and hygrometers/psychrometers when they are in service as of the effective date of this proposed rule; and in portable battery-powered motor-aspirated psychrometers that contain less than seven grams of elemental mercury.

D. Request for Comment

EPA welcomes comment on all aspects of this proposed rule, including comments on the basis for the significant new use determinations presented for this proposed rule.

V. Alternatives

Before proposing this SNUR, EPA considered the following alternative regulatory actions.

A. Promulgate a TSCA Section 8(a) Reporting Rule

Under a TSCA section 8(a) rule, EPA could, among other things, generally require persons to report information to the Agency when they intend to manufacture or process a listed chemical for a specific use or any use. However, for elemental mercury used in barometers, manometers, and

hygrometers/psychrometers, the use of TSCA section 8(a) rather than SNUR authority would have several limitations. First, if EPA were to require reporting under TSCA section 8(a) instead of TSCA section 5(a), EPA would not have the opportunity to review human and environmental hazards and exposures associated with the proposed significant new use and, if necessary, take immediate follow-up regulatory action under TSCA sections 5(e) or 5(f) to prohibit or limit the activity before it begins. In addition, EPA may not receive important information from small businesses, because such firms generally are exempt from TSCA section 8(a) reporting requirements. In view of the level of health and environmental concerns about elemental mercury, if used for the proposed significant new uses, EPA believes that a TSCA section 8(a) rule for this substance would not meet EPA's regulatory objectives.

B. Regulate Elemental Mercury for Use in Barometers, Manometers, and Hygrometers/Psychrometers Under TSCA Section 6

EPA may regulate under TSCA section 6 if "the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture * * * presents or will present an unreasonable risk of injury to health or the environment" (TSCA section 6(a)). Given that elemental mercury is no longer being used in the manufacture of barometers, manometers, or hygrometers/psychrometers (with the exception of one psychrometer), EPA concluded that risk management action under TSCA section 6 is not necessary at this time. This proposed SNUR would allow the Agency to address the potential risks associated with the proposed significant new use. Note that EPA is also considering whether risk management or other regulatory action may be appropriate for the one remaining psychrometer use.

C. Allow the Exemption for Persons That Import or Process Elemental Mercury as Part of Articles That Could Be Subject to the SNUR

Under the SNUR exemption provision at § 721.45(f), a person who imports or processes a substance covered by a SNUR identified in subpart E of part 721 as part of an article is not generally subject to the notification requirements of § 721.25 for that substance. However, EPA is concerned that exempting articles would render the SNUR less effective because of the possibility that

barometers, manometers, and hygrometers/psychrometers containing elemental mercury could be imported or processed for uses subject to this proposed SNUR without the submission of a SNUN. Because mercury-containing barometers, manometers, and hygrometers/psychrometers are the primary concerns in this SNUR, EPA wishes to include not only bulk elemental mercury but also these and other articles when they contain elemental mercury imported or processed for a significant new use. Thus, EPA is proposing to promulgate this rule without the exemption generally provided for in § 721.45(f).

VI. Applicability of Rule to Uses Occurring Before Effective Date of the Final Rule

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376), EPA has decided that the intent of section 5(a)(1)(B) of TSCA is best served by designating a use as a significant new use as of the date of publication of this proposed rule rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements, because a person could defeat the SNUR by initiating the proposed significant new use before the rule became final, and then argue that the use was ongoing as of the effective date of the final rule. Thus, persons who begin commercial manufacture or processing of the chemical substance for a use that would be regulated through this proposed rule, if finalized, would have to cease any such activity before the effective date of the rule if and when finalized. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires. EPA has promulgated provisions to allow persons to comply with this SNUR before the effective date. If a person were to meet the conditions of advance compliance under § 721.45(h), that person would be considered to have met the requirements of the final SNUR for those activities.

VII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require the development of any particular test data before submission of a SNUN. There are two exceptions: (1) Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)); and (2) development of

test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)). In the absence of a section 4 test rule or a section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (TSCA section 5(d); § 721.25 and § 720.50). However, as a general matter, EPA recommends that SNUN submitters include data that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacture, processing, use, distribution in commerce, or disposal. EPA encourages persons to consult with the Agency before submitting a SNUN. As part of this optional pre-notice consultation, EPA would discuss specific data it believes may be useful in evaluating a significant new use. SNUNs submitted for significant new uses without any test data may increase the likelihood that EPA will take action under TSCA section 5(e) to prohibit or limit activities associated with this chemical.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information on:

1. Human exposure and environmental releases that may result from the significant new uses of the chemical substance.
2. Potential benefits of the chemical substance.
3. Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

VIII. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in § 720.50. SNUNs must be on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in §§ 721.25 and 720.40. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of the chemical substance included in this proposed rule. EPA's economic analysis (Ref. 1), which is briefly summarized

here, is available in the docket for this proposed rule.

Because the use of elemental mercury for manufacturing the specified mercury-containing products in the U.S. appears to have ceased, EPA expects very few, if any, entities will submit a SNUN. As a result, the economic impact of this rule is anticipated to be either zero or very low.

The costs of submission of a SNUN would not be incurred by any company until a company decides to pursue a significant new use as defined in this proposed SNUR. In the event that a SNUN is submitted, costs are estimated at approximately \$8,100 per SNUN submission, and include the cost to prepare and submit the SNUN, and the payment of a user fee. Businesses that submit a SNUN would be subject to either a \$2,500 user fee required by § 700.45(b)(2)(iii), or, if they are a small business with annual sales of less than \$40 million when combined with those of the parent company (if any), a reduced user fee of \$100 (§ 700.45(b)(1)). In its evaluation of this rule, EPA also considered the potential costs a company might incur by avoiding or delaying the significant new use in the future, but these costs have not been quantified.

X. References

The following document is specifically referenced in the preamble for this rulemaking. In addition to this document, other materials may be available in the docket established for this rulemaking under docket ID number EPA-HQ-OPPT-2010-0630, which you can access through <http://www.regulations.gov>. Those interested in the information considered by EPA in developing this proposed rule, should also consult documents that are referenced in the documents that EPA has placed in the docket, regardless of whether the other documents are physically located in the docket.

1. EPA, 2010. Economic Analysis of the Proposed Significant New Use Rule for Mercury-Containing Barometers, Manometers, Hygrometers, and Psychrometers, Washington, DC OPPT/EETD/EPAB, July 16, 2010.

XI. Statutory and Executive Order Reviews

A. Regulatory Planning and Review

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has determined that this action is a “significant regulatory action.” Accordingly, EPA submitted this action

to OMB for review under Executive Order 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action as required by section 6(a)(3)(E) of the Executive Order.

B. Paperwork Reduction Act

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for certain EPA regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument, or form, if applicable.

The information collection requirements related to this action have already been approved by OMB pursuant to the PRA under OMB control number 2070-0038 (EPA ICR No. 1188). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average 97 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Small Entity Impacts

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of this SNUR would not have a significant adverse economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows.

Under the RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. Small entity is defined in accordance with section 601 of the RFA as: A small business as defined by the Small Business Administration’s (SBA) regulations at 13 CFR 121.201; A small

governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and A small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. For purposes of assessing the impacts of this proposed rule on small entities, EPA has determined that this proposed rule is not expected to impact any small not-for-profit organizations or small governmental jurisdictions. As such, the Agency estimated potential impacts on small business.

A SNUR applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a “significant new use.” By definition of the word “new,” and based on all information currently available to EPA, it appears that no small or large entities presently engage in such activity. Since this proposed SNUR would require a person who intends to engage in such activity in the future to first notify EPA by submitting a SNUN, no economic impact will occur unless someone files a SNUN to pursue a significant new use in the future or forgoes profits by avoiding or delaying the significant new use. Although some small entities may decide to conduct such activities in the future, EPA cannot presently determine how many, if any, there may be. However, EPA’s experience to date is that, in response to the promulgation of over 1,000 SNURs, the Agency receives on average only five notices per year. Of those SNUNs submitted, only one appears to be from a small entity in response to any SNUR. Therefore, EPA believes that the potential economic impact of complying with a SNUR is not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published as a final rule on August 8, 1997 (62 FR 42690) (FRL-5735-4), the Agency presented its general determination that proposed and final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates

Based on EPA’s experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reason to believe that any State, local, or Tribal government would be impacted by this rulemaking. As such, EPA has determined that this regulatory action

would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1531–1538).

E. Federalism

This action would not have federalism implications because it is not expected to have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999).

F. Indian Tribal Governments

This action would not have tribal implications as specified in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000). This action is not expected to have substantial direct effects on Indian Tribes, would not significantly or uniquely affect the communities of Indian Tribal governments, and would not involve or impose any requirements that affect Indian Tribes. Thus, Executive Order 13175 does not apply to this action.

G. Protection of Children

EPA interprets Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it would not establish an environmental standard intended to mitigate health or safety risks.

H. Effect on Energy Supply, Distribution, or Use

This action is not a “significant energy action” as defined in Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

I. Technical Standards

Because this action would not involve any technical standards, section 12(d) of the National Technology Transfer and

Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Environmental Justice

This action would not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: April 29, 2011.

Wendy C. Hamnett,

Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

PART 721—[AMENDED]

1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. In § 721.10068, add the following definitions in alphabetical order to paragraph (a) and add a new paragraph (b)(2)(viii) to read as follows:

§ 721.10068 Elemental mercury.

(a) * * *

Barometer means an instrument used in various applications to measure atmospheric pressure.

Hygrometer or *psychrometer* means an instrument used in various applications to measure humidity of gases.

Manometer means an instrument used in various applications to measure pressure of gases or liquids.

(b) * * *

(2) * * *

(viii) Manufacturing or processing of elemental mercury for use in barometers, manometers, hygrometers, and psychrometers except for: Natural gas manometers covered by paragraph (b)(2)(vii) of this section; barometers, manometers, hygrometers, and psychrometers when these articles are in service as of May 6, 2011; and portable battery powered and motor-aspirated psychrometers that contain fewer than seven grams of elemental mercury.

[FR Doc. 2011–11025 Filed 5–5–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

48 CFR Part 1511

[EPA–HQ–OARM–2010–0273; FRL–9288–3]

EPAAR Prescription for Work Assignments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) amends the EPA Acquisition Regulation (EPAAR) to update policy, procedures, and contract clauses. The proposed rule provides revised language to the prescription for the work assignment clause, incorporating prescriptive language that provides further instructions on use of the related clause.

DATES: Comments must be received on or before June 6, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OARM–2010–0273, by one of the following methods:

- <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.
- *E-mail:* docket.oei@epa.gov.
- *Fax:* (202) 566–1753.
- *Mail:* EPA–HQ–OARM–2010–0273, OEI Docket, Environmental Protection Agency, 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Please include a total of three (3) copies.
- *Hand Delivery:* EPA Docket

Center—Attention OEI Docket, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC 20004. Such deliveries are only accepted during the Docket’s normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OARM–2010–0273. EPA’s policy is that all comments received will be included in the public docket without change, and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment.

If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket, and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment, and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties, and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov>, or in hard copy at the Office of Environmental Information (OEI) Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the EPA Docket Center is (202) 566-1752. This Docket Facility is open from 8:30 a.m. to 4:30 p.m. Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT:

Donna S. Blanding, Policy, Training, and Oversight Division, Office of Acquisition Management (3802R), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 202-564-1130; fax number: 202-565-2475; e-mail address: blanding.donna@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

1. *Submitting CBI.* Do not submit this information to EPA through <http://www.regulations.gov> or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the

disk or CD ROM as CBI, and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

II. Background

Recent contract file review activities revealed better guidance is needed for EPA Contracting Officers (COs) on the work plan and work assignment processes with regard to when a CO should provide the expected level of service needed to the contractor.

As a result, clarifying policy is being added to the prescription for 1511.011-74. Accordingly, the revised language incorporated into EPAAR prescription 1511.011-74 provides the EPA contracting officer with further instructions on the use of EPAAR clause 1552.211-74, when administering work assignments under Cost Reimbursable type term form contracts.

III. Proposed Rule

This rule amends the EPAAR to add policy to the prescription for using the work assignment clause. The original prescription language generally states

that the work assignment clause, 1552.211-74, shall be used when a Cost Reimbursable type term form contract with work assignments will be issued. This policy only adds additional instructive language. The new policy language contained under 1511.011-74, Work Assignments (Deviation), will serve to provide contracting officers with better guidance on issuing a work assignment. Therefore a revision will not be required to the related EPAAR clause, 1552.211-74 Work Assignments; as this change does not affect the meaning of the clause. The revised language communicates to contract personnel and program staff that government cost-related estimates should not be provided to contractors prior to receiving the contractor's work plan (proposal); and how to address exceptions. The exceptions addressed in the policy involve circumstances where a contracting officer may need to be able to provide some of the expected level of service needed to the contractor prior to receipt of the work plan (proposal) due to the nature of the work.

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

This action is not a "significant regulatory action" under the terms of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993) and therefore, not subject to review under the EO.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* No information is collected under this action.

C. Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.*

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

For purposes of assessing the impact of today's final rule on small entities, "small entity" is defined as: (1) A small business that meets the definition of a

small business found in the Small Business Act and codified at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This action revises a current EPAAR provision and does not impose requirements involving capital investment, implementing procedures, or record keeping. This rule will not have a significant economic impact on small entities.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, Local, and Tribal governments and the private sector.

This rule contains no Federal mandates (under the regulatory provisions of the Title II of the UMRA) for State, Local, and Tribal governments or the private sector. The rule imposes no enforceable duty on any State, Local or Tribal governments or the private sector. Thus, the rule is not subject to the requirements of Sections 202 and 205 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), requires EPA 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” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.”

This rule does not have federalism implications. It 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, as specified in Executive Order 13132. Rather, this rule

on work assignments only provides clarification to Contracting Officers when issuing level of effort estimates in a work assignment. Thus, Executive Order 13132 does not apply to this rule. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed action from State and local officials.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” This rule does not have Tribal implications, as specified in Executive Order 13175. Rather, this rule on work assignments only provides clarification to Contracting Officers when issuing level of effort estimates in a work assignment. Thus, Executive Order 13175 does not apply to this action. EPA specifically solicits additional comment on this proposed action from Tribal officials.

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

Executive Order 13045, entitled “Protection of Children from Environmental Health and Safety Risks” (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be economically significant as defined under Executive Order 12886, and (2) concerns an environmental health or safety risk that may have a proportionate effect on children. This rule is not subject to Executive Order 13045 because it is not an economically significant rule as defined by Executive Order 12866, and because it does not involve decisions on environmental health or safety risks.

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

This proposed rule is not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution of Use” (66 FR 28335, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act of 1995 (NTTAA)

Section 12(d) (15 U.S.C. 272 note) of NTTA, Public Law 104–113, directs EPA to use voluntary consensus standards in its regulatory activities, unless to do so would be inconsistent with applicable law, or otherwise impractical. Voluntary consensus standards are technical standards (e.g. materials specifications, test methods, sampling procedures and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

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

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

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. This proposed rulemaking does not involve human health or environmental effects.

This proposed rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

List of Subjects in 48 CFR Part 1511

Environmental protection,
Government procurement.

Dated: March 16, 2011.

John R. Bashista,
Director, Office of Acquisition Management.

Therefore, 48 CFR chapter 15 is proposed to be amended as set forth below:

PART 1511—DESCRIBING AGENCY NEEDS

1. The authority citation for part 1511 continues to read as follows:

Authority: 5 U.S.C. 301; Sec. 205(c), 63 Stat. 390, as amended, 40 U.S.C. 486(c); and 41 U.S.C. 418b.

2. Revise section 1511.011–74 to read as follows:

1511.011–74 Work Assignments. (Deviation) (Nov 2009).

3. Add sections 1511.011–74–1 and 1511.011–74–2 to read as follows:

1511.011–74–1 Policy.

When issuing work assignments, the independent government cost estimate shall not be released to the contractor. In most cases the Contracting Officer (CO) should authorize the contractor to expend only the estimated labor hours necessary to develop the work plan and to initiate preliminary tasks which must be performed before work plan approval can be made. However, in cases where the uncertainties involved in the effort are of such a magnitude that there is no reasonable expectation that the contractor can estimate the level of effort required by the tasks, objectives, or outcomes of the requirement, the CO may provide a ceiling level of effort for the entire work assignment at the time of its issuance. In such cases, the specific uncertainties precluding reasonable estimation of the required level of effort on the contractor's part must be documented in the contract file.

1511.011–74–2 Solicitation provision.

The CO shall insert the contract clause at 1552.211.74, Work Assignments, in cost-reimbursement type term form contracts when work assignments are used. For Superfund contracts, except for contracts which require annual conflict of interest certificates (e.g., Site Specific contracts, the Contract Laboratory Program (CLP), and Sample Management Office (SMO) contracts), the CO shall use the clause with either Alternate I or Alternate II. Alternate I shall be used for contractors who have at least three (3) years of records that may be searched for certification purposes. Alternate II shall be used for contractors who do not have at least three (3) years of records that may be searched.

[FR Doc. 2011–10422 Filed 5–5–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

48 CFR Part 1552

[EPA–HQ–OARM–2010–0764; FRL–9288–4]

EPAAR Clause for Compliance with EPA Policies for Information Resources Management

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) amends the EPA Acquisition Regulation (EPAAR) to update policy, procedures, and contract clauses. The proposed rule provides revisions to the clause for Compliance with EPA Policies for Information Resources Management. This revision provides updates to out-dated information currently in the clause.

DATES: Comments must be received on or before June 6, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OARM–2010–0764, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail:* docket.oei@epa.gov.
- *Fax:* (202) 566–1753.
- *Mail:* EPA–HQ–OARM–2010–0764, OEI Docket, Environmental Protection Agency, 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Please include a total of three (3) copies.
- *Hand Delivery:* EPA Docket Center—Attention OEI Docket, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC 20004. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OARM–2010–0764. 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 www.regulations.gov or e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you

provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket, and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment, and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties, and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov>, or in hard copy at the Office of Environmental Information (OEI) Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1752. This Docket Facility is open from 8:30 a.m. to 4:30 p.m. Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Donna S. Blanding, Policy, Training, and Oversight Division, Office of Acquisition Management (3802R), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; *telephone number:* 202–564–1130; *fax number:* 202–565–2475; *e-mail address:* blanding.donna@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

1. *Submitting CBI.* Do not submit this information to EPA through <http://www.regulations.gov> or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that

you mail to EPA, mark the outside of the disk or CD-ROM as CBI, and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

II. Background

In May, 2010 during the review of clause 1552.211–79 the EPA Office of Environmental Information (OEI), the Office of Acquisition Management (OAM) and other offices found information within this clause to be outdated. The proposed administrative updates to the clause will bring it in line with current EPA policy.

III. Proposed Rule

This proposed rule amends the EPAAR to revise the following within the Compliance with EPA Policies for Information Resources Management clause:

1. Paragraph (a)(5) of said EPAAR clause states that this clause applies to services that are subject to the Brooks Act of 1965. The Brooks Act has been repealed as it relates to Information Technology and has been replaced with

the Clinger-Cohen Act. The Clinger-Cohen Act is sufficiently covered in the Information Resource Management documents and does not need to be separately called out.

2. Paragraphs (b)(3)(Enterprise Architecture) and (4)(Earned Value Management) is deleted.

3. Paragraph (b)(2), Groundwater Program Information Resources Management Requirement, is deleted, and the OEI Quality group, plans on updating these documents and removing obsolete references. Also, the document, EPA Order 7500.1A—Minimum Set of Data elements for Groundwater, can only be found in a repository of documents on the Office of Human Resources Web site and the National Service Center for Environmental Publications Web site. As a result, the Office of Water stated the EPA Order could be removed from this clause.

4. Paragraph (c), Printing, is deleted. The printing office does not offer these services. If a contractor requires these documents be printed, they can request such from the contracting officer.

5. Paragraph (d), Electronic Access, is obsolete and should be deleted and replaced with the proposed paragraph (d).

6. All offices agreed that information on EPA's section 508 policy needed to be included in the clause.

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

This action is not a “significant regulatory action” under the terms of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993) and therefore, not subject to review under the EO.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* No information is collected under this action.

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

The Regulatory Flexibility Act generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute; unless the agency certifies that the rule will not have a significant economic impact on a substantial

number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impact of today's final rule on small entities, “small entity” is defined as: (1) A small business that meets the definition of a small business found in the Small Business Act and codified at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This action revises a current EPAAR provision and does not impose requirements involving capital investment, implementing procedures, or record keeping. This rule will not have a significant economic impact on small entities.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, Local, and Tribal governments and the private sector.

This rule contains no Federal mandates (under the regulatory provisions of the Title II of the UMRA) for State, Local, and Tribal governments or the private sector. The rule imposes no enforceable duty on any State, Local or Tribal governments or the private sector. Thus, the rule is not subject to the requirements of Sections 202 and 205 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), requires EPA 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” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.”

This rule does not have federalism implications. It 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, as specified in Executive Order 13132. Today's rule on Compliance with EPA Policies for Information Resources Management provides updates to outdated information currently in the clause, these changes are administrative. Thus, Executive Order 13132 does not apply to this rule. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed action from State and local officials.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." This rule does not have tribal implications, as specified in Executive Order 13175. Today's rule on Compliance with EPA Policies for Information Resources Management provides updates to outdated information currently in the clause, these changes are administrative.

Thus, Executive Order 13175 does not apply to this action. EPA specifically solicits additional comment on this proposed action from tribal officials.

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

Executive Order 13045, entitled "Protection of Children from Environmental Health and Safety Risks" (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be economically significant as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that may have a proportionate effect on children. This rule is not subject to Executive Order 13045 because it is not an economically significant rule as defined by Executive Order 12866, and because it does not involve decisions on environmental health or safety risks.

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

This proposed rule is not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28335 (MAY 22, 2001)), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act of 1995 (NTTAA)

Section 12(d) (15 U.S.C. 272 note) of NTTA, Public Law 104-113, directs EPA to use voluntary consensus standards in its regulatory activities, unless to do so would be inconsistent with applicable law, or otherwise impractical. Voluntary consensus standards are technical standards (e.g. materials specifications, test methods, sampling procedures and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

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

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

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. This proposed rulemaking does not involve human health or environmental effects.

This proposed rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

List of Subjects in 48 CFR Part 1552

Environmental protection,
Government procurement.

Dated: March 16, 2011.

John R. Bashista,

Director, Office of Acquisition Management.

Therefore, 48 CFR Chapter 15 is proposed to be amended as set forth below:

PART 1552—DESCRIBING AGENCY NEEDS

1. The authority citation for part 1552 continues to read as follows:

Authority: 5 U.S.C. 301; Sec. 205(c), 63 Stat. 390, as amended, 40 U.S.C. 486(c); and 41 U.S.C. 418b.

2. Revise section 1552.211-79 to read as follows:

1552.211-79 Compliance with EPA Policies for Information Resources Management.

As prescribed in 1511.011-79, insert the following clause:

Compliance With EPA Policies for Information Resources Management

(a) *Definition.* Information Resources Management (IRM) is defined as any planning, budgeting, organizing, directing, training, promoting, controlling, and managing activities associated with the burden, collection, creation, use and dissemination of information. IRM includes both information itself and the management of information and related resources such as personnel, equipment, funds, and technology. Examples of these services include but are not limited to the following:

(1) The acquisition, creation, or modification of a computer program or automated data base for delivery to EPA or use by EPA or contractors operating EPA programs.

(2) The analysis of requirements for, study of the feasibility of, evaluation of alternatives for, or design and development of a computer program or automated data base for use by EPA or contractors operating EPA programs.

(3) Services that provide EPA personnel access to or use of computer or word processing equipment, software, or related services.

(4) Services that provide EPA personnel access to or use of: Data communications; electronic messaging services or capabilities; electronic bulletin boards, or other forms of electronic information dissemination; electronic record-keeping; or any other automated information services.

(b) *General.* The Contractor shall perform any IRM related work under this contract in accordance with the IRM policies, standards, and procedures set forth on the Office of Environmental Information policy Web site. Upon

receipt of a work request (i.e. delivery order, task order, or work assignment), the Contractor shall check this listing of directives. The applicable directives for performance of the work request are those in effect on the date of issuance of the work request. The 2100 Series (2100–2199) of the Agency's Directive System contains the majority of the Agency's IRM policies, standards, and procedures.

(c) *Section 508 Requirements.* Contract deliverables are required to be compliant with Section 508 requirements. The Environmental Protection Agency policy for 508 compliance can be found on the Agency's Directive System identified in section (d) of this clause under policy number CIO 2130.0, Accessible Electronic and Information Technology. Additional information on Section 508 including EPA's 508 policy can be

found at <http://www.epa.gov/accessibility>.

(d) *Electronic Access.* A complete listing, including full text, of documents included in the 2100 Series of the Agency's Directive System is maintained on the EPA Public Access Server on the Internet at <http://epa.gov/docs/irmpoli8/>.

[FR Doc. 2011–10423 Filed 5–5–11; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 76, No. 88

Friday, May 6, 2011

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

Animal and Plant Health Inspection Service

[Docket No. APHIS–2011–0044]

Bovine Tuberculosis and Brucellosis; Public Meetings

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of public meetings.

SUMMARY: This is to inform the public of upcoming meetings in Lansing, MI, Atlanta, GA, Bozeman, MT, and Amarillo, TX, to provide an opportunity for stakeholders to offer their input on a new framework being developed for the bovine tuberculosis and brucellosis programs in the United States. The meetings are being organized by the Animal and Plant Health Inspection Service.

DATES: The meetings will be held on May 19, May 24, June 1, and June 6, 2011, from 8 a.m. to 4 p.m. (local time) each day. Registration for each meeting will begin at 7:30 a.m.

ADDRESSES: The public meeting on May 19, 2011, will be held at the Causeway Bay Hotel and Convention Center, 6820 South Cedar Street, Lansing, MI. The public meeting on May 24, 2011, will be held at the Renaissance Concourse Atlanta Airport Hotel, 1 Hartsfield Center Parkway, Atlanta, GA. The public meeting on June 1, 2011, will be held at the Holiday Inn Bozeman Airport, 5 East Baxter Lane, Bozeman, MT. The public meeting on June 6, 2011, will be held at the Holiday Inn Airport, 1911 I–40 East, Ext. 71 and Ross-Osage, Amarillo, TX.

FOR FURTHER INFORMATION CONTACT: Dr. Lee Ann Thomas, Director, Ruminant Health Programs, National Center for Animal Health Programs, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737, (301) 734–5256.

SUPPLEMENTARY INFORMATION: The U.S. Department of Agriculture (USDA) is currently developing proposed revisions to its programs regarding bovine tuberculosis (TB) and bovine brucellosis in the United States. In keeping with its commitment to partnering with States, Tribal Nations, and industry in identifying appropriate changes to the two programs, USDA is planning to host four public meetings to discuss potential changes to these programs. The meetings will take place in Lansing, MI, Atlanta, GA, Bozeman, MT, and Amarillo, TX, on May 19, May 24, June 1, and June 6, 2011, respectively (see **ADDRESSES**).

Topics to be discussed at the meetings are contained in a TB and brucellosis regulatory framework developed jointly by USDA and State and Tribal representatives, and include:

1. Program (State) requirements;
2. Surveillance;
3. Zoning;
4. Affected herd management and epidemiological investigations;
5. Importation of animals;
6. Indemnity;
7. Interstate movement requirements; and
8. Approval of diagnostic tests and laboratories.

The regulatory framework will be available as of May 5, 2011, on the Regulations.gov Web site (see link below) and on the APHIS Web site at http://www.aphis.usda.gov/animal_health/tb_bruc/meetings.html.

Due to time constraints, public discussion at each meeting will be limited. Written statements on meeting topics may be filed with USDA through June 20, 2011, via the Federal eRulemaking Portal at <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2011-0044> or by sending them to the person listed under **FOR FURTHER INFORMATION CONTACT**. Written statements may also be filed at the meetings. Please refer to Docket No. APHIS–2011–0044 when submitting your statements.

Done in Washington, DC, this 3rd day of May 2011.

Gregory L. Parham,
Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2011–11111 Filed 5–5–11; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Umatilla National Forest, Walla Walla Ranger District, Oregon, Cobbler II Timber Sale and Fuels Reduction Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare a Supplemental Environmental Impact Statement (SEIS) to the Final Environmental Impact Statement (FEIS) for the Cobbler II Timber Sale and Fuels Reduction Project.

SUMMARY: On January 27, 2011, Umatilla National Forest Supervisor Kevin Martin withdrew his October 8, 2010 Record of Decision (ROD) for the Cobbler II Timber Sale and Fuels Reduction Final Environmental Impact Statement (FEIS).

The Umatilla National Forest will prepare a Supplemental Environmental Impact Statement (SEIS) to clarify and revise portions of the Cobbler II Timber Sale and Fuels Reduction project FEIS analysis.

DATES: There will be no additional scoping period for the Cobbler II Timber Sale and Fuels Reduction Supplemental Environmental Impact Statement (SEIS). This is consistent with regulations found at 40 CFR 1509.2 (ii)(4). There will be a 45-day public comment period held when the Draft SEIS is released.

The Draft SEIS is expected in June 2011. The final SEIS is expected in October 2011.

ADDRESSES: This SEIS analysis is being overseen by: Michael Rassbach, District Ranger; Walla Walla Ranger District; 1415 W. Rose; Walla Walla, Washington 99362.

FOR FURTHER INFORMATION CONTACT: Kimpton Cooper, 509–522–6290 or kmcooper@fs.fed.us.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

Information concerning the Cobbler II Timber Sale and Fuels Reduction project FEIS can be found on the Umatilla National Forest Web site at (http://www.fs.fed.us/nepa/nepa_test/fs-usda-pop.html?project=29678).

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The Purpose and Need for the Cobbler II Timber Sale and Fuels Reduction SEIS is the same as identified within the Cobbler II Timber Sale and Fuels Reduction Final Environmental Impact Statement (FEIS) on pages 1–4 and 1–5. The Forest Service is preparing this Supplemental Environmental Impact Statement (SEIS) to clarify and revise sections of the environmental analysis conducted for the original October 2010 Cobbler II FEIS.

Proposed Action

The actions proposed and analyzed in the Cobbler II FEIS will not change in the SEIS. The Umatilla National Forest proposes to supplement the following analysis to that which was originally presented in the Cobbler II Timber Sale and Fuels Reduction FEIS (October 2010).

- Chapter 1
 - Minor editorial changes and additional clarifying information.
- Chapter 2
 - Minor editorial changes and additional clarifying information.
- Chapter 3
 - Clarification of cumulative effects analysis for all resources.
 - Revision of wildlife environmental effects section.
 - Revision of vegetation environmental effects section.
 - Other editorial changes and additional clarifying information.

The supplemental information presented within the SEIS will replace the corresponding information found in the October 2010 Cobbler II FEIS. For example, the revised wildlife environmental effects section of the SEIS will replace the wildlife environmental effects section of the FEIS. All other areas of the analysis that are not identified for supplementation within the SEIS will remain unaltered from its presentation in the FEIS. In this manner the SEIS and FEIS will be companion documents.

Responsible Official

Forest Supervisor for the Umatilla National Forest, Kevin Martin.

Nature of Decision To Be Made

The decisions to be made include:

1. Whether a Forest Plan amendment should occur at this time?
2. Whether harvest and prescribed landscape fire along with associated activities should occur, and if so, how much and where?
3. Whether other vegetation management activities (hardwood restoration, meadow restoration, and

non-commercial thinning) and their associated activities should occur and when should they occur?

4. What monitoring or mitigation measures should be taken or needed?

Opportunity to Comment

This notice is for a supplemental EIS, and therefore no further scoping is necessary (40 CFR 1502.9 (ii)(4)).

The public has had several formal opportunities to comment on this project prior to the initiation of this SEIS. The public will be provided a formal opportunity to comment when the Draft SEIS is released in June 2011.

Comments received in response to this notice, including names and addresses of those who comment, will become part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered; however, anonymous comments will not provide the respondent with standing to participate in subsequent administrative review or judicial review.

Dated: April 28, 2011.

Kevin Martin,

Forest Supervisor.

[FR Doc. 2011–11097 Filed 5–5–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Big Horn County Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Big Horn County Resource Advisory Committee will meet in Greybull, Wyoming. The committee is meeting as authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110–343) and in compliance with the Federal Advisory Committee Act. The purpose is to hold the fourth meeting and to vote on project proposals.

DATES: The meeting will be held on June 2, 2011, and will begin at 10 a.m.

ADDRESSES: The meeting will be held at the Big Horn County Weed and Pest Building, 4782 Highway 310, Greybull, Wyoming. Written comments about this meeting should be sent to Laurie Walters-Clark, Bighorn National Forest, 2013 Eastside 2nd Street, Sheridan, Wyoming 82801. Comments may also be sent via e-mail to comments-bighorn@fs.fed.us, with the words Big Horn County RAC in the subject line. Facsimiles may be sent to 307–674–2668.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Bighorn National Forest, 2013 Eastside 2nd Street, Sheridan, Wyoming 82801. Visitors are encouraged to call ahead to 307–674–2600 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT:

Laurie Walters-Clark, RAC Coordinator, USDA, Bighorn National Forest, 2013 Eastside 2nd Street, Sheridan, Wyoming 82801; (307) 674–2627.

Individuals who use telecommunication devices for the hearing impaired may call 1–307–674–2604 between 8 a.m. and 5 p.m., Mountain time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. The following business will be conducted: (1) Introductions of all committee members and Forest Service personnel, (2) Finalization and approval of Project Evaluation Criteria, (3) Project reviews, and (4) Public Comment, and (5) Project voting for recommendation. Persons who wish to bring related matters to the attention of the Committee may file written statements with the Committee staff before or after the meeting.

Dated: April 29, 2011.

William T. Bass,

Forest Supervisor.

[FR Doc. 2011–11093 Filed 5–5–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Butte County Resource Advisory Committee (RAC)

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Butte County Resource Advisory Committee (RAC) will hold a meeting on May 23, 2011 in Oroville, CA. The purpose of the meeting is to: Review Secure Rural Schools legislation, Sec. 204 (f) and discuss the 50% watershed restoration/road maintenance funding goal; discuss developing a process for providing partial funding; discuss requiring a maximum request amount; review and discuss examples of watershed/stream restoration and road maintenance projects along with monitoring projects such as GPS/GIS mapping; review funding Cycle 2 application and instructions and discuss improvements as necessary; review a timeline for Cycle

2 project funding and schedule out meeting(s).

The funding is made available under Title II provisions of the Secure Rural Schools and Community Self-Determination Act of 2000.

DATE AND ADDRESS: The meeting will take place from 6:30–9 p.m. at the Feather River Ranger District Office, 875 Mitchell Avenue, Oroville, CA.

FOR FURTHER INFORMATION CONTACT: (or for special needs): Lee Anne Schramel Taylor, Forest Coordinator, USDA, Plumas National Forest, P.O. Box 11500/159 Lawrence Street, Quincy, CA 95971; (530) 283–7850; or by E-MAIL eataylor@fs.fed.us. Other RAC information may be obtained at <http://www.fs.usda.gov> and <http://www.fs.fed.us/srs>.

Dated: April 29, 2011.

Matt Janowiak,

Acting Deputy Forest Supervisor.

[FR Doc. 2011–11079 Filed 5–5–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–549–822]

Certain Frozen Warmwater Shrimp From Thailand: Notice of Court Decision Not in Harmony With Final Results of Administrative Review and Notice of Amended Final Results of Administrative Review Pursuant to Court Decision

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On April 26, 2011, the United States Court of International Trade (CIT) sustained the Department of Commerce's (the Department's) results of redetermination pursuant to the CIT's remand order in *Ad Hoc Shrimp Trade Action Committee v. United States*, 675 F. Supp. 2d 1287 (CIT 2010). The Department is notifying the public that the final CIT judgment in this case is not in harmony with the Department's final results and is amending the final results of the administrative review of the antidumping duty order on certain frozen warmwater shrimp from Thailand covering the period of review (POR) of February 1, 2006, through January 31, 2007.

DATES: *Effective Date:* May 6, 2011.

FOR FURTHER INFORMATION CONTACT: Kate Johnson, AD/CVD Operations, Office 2, Import Administration—International Trade Administration, U.S. Department of Commerce, 14th Street and

Constitution Avenue, NW., Washington, DC, 20230; telephone (202) 482–4929.

SUPPLEMENTARY INFORMATION:

Background

On August 29, 2008, the Department published its final results in the antidumping duty administrative review of certain frozen warmwater shrimp from Thailand covering the POR of February 1, 2006, through January 31, 2007. *See Certain Frozen Warmwater Shrimp from Thailand: Final Results and Final Partial Rescission of Antidumping Duty Administrative Review*, 73 FR 50933 (August 29, 2008) (*Final Results*). In the *Final Results*, the Department determined that the Rubicon Group¹ was not entitled to a constructed export price (CEP) offset. On October 24, 2008, the Rubicon Group filed a complaint with the Court challenging the Department's determination that the Rubicon Group was not entitled to a CEP offset. On July 17, 2009, the Department requested a voluntary remand to reconsider and further explain the CEP offset issue. On December 29, 2009, the Court granted the Department's request to reconsider and further explain its decision as to whether the Rubicon Group is entitled to a CEP offset. On June 18, 2010, the Department issued its final results of redetermination. *See Final Results of Redetermination Pursuant to Court Remand*, dated June 18, 2010 (Remand Results) (available at <http://ia.ita.doc.gov/remands>). The remand redetermination explained that, pursuant to the Court's remand order, the Department reconsidered the CEP offset issue with respect to the Rubicon Group and determined that the Rubicon Group was entitled to a CEP offset adjustment to normal value in the 2006–2007 administrative review. On April 26, 2011, the CIT sustained the Remand Results. *See Andaman Seafood Co., Ltd. et al. v. United States*, Court No. 08–00330, Slip Op. 11–46 (April 26, 2011).

Timken Notice

Consistent with the decision of the United States Court of Appeals for the Federal Circuit (CAFC) in *Timken Co. v. United States*, 893 F. 2d 337 (CAFC 1990) (*Timken*), as clarified by *Diamond Sawblades Mfrs. Coalition v. United States*, 626 F. 3d 1374 (CAFC 2010), pursuant to section 516A(c) of the Tariff

¹ This group is comprised of the following companies: Andaman Seafood Co., Ltd., Chanthaburi Frozen Food Co., Ltd., Chanthaburi Seafoods Co., Ltd., Phatthana Seafood Co., Ltd., Phatthana Frozen Food Co., Ltd., Thailand Fishery Cold Storage Public Co., Ltd., Thai International Seafood Co., Ltd., and Rubicon Resources, LLC (collectively, the Rubicon Group).

Act of 1930, as amended (the Act), the Department must publish a notice of a court decision that is not “in harmony” with a Department determination and must suspend liquidation of entries pending a “conclusive” court decision. The CIT's April 26, 2011, judgment sustaining the Department's *Remand Results* with respect to the Rubicon Group constitutes a final decision of that court that is not in harmony with the Departments *Final Results*. This notice is published in fulfillment of the publication requirements of *Timken*. Accordingly, the Department will continue the suspension of liquidation of the subject merchandise pending the expiration of the period of appeal or, if appealed, pending a final and conclusive court decision.

Amended Final Results

Because there is now a final court decision with respect to the Rubicon Group, the Department amends its *Final Results*, and the weighted-average margin for the Rubicon Group for the period February 1, 2006, through January 31, 2007, is 3.00 percent.

In the event the CIT's ruling is not appealed or, if appealed, upheld by the CAFC, the Department will instruct U.S. Customs and Border Protection to assess antidumping duties on entries of the subject merchandise exported during the POR from the Rubicon Group based on the revised assessment rates calculated by the Department.

This notice is issued and published in accordance with sections 516A(c)(1), 751(a)(1), and 777(i)(1) of the Act.

Dated: May 2, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011–11119 Filed 5–5–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–549–821]

Polyethylene Retail Carrier Bags From Thailand: Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* May 6, 2011.

FOR FURTHER INFORMATION CONTACT: Dustin Ross, AD/CVD Operations, Office 5, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and

Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482-0747.

SUPPLEMENTARY INFORMATION:

Background

At the request of interested parties, the Department of Commerce (the Department) initiated an administrative review of the antidumping duty order on polyethylene retail carrier bags from Thailand for the period August 1, 2009, through July 31, 2010. See *Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part*, 75 FR 60076 (September 29, 2010). The preliminary results of this administrative review are currently due no later than May 3, 2011.

Extension of Time Limit for Preliminary Results

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), requires the Department to complete the preliminary results within 245 days after the last day of the anniversary month of an order for which a review is requested and the final results within 120 days after the date on which the preliminary results are published in the **Federal Register**. If it is not practicable to complete the review within these time periods, section 751(a)(3)(A) of the Act allows the Department to extend the time limit for the preliminary results to a maximum of 365 days after the last day of the anniversary month.

We determine that it is not practicable to complete the preliminary results of this review by the current deadline of May 3, 2011, because we require additional time to analyze complex cost issues raised by the petitioner in this administrative review. Therefore, in accordance with section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2), we are extending the time period for issuing the preliminary results of this review by 15 days to May 18, 2011.

This notice is published in accordance with sections 751(a)(3)(A) and 777(i)(1) of the Act.

Dated: May 2, 2011.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2011-11124 Filed 5-5-11; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-826]

Paper Clips From the People's Republic of China: Final Results of Expedited Sunset Review of Antidumping Duty Order

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On January 3, 2011, the Department of Commerce ("the Department") initiated the third sunset review of the antidumping duty order on paper clips from the People's Republic of China ("PRC") pursuant to section 751(c) of the Tariff Act of 1930, as amended ("the Act"). Based on the notice of intent to participate and adequate substantive response filed by a domestic interested party, and the lack of response from any respondent interested party, the Department conducted an expedited (120-day) sunset review of the antidumping duty order on paper clips from the PRC, 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 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, *infra*.

DATES: *Effective Date:* May 6, 2011.

FOR FURTHER INFORMATION CONTACT:

Krishna Hill or Charles Riggall, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482-4037 or (202) 482-0650, respectively.

SUPPLEMENTARY INFORMATION: On November 25, 1994, the Department published the antidumping duty order on paper clips from the PRC.¹ On January 3, 2011, the Department published the notice of initiation of the third sunset review of the antidumping duty order on paper clips from the PRC pursuant to section 751(c) of the Tariff Act of 1930, as amended ("the Act"). See *Initiation of Five-Year ("Sunset") Review*, 76 FR 89 (January 3, 2011). On January 10, 2011, the Department received a notice of intent to participate from ACCO Brands USA LLP ("ACCO"), a domestic interested party, within the

deadline specified in 19 CFR 351.218(d)(1)(i). ACCO claimed interested parties status under section 771(9)(C) of the Act, as a producer in the United States of a domestic like product. On February 2, 2011, the Department received a complete and adequate substantive response from ACCO within 30 days of publication of the initiation. The Department did not receive a response from any respondent interested parties to this proceeding. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), the Department conducted an expedited (120-day) sunset review of the antidumping duty order on paper clips from the PRC.

Scope of the Order

The products covered by the order are certain paper clips, wholly of wire of base metal, whether or not galvanized, whether or not plated with nickel or other base metal (e.g., copper), with a wire diameter between 0.025 inches and 0.075 inches (0.64 to 1.91 millimeters), regardless of physical configuration, except as specifically excluded. The products subject to the order may have a rectangular or ring-like shape and include, but are not limited to, clips commercially referred to as No. 1 clips, No. 3 clips, Jumbo or Giant clips, Gem clips, Frictioned clips, Perfect Gems, Marcel Gems, Universal clips, Nifty clips, Peerless clips, Ring clips, and Glide-On clips. The products subject to the order are currently classifiable under subheading 8305.90.3010 of the Harmonized Tariff Schedule of the United States ("HTSUS").

Specifically excluded from the scope of the order are plastic and vinyl covered paper clips, butterfly clips, binder clips, or other paper fasteners that are not made wholly of wire of base metal and are covered under a separate subheading of the HTSUS.

Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review is provided in the accompanying Issues and Decision Memorandum ("I&D Memo"), dated concurrently with this notice. The issues discussed in the I&D Memo include the likelihood of continuation or recurrence of dumping and the magnitude of the margins likely to prevail if the order is revoked. Parties can obtain a public copy of the I&D Memo from the Central Records Unit, room 7046, of the main Commerce building. In addition, a complete public

¹ See *Antidumping Duty Order: Certain Paper Clips From the People's Republic of China*, 59 FR 60606 (November 25, 1994).

version of the I&D Memo can be accessed directly on the Web at <http://ia.ita.doc.gov/frn>. The paper copy and electronic version of the I&D Memo are identical in content.

Final Results of Review

The Department determines that revocation of the antidumping duty order on paper clips from the PRC

would be likely to lead to continuation or recurrence of dumping at the following weighted-average margins:

| Manufacturers/exporters/producers | Weighted-average margin (percent) |
|--|-----------------------------------|
| Shanghai Lansheng Corporation | 57.64 |
| Zhejiang Light Industrial Products Import & Export Corporation | 46.01 |
| Zhejiang Machinery and Equipment Import & Export Corporation | 60.70 |
| PRC-wide Rate | 126.94 |

Notification Regarding Administrative Protective Order

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.

We are issuing and publishing the results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act.

Dated: April 26, 2011.

Paul Piquado,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011-11126 Filed 5-5-11; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-821-807]

Initiation of Anticircumvention Inquiry on Antidumping Duty Order on Ferrovanadium and Nitrided Vanadium From the Russian Federation

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: In response to a request from AMG Vanadium, Inc. (AMG Vanadium), the Department of Commerce (the Department) is initiating an anticircumvention inquiry to determine whether imports of vanadium pentoxide from the Russian Federation (Russia) that is converted into ferrovanadium in the United States are circumventing the antidumping duty order on ferrovanadium and nitrided vanadium (ferrovanadium) from Russia. *See Notice*

of Antidumping Order: Ferrovanadium and Nitrided Vanadium From the Russian Federation, 60 FR 35550 (July 10, 1995).

DATES: *Effective Date:* May 6, 2011.

FOR FURTHER INFORMATION CONTACT: David Goldberger or Rebecca Trainor, AD/CVD Operations, Office 2, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482-4136 or (202) 482-4007, respectively.

SUPPLEMENTARY INFORMATION:

Background

On February 25, 2011, AMG Vanadium submitted a request that the Department initiate an anticircumvention inquiry (AMG Request), pursuant to section 781(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.225(c) and (g), to determine whether imports of vanadium pentoxide from Russia that is processed into ferrovanadium in the United States are circumventing the antidumping duty order on ferrovanadium from Russia. Specifically, AMG Vanadium alleges that the Evraz Group¹ is importing vanadium pentoxide, an intermediate product used in the production of ferrovanadium, from its Russian affiliate OAO Vanady-Tula. The imported vanadium pentoxide is then toll-converted into ferrovanadium in the United States by an unaffiliated processor (which never takes title), prior to sale in the United States. AMG Vanadium alleges that this trade pattern is circumventing the antidumping duty order within the meaning of section 781(a) of the Act.

AMG Vanadium further claims that:

- (1) The ferrovanadium sold in the United States is of the same class or kind of merchandise as the ferrovanadium that is subject to the order;
- (2) the ferrovanadium is

completed or assembled in the United States from parts or components produced in Russia; (3) the process of converting vanadium pentoxide to ferrovanadium in the United States is minor or insignificant; and (4) the value of the Russian vanadium pentoxide constitutes a significant portion of the value of the finished ferrovanadium sold in the United States. Accordingly, AMG Vanadium requests that the Department include within the scope of the ferrovanadium order vanadium pentoxide manufactured in Russia, regardless of form, that is produced, exported, or imported by the Evraz Group or any of its affiliates.

In response to the Department's March 9, 2011, request, on March 16, 2011, AMG Vanadium provided additional information pertinent to its anticircumvention inquiry request (March 16 Submission).

On March 25, 2011, the Evraz Group filed comments opposing AMG Vanadium's circumvention allegation on the grounds that the Department is legally precluded from including vanadium pentoxide in the scope of the order. The Evraz Group included in its submission calculations performed using a cost-based methodology, as an alternative to the value-based methodology used by AMG Vanadium, arguing that AMG Vanadium's approach leads to misleading results. Between April 1 and 22, 2011, AMG Vanadium and the Evraz Group submitted additional comments with respect to whether the Department should initiate this anticircumvention inquiry. The Department met with representatives of AMG Vanadium and the Evraz Group on March 3, and April 5, 2011, respectively, to discuss the request.

Scope of the Order

The products covered by the antidumping duty order are ferrovanadium and nitrided vanadium, regardless of grade, chemistry, form or size, unless expressly excluded from the scope of this order. Ferrovanadium

¹ The Evraz Group includes OAO Vanady-Tula, East Metals S.A., and East Metals N.A.

includes alloys containing ferrovanadium as the predominant element by weight (*i.e.*, more weight than any other element, except iron in some instances) and at least 4 percent by weight of iron. Nitrided vanadium includes compounds containing vanadium as the predominant element, by weight, and at least 5 percent, by weight, of nitrogen. Excluded from the scope of the order are vanadium additives other than ferrovanadium and nitrided vanadium, such as vanadium-aluminum master alloys, vanadium chemicals, vanadium waste and scrap, vanadium-bearing raw materials, such as slag, boiler residues, fly ash, and vanadium oxides.

The products subject to this order are currently classifiable under subheadings 2850.00.20, 7202.92.00, 7202.99.50.40, 8112.40.30.00, and 8112.40.60.00 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope is dispositive.

Scope of the Anticircumvention Inquiry

The product subject to this anticircumvention inquiry is vanadium pentoxide (V_2O_5) from Russia, which is usually in a granular form and may contain other substances, including silica (SiO_2), manganese, and sulfur, and which is converted into ferrovanadium in the United States. Such merchandise is classifiable under subheading 2825.30.0010 of the HTSUS.

As noted above, interested parties have filed comments concerning the initiation of this anticircumvention inquiry. Although vanadium pentoxide is excluded from the scope of the order, AMG Vanadium argues that the Department's regulations and legal precedent allow for the Department to consider expressly-excluded merchandise in an anticircumvention proceeding. AMG Vanadium cites *Steel Wire Rope from Mexico; Affirmative Final Determination of Circumvention of Antidumping Duty Order*, 60 FR 10831 (February 28, 1995) and several cases decided by the Court of Appeals for the Federal Circuit (the Court),² in support of its contention that anticircumvention determinations are distinguished from conventional scope determinations, in that the criteria the Department considers in making an anticircumvention determination do not include whether the imported

merchandise was initially excluded from the scope of the order.

The Evraz Group argues that including vanadium pentoxide within the scope of the antidumping duty order would be inconsistent with the International Trade Commission's (ITC) injury investigation, and the legal precedent in *Wheatland Tube Co. v. United States*, 161 F.3d 1365, 1370 (Fed. Cir. 1998) (*Wheatland Tube*). Specifically, the Evraz Group argues that the ITC expressly excluded vanadium pentoxide from the scope of the injury investigation at the request of the domestic industry. In *Wheatland Tube*, the Evraz Group asserts, the Court ruled that the domestic industry cannot seek to broaden the scope after having made representations to the ITC that the product at issue was not a like product for purposes of the injury determination; and that although the Department may interpret and clarify the scope of the antidumping duty orders, it may not change or interpret them contrary to their terms.

The Department addressed this issue in the *Initiation of Anticircumvention Inquiry on Antidumping and Countervailing Duty Orders on Hot-Rolled Lead and Bismuth Carbon Steel Products from the United Kingdom and Germany*, 62 FR 34213 (June 25, 1997) (*Lead and Bismuth*). In that case, the Department concluded that the theory that parts expressly excluded from the scope of an antidumping order cannot be subject to an anticircumvention inquiry is contrary to, and would undermine, the core principles of the anticircumvention statute. Citing the legislative history, we observed that Congress intended to allow anticircumvention inquiries into parts or components that meet the criteria of section 781(a), as “{t}he underlying rationale of the anticircumvention statute is that, where the criteria of section 781(a) are met, the parts and components subject to the finding of circumvention are, in all meaningful respects, being imported as the subject merchandise, not as parts or components *per se*. The processing in the United States is of such a minor or insignificant nature as to be irrelevant.”³ Thus, “{t}he application of the U.S. finishing or assembly provision will not require new injury findings as to each part or component. The anticircumvention provision is intended to cover efforts to circumvent an order by importing disassembled or unfinished merchandise for assembly in

the United States. Hence, the ITC would generally advise as to whether the parts or components taken as a whole fall within the injury determination.”⁴

This is consistent with the Federal Circuit's opinions reviewing the Department's anticircumvention inquiries. Although *Wheatland Tube* and *Nippon Steel* dealt with the minor alteration provision (section 781(c) of the Act), rather than the provision for merchandise completed in the United States (section 781(a) of the Act) at issue here, the Court's analysis is instructive. In *Wheatland Tube*, the Court held that “the line and dual-certified pipe accused of circumventing the Standard Pipe Orders is the same pipe that the orders expressly exclude.” *Wheatland Tube*, 161 F. 3d at 1369. In contrast, in *Nippon Steel*, the Court held that “Commerce was performing a function Congress has given to it—to determine whether an antidumping duty order has been circumvented by making minor alterations in the form of the product otherwise subject to that order.” *Nippon Steel*, 219 F. 3d at 1354. The Court's analysis allowed that a circumvention inquiry is proper where, but for an act meant to circumvent the order, the product would be covered (contrast the carbon steel in *Nippon Steel* with the line pipe in *Wheatland Tube*). Here, the covered product is ferrovanadium and the alleged act meant to circumvent the order on ferrovanadium from Russia is further processing in the United States. For these reasons, we determine that the Evraz Group's arguments do not provide a legal basis for rejecting AMG Vanadium's application for an anticircumvention inquiry pursuant to section 781(a) of the Act.

Initiation of Anticircumvention Proceeding

Applicable Statute

Section 781(a) of the Act provides that the Department may find circumvention of an antidumping duty order when merchandise of the same class or kind subject to the order is completed or assembled in the United States. In conducting anticircumvention inquiries under section 781(a)(1) of the Act, the Department relies upon the following criteria: (A) Merchandise sold in the United States is of the same class or kind as any other merchandise that is the subject of an antidumping duty order produced in a foreign country that is subject to an antidumping duty order; (B) such merchandise sold in the United States is completed or assembled in the United States from parts or components

² See, e.g., *Nippon Steel Corp. v. United States*, 219 F.3d 1348 (Fed. Cir. 2000) (*Nippon Steel*); and *Target Corp. v. United States*, 609 F.3d 1352 (July 23, 2010).

³ See, H.R. Conf. Rep. No. 576, 100th Cong., 2d Sess. 603 (1988) and *Lead and Bismuth*, 62 FR 34213, 34215.

⁴ *Id.*

produced in the foreign country with respect to which the antidumping duty order applies; (C) the process of assembly or completion in the United States is minor or insignificant; and (D) the value of the parts or components referred to in (B) is a significant portion of the total value of the merchandise. As discussed below, AMG Vanadium presented evidence with respect to these criteria.

A. Merchandise of the Same Class or Kind

AMG Vanadium states that the merchandise sold in the United States is ferrovanadium. As this merchandise is covered by the scope of the antidumping duty order, the merchandise is of the same class or kind as the merchandise subject to the antidumping duty order.

B. Completion of Merchandise in the United States

AMG Vanadium alleges that vanadium pentoxide produced in Russia is imported into the United States and further processed into ferrovanadium. According to AMG Vanadium, the Russian vanadium pentoxide is converted into ferrovanadium by Bear Metallurgical Company (Bear), a toll processor unaffiliated with the Evraz Group. AMG Vanadium believes that Evraz Group member, East Metals NA, retains title to the merchandise during the toll conversion. See AMG Request at pages 5–7, and March 16 Response at pages 6–10.

C. Minor or Insignificant Process

AMG Vanadium asserts that the process of converting vanadium pentoxide into ferrovanadium is a limited and minor process as compared to the production process for vanadium pentoxide. See AMG Request at pages 7–10, and Exhibits 13–15 for a detailed discussion of the two production processes.

AMG Vanadium argues that an analysis of the relevant statutory factors of section 781(a)(2) of the Act supports its conclusion that the processing in the United States is “minor or insignificant.” These factors include: (1) The level of investment in the United States; (2) the level of research and development in the United States; (3) the nature of the production process in the United States; (4) the extent of production facilities in the United States; and (5) whether the value of the processing performed in the United States represents a small proportion of the value of the merchandise sold in the United States.

AMG Vanadium argues that the processing in the United States is

“minor and insignificant” as the term is defined in section 781(a)(2) of the Act when compared to the complex and capital-intensive process involved in producing vanadium pentoxide. AMG Vanadium’s analysis of the statutory factors to determine whether the process is minor or insignificant in accordance with section 782(a)(2) of the Act follows below.

(1) Level of Investment

AMG Vanadium asserts that the processing of vanadium pentoxide into ferrovanadium, as discussed in the AMG Request,⁵ is neither complex nor capital-intensive and does not require extensive production facilities. Accordingly, AMG Vanadium contends that the level of investment for ferrovanadium conversion from vanadium pentoxide is low relative to the level of investment associated with vanadium pentoxide production.

(2) Level of Research and Development

AMG Vanadium states that the process for converting vanadium pentoxide into ferrovanadium as performed by the toll-processor Bear is unchanged since the initiation of the underlying antidumping duty investigation in 1994. Accordingly, AMG Vanadium believes the level of research and development in the United States for converting vanadium pentoxide into ferrovanadium is low.

(3) Nature of the Production Process in the United States

The production processes for both vanadium pentoxide and ferrovanadium are detailed in the AMG Request, as referenced above. AMG Vanadium maintains that the process of converting vanadium pentoxide into ferrovanadium is limited and minor as compared to the process of manufacturing vanadium pentoxide.

(4) Extent of Production Facilities in the United States

AMG Vanadium asserts that, consistent with its description of the production process, the conversion of vanadium pentoxide requires minimal capital equipment. At Exhibit 16 of the AMG Request, AMG Vanadium provided overhead photos comparing the extensive size of the Evraz Group’s vanadium pentoxide production facility with the considerably smaller “footprint” of Bear’s toll-processing facility in order to support its contention that the facilities necessary for processing vanadium pentoxide into ferrovanadium are significantly smaller

than those necessary for vanadium pentoxide production.

(5) Value of Processing in the United States Compared to Value of the Merchandise Sold in the United States

To support its contention that the value of the processing performed in the United States is a small portion of the total value of the merchandise sold in the United States, AMG Vanadium calculated the difference between the value of ferrovanadium sold in the United States, and the value of the vanadium pentoxide consumed to produce the ferrovanadium. For this calculation, AMG Vanadium based the value of ferrovanadium on the monthly average of the U.S. market prices for ferrovanadium with 80 percent vanadium content, as published in the metals industry publication *Ryan’s Notes*. Similarly, AMG Vanadium based the value of vanadium pentoxide on the monthly average of the U.S. market prices for vanadium pentoxide published in *Ryan’s Notes*, and then calculated the total value of vanadium pentoxide required to produce one unit of ferrovanadium with 80 percent vanadium content. In its calculations, AMG Vanadium added an amount to the vanadium pentoxide price to represent the estimated cost of freight from the U.S. port to the processing facility. AMG Vanadium calculated a ratio of the differences between the two sets of prices to average ferrovanadium prices, and found that the average annual value for processing vanadium pentoxide into ferrovanadium ranged from 6.5 to approximately 7 percent of the value of finished ferrovanadium during 2009, and approximately 15 to 15.8 percent in 2010. See AMG Request at pages 12–14 and Exhibits 17 and 18, and March 16 Response at pages 13–18 and Exhibit 10.

D. Value of Merchandise Produced in the Foreign Country Is a Significant Portion of the Value of the Merchandise Sold in the United States

As stated above, AMG Vanadium contends that the value of the processing performed in the United States represents a minor portion of the value of the completed merchandise. Therefore, that analysis necessarily implies that the value of the Russian-origin vanadium pentoxide consumed to produce ferrovanadium is a significant portion of the total value of the merchandise sold in the United States. AMG Vanadium estimates the value of the Russian vanadium pentoxide consumed to produce ferrovanadium to be 84 percent or greater of the value of the ferrovanadium sold in the United States (*i.e.*, the difference between the

⁵ See AMG Request at 7–11.

total value of the ferrovanadium sold in the United States and the value of the U.S. conversion described above). See AMG Request at page 14.

E. Factors To Consider in Determining Whether Action Is Necessary

Section 781(a)(3) of the Act identifies additional factors that the Department shall consider in the Department's decision to include parts or components in an antidumping duty order as part of an anticircumvention investigation. These factors are discussed below.

Pattern of Trade, Including Sourcing Patterns

AMG Vanadium explains in the AMG Request that, following the imposition of the antidumping duty order in 1995, imports of ferrovanadium from Russia ceased in total by 1997. Since 2005, however, imports of vanadium pentoxide from Russia have increased from 27 MT in 2005, to 450 MT in 2006, to 2,680 MT in 2010. At the same time, AMG Vanadium states that the average unit value of the vanadium pentoxide imports, according to U.S. import statistics, has decreased by half. AMG Vanadium concludes that this information demonstrates that the pattern of trade has shifted from imports of ferrovanadium from Russia to an increasing flow of vanadium pentoxide from Russia that is converted into ferrovanadium in the United States.

Affiliation

Under section 781(a)(3)(B) of the Act, the Department shall take into account whether the manufacturer or exporter of the parts or components is affiliated with the person who assembles or completes the merchandise sold in the United States from the parts or components produced in the foreign country when making a decision in an anticircumvention case. As described above and in the AMG Request, AMG Vanadium states that the Evraz Group, through its affiliates, produces vanadium pentoxide in Russia, ships and imports it into the United States, has it converted into ferrovanadium by an unaffiliated company while maintaining title to the product, and sells the completed ferrovanadium to customers in the United States. Accordingly, AMG Vanadium maintains that the manufacturer, exporter, and U.S. importer of the Russian vanadium pentoxide, as well as the party overseeing the conversion process and ultimate sale of the ferrovanadium, are all under the common ownership and control of a single entity, the Evraz Group.

Subsequent Import Volume

Under section 781(a)(3)(C) of the Act, the Department shall take into account whether imports into the United States of the parts or components produced in the foreign country have increased after the initiation of the investigation, which resulted in the issuance of the order, when making a decision in an anticircumvention case. As described above, AMG Vanadium reports that imports of vanadium pentoxide from Russia have risen from zero from 1995 to 2004, to approximately 2,680 MT in 2010.

Analysis

Based on our analysis of the AMG Request and the March 16 Response, the Department determines that a formal anticircumvention inquiry is warranted. In accordance with 19 CFR 351.225(e), if the Department finds that the issue of whether a product is included within the scope of an order cannot be determined based solely upon the request and the descriptions of the merchandise, the Department will notify by mail all parties on the Department's scope service list of the initiation of a scope inquiry, including an anticircumvention inquiry. In addition, in accordance with 19 CFR 351.225(f)(1), a notice of the initiation of an anticircumvention inquiry issued under 19 CFR 351.225(e) will include a description of the product that is the subject of the anticircumvention inquiry—in this case, vanadium pentoxide from Russia that is converted into ferrovanadium in the United States—and an explanation of the reasons for the Department's decision to initiate an anticircumvention inquiry, as provided below.

With regard to whether the merchandise sold in the United States is of the same class or kind as the merchandise covered by the antidumping duty order, AMG Vanadium presented information indicating that the merchandise sold in the United States, ferrovanadium, is of the same class or kind as ferrovanadium from Russia, which is subject to the antidumping duty order.

With regard to completion of merchandise in the United States, AMG Vanadium has also presented information to support its contention that ferrovanadium sold in the United States is produced from vanadium pentoxide imported into the United States from Russia which is further processed in the United States.

With regard to whether the conversion of ferrovanadium in the United States from vanadium pentoxide

imported from Russia is a "minor or insignificant process," AMG Vanadium addressed the relevant statutory factors used to determine whether the processing of vanadium pentoxide is minor or insignificant with the best information available to it at the time of its anticircumvention inquiry request. AMG Vanadium relied on publicly-available information for this purpose. As AMG noted in the March 16 Response at pages 10–12, it does not have access to the Evraz Group's cost or price data regarding vanadium pentoxide and ferrovanadium prices, and therefore relied on the *Ryan's Notes* price comparisons to demonstrate that, quantitatively, the value of the vanadium pentoxide conversion in the United States is minor or insignificant.

Based on our analysis of the information in AMG Vanadium's submissions, we find that AMG Vanadium provided sufficient evidence for each of the criteria enumerated in the statute to initiate an anticircumvention inquiry. As AMG Vanadium acknowledged, the price information derived from *Ryan's Notes* is based on price observations for domestic and imported products and, thus, is not limited to the Russian-sourced vanadium pentoxide or U.S.-converted ferrovanadium at issue. However, AMG Vanadium explained that the *Ryan's Notes* prices are widely used in price negotiations in the industry and fairly represent the value of ferrovanadium and vanadium pentoxide in the United States, regardless of source, and are the best information available to AMG Vanadium regarding the value of the imported input and the finished product. See March 16 Response at pages 10–15.

AMG Vanadium also acknowledged certain inconsistent fluctuations in the pricing spread between vanadium pentoxide and ferrovanadium according to the *Ryan's Notes* prices listed for certain months in Exhibit 18 of the AMG Request. AMG Vanadium asserted that these short-term fluctuations do not adversely affect the reliability of using the difference between the published *Ryan's Notes* market prices for ferrovanadium and vanadium pentoxide over a longer period of time to determine the value of the U.S. processing. We note that the inconsistent price fluctuations occurred in 2009, when vanadium pentoxide imports from Russia were much lower than during 2010 (see Exhibit 2 of the ACI Request). According to AMG Request Exhibit 18 and March 16 Response Exhibit 10, the price spread between vanadium pentoxide and

ferrovanadium was more stable during 2010, and provides reasonable support for AMG Vanadium's contention that the value of processing vanadium pentoxide into ferrovanadium may be considered minor or insignificant for purposes of initiating this anticircumvention inquiry. At the same time, we acknowledge the Evraz Group's comments regarding the use of this pricing information and an alternative, cost-based comparison methodology for determining whether the value of processing vanadium pentoxide into ferrovanadium in the United States is minor or insignificant. We will consider this issue further during our anticircumvention inquiry.

With respect to the value of the merchandise produced in Russia, AMG Vanadium relied on the information and arguments in the "minor or insignificant process" portion of its anticircumvention request to indicate that the value of the Russian vanadium pentoxide is significant relative to the total value of finished ferrovanadium sold in the United States. We find that this information adequately meets the requirements of this factor, as discussed above.

Finally, AMG Vanadium argued that the Department should also consider the pattern of trade, affiliation, and subsequent import volume as factors in determining whether to initiate the anticircumvention inquiry. The import volume data submitted by AMG Vanadium indicates that vanadium pentoxide imports from Russia have increased significantly in recent years, while imports of ferrovanadium from Russia ceased within a few years after imposition of the antidumping duty order. In addition, AMG Vanadium provided information suggesting that the Evraz Group, through its various affiliates, is managing the importation of vanadium pentoxide from Russia, the processing of this vanadium pentoxide into ferrovanadium in the United States, and the sale of the ferrovanadium in the United States, which together reflect an intention to shift to the United States completion of merchandise subject to the order on ferrovanadium from Russia.

Accordingly, we are initiating an anticircumvention inquiry concerning the antidumping duty order on ferrovanadium from Russia, pursuant to section 781(a) of the Act. In accordance with 19 CFR 351.225(l)(2), if the Department issues a preliminary affirmative determination, we will then instruct U.S. Customs and Border Protection to suspend liquidation and require a cash deposit of estimated duties, at the applicable rate, for each unliquidated entry of the merchandise

at issue, entered or withdrawn from warehouse for consumption on or after the date of initiation of the inquiry.

The Department is focusing its analysis of the significance of the ferrovanadium production process in the United States based on the entries of vanadium pentoxide produced in Russia by OAO Vanady-Tula that are imported by or consigned to any company in the Evraz Group, as discussed in the AMG Request and about which sufficient information to initiate an anticircumvention inquiry has been provided. If the Department receives a request from an interested party regarding potential circumvention by other companies involved in processing Russian vanadium pentoxide into ferrovanadium in the United States within sufficient time, we will consider conducting the inquiries concurrently.

The Department will, following consultation with interested parties, establish a schedule for questionnaires and comments on the issues. The Department intends to issue its final determination within 300 days of the date of publication of this initiation consistent with section 781(f) of the Act.

This notice is published in accordance with 19 CFR 351.225(f).

Dated: May 2, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011-11121 Filed 5-5-11; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

Environmental Technologies Trade Advisory Committee Public Meeting

AGENCY: International Trade Administration, DOC.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a meeting of the Environmental Technologies Trade Advisory Committee (ETTAC).

DATES: The meeting is scheduled for Thursday, June 16, 2011, at 9 a.m. Eastern Daylight Time (EDT).

ADDRESSES: The meeting will be held in Room 4830 at the U.S. Department of Commerce, Herbert Clark Hoover Building, 1401 Constitution Ave., NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Mr. Todd DeLelle, Office of Energy & Environmental Industries (OEEI), International Trade Administration,

Room 4053, 1401 Constitution Ave., NW., Washington, DC 20230. (Phone: 202-482-4877; Fax: 202-482-5665; e-mail: todd.delelle@trade.gov.) This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to OEEI at (202) 482-5225 no less than one week prior to the meeting.

SUPPLEMENTARY INFORMATION: This is the first meeting of the newly appointed committee. The meeting will take place from 9 a.m. to 3:30 p.m. This meeting is open to the public and time will be permitted for public comment from 3-3:30 p.m. Written comments concerning ETTAC affairs are welcome any time before or after the meeting. Minutes will be available within 30 days of this meeting.

Background: The ETTAC is mandated by Public Law 103-392. It was created to advise the U.S. government on environmental trade policies and programs, and to help it to focus its resources on increasing the exports of the U.S. environmental industry.

ETTAC operates as an advisory committee to the Secretary of Commerce and the Trade Promotion Coordinating Committee (TPCC). ETTAC was originally chartered in May of 1994. It was most recently re-chartered until October 2012.

Edward A. O'Malley,

Director, Office of Energy and Environmental Industries.

[FR Doc. 2011-11051 Filed 5-5-11; 8:45 am]

BILLING CODE 3510-DR-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-821-819]

Magnesium Metal From the Russian Federation: Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: In response to timely requests, the Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on magnesium metal from the Russian Federation for the period of review (POR) April 1, 2009, through March 31, 2010. The review covers two respondents, PSC VSMPO-AVISMA Corporation (AVISMA) and Solikamsk Magnesium Works (SMW).

The Department preliminarily determines that AVISMA did not make sales to the United States at less than normal value. If these preliminary results are adopted in the final results of this administrative review, we will instruct U.S. Customs and Border Protection (CBP) to assess no antidumping duties on entries by AVISMA during the POR. SMW reported that it had no shipments to the United States during the POR. The preliminary results are listed below in the section titled "Preliminary Results of Review."

DATES: *Effective Date:* May 6, 2011.

FOR FURTHER INFORMATION CONTACT: Hermes Pinilla or Minoo Hatten, AD/CVD Operations, Office 5, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482-3477 or (202) 482-1690, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department published the antidumping duty order on magnesium metal from the Russian Federation on April 15, 2005. See *Notice of Antidumping Duty Order: Magnesium Metal From the Russian Federation*, 70 FR 19930 (April 15, 2005). On April 1, 2010, the Department published in the **Federal Register** a notice of opportunity to request an administrative review of the order on magnesium metal from the Russian Federation. See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review*, 75 FR 16426 (April 1, 2010). On April 30, 2010, U.S. Magnesium Corporation LLC, the petitioner in this proceeding, requested that the Department conduct an administrative review with respect to AVISMA and SMW, both Russian Federation producers of the subject merchandise. On May 28, 2010, the Department published a notice of initiation of an administrative review of the antidumping duty order on magnesium metal from the Russian Federation for the period April 1, 2009, through March 31, 2010. See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 75 FR 29976 (May 28, 2010).

We have extended the deadline for the preliminary results of this administrative review from December 31, 2010, to April 30, 2011.¹ See

Magnesium Metal From the Russian Federation: Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review, 75 FR 78968 (December 17, 2010), and *Magnesium Metal From the Russian Federation: Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review*, 76 FR 12938 (March 9, 2011).

We are conducting this review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order²

The merchandise covered by the order is magnesium metal (also referred to as magnesium), which includes primary and secondary pure and alloy magnesium metal, regardless of chemistry, raw material source, form, shape, or size. Magnesium is a metal or alloy containing by weight primarily the element magnesium. Primary magnesium is produced by decomposing raw materials into magnesium metal. Secondary magnesium is produced by recycling magnesium-based scrap into magnesium metal. The magnesium covered by the order includes blends of primary and secondary magnesium.

The subject merchandise includes the following pure and alloy magnesium metal products made from primary and/or secondary magnesium, including, without limitation, magnesium cast into ingots, slabs, rounds, billets, and other shapes, and magnesium ground, chipped, crushed, or machined into raspings, granules, turnings, chips, powder, briquettes, and other shapes: (1) Products that contain at least 99.95 percent magnesium, by weight (generally referred to as "ultra-pure" magnesium); (2) products that contain less than 99.95 percent but not less than 99.8 percent magnesium, by weight (generally referred to as "pure" magnesium); and (3) chemical combinations of magnesium and other material(s) in which the magnesium content is 50 percent or greater, but less than 99.8 percent, by weight, whether or not conforming to an "ASTM Specification for Magnesium Alloy."

day when the Department is closed. See *Notice of Clarification: Application of "Next Business Day" Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, as Amended*, 70 FR 24533 (May 10, 2005). Accordingly, the deadline for completion of the preliminary results is May 2, 2011.

² On March 10, 2011, the Department revoked the order, effective April 15, 2010. See *Magnesium Metal From the Russian Federation: Revocation of Antidumping Duty Order Pursuant to Five-Year Sunset Review*, 76 FR 13128 (March 10, 2011). This review covers merchandise that entered the United States for consumption during the POR which met the description of the scope of the order.

The scope of the order excludes: (1) Magnesium that is in liquid or molten form; and (2) mixtures containing 90 percent or less magnesium in granular or powder form by weight and one or more of certain non-magnesium granular materials to make magnesium-based reagent mixtures, including lime, calcium metal, calcium silicon, calcium carbide, calcium carbonate, carbon, slag coagulants, fluorspar, nepheline syenite, feldspar, alumina (Al₂O₃), calcium aluminate, soda ash, hydrocarbons, graphite, coke, silicon, rare earth metals/mischmetal, cryolite, silica/fly ash, magnesium oxide, periclase, ferroalloys, dolomite lime, and colesmanite.³

The merchandise subject to the order is currently classifiable under items 8104.11.00, 8104.19.00, 8104.30.00, and 8104.90.00 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS item numbers are provided for convenience and customs purposes, the written description of the merchandise covered by the order is dispositive. See *id.*

SMW

On June 8, 2010, SMW submitted a letter indicating that it made no sales of the subject merchandise to the United States during the POR. We have not received any comments on SMW's submission. We examined SMW's claim of no shipments by issuing a "No Shipments Inquiry" to CBP and by reviewing electronic CBP data. See Memorandum to the File entitled "Magnesium Metal from the Russian Federation—Request for U.S. Entry Documents," dated October 27, 2010. Based on our review of the electronic CBP data, we found that there were entries of subject merchandise produced by SMW to the United States during the POR. On November 29, 2010, we requested clarification from SMW on the entries we found in the electronic CBP data. On December 8, 2010, SMW filed a response indicating that the shipments in question were made by a third party which resold the subject

³ This second exclusion for magnesium-based reagent mixtures is based on the exclusion for reagent mixtures in the 2001 investigations of magnesium from the People's Republic of China, Israel, and the Russian Federation. See *Notice of Final Determination of Sales at Less Than Fair Value: Pure Magnesium in Granular Form From the People's Republic of China*, 66 FR 49345 (September 27, 2001), *Notice of Final Determination of Sales at Less Than Fair Value: Pure Magnesium From Israel*, 66 FR 49349 (September 27, 2001), and *Notice of Final Determination of Sales at Not Less Than Fair Value: Pure Magnesium From the Russian Federation*, 66 FR 49347 (September 27, 2001). These mixtures are not magnesium alloys, because they are not chemically combined in liquid form and cast into the same ingot.

¹ Because April 30, 2011 falls on a Saturday, it is the Department's practice to issue a determination the next business day when the statutory deadline falls on a weekend, federal holiday, or any other

merchandise produced by SMW to the United States without the specific knowledge of SMW. Thus, according to SMW, it had no knowledge of or involvement in the importation of magnesium metal into the United States during the POR. See SMW's response to the Department's inquiry dated December 8, 2010. Based on the information SMW provided on the record, we find that SMW did not have knowledge of exports or involvement in imports of magnesium metal into the United States during the POR. Thus, we did not request SMW to report such sales to the Department for purposes of calculating a dumping margin in this administrative review.

Affiliated-Party Sales

Based on information on the record, we preliminarily determined that AVISMA is affiliated with one of its home-market customers. See memorandum entitled "Magnesium Metal from the Russian Federation: Affiliation Analysis" dated March 30, 2011. As a result, we requested that AVISMA respond to our June 7, 2010, questionnaire concerning sales of the foreign like product by AVISMA's home-market customer to its unaffiliated home-market customers. See the Department's letter to AVISMA dated March 31, 2011. On April 14, 2011, we received a response from AVISMA indicating that the home-market customer in question consumed all of the magnesium metal it purchased from AVISMA during the POR. Thus, according to AVISMA, it does not have any downstream sales to report to the Department. See AVISMA's response to the Department's request for affiliated-party sales dated April 14, 2011. Based on this information, we preliminarily find that no further action is required with respect to AVISMA's affiliated-party sales regarding the home-market customer in question. See *Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Magnesium Metal From the Russian Federation*, 69 FR 59197, 59200 (October 4, 2004), unchanged in *Magnesium Metal from the Russian Federation: Notice of Final Determination of Sales at Less Than Fair Value*, 70 FR 9041 (February 24, 2005).

Constructed Export Price

AVISMA identified all of its sales to the United States as constructed export price (CEP) sales because the U.S. sales were made on behalf of AVISMA by AVISMA's U.S. affiliate, VSMPO-Tirus, U.S., Inc. (Tirus US), to unaffiliated purchasers in the United States.

AVISMA and Tirus US are affiliated because Tirus US is a wholly owned subsidiary of AVISMA. See section 771(33)(E) of the Act. U.S. sales to the first unaffiliated party were made in the United States by the U.S. affiliate, thus satisfying the legal requirements for considering these transactions to be CEP sales. See section 772(b) of the Act.

We calculated CEP based on the packed, C.I.F. price to unaffiliated purchasers in the United States. In accordance with section 772(c)(2) of the Act, we made deductions from price for movement expenses and discounts, where appropriate. More specifically, we deducted early-payment discounts, expenses for Russian railway freight from plant to port, freight insurance, Russian brokerage, handling and port charges, international freight and marine insurance, U.S. customs duties, U.S. brokerage, handling, and port charges, U.S. warehousing, and U.S. inland freight.

In accordance with section 772(d)(1) of the Act, we deducted direct selling expenses and indirect selling expenses related to commercial activity in the United States. See also Statement of Administrative Action accompanying the Uruguay Round Agreements Act, H.R. Doc. No. 103-316, Vol. 1 (1994) at 823-824. Pursuant to sections 772(d)(3) and 772(f) of the Act, we made an adjustment for CEP profit allocated to expenses deducted under section 772(d)(1) of the Act. In accordance with section 772(f) of the Act, we computed profit based on the total revenues realized on sales in both the U.S. and home markets, less all expenses associated with those sales. We then allocated profit to expenses incurred with respect to U.S. economic activity based on the ratio of total U.S. expenses to total expenses for both the U.S. and home markets. See AVISMA Preliminary Results Analysis Memorandum dated May 2, 2011 (Preliminary Analysis Memo).

Normal Value

Based on a comparison of the aggregate quantity of home-market and U.S. sales and absent any information that a particular market situation in the exporting country did not permit a proper comparison, we determined that the quantity of foreign like product sold by AVISMA in the exporting country was sufficient to permit a proper comparison with the sales of the subject merchandise to the United States under section 773(a) of the Act. AVISMA's quantity of sales in its home market was greater than five percent of its sales to the U.S. market. Therefore, in accordance with section 773(a)(1)(B)(i)

of the Act, we considered basing normal value on the prices at which the foreign like product was first sold for consumption in the exporting country in the usual commercial quantities and in the ordinary course of trade and, to the extent practicable, at the same level of trade as the CEP sales.

In accordance with section 771(16)(A) of the Act, we considered all products produced by AVISMA that are covered by the description in the "Scope of the Order" section, above, and that were sold in the home market during the POR to be foreign like products for purposes of determining appropriate product comparisons to U.S. sales. In accordance with sections 771(16)(B) and (C) of the Act, where there were no sales of identical merchandise in the home market to compare to U.S. sales, we considered comparing U.S. sales to the most similar foreign like product on the basis of the product characteristics we determined to be the most appropriate for purposes of matching products.

Cost of Production Analysis

We disregarded below-cost sales in accordance with section 773(b) of the Act in the last completed review with respect to AVISMA in which it participated as of the date of initiation of this review. See *Magnesium Metal from the Russian Federation: Final Results of Antidumping Duty Administrative Review*, 73 FR 52642, 52643 (September 10, 2008). Therefore, we have reasonable grounds to believe or suspect that sales of the foreign like product under consideration for the determination of normal value in this review may have been made at prices below the cost of production (COP) as provided by section 773(b)(2)(A)(ii) of the Act. Therefore, pursuant to section 773(b)(1) of the Act, we conducted a COP investigation of sales by AVISMA in the home market.

In accordance with section 773(b)(3) of the Act, we calculated a weighted-average COP based on the sum of the cost of materials and fabrication for the foreign like product plus amounts for home-market selling, general and administrative expenses, interest expense, and packing expenses.

During the POR, AVISMA used two different accounting methodologies in its normal books and records to determine the costs of raw magnesium. AVISMA treated raw magnesium as a by-product in its normal books and records during the period April 1 through December 31, 2009. Raw magnesium and chlorine gas are produced jointly during the third major processing step, the electrolysis stage (*i.e.*, the split-off point), during which

both products become identifiable physically. AVISMA's calculation of the by-product value for raw magnesium started with the total sales value of finished goods produced. It reduced this amount by the budgeted profit, selling expenses, and post-split-off costs. Because AVISMA considers the remaining amount to represent the total net realizable value (NRV) of raw magnesium, it used this value as the offset for raw magnesium in calculating a total NRV for chlorine gas for its response to our questionnaire.

On January 1, 2010, AVISMA revised its accounting methodology in its normal books and records and began to treat chlorine gas as a by-product of raw magnesium. AVISMA's calculation of the by-product value for chlorine gas was based on the budgeted cost of production of AVISMA's new gasification plant. AVISMA valued chlorine gas at the estimated cost of liquid chlorine plus estimated transportation and gasification costs at its new facility. AVISMA then deducted the total estimated value of chlorine gas from the total joint costs and assigned the remaining joint costs to raw magnesium.

For reporting purposes in this administrative review, AVISMA departed from its normal books and records and relied instead on the Department's calculation methodology in *Magnesium Metal From the Russian Federation: Preliminary Results of Antidumping Duty Administrative Review*, 75 FR 26922 (May 13, 2010) (*Preliminary Results 08–09 Review*). See also Memorandum entitled "Cost of Production and Constructed Value Calculation Adjustments for the Preliminary Results—PSC VSMPO—AVISMA Corporation and VSMPO—Tirus US Inc.," dated May 7, 2010 (*Preliminary Results 08–09 Review Cost Memo*); the Department followed the same methodology in *Magnesium Metal From the Russian Federation: Final Results of Antidumping Duty Administrative Review*, 75 FR 56989 (September 17, 2010) (*Final Results 08–09 Review*).

As such, AVISMA considered chlorine gas and market-quality raw magnesium produced jointly at the split-off point as co-products. For the purpose of allocating the split-off-point joint costs to the co-products, AVISMA used the NRV of chlorine gas as calculated by the Department in the *Final Results 08–09 Review*. See Attachment 5 of the *Preliminary Results 08–09 Review Cost Memo*.

In accordance with section 773(f)(1)(A) of the Act, we have examined both accounting

methodologies employed by AVISMA in its normal books and records during the POR. We agree with AVISMA that for purposes of this review it is proper to depart from AVISMA's normal books and records for the period April 1 through December 31, 2009. See Memorandum entitled "Cost of Production and Constructed Value Calculation Adjustments for the Preliminary Results—PSC VMPPO—AVISMA Corporation and VSMPO—Tirus, U.S. Inc.," dated May 2, 2011 (*Preliminary Results 09–10 Review Cost Memo*). We have accepted AVISMA's reported costs for the period April 1 through December 31, 2009, for the sake of maintaining consistency with the prior segments of this proceeding. In the previous review, we also deviated from AVISMA's normal books and records (which considered raw magnesium to be a by-product of the joint process) and used the same co-product approach in allocating joint costs to raw magnesium and chlorine gas as reported by AVISMA for the first nine months of the instant POR (April 1 through December 31, 2009). See, e.g., *Preliminary Results 08–09 Review*, 75 FR at 26925 (unchanged in *Final Results 08–09 Review*).

As explained in the *Preliminary Results 09–10 Review Cost Memo*, we find AVISMA's new methodology to be a reasonable reflection of the costs associated with the production of the subject merchandise. Therefore, for these preliminary results, we have recalculated AVISMA's costs of raw magnesium and chlorine gas for the period January 1 through March 31, 2010, to reflect AVISMA's normal books and records as instructed by section 773(f)(1)(A) of the Act.

We have calculated the weighted-average COP using the costs of the final products for the period April 1 through December 31, 2009, and the costs of the final products for the period January 1 through March 31, 2010, in order to determine the weighted-average per-unit costs of the merchandise under consideration. See *Preliminary Results 09–10 Review Cost Memo*.

We have not considered the comments filed by the petitioner on April 20, 2011, in our analysis of AVISMA's reported costs for these preliminary results because of the lack of time between the date of the petitioner's filing and the statutory deadline for completion of the preliminary results. With less than two weeks between the submission of the comments and the fully extended statutory deadline for issuing these preliminary results, we could not ensure full participation by all parties in the

process of determining whether sufficient information is on the record to apply the proposed analysis. We will consider the petitioner's comments carefully for the final results of this review and we invite comments from the parties concerning the implications of applying the petitioner's proposed analysis for the purposes of this review (e.g., what to use for constructed value in the event we must rely on one of the alternative methods described in section 773(e)(2)(B) of the Act). Such comments should be filed in accordance with the schedule for filing case briefs as discussed in the "Disclosure and Public Comment" section below.

We also revised AVISMA's reported net interest expense ratio to exclude that portion of the reported interest income offset related to loans receivable. AVISMA's auditor could not determine that the carrying value of AVISMA's loans receivable was reasonable. As such, we cannot determine whether the interest income calculated by AVISMA based on the value of the loans receivable is a reasonable reflection of the actual interest received. Therefore, we have disallowed the offset for this interest income because we cannot conclude that the value of the reported interest income offset related to loans receivable is reasonable. See *id.*

After calculating the COP and in accordance with section 773(b)(1) of the Act, we tested whether home market sales of the foreign like product were made at prices below the COP within an extended period of time in substantial quantities and whether such prices permitted the recovery of all costs within a reasonable period of time. We compared model-specific COPs to the reported home market prices less any applicable movement charges, discounts, and rebates. Pursuant to section 773(b)(2)(C) of the Act, when less than 20 percent of a respondent's sales of a given product were at prices less than the COP, we do not disregard any below-cost sales of that product because the below-cost sales were not made in substantial quantities within an extended period of time. When 20 percent or more of a respondent's sales of a given product were at prices less than the COP, we disregard the below-cost sales because they were made in substantial quantities within an extended period of time pursuant to sections 773(b)(2)(B) and (C) of the Act and because, based on comparisons of prices to weighted-average COPs for the POR, such sales were at prices which would not permit recovery of all costs within a reasonable period of time in accordance with section 773(b)(2)(D) of the Act. Based on this test, we

disregarded certain home market sales of magnesium metal because such sales did not pass the cost test. See Preliminary Analysis Memo.

Level of Trade

In the U.S. market, AVISMA made CEP sales. In the case of CEP sales, we identified the level of trade based on the price after the deduction of expenses and profit under section 772(d) of the Act. Although the starting price for CEP sales was based on sales made by the affiliated reseller to unaffiliated customers through two channels of distribution, sales to end-users and distributors, AVISMA reported similar selling activities associated with all sales to the affiliated reseller (*i.e.*, at the CEP level of trade).

AVISMA reported one channel of distribution in the home market, sales to end-users. We found that this channel of distribution constitutes a single level of trade in the home market. To determine whether home market sales were made at a different level of trade than U.S. sales, we examined stages in the marketing process and selling functions along the chain of distribution between the producer and the unaffiliated customer. We found that there were significant differences between the selling activities associated with the CEP level of trade and those associated with the home market level of trade and, thus, we found the CEP level of trade to be different from the home market level of trade. Further, we found the CEP level of trade to be at a less advanced stage of distribution than the home market level of trade.

Because AVISMA reported no home market levels of trade that were equivalent to the CEP level of trade and because we determined that the CEP level of trade was at a less advanced stage than the single home market level of trade, we were unable to determine a level-of-trade adjustment based on the respondent's home market sales of the foreign like product. Furthermore, we have no other information that provides an appropriate basis for determining a level-of-trade adjustment. For AVISMA's CEP sales, we made a CEP-offset adjustment in accordance with section 773(a)(7)(B) of the Act. For a description of our level-of-trade analysis for these preliminary results, see Preliminary Analysis Memo.

Currency Conversion

For purposes of the preliminary results and in accordance with section 773A of the Act, we made currency conversions based on the official exchange rates in effect on the dates of the U.S. sales as certified by the Federal

Reserve Bank of New York. See 19 CFR 351.415.

Preliminary Results of Review

As a result of our review, we preliminarily determine that the following weighted-average dumping margins on magnesium metal from the Russian Federation exist for the period April 1, 2009, through March 31, 2010:

| Manufacturer/exporter | Margin (percent) |
|------------------------------------|------------------|
| PSC VSMPO-AVISMA Corporation | 0.00 |
| Solikamsk Magnesium Works .. | * |

* No shipments or sales subject to this review. The firm has an individual rate from the last segment of the proceeding in which the firm had shipments or sales.

Disclosure and Public Comment

Pursuant to 19 CFR 351.224(b), the Department will disclose to any party to the proceeding the calculations performed in connection with these preliminary results within five days after the date of publication of this notice. Interested parties are invited to comment on the preliminary results of this review. Pursuant to 19 CFR 351.309(c), case briefs or other written comments may be submitted to the Assistant Secretary for Import Administration. Interested parties may submit case briefs within 30 days of the date of publication of this notice. See 19 CFR 351.309(c). Rebuttal briefs, which must be limited to issues raised in the case briefs, may be filed not later than 35 days after the date of publication of this notice. See 19 CFR 351.309(d). Parties who submit case briefs or rebuttal briefs in this review 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. A list of authorities used and an executive summary of issues should accompany any briefs submitted to the Department. This summary should be limited to five pages total, including footnotes.

In accordance with 19 CFR 351.310, we will hold a public hearing, if requested, to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs. If requested, a hearing will be held two days after the deadline for submission of the rebuttal briefs at the U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, at a time and location to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date. Interested parties who wish to request a

hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, Room 1870, within 30 days of the date of publication of this notice. See 19 CFR 351.310(c). Requests should contain (1) the party's name, address, and telephone number, (2) the number of participants, and (3) a list of the issues to be discussed. At the hearing, each party may make an affirmative presentation only on issues raised in that party's case brief and may make rebuttal presentations only on arguments included in that party's rebuttal brief. See 19 CFR 351.310(c).

Assessment Rates

The Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries. In accordance with 19 CFR 351.212(b)(1), we have calculated an importer-specific assessment rate for AVISMA reflecting these preliminary results of review.

The Department clarified its "automatic assessment" regulation on May 6, 2003. This clarification will apply to entries of subject merchandise during the POR produced by AVISMA or SMW for which AVISMA or SMW did not know their merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries of merchandise produced by AVISMA or SMW at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction. For a full discussion of this clarification, see *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

The Department intends to issue liquidation instructions to CBP 15 days after the publication of the final results of review.

Cash-Deposit Requirements

Because we revoked the order effective April 15, 2010, no cash deposits for estimated antidumping duties are required.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties

occurred and the subsequent assessment of double antidumping duties.

The preliminary results of this administrative review and this notice are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: May 2, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011-11122 Filed 5-5-11; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XA416

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Pacific Fishery Management Council (Pacific Council) will convene a Sardine Research Planning Workshop that is open to the public.

DATES: The meeting will be held Monday, May 23, 2011 through Tuesday, May 24, 2011. Business will begin each day at 8 a.m., and conclude each day at 5 p.m. or until business for the day is completed.

ADDRESSES: The workshop will be held at Best Western Inn by the Sea, 7830 Fay Avenue, La Jolla, CA 92037.

FOR FURTHER INFORMATION CONTACT: Kerry Griffin, Staff Officer; telephone: (503) 820-2280.

SUPPLEMENTARY INFORMATION: The objectives of the Workshop are to: (1) Develop a coordinated synoptic sardine survey plan designed to compare the results of abundance estimates developed from different survey methods; (2) Improve collaborative research opportunities and coordination between the sardine industry and NMFS; and (3) Develop a proposed survey budget, timeframe, Principal Investigators, and operational requirements.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice

that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Ms. Carolyn Porter at (503) 820-2280 at least 5 days prior to the meeting date.

Dated: May 3, 2011.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2011-11104 Filed 5-5-11; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XA414

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Scientific and Statistical Committee (SSC) of the Mid-Atlantic Fishery Management Council (Council) Meeting.

DATES: The meeting will be held Wednesday, May 25, 2011 from 9 a.m. until 5 p.m. and Thursday, May 26, 2011 from 8 a.m. until 12 p.m.

ADDRESSES: The meeting will be held at the Admiral Fell Inn, 888 South Broadway, Baltimore, MD 21231; telephone: (410) 522-7377.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674-2331.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore PhD, Executive Director, Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 526-5255.

SUPPLEMENTARY INFORMATION: The primary purpose of the meeting is to develop ABC recommendations for the Council for Atlantic mackerel, butterfish, *Loligo* and *Illex* Squids for 2012 (potentially multi-year specifications for some species). In addition, an update on activities relevant to the SSC will be given

including (but not limited to): AP Performance Report, Ecosystem Subcommittee activities, 2011 National SSC Workshop program development, University of Maryland MSE Study, Surfclam Ocean Quahog Excessive Share Project, and ACL/AM Working Group recommendations.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to M. Jan Saunders at the Mid-Atlantic Council Office, (302) 526-5251, at least 5 days prior to the meeting date.

Dated: May 3, 2011.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2011-11103 Filed 5-5-11; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XA415

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council will convene a meeting of the Vessel Monitoring System (VMS) Advisory Panel.

DATES: The meeting will convene at 12 noon on Tuesday, May 24, 2011 and conclude by 1 p.m. on Wednesday, May 25, 2011.

ADDRESSES: The meeting will be held at the Gulf of Mexico Fishery Management Council, 2203 N. Lois Avenue, Suite 1100, Tampa, FL 33607; telephone: (813) 348-1630.

FOR FURTHER INFORMATION CONTACT: Dr. John Froeschke, Fishery Biologist-Statistician; Gulf of Mexico Fishery Management Council; *telephone:* (813) 348-1630 x235.

SUPPLEMENTARY INFORMATION: The Vessel Monitoring System (VMS) Advisory Panel will meet to discuss operation, design, usage of vessel monitoring systems (VMS), and resulting data from these systems. The Advisory Panel will discuss the current and future needs of VMS software including methods to improve VMS products and services to Gulf of Mexico VMS users. Presentations will be given from current VMS software providers in Gulf of Mexico fisheries. The Advisory Panel will also consider technical issues with VMS including a review of existing procedures to safeguard VMS data from unauthorized use or distribution. Finally, the Advisory Panel will also consider future roles and potential applications of VMS in other Gulf of Mexico fisheries. The meeting will conclude with draft recommendations presented to the Gulf of Mexico Fishery Management Council at its June 6-10, 2011 meeting in Key West, FL.

Copies of the agenda and other related materials can be obtained by calling (813) 348-1630.

Although other non-emergency issues not on the agenda may come before the Advisory Panel for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during this meeting. Actions of the Advisory Panel will be restricted to those issues specifically identified in the agenda and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Council (see **ADDRESSES**) at least 5 working days prior to the meeting.

Dated: May 3, 2011.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2011-11105 Filed 5-5-11; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XA412

Marine Fisheries Advisory Committee Meeting

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

ACTION: Notice of open public meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the Marine Fisheries Advisory Committee (MAFAC). The members will discuss and provide advice on issues outlined under **SUPPLEMENTARY INFORMATION** below.

DATES: The meeting will be held May 24-26, 2011, from 8:30 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the Florida Keys Eco-Discovery Center, 35 East Quay Road, Key West, FL 33040; 305-809-4700.

FOR FURTHER INFORMATION CONTACT: Mark Holliday, MAFAC Executive Director; (301) 713-2239 x-120; e-mail: Mark.Holliday@noaa.gov.

SUPPLEMENTARY INFORMATION: As required by section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. 2, notice is hereby given of a meeting of MAFAC. The MAFAC was established by the Secretary of Commerce (Secretary), and, since 1971, advises the Secretary on all living marine resource matters that are the responsibility of the Department of Commerce. The complete charter and summaries of prior meetings are located online at <http://www.nmfs.noaa.gov/ocs/mafac/>.

Matters To Be Considered

This agenda is subject to change.

The meeting is convened to hear presentations and discuss policies and guidance on the following topics: Gulf Ecosystem Restoration Task Force; National Ocean Policy, coastal and marine spatial planning, ocean energy and climate change adaptation; fisheries management; quota re-allocation policy; and aquaculture policy implementation. Updates will be presented on NOAA budgets, seafood safety, and recreational fisheries engagement. The meeting will include discussion of various MAFAC administrative and organizational matters and meetings of the standing subcommittees.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mark Holliday, MAFAC Executive Director; (301) 713-2239 x120 by May 13, 2011.

Dated: May 2, 2011.

Eric C. Schwaab,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 2011-11147 Filed 5-5-11; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XA417

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Scallop Oversight Committee, in May, 2011, to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Wednesday, May 25, 2011 at 9 a.m.

ADDRESSES: This meeting will be held at the Fairfield Inn & Suites, 185 MacArthur Drive, New Bedford, MA 02740; *telephone:* (774) 634-2000; *fax:* (774) 634-2001.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council; *telephone:* (978) 465-0492.

SUPPLEMENTARY INFORMATION: The Committee will review input from the Scallop Plan Development Team and the Scallop Advisory Panel related to development of Framework 23 to the Scallop Fishery Management Plan. To date, Framework 23 is considering alternatives to potentially require a turtle deflector dredge, revise the yellowtail flounder accountability measures (AMs) proposed in Amendment 15, and possibly modify

the limited access general category management program for the Northern Gulf of Maine (NGOM) area. The action may also include measures to develop alternatives to modify the current vessel monitoring system (VMS) regulations to improve scallop fleet operations (e.g., how days-at-sea are charged and how a vessel declares into the fishery). There will be a presentation from NMFS staff on the current estimate of yellowtail flounder catch by the scallop fishery in FY2010 as well as a description of how yellowtail flounder will be monitored in the future. The Committee will review recent correspondence related to potentially initiating an action to consider an additional limited access general category permit based on medical hardship. The Committee may also discuss other business at this meeting.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard, Executive Director, at (978) 465-0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: May 3, 2011.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2011-11106 Filed 5-5-11; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration (NOAA)

NOAA's Office of Ocean Exploration and Research (OER) Strategic Plan FY 2011-FY 2015

AGENCY: Office of Ocean Exploration and Research (OER), Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of publication and availability of the office of Ocean Exploration and Research Strategic Plan FY2011-FY2015.

SUMMARY: NOAA'S Office of Ocean Exploration and Research (OER) is electronically publishing the OER Strategic Plan for Fiscal Year (FY) 2011-2015. The strategic plan is published to meet the requirement for program direction under Public Law 111-11, Section 12104(b). The OER Strategic Plan describes the vision, mission, goals, core activities, and organization of the Office of Ocean Exploration and Research.

FOR FURTHER INFORMATION CONTACT: Electronic copies of the OER Strategic Plan and Public Law 111-11 Chapter XII are available and may be obtained from <http://www.regulations.gov> or from the OER Web site at <http://explore.noaa.gov/OERPlan>.

If you need further information, please contact: NOAA Office of Ocean Exploration and Research (OER), Attn: OER Plan Questions, 1315 East-West Highway-R/OER, Silver Spring, Maryland 20910.

Executive Summary of the OER 2011-2015 Strategic Plan

The ocean is important to humanity and is still mostly unknown. Current methods of studying its interior, boundaries, processes, resources, and changes are slow and expensive, causing management decisions to be made from relatively uninformed and incomplete knowledge. NOAA formed OER to explicitly address these issues, accelerate the pace of discoveries, and increase our understanding of the ocean.

OER supports a continuum of ocean science that makes discoveries via exploration and research, and transitions the new knowledge and capabilities to the rest of NOAA, and the national and international science, technology, and ocean management communities. OER integrates science, education, and outreach to raise awareness and increase ocean science literacy.

OER discoveries and activities help address issues such as the causes and consequences of natural events and human activities (e.g., climate change, ocean acidification), establishing the baseline in order to assess changes in biodiversity, marine life and other natural resources or habitats, understanding the dynamics of complex ecosystems, and improving the ability to model and predict future state of ocean and Great Lakes ecosystems.

This plan is centered on four cornerstone goals: Exploration, research,

advanced undersea technology development, and education and outreach. OER enables discovery through the interdisciplinary efforts of ocean scientists. NOAA mission-related discoveries are transitioned to focused research (Exploration to Research = E2R) sponsored by OER and by other agencies and programs with ocean-related missions. Subsequent research-to-application and technology-to-application transitions (Research to Application = R2A) are the ultimate goal of OER activities and will strengthen science, education, and awareness of the ocean role in the life and health of our planet, and will result in improved societal understanding and management of the ocean.

SUPPLEMENTARY INFORMATION: NOAA's Office of Ocean Exploration and Research (OER) is publishing the OER Strategic Plan Fiscal Year (FY) 2011-2015, to meet the requirement for program direction under Public Law 111-11, Section 12104(b). The preparation of the Plan was also directed by the Appropriations Committee in the Joint Explanatory Statement and Senate Report (S. Rept. 110-124) accompanying the Consolidated Fiscal Year 2008 Appropriations (Pub. L. 110-161).

OER seeks to better understand our ocean frontiers through bold and innovative exploration, research and technology development. The Office explores, maps, observes, detects and characterizes ocean areas and phenomena; obtains, archives, and distributes ocean data in new ways to describe the ocean's marine life and features, living and non-living resources, and physical, chemical and biological characteristics. Data and observations resulting from OER investments will result in new discoveries, insights, knowledge and identification of new frontiers, and will likely lead to new or revised understandings of our largely unknown ocean. The OER Strategic Plan describes how NOAA will implement Chapter XII of Public Law 111-11 through the vision, mission, goals, cores and activities, and organization of the Office of Ocean Exploration and Research.

Dated: May 2, 2011.

Mark E. Brown,

Chief Financial Officer/Chief Administrative Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2011-11146 Filed 5-5-11; 8:45 am]

BILLING CODE 3510-KA-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XA398

Marine Mammals; File No. 116-1691

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 Sea World LLC, Sea World of San Diego, 500 SeaWorld Drive, San Diego, California 92109 [Todd Robeck, D.V.M., PhD, Responsible Party and Principal Investigator (PI)] has been issued a minor amendment to Scientific Research Permit No. 116-1691-01.

ADDRESSES: The amendment and related documents are available for review upon written request or by appointment in the following offices:

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 713-2289; fax (301) 713-0376; and

Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802-4213; phone (562) 980-4001; fax (562) 980-4018.

FOR FURTHER INFORMATION CONTACT: Jennifer Skidmore and Amy Sloan, (301) 713-2289.

SUPPLEMENTARY INFORMATION: The requested amendment has been granted under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The original permit (No. 116-1691), issued on September 8, 2006 (71 FR 53089) authorized the permit holder to collect, receive, import, and export marine mammal specimens for scientific research purposes through August 31, 2011. The minor amendment (No. 116-1691-02) extends the duration of the permit through August 31, 2012, but does not change any other terms or conditions of the permit.

Dated: May 2, 2011.

P. Michael Payne,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2011-11149 Filed 5-5-11; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XA343

Takes of Marine Mammals Incidental to Specified Activities; Marine Geophysical Survey in the Western Gulf of Alaska, June to August, 2011

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

ACTION: Notice; proposed Incidental Harassment Authorization; request for comments.

SUMMARY: NMFS has received an application from the Lamont-Doherty Earth Observatory of Columbia University (L-DEO) for an Incidental Harassment Authorization (IHA) to take marine mammals, by harassment, incidental to conducting a marine geophysical survey in the western Gulf of Alaska (GOA), June to August, 2011. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an IHA to L-DEO to incidentally harass, by Level B harassment only, 16 species of marine mammals during the specified activity.

DATES: Comments and information must be received no later than June 6, 2011.

ADDRESSES: Comments on the application should be addressed to P. Michael Payne, Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910. The mailbox address for providing e-mail comments is ITP.Goldstein@noaa.gov. NMFS is not responsible for e-mail comments sent to addresses other than the one provided here. Comments sent via e-mail, including all attachments, must not exceed a 10-megabyte file size.

All comments received are a part of the public record and will generally be posted to <http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications> without change. All Personal Identifying Information (for example, name, address, *etc.*) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

A copy of the application containing a list of the references used in this document may be obtained by writing to the above address, telephoning the contact listed here (see **FOR FURTHER**

INFORMATION CONTACT) or visiting the Internet at: <http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications>.

The L-DEO, with support from the National Science Foundation (NSF), has prepared a draft "Environmental Assessment (EA) of a Marine Geophysical Survey by the R/V *Marcus G. Langseth* in the western Gulf of Alaska, July-August 2011," prepared by LGL Ltd., Environmental Research Associates (LGL), on behalf of L-DEO, which is also available at the same internet address. Documents cited in this notice may be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Howard Goldstein or Jolie Harrison, Office of Protected Resources, NMFS, (301) 713-2289, ext. 172.

SUPPLEMENTARY INFORMATION:**Background**

Section 101(a)(5)(D) of the MMPA (16 U.S.C. 1371 (a)(5)(D)) directs the Secretary of Commerce (Secretary) to authorize, upon request, the incidental, but not intentional, taking of small numbers of marine mammals of a species or population stock, by United States citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Authorization for the incidental taking of small numbers of marine mammals shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), and will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant). The authorization must set forth the permissible methods of taking, other means of effecting the least practicable adverse impact on the species or stock and its habitat, and requirements pertaining to the mitigation, monitoring and reporting of such takings. NMFS has defined "negligible impact" in 50 CFR 216.103 as "an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival."

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Section 101(a)(5)(D) of the MMPA

establishes a 45-day time limit for NMFS' review of an application followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of small numbers of marine mammals. Within 45 days of the close of the public comment period, NMFS must either issue or deny the authorization.

Except with respect to certain activities not pertinent here, the MMPA defines "harassment" as "any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment]."

Summary of Request

NMFS received an application on April 1, 2010, from L-DEO for the taking by harassment, of marine mammals, incidental to conducting a marine geophysical survey in the western GOA within the U.S. Exclusive Economic Zone (EEZ) in depths from approximately 25 meters (m) (82 feet [ft]) to greater than 6,000 m (19,685 ft). The cruise was postponed in 2010 and rescheduled for 2011. NMFS received a revised application on March 4, 2011 from L-DEO. L-DEO plans to conduct the proposed survey from approximately June 28 to August 4, 2011.

L-DEO plans to use one source vessel, the R/V *Marcus G. Langseth* (*Langseth*) and a seismic airgun array to collect seismic reflection and refraction profiles from the Shumagin Islands to east of Kodiak Island in the GOA. In addition to the proposed operations of the seismic airgun array, L-DEO intends to operate a multibeam echosounder (MBES) and a sub-bottom profiler (SBP) continuously throughout the survey.

Acoustic stimuli (*i.e.*, increased underwater sound) generated during the operation of the seismic airgun array may have the potential to cause a short-term behavioral disturbance for marine mammals in the survey area. This is the principal means of marine mammal taking associated with these activities and L-DEO has requested an authorization to take 16 species of marine mammals by Level B harassment. Take is not expected to result from the use of the MBES or SBP, for reasons discussed in this notice; nor is take expected to result from collision with the vessel because it is a single

vessel moving at a relatively slow speed during seismic acquisition within the survey, for a relatively short period of time (approximately 38 days). It is likely that any marine mammal would be able to avoid the vessel.

Description of the Specified Activity

L-DEO's proposed seismic survey in the western GOA, from the Shumagin Islands to east of Kodiak Island, will take place during June to August, 2011, in the area 52.5° to 59° North, 147.5° to 161° West (see Figure 1 of the IHA application). The proposed seismic survey will take place in water depths ranging from 25 m (82 ft) to greater than 6,000 m (82 to 19,685 ft) and consists of approximately 2,553 kilometers (km) (1,378.5 nautical miles [nmil]) of transect lines in the study area. The project is scheduled to occur from approximately June 28 to August 4, 2011. Some minor deviation from these dates is possible, depending on logistics and weather.

The proposed seismic survey will collect seismic reflection and refraction data to characterize the subduction zone off southern Alaska, which produces large and destructive earthquakes. The data from this study will be used to: (1) Estimate the size of the seismogenic zone, the portion of the fault that controls the magnitude of earthquakes, and (2) provide critical information on how the properties of the seismogenic zone change along the subduction zone such that some areas produce large earthquakes and others do not. The proposed study focuses on the Semidi segment, whose earthquake recurrence interval is 50 to 75 years and which last ruptured in 1938.

The survey will involve one source vessel, the *Langseth*. The *Langseth* will deploy an array of 36 airguns as an energy source at a tow depth of 12 m (39.4 ft). The receiving system will consist of two 8 km (4.3 nmil) long hydrophone streamers and/or 21 ocean bottom seismometers (OBSs). As the airgun is towed along the survey lines, the hydrophone streamers will receive the returning acoustic signals and transfer the data to the on-board processing system. The OBSs record the returning acoustic signals internally for later analysis.

The planned seismic survey (*e.g.*, equipment testing, startup, line changes, repeat coverage of any areas, and equipment recovery) will consist of approximately 2,553 km of transect lines in the western GOA survey area (see Figure 1 of the IHA application). Just over half of the survey (1,363 km [736 nmil]) will take place in water deeper than 1,000 m; 30% or 754 km (407.1 nmil) will be surveyed in

intermediate depth (100 to 1,000 m) water; and 17% (463 km [250 nmil]) will take place in water less than 100 m deep. Approximately 30 km (16.2 nmil) of seismic surveying will occur in water less than 40 m deep. A refraction survey using OBSs will take place along two lines (lines 3 and 5). Following the refraction survey, a multichannel (MCS) survey using two hydrophone streamers will take place along all of the transect lines. Thus, lines 3 and 5 will be surveyed twice. In addition to the operations of the airgun array, a Kongsberg EM 122 MBES and Knudsen 320B SBP will also be operated from the *Langseth* continuously throughout the cruise. There will be additional seismic operations associated with equipment testing, start-up, and possible line changes or repeat coverage of any areas where initial data quality is sub-standard. In L-DEO's calculations, 25% has been added for those additional operations.

All planned geophysical data acquisition activities will be conducted by L-DEO, the *Langseth's* operator, with on-board assistance by the scientists who have proposed the study. The Principal Investigators are Drs. Donna Shillington, Spahr Webb, and Mladen Nedimovic, all of L-DEO. The vessel will be self-contained, and the crew will live aboard the vessel for the entire cruise.

Vessel Specifications

The *Langseth*, owned by the National Science Foundation, will tow the 36 airgun array, as well as the hydrophone streamer, along predetermined lines. The *Langseth* will also deploy and retrieve the OBSs. When the *Langseth* is towing the airgun array and the hydrophone streamer, the turning rate of the vessel is limited to five degrees per minute. Thus, the maneuverability of the vessel is limited during operations with the streamer.

The vessel has a length of 71.5 m (235 ft); a beam of 17.0 m (56 ft); a maximum draft of 5.9 m (19 ft); and a gross tonnage of 3,834. The *Langseth* was designed as a seismic research vessel with a propulsion system designed to be as quiet as possible to avoid interference with the seismic signals emanating from the airgun array. The ship is powered by two 3,550 horsepower (hp) Bergen BRG-6 diesel engines which drive two propellers directly. Each propeller has four blades and the shaft typically rotates at 750 revolutions per minute. The vessel also has an 800 hp bowthruster, which is not used during seismic acquisition. The *Langseth's* operation speed during seismic acquisition is typically 7.4 to 9.3 km per

hour (hr) (km/hr) (4 to 5 knots [kts]). When not towing seismic survey gear, the *Langseth* typically cruises at 18.5 km/hr (10 kts). The *Langseth* has a range of 25,000 km (13,499 nmi) (the distance the vessel can travel without refueling).

The vessel also has an observation tower from which protected species visual observers (PSVO) will watch for marine mammals before and during the proposed airgun operations. When stationed on the observation platform, the PSVO's eye level will be approximately 21.5 m (71 ft) above sea level providing the PSVO an unobstructed view around the entire vessel.

Acoustic Source Specifications

Seismic Airguns

The *Langseth* will deploy a 36 airgun array, with a total volume of approximately 6,600 cubic inches (in³). The airgun array will consist of a mixture of Bolt 1500LL and Bolt 1900LLX airguns ranging in size from 40 to 360 in³, with a firing pressure of 1,900 pounds per square inch. The airguns will be configured as four identical linear arrays or "strings" (see Figure 2 of the application). Each string will have 10 airguns, the first and last airguns in the strings are spaced 16 m (52 ft) apart. Of the 10 airguns, nine airguns in each string will be fired simultaneously, whereas the tenth is kept in reserve as a spare, to be turned on in case of failure of another airgun. The four airgun strings will be distributed across an area of approximately 24x16 m (78.7 × 52.5 ft) behind the *Langseth* and will be towed approximately 100 m (328 ft) behind the vessel. The shot interval will be relatively short, 50 m (164 ft) or approximately 22 seconds (s), for the MCS survey or reflection surveying and relatively longer, 280 m (918.6 ft) or approximately 120 s, when recording data on the OBSs during the refraction survey. The firing pressure of the array is 1,900 pounds per square inch (psi). During firing, a brief (approximately 0.1 s) pulse sound is emitted; the airguns will be silent during the intervening periods. The dominant frequency components range from two to 188 Hertz (Hz).

The tow depth of the array will be 12 m (39.4 ft) during OBS refraction and MCS surveys. Because the actual source is a distributed sound source (36 airguns) rather than a single point source, the highest sound measurable at any location in the water will be less than the nominal source level. In addition, the effective source level for sound propagating in near-horizontal

directions will be substantially lower than the nominal source level applicable to downward propagation because of the directional nature of the sound from the airgun array.

Metrics Used in This Document

This section includes a brief explanation of the sound measurements frequently used in the discussions of acoustic effects in this document. Sound pressure is the sound force per unit area, and is usually measured in micropascals (μPa), where 1 pascal (Pa) is the pressure resulting from a force of one newton exerted over an area of one square meter. Sound pressure level (SPL) is expressed as the ratio of a measured sound pressure and a reference level. The commonly used reference pressure level in underwater acoustics is 1 μPa, and the units for SPLs are dB re: 1 μPa. SPL (in decibels [dB]) = 20 log (pressure/reference pressure).

SPL is an instantaneous measurement and can be expressed as the peak, the peak-peak (p-p), or the root mean square (rms). Root mean square, which is the square root of the arithmetic average of the squared instantaneous pressure values, is typically used in discussions of the effects of sounds on vertebrates and all references to SPL in this document refer to the root mean square unless otherwise noted. SPL does not take the duration of a sound into account.

Characteristics of the Airgun Pulses

Airguns function by venting high-pressure air into the water which creates an air bubble. The pressure signature of an individual airgun consists of a sharp rise and then fall in pressure, followed by several positive and negative pressure excursions caused by the oscillation of the resulting air bubble. The oscillation of the air bubble transmits sounds downward through the seafloor and the amount of sound transmitted in the near horizontal directions is reduced. However, the airgun array also emits sounds that travel horizontally toward non-target areas.

The nominal source levels of the airgun arrays used by L-DEO on the *Langseth* are 236 to 265 dB re 1 μPa (p-p) and the rms value for a given airgun pulse is typically 16 dB re 1 μPa lower than the peak-to-peak value. However, the difference between rms and peak or peak-to-peak values for a given pulse depends on the frequency content and duration of the pulse, among other factors.

Accordingly, L-DEO has predicted the received sound levels in relation to

distance and direction from the 36 airgun array and the single Bolt 1900LL 40 in³ airgun, which will be used during power-downs. A detailed description of L-DEO's modeling for marine seismic source arrays for species mitigation is provided in Appendix A of L-DEO's EA. These are the nominal source levels applicable to downward propagation. The effective source levels for horizontal propagation are lower than those for downward propagation when the source consists of numerous airguns spaced apart from one another.

Appendix B of L-DEO's EA discusses the characteristics of the airgun pulses. NMFS refers the reviewers to the application and EA documents for additional information.

Predicted Sound Levels for the Airguns

Tolstoy *et al.*, (2009) reported results for propagation measurements of pulses from the *Langseth*'s 36 airgun, 6,600 in³ array in shallow-water (approximately 50 m [164 ft]) and deep-water depths (approximately 1,600 m [5,249 ft]) in the Gulf of Mexico in 2007 and 2008. L-DEO has used these reported and corrected empirical values to determine exclusion zones (EZs) for the 36 airgun array and modeled measurements for the single airgun; to designate EZs for purposes of mitigation, and to estimate take for marine mammals in the GOA.

Results of the Gulf of Mexico calibration study (Tolstoy *et al.*, 2009) showed that radii around the airguns for various received levels varied with water depth. Empirical measurements from the Gulf of Mexico were used for GOA and those measurements were used to determine the algorithm for the model. The empirical data for deep water (greater than 1,000 m; 3,280 ft) indicated that the L-DEO model (as applied to the *Langseth*'s 36 airgun array) overestimated the received sound levels at a given distance. For intermediate depths, a correction of the empirical measurements for shallow and deep depths were made.

Using the corrected measurements (airgun array) or model (single airgun), Table 1 (below) shows the distances at which three rms sound levels are expected to be received from the 36 airgun array and a single airgun. The 180 and 190 dB re 1 μPa (rms) distances are the safety criteria for potential Level A harassment as specified by NMFS (2000) and are applicable to cetaceans and pinnipeds, respectively. If marine mammals are detected within or about to enter the appropriate EZ, the airguns will be powered-down (or shut-down, if necessary) immediately.

Table 1 summarizes the predicted distances at which sound levels (160,

180, and 190 dB [rms]) are expected to be received from the 36 airgun array and a single airgun operating in deep, intermediate, and shallow water depths.

TABLE 1—MEASURED (ARRAY) OR PREDICTED (SINGLE AIRGUN) DISTANCES TO WHICH SOUND LEVELS \geq 190, 180, AND 160 DB RE: 1 μ Pa (RMS) COULD BE RECEIVED IN VARIOUS WATER DEPTH CATEGORIES DURING THE PROPOSED SURVEY IN THE WESTERN GOA, JUNE TO AUGUST, 2011.

| Source and volume | Tow depth (m) | Water depth (m) | Predicted RMS radii distances (m) | | |
|---|---------------|-----------------------------------|-----------------------------------|--------|--------|
| | | | 190 dB | 180 dB | 160 dB |
| Single Bolt airgun (40 in ³) ... | 6 to 12 | Deep (> 1,000) | 12 | 40 | 385 |
| | | Intermediate (100 to 1,000) | 18 | 60 | 578 |
| | | Shallow (< 100) | 150 | 296 | 1,050 |
| 4 Strings, 36 airguns (6,600 in ³). | 12 | Deep (> 1,000) | 460 | 1,100 | 4,400 |
| | | Intermediate (100 to 1,000) | 615 | 1,810 | 13,935 |
| | | Shallow (<100) | 770 | 2,520 | 23,470 |

OBS Description and Deployment

The study will commence with a refraction survey using OBSs. Approximately 21 OBSs will be deployed by the *Langseth* at the beginning of the survey along one transect. After data are collected along this transect line, the OBSs will be picked up, and they will be re-deployed along the next refraction line. At the end of the refraction survey (approximately 3 days of seismic operations), all OBSs will be retrieved. OBS deployment is expected to take approximately 3 days, and OBS retrieval will take approximately 5 days.

Scripps Institution of Oceanography LC4x4 OBSs will be used during the cruise. This OBS has a volume of approximately 1 m³, with an anchor that consists of a large piece of steel grating (approximately 1 m²). Once an OBS is ready to be retrieved, an acoustic release transponder interrogates the OBS at a frequency of 9 to 11 kHz, and a response is received at a frequency of 9 to 13 kHz. The burn-wire release assembly is then activated, and the instrument is released from the anchor to float to the surface.

Along with the airgun operations, two additional acoustical data acquisition systems will be operated from the *Langseth* continuously during the survey. The ocean floor will be mapped with the Kongsberg EM 122 MBES and a Knudsen 320B SBP. These sound sources will be operated continuously from the *Langseth* throughout the cruise.

MBES

The *Langseth* will operate a Kongsberg EM 122 MBES concurrently during airgun operations to map characteristics of the ocean floor. The hull-mounted MBES emits brief pulses of sound (also called a ping) (10.5 to 13, usually 12 kHz) in a fan-shaped beam that extends downward and to the sides

of the ship. The transmitting beamwidth is 1° or 2° fore-aft and 150° athwartship and the maximum source level is 242 dB re: 1 μ Pa.

Each ping consists of eight (in water greater than 1,000 m) or four (less than 1,000 m) successive, fan-shaped transmissions, each encompassing a sector that extends 1° fore-aft. Continuous-wave pulses increase from 2 to 15 milliseconds (ms) long in water depths up to 2,600 m (8,530.2 ft), and FM chirp pulses up to 100 ms long are used in water greater than 2,600 m. The successive transmissions span an overall cross-track angular extent of about 150°, with 2 ms gaps between the pulses for successive sectors.

SBP

The *Langseth* will also operate a Knudsen 320B SBP continuously throughout the cruise simultaneously with the MBES to map and provide information about the sedimentary features and bottom topography. The beam is transmitted as a 27° cone, which is directed downward by a 3.5 kHz transducer in the hull of the *Langseth*. The maximum output is 1,000 watts (204 dB re 1 μ Pa), but in practice, the output varies with water depth. The pulse interval is one second, but a common mode of operation is to broadcast five pulses at one second intervals followed by a five second pause.

NMFS expects that acoustic stimuli resulting from the proposed operation of the single airgun or the 36 airgun array has the potential to harass marine mammals, incidental to the conduct of the proposed seismic survey. NMFS expects these disturbances to be temporary and result, at worst, in a temporary modification in behavior and/or low-level physiological effects (Level B harassment) of small numbers of certain species of marine mammals. NMFS does not expect that the

movement of the *Langseth*, during the conduct of the seismic survey, has the potential to harass marine mammals because of the relatively slow operation speed of the vessel (4.6 knots [kts]; 8.5 km/hr; 5.3 mph) during seismic acquisition.

Description of the Proposed Dates, Duration, and Specified Geographic Region

The survey will occur in the western GOA in the area 52.5° to 59° North, 147.5 to 161° West. The seismic survey will take place in water depths of 25 m to greater than 6,000 m. The *Langseth* will depart from Kodiak, Alaska on approximately June 28, 2011. The program will start with a refraction survey using OBSs. Approximately 21 OBSs will be deployed along one line; the OBSs will then be retrieved and re-deployed along the next refraction line. OBS deployment will take approximately three days and recovery will take approximately five days; there will be a total of approximately three days of refraction shooting. Following the refraction survey, the MCS survey will take place using the two streamers. MCS and airgun deployment will take approximately three days, and there will be approximately 13 days of MCS operations. Upon completion of seismic operations, all gear will be picked up and the vessel will travel to Dutch Harbor, for arrival on approximately August 4, 2011. Seismic operations in the study area will be carried out for approximately 16 days. Some minor deviation from this schedule is possible, depending on logistics and weather (*i.e.*, the cruise may depart earlier or be extended due to poor weather; there could be an additional three days of seismic operations if collected data are deemed to be of substandard quality).

Description of the Marine Mammals in the Area of the Proposed Specified Activity

Twenty-five marine mammal species (18 cetacean, 6 pinniped, and the sea otter) are known to or could occur in the GOA study area. Several of these species are listed as endangered under the U.S. Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*), including the North Pacific right (*Eubalaena japonica*), humpback (*Megaptera novaeangliae*), sei (*Balaenoptera borealis*), fin (*Balaenoptera physalus*), blue (*Balaenoptera musculus*), and sperm (*Physeter macrocephalus*) whales, as well as the Cook Inlet distinct population segment (DPS) of beluga whales (*Dezhnevius leucas*)

and the western stock of Steller sea lions (*Eumetopias jubatus*). The eastern stock of Steller sea lions is listed as threatened, as is the southwest Alaska DPS of the sea otter (*Enhydra lutris*).

The marine mammals that occur in the proposed survey area belong to four taxonomic groups: odontocetes (toothed cetaceans, such as dolphins), mysticetes (baleen whales), pinnipeds (seals, sea lions, and walrus), and fissipeds (sea otter). Cetaceans and pinnipeds are the subject of the IHA application to NMFS. Walrus sightings are rare in the GOA. Sea otters generally inhabit nearshore areas inside the 40 m (131.2 ft) depth contour (Riedman and Estes, 1990) and could be encountered in coastal waters, but likely would not be encountered in the deep, offshore waters of the study

area. The sea otter and Pacific walrus are two marine mammal species mentioned in this document that are managed by the U.S. Fish and Wildlife Service (USFWS) and are not considered further in this analysis; all others are managed by NMFS. The Cook Inlet DPS of beluga whales, California sea lions (*Zalophus c. californianus*), northern fur seals (*Callorhinus ursinus*), and northern elephant seals (*Mirounga angustirostris*) are not likely to be found in the waters of the survey area.

Table 2 (below) presents information on the abundance, distribution, population status, conservation status, and density of the marine mammals that may occur in the proposed survey area during June to August, 2011.

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Table 2. The habitat, regional abundance, and conservation status of marine mammals that may occur in or near the proposed seismic survey area in the western GOA. [See text and Tables 2 to 4 in L-DEO's application and EA for further details.]

| Species | Occurrence in/near Survey Area | Habitat | Abundance (Alaska) | Regional Abundance | ESA ¹ | MMPA ² | Density (#/1,000 km ²) Shallow Intermediate Deep Best ³ Max ⁴ | |
|--|-----------------------------------|----------------------------|-----------------------------|-----------------------------------|-----------------------------------|-------------------------------|--|-----------------------|
| Mysticetes | | | | | | | | |
| North Pacific right whale (<i>Eubalaena japonica</i>) | Rare | Coastal, shelf | 28-31 ⁵ | Low hundreds ⁶ | EN | D | 0 0 0 | 0 0 0 |
| Gray whale (<i>Eschrichtius robustus</i>) | Uncommon | Coastal | N.A. | 19,126 ⁷ | DL EN (West ern pop.) | NC D (Wester n pop.) | 0 0 0 | 0 0 0 |
| Humpback whale (<i>Megaptera novaeangliae</i>) | Common | Coastal, banks | 3,000 to 5,000 ⁸ | 20,800 ⁹ | EN | D | 40.90 12.69 2.61 | 66.0 66.0 6.53 |
| Minke whale (<i>Balaenoptera acutorostrata</i>) | Uncommon | Coastal, shelf | 1,233 ¹⁰ | 25,000 ¹¹ | NL | NC | 1.40 0.31 0 | 6.0 6.0 0 |
| Sei whale (<i>Balaenoptera borealis</i>) | Rare | Pelagic | N.A. | 7,260 to 12,620 ¹² | EN | D | 0 0 0 | 0 0 0 |
| Fin whale (<i>Balaenoptera physalus</i>) | Common | Pelagic | 1,652 ¹⁰ | 13,620 to 18,680 ¹³ | EN | D | 10.62 12.61 2.90 | 40.0 40.0 10.38 |
| Blue whale (<i>Balaenoptera musculus</i>) | Rare | Pelagic, shelf, coastal | N.A. | 3,500 ¹⁴ | EN | D | 0 0 0 | 0 0 0 |
| Odontocetes | | | | | | | | |
| Sperm whale (<i>Physeter macrocephalus</i>) | Uncommon | Pelagic | 159 ¹⁵ | 24,000 ¹⁶ | EN | D | 0 0.11 0.38 | 0 0.26 1.69 |
| Cuvier's beaked whale (<i>Ziphius cavirostris</i>) | Common | Pelagic | N.A. | 20,000 ¹⁷ | NL | NC | 0 1.12 0 | 0 1.81 0 |

| Species | Occurrence in/near Survey Area | Habitat | Abundance (Alaska) | Regional Abundance | ESA 1 | MMPA 2 | Density (#/1,000 km ²) Shallow Intermediate Deep Best ³ Max ⁴ | |
|--|-----------------------------------|------------------------------|---|------------------------------|-------------------------------------|-----------------------|--|-------------------------|
| Baird's beaked whale (<i>Berardius bairdii</i>) | Rare | Pelagic | N.A. | 6,000 ¹⁸ | NL | NC | 0 0.37 0 | 0 0.60 0 |
| Stejneger's beaked whale (<i>Mesoplodon stejnegeri</i>) | Common | Likely pelagic | N.A. | N.A. | NL | NC | 0 0 0 | 0 0 0 |
| Beluga whale (<i>Delphinapterus leucas</i>) | Extralimital | Coastal and ice edges | 340 ¹⁹ | N.A. | EN ³⁴ NL | D ³⁴ NC | 0 0 0 | 0 0 0 |
| Pacific white-sided dolphin (<i>Lagenorhynchus obliquidens</i>) | Common | Pelagic, shelf, coastal | 26,880 ²⁰ | 988,000 ²¹ | NL | NC | 2.08 3.96 0 | 4.76 14.36 0 |
| Risso's dolphin (<i>Grampus griseus</i>) | Extralimital | Pelagic, shelf, coastal | N.A. | 838,000 ²² | NL | NC | 0 0 0 | 0 0 0 |
| Killer whale (<i>Orcinus orca</i>) | Common | Pelagic, shelf, coastal | 2,636 ²³ | 8,500 ²⁴ | NL ³⁵ | NC | 7.26 7.34 3.79 | 41.80 41.80 13.53 |
| Short-finned pilot whale (<i>Globicephala macrorhynchus</i>) | Extralimital | Pelagic, shelf, coastal | N.A. | 53,000 ²² | NL | NC | 0 0 0 | 0 0 0 |
| Harbor porpoise (<i>Phocoena phocoena</i>) | Uncommon | Coastal | 11,146 ²⁵ 31,046 ²⁶ | 168,387 ²⁷ | NL | NC | 3.67 2.87 0 | 46.71 14.43 0 |
| Dall's porpoise (<i>Phocoenoides dalli</i>) | Common | Pelagic, shelf | 83,400 ²⁰ | 1,186,000 ²⁸ | NL | NC | 13.57 31.56 25.69 | 21.77 37.23 62.50 |
| Pinnipeds | | | | | | | | |
| Northern fur seal (<i>Callorhinus ursinus</i>) | Uncommon | Pelagic, breeds coastally | 653,171 ⁷ | 1.1 million ²⁹ | NL | D | 0 0 0 | 0 0 0 |
| Steller sea lion (<i>Eumetopias jubatus</i>) | Common | Coastal, offshore | 58,334 ⁴ 72,223 ³⁰ 42,366 ³¹ | N.A. | T ³⁶ EN ³⁶ | D | 3.29 2.91 9.80 | 3.99 4.20 14.70 |
| California sea lion (<i>Zalophus c. californianus</i>) | Uncommon | Coastal | N.A. | 238,000 ³³ | NL | NC | N.A. | N.A. |
| Harbor seal (<i>Phoca vitulina richardsi</i>) | Uncommon | Coastal | 45,975 ²⁶ | 180,017 ³² | NL | NC | 1.65 14.03 0 | 2.0 20.28 0 |

| Species | Occurrence in/near Survey Area | Habitat | Abundance (Alaska) | Regional Abundance | ESA ¹ | MMPA ² | Density (#/1,000 km ²) | |
|--|--------------------------------|-------------------|--------------------|-----------------------|------------------|-------------------|------------------------------------|--------------------------------------|
| | | | | | | | Shallow | Intermediate |
| | | | | | | | Deep | Best ³ Max ⁴ |
| Northern elephant seal (<i>Mirounga angustirostris</i>) | Uncommon | Coastal, offshore | N.A. | 124,000 ³³ | NL | NC | 0 0 0 | 0 0 0 |

N.A. Not available or not assessed.

¹ U.S. Endangered Species Act: EN = Endangered, T = Threatened, NL = Not listed.

² U.S. Marine Mammal Protection Act: D = Depleted, NC = Not Classified.

³ Best density estimate as listed in Table 3 of the application.⁴ Maximum density estimate as listed in Table 3 of the application.

⁵ Bering Sea and Aleutian Islands (Wade *et al.*, 2010).

⁶ Western population (Brownell *et al.*, 2001)

⁷ Eastern North Pacific (Allen and Angliss, 2010).

⁸ GOA (Calambokidis *et al.*, 2008).

⁹ North Pacific Ocean (Barlow *et al.*, 2009).

¹⁰ Western GOA and eastern Aleutians (Zerbini *et al.*, 2006).

¹¹ Northwest Pacific (Buckland *et al.*, 1992; IWC, 2009).

¹² North Pacific (Tillman, 1977).

¹³ North Pacific (Ohsumi and Wada, 1974).

¹⁴ Eastern North Pacific (NMFS, 1998).

¹⁵ Western GOA and eastern Aleutians (Zerbini *et al.*, 2004).

¹⁶ Eastern temperate North Pacific (Whitehead, 2002b).

¹⁷ Eastern Tropical Pacific (Wade and Gerrodette, 1993).

¹⁸ Western North Pacific (Reeves and Leatherwood, 1994; Kasuya, 2002).

¹⁹ Cook Inlet stock (Shelden *et al.*, 2010)

²⁰ Alaska stock (Allen and Angliss, 2010).

²¹ North Pacific Ocean (Miyashita, 1993b).

²² Western North Pacific Ocean (Miyashita, 1993a).

²³ Minimum abundance in Alaska, includes 2,084 resident and 552 GOA, Bering Sea, Aleutian Islands transients (Allen and Angliss, 2010).

²⁴ Eastern Tropical Pacific (Ford, 2002).

²⁵ Southeast Alaska stock (Allen and Angliss, 2010).

²⁶ GOA stock (Allen and Angliss, 2010).

²⁷ Eastern North Pacific (totals from Carretta *et al.*, 2009 and Allen and Angliss, 2010).

²⁸ North Pacific Ocean and Bering Sea (Houck and Jefferson, 1999).

²⁹ North Pacific (Gelatt and Lowry, 2008).

³⁰ Eastern U.S. Stock (Allen and Angliss, 2010).

³¹ Western U.S. Stock (Allen and Angliss, 2010).

³² Alaska statewide (Allen and Angliss, 2010).

³³ Carretta *et al.*, 2009.

³⁴ Cook Inlet DPS is listed as Endangered and Depleted; other stocks are not listed.

³⁵ Stocks in Alaska are not listed, but the southern resident DPS is listed as endangered. ATI transient in Alaska is considered depleted and a strategic stock (NOAA, 2004a).

³⁶ Eastern stock is listed as threatened, and the western stock is listed as endangered.

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Refer to Section III and IV of L-DEO's application for detailed information regarding the abundance and distribution, population status, and life history and behavior of these species and their occurrence in the proposed project area. The application also presents how L-DEO calculated the estimated densities for the marine mammals in the proposed survey area. NMFS has reviewed these data and determined them to be the best available scientific information for the purposes of the proposed IHA.

Potential Effects on Marine Mammals

Acoustic stimuli generated by the operation of the airguns, which introduce sound into the marine environment, may have the potential to cause Level B harassment of marine mammals in the proposed survey area. The effects of sounds from airgun operations might include one or more of the following: Tolerance, masking of natural sounds, behavioral disturbance, temporary or permanent hearing impairment, or non-auditory physical or physiological effects (Richardson *et al.*, 1995; Gordon *et al.*, 2004; Nowacek *et al.*, 2007; Southall *et al.*, 2007).

Permanent hearing impairment, in the unlikely event that it occurred, would

constitute injury, but temporary threshold shift (TTS) is not an injury (Southall *et al.*, 2007). Although the possibility cannot be entirely excluded, it is unlikely that the proposed project would result in any cases of temporary or permanent hearing impairment, or any significant non-auditory physical or physiological effects. Based on the available data and studies described here, some behavioral disturbance is expected, but NMFS expects the disturbance to be localized and short-term.

Tolerance to Sound

Studies on marine mammals' tolerance to sound in the natural

environment are relatively rare. Richardson *et al.* (1995) defines tolerance as the occurrence of marine mammals in areas where they are exposed to human activities or man-made noise. In many cases, tolerance develops by the animal habituating to the stimulus (*i.e.*, the gradual waning of responses to a repeated or ongoing stimulus) (Richardson *et al.*, 1995; Thorpe, 1963), but because of ecological or physiological requirements, many marine animals may need to remain in areas where they are exposed to chronic stimuli (Richardson *et al.*, 1995).

Numerous studies have shown that pulsed sounds from airguns are often readily detectable in the water at distances of many kilometers. Malme *et al.*, (1985) studied the responses of humpback whales on their summer feeding grounds in southeast Alaska to seismic pulses from an airgun with a total volume of 100 in³. They noted that the whales did not exhibit persistent avoidance when exposed to the airgun and concluded that there was no clear evidence of avoidance, despite the possibility of subtle effects, at received levels up to 172 dB re 1 μ Pa.

Weir (2008) observed marine mammal responses to seismic pulses from a 24 airgun array firing a total volume of either 5,085 in³ or 3,147 in³ in Angolan waters between August 2004 and May 2005. She recorded a total of 207 sightings of humpback whales ($n = 66$), sperm whales ($n = 124$), and Atlantic spotted dolphins ($n = 17$) and reported that there were no significant differences in encounter rates (sightings/hr) for humpback and sperm whales according to the airgun array's operational status (*i.e.*, active versus silent).

Masking of Natural Sounds

The term masking refers to the inability of a subject to recognize the occurrence of an acoustic stimulus as a result of the interference of another acoustic stimulus (Clark *et al.*, 2009). Introduced underwater sound may, through masking, reduce the effective communication distance of a marine mammal species if the frequency of the source is close to that used as a signal by the marine mammal, and if the anthropogenic sound is present for a significant fraction of the time (Richardson *et al.*, 1995).

Masking effects of pulsed sounds (even from large arrays of airguns) on marine mammal calls and other natural sounds are expected to be limited. Because of the intermittent nature and low duty cycle of seismic airgun pulses, animals can emit and receive sounds in the relatively quiet intervals between

pulses. However, in some situations, reverberation occurs for much or the entire interval between pulses (*e.g.*, Simard *et al.*, 2005; Clark and Gagnon, 2006) which could mask calls. Some baleen and toothed whales are known to continue calling in the presence of seismic pulses, and their calls can usually be heard between the seismic pulses (*e.g.*, Richardson *et al.*, 1986; McDonald *et al.*, 1995; Greene *et al.*, 1999; Nieukirk *et al.*, 2004; Smultea *et al.*, 2004; Holst *et al.*, 2005a,b, 2006; and Dunn and Hernandez, 2009). However, Clark and Gagnon (2006) reported that fin whales in the northeast Pacific Ocean went silent for an extended period starting soon after the onset of a seismic survey in the area. Similarly, there has been one report that sperm whales ceased calling when exposed to pulses from a very distant seismic ship (Bowles *et al.*, 1994). However, more recent studies found that they continued calling in the presence of seismic pulses (Madsen *et al.*, 2002; Tyack *et al.*, 2003; Smultea *et al.*, 2004; Holst *et al.*, 2006; and Jochens *et al.*, 2008). Dolphins and porpoises commonly are heard calling while airguns are operating (*e.g.*, Gordon *et al.*, 2004; Smultea *et al.*, 2004; Holst *et al.*, 2005a, b; and Potter *et al.*, 2007). The sounds important to small odontocetes are predominantly at much higher frequencies than are the dominant components of airgun sounds, thus limiting the potential for masking.

In general, NMFS expects the masking effects of seismic pulses to be minor, given the normally intermittent nature of seismic pulses. Refer to Appendix B(4) of L-DEO's EA for a more detailed discussion of masking effects on marine mammals.

Behavioral Disturbance

Disturbance includes a variety of effects, including subtle to conspicuous changes in behavior, movement, and displacement. Reactions to sound, if any, depend on species, state of maturity, experience, current activity, reproductive state, time of day, and many other factors (Richardson *et al.*, 1995; Wartzok *et al.*, 2004; Southall *et al.*, 2007; Weilgart, 2007). If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (*e.g.*, Lusseau and Bejder, 2007; Weilgart, 2007). Given the many uncertainties in predicting the

quantity and types of impacts of noise on marine mammals, it is common practice to estimate how many mammals would be present within a particular distance of industrial activities and/or exposed to a particular level of industrial sound. In most cases, this approach likely overestimates the numbers of marine mammals that would be affected in some biologically-important manner.

The sound criteria used to estimate how many marine mammals might be disturbed to some biologically-important degree by a seismic program are based primarily on behavioral observations of a few species. Scientists have conducted detailed studies on humpback, gray, bowhead (*Balaena mysticetus*), and sperm whales. Less detailed data are available for some other species of baleen whales, small toothed whales, and sea otters, but for many species there are no data on responses to marine seismic surveys.

Baleen Whales—Baleen whales generally tend to avoid operating airguns, but avoidance radii are quite variable (reviewed in Richardson *et al.*, 1995). Whales are often reported to show no overt reactions to pulses from large arrays of airguns at distances beyond a few kms, even though the airgun pulses remain well above ambient noise levels out to much longer distances. However, as reviewed in Appendix B (5) of L-DEO's EA, baleen whales exposed to strong noise pulses from airguns often react by deviating from their normal migration route and/or interrupting their feeding and moving away. In the cases of migrating gray and bowhead whales, the observed changes in behavior appeared to be of little or no biological consequence to the animals (Richardson, *et al.*, 1995). They simply avoided the sound source by displacing their migration route to varying degrees, but within the natural boundaries of the migration corridors.

Studies of gray, bowhead, and humpback whales have shown that seismic pulses with received levels of 160 to 170 dB re 1 μ Pa (rms) seem to cause obvious avoidance behavior in a substantial fraction of the animals exposed (Malme *et al.*, 1986, 1988; Richardson *et al.*, 1995). In many areas, seismic pulses from large arrays of airguns diminish to those levels at distances ranging from four to 15 km from the source. A substantial proportion of the baleen whales within those distances may show avoidance or other strong behavioral reactions to the airgun array. Subtle behavioral changes sometimes become evident at somewhat lower received levels, and studies summarized in Appendix B (5) of L-

DEO's EA have shown that some species of baleen whales, notably bowhead and humpback whales, at times, show strong avoidance at received levels lower than 160 to 170 dB re 1 μ Pa (rms).

McCauley *et al.* (1998, 2000a) studied the responses of humpback whales off western Australia to a full-scale seismic survey with a 16 airgun array (2,678 in³) and to a single airgun (20 in³) with source level of 227 dB re 1 μ Pa (p-p). In the 1998 study, they documented that avoidance reactions began at five to eight km from the array, and that those reactions kept most pods approximately three to four km from the operating seismic boat. In the 2000 study, they noted localized displacement during migration of four to five km by traveling pods and seven to 12 km by more sensitive resting pods of cow-calf pairs. Avoidance distances with respect to the single airgun were smaller but consistent with the results from the full array in terms of the received sound levels. The mean received level for initial avoidance of an approaching airgun was 140 dB re 1 μ Pa (rms) for humpback pods containing females, and at the mean closest point of approach distance the received level was 143 dB re 1 μ Pa (rms). The initial avoidance response generally occurred at distances of five to eight km from the airgun array and two km from the single airgun. However, some individual humpback whales, especially males, approached within distances of 100 to 400 m (328 to 1,312 ft), where the maximum received level was 179 dB re 1 μ Pa (rms).

Data collected by observers during several seismic surveys in the Northwest Atlantic showed that sighting rates of humpback whales were significantly greater during non-seismic periods compared with periods when a full array was operating (Moulton and Holst, 2010). In addition, humpback whales were more likely to swim away and less likely to swim towards a vessel during seismic vs. non-seismic periods (Moulton and Holst, 2010).

Humpback whales on their summer feeding grounds in southeast Alaska did not exhibit persistent avoidance when exposed to seismic pulses from a 1.64-L (100 in³) airgun (Malme *et al.*, 1985). Some humpbacks seemed "startled" at received levels of 150 to 169 dB re 1 μ Pa. Malme *et al.* (1985) concluded that there was no clear evidence of avoidance, despite the possibility of subtle effects, at received levels up to 172 dB re 1 μ Pa (rms). However, Moulton and Holst (2010) reported that humpback whales monitored during seismic surveys in the Northwest Atlantic had lower sighting rates and

were most often seen swimming away from the vessel during seismic periods compared with periods when airguns were silent.

Studies have suggested that south Atlantic humpback whales wintering off Brazil may be displaced or even strand upon exposure to seismic surveys (Engel *et al.*, 2004). The evidence for this was circumstantial and subject to alternative explanations (IAGC, 2004). Also, the evidence was not consistent with subsequent results from the same area of Brazil (Parente *et al.*, 2006), or with direct studies of humpbacks exposed to seismic surveys in other areas and seasons. After allowance for data from subsequent years, there was no observable direct correlation between strandings and seismic surveys (IWC, 2007:236).

There are no data on reactions of right whales to seismic surveys, but results from the closely-related bowhead whale show that their responsiveness can be quite variable depending on their activity (migrating versus feeding). Bowhead whales migrating west across the Alaskan Beaufort Sea in autumn, in particular, are unusually responsive, with substantial avoidance occurring out to distances of 20 to 30 km from a medium-sized airgun source at received sound levels of around 120 to 130 dB re 1 μ Pa (Miller *et al.*, 1999; Richardson *et al.*, 1999; see Appendix B (5) of L-DEO's EA). However, more recent research on bowhead whales (Miller *et al.*, 2005; Harris *et al.*, 2007) corroborates earlier evidence that, during the summer feeding season, bowheads are not as sensitive to seismic sources. Nonetheless, subtle but statistically significant changes in surfacing-respiration-dive cycles were evident upon statistical analysis (Richardson *et al.*, 1986). In the summer, bowheads typically begin to show avoidance reactions at received levels of about 152 to 178 dB re 1 μ Pa (Richardson *et al.*, 1986, 1995; Ljungblad *et al.*, 1988; Miller *et al.*, 2005).

Reactions of migrating and feeding (but not wintering) gray whales to seismic surveys have been studied. Malme *et al.* (1986, 1988) studied the responses of feeding eastern Pacific gray whales to pulses from a single 100 in³ airgun off St. Lawrence Island in the northern Bering Sea. They estimated, based on small sample sizes, that 50 percent of feeding gray whales stopped feeding at an average received pressure level of 173 dB re 1 μ Pa on an (approximate) rms basis, and that 10 percent of feeding whales interrupted feeding at received levels of 163 dB re 1 μ Pa (rms). Those findings were generally consistent with the results of

experiments conducted on larger numbers of gray whales that were migrating along the California coast (Malme *et al.*, 1984; Malme and Miles, 1985), and western Pacific gray whales feeding off Sakhalin Island, Russia (Wursig *et al.*, 1999; Gailey *et al.*, 2007; Johnson *et al.*, 2007; Yazvenko *et al.*, 2007a, b), along with data on gray whales off British Columbia (Bain and Williams, 2006).

Various species of *Balaenoptera* (blue, sei, fin, and minke whales) have occasionally been seen in areas ensounded by airgun pulses (Stone, 2003; MacLean and Haley, 2004; Stone and Tasker, 2006), and calls from blue and fin whales have been localized in areas with airgun operations (*e.g.*, McDonald *et al.*, 1995; Dunn and Hernandez, 2009; Castellote *et al.*, 2010). Sightings by observers on seismic vessels off the United Kingdom from 1997 to 2000 suggest that, during times of good sightability, sighting rates for mysticetes (mainly fin and sei whales) were similar when large arrays of airguns were shooting vs. silent (Stone, 2003; Stone and Tasker, 2006). However, these whales tended to exhibit localized avoidance, remaining significantly further (on average) from the airgun array during seismic operations compared with non-seismic periods (Stone and Tasker, 2006). Castellote *et al.* (2010) reported that singing fin whales in the Mediterranean moved away from an operating airgun array.

Ship-based monitoring studies of baleen whales (including blue, fin, sei, minke, and humpback whales) in the Northwest Atlantic found that overall, this group had lower sighting rates during seismic vs. non-seismic periods (Moulton and Holst, 2010). Baleen whales as a group were also seen significantly farther from the vessel during seismic compared with non-seismic periods, and they were more often seen to be swimming away from the operating seismic vessel (Moulton and Holst, 2010). Blue and minke whales were initially sighted significantly farther from the vessel during seismic operations compared to non-seismic periods; the same trend was observed for fin whales (Moulton and Holst, 2010). Minke whales were most often observed to be swimming away from the vessel when seismic operations were underway (Moulton and Holst, 2010).

Data on short-term reactions by cetaceans to impulsive noises are not necessarily indicative of long-term or biologically significant effects. It is not known whether impulsive sounds affect reproductive rate or distribution and

habitat use in subsequent days or years. However, gray whales have continued to migrate annually along the west coast of North America with substantial increases in the population over recent years, despite intermittent seismic exploration (and much ship traffic) in that area for decades (Appendix A in Malme *et al.*, 1984; Richardson *et al.*, 1995; Allen and Angliss, 2010). The western Pacific gray whale population did not seem affected by a seismic survey in its feeding ground during a previous year (Johnson *et al.*, 2007). Similarly, bowhead whales have continued to travel to the eastern Beaufort Sea each summer, and their numbers have increased notably, despite seismic exploration in their summer and autumn range for many years (Richardson *et al.*, 1987; Allen and Angliss, 2010).

Toothed Whales—Little systematic information is available about reactions of toothed whales to noise pulses. Few studies similar to the more extensive baleen whale/seismic pulse work summarized above and (in more detail) in Appendix B of L-DEO's EA have been reported for toothed whales. However, there are recent systematic studies on sperm whales (*e.g.*, Gordon *et al.*, 2006; Madsen *et al.*, 2006; Winsor and Mate, 2006; Jochens *et al.*, 2008; Miller *et al.*, 2009). There is an increasing amount of information about responses of various odontocetes to seismic surveys based on monitoring studies (*e.g.*, Stone, 2003; Smultea *et al.*, 2004; Moulton and Miller, 2005; Bain and Williams, 2006; Holst *et al.*, 2006; Stone and Tasker, 2006; Potter *et al.*, 2007; Hauser *et al.*, 2008; Holst and Smultea, 2008; Weir, 2008; Barkaszi *et al.*, 2009; Richardson *et al.*, 2009; Moulton and Holst, 2010).

Seismic operators and marine mammal observers on seismic vessels regularly see dolphins and other small toothed whales near operating airgun arrays, but in general there is a tendency for most delphinids to show some avoidance of operating seismic vessels (*e.g.*, Goold, 1996a,b,c; Calambokidis and Osmeck, 1998; Stone, 2003; Moulton and Miller, 2005; Holst *et al.*, 2006; Stone and Tasker, 2006; Weir, 2008; Richardson *et al.*, 2009; Barkaszi *et al.*, 2009; Moulton and Holst, 2010). Some dolphins seem to be attracted to the seismic vessel and floats, and some ride the bow wave of the seismic vessel even when large arrays of airguns are firing (*e.g.*, Moulton and Miller, 2005). Nonetheless, small toothed whales more often tend to head away, or to maintain a somewhat greater distance from the vessel, when a large array of airguns is operating than when it is silent (*e.g.*,

Stone and Tasker, 2006; Weir, 2008; Barry *et al.*, 2010; Moulton and Holst, 2010). In most cases, the avoidance radii for delphinids appear to be small, on the order of one km or less, and some individuals show no apparent avoidance. The beluga whale (*Delphinapterus leucas*) is a species that (at least at times) shows long-distance avoidance of seismic vessels. Aerial surveys conducted in the southeastern Beaufort Sea during summer found that sighting rates of beluga whales were significantly lower at distances 10 to 20 km compared with 20 to 30 km from an operating airgun array, and observers on seismic boats in that area rarely see belugas (Miller *et al.*, 2005; Harris *et al.*, 2007).

Captive bottlenose dolphins (*Tursiops truncatus*) and beluga whales exhibited changes in behavior when exposed to strong pulsed sounds similar in duration to those typically used in seismic surveys (Finneran *et al.*, 2000, 2002, 2005). However, the animals tolerated high received levels of sound before exhibiting aversive behaviors.

Results for porpoises depend on species. The limited available data suggest that harbor porpoises show stronger avoidance of seismic operations than do Dall's porpoises (Stone, 2003; MacLean and Koski, 2005; Bain and Williams, 2006; Stone and Tasker, 2006). Dall's porpoises seem relatively tolerant of airgun operations (MacLean and Koski, 2005; Bain and Williams, 2006), although they too have been observed to avoid large arrays of operating airguns (Calambokidis and Osmeck, 1998; Bain and Williams, 2006). This apparent difference in responsiveness of these two porpoise species is consistent with their relative responsiveness to boat traffic and some other acoustic sources (Richardson *et al.*, 1995; Southall *et al.*, 2007).

Most studies of sperm whales exposed to airgun sounds indicate that the sperm whale shows considerable tolerance of airgun pulses (*e.g.*, Stone, 2003; Moulton *et al.*, 2005, 2006a; Stone and Tasker, 2006; Weir, 2008). In most cases the whales do not show strong avoidance, and they continue to call (see Appendix B of L-DEO's EA for review). However, controlled exposure experiments in the Gulf of Mexico indicate that foraging behavior was altered upon exposure to airgun sound (Jochens *et al.*, 2008; Miller *et al.*, 2009; Tyack, 2009).

There are almost no specific data on the behavioral reactions of beaked whales to seismic surveys. However, some northern bottlenose whales (*Hyperoodon ampullatus*) remained in the general area and continued to

produce high-frequency clicks when exposed to sound pulses from distant seismic surveys (Gosselin and Lawson, 2004; Laurinoli and Cochrane, 2005; Simard *et al.*, 2005). Most beaked whales tend to avoid approaching vessels of other types (*e.g.*, Wursig *et al.*, 1998). They may also dive for an extended period when approached by a vessel (*e.g.*, Kasuya, 1986), although it is uncertain how much longer such dives may be as compared to dives by undisturbed beaked whales, which also are often quite long (Baird *et al.*, 2006; Tyack *et al.*, 2006). Based on a single observation, Aguilar-Soto *et al.* (2006) suggested that foraging efficiency of Cuvier's beaked whales may be reduced by close approach of vessels. In any event, it is likely that most beaked whales would also show strong avoidance of an approaching seismic vessel, although this has not been documented explicitly. In fact, Moulton and Holst (2010) reported 15 sightings of beaked whales during seismic studies in the Northwest Atlantic; seven of those sightings were made at times when at least one airgun was operating. There was little evidence to indicate that beaked whale behavior was affected by airgun operations; sighting rates and distances were similar during seismic and non-seismic periods (Moulton and Holst, 2010).

There are increasing indications that some beaked whales tend to strand when naval exercises involving mid-frequency sonar operation are ongoing nearby (*e.g.*, Simmonds and Lopez-Jurado, 1991; Frantzis, 1998; NOAA and USN, 2001; Jepson *et al.*, 2003; Hildebrand, 2005; Barlow and Gisiner, 2006; see also the Stranding and Mortality section in this notice). These strandings are apparently a disturbance response, although auditory or other injuries or other physiological effects may also be involved. Whether beaked whales would ever react similarly to seismic surveys is unknown. Seismic survey sounds are quite different from those of the sonar in operation during the above-cited incidents.

Odontocete reactions to large arrays of airguns are variable and, at least for delphinids and Dall's porpoises, seem to be confined to a smaller radius than has been observed for the more responsive of the mysticetes, belugas, and harbor porpoises (Appendix B of L-DEO's EA).

Pinnipeds—Pinnipeds are not likely to show a strong avoidance reaction to the airgun array. Visual monitoring from seismic vessels has shown only slight (if any) avoidance of airguns by pinnipeds, and only slight (if any) changes in behavior, see Appendix B(5) of L-DEO's EA. In the Beaufort Sea, some ringed

seals avoided an area of 100 m to (at most) a few hundred meters around seismic vessels, but many seals remained within 100 to 200 m (328 to 656 ft) of the trackline as the operating airgun array passed by (*e.g.*, Harris *et al.*, 2001; Moulton and Lawson, 2002; Miller *et al.*, 2005). Ringed seal sightings averaged somewhat farther away from the seismic vessel when the airguns were operating than when they were not, but the difference was small (Moulton and Lawson, 2002). Similarly, in Puget Sound, sighting distances for harbor seals and California sea lions tended to be larger when airguns were operating (Calambokidis and Osmeck, 1998). Previous telemetry work suggests that avoidance and other behavioral reactions may be stronger than evident to date from visual studies (Thompson *et al.*, 1998).

Hearing Impairment and Other Physical Effects

Exposure to high intensity sound for a sufficient duration may result in auditory effects such as a noise-induced threshold shift—an increase in the auditory threshold after exposure to noise (Finneran, Carder, Schlundt, and Ridgway, 2005). Factors that influence the amount of threshold shift include the amplitude, duration, frequency content, temporal pattern, and energy distribution of noise exposure. The magnitude of hearing threshold shift normally decreases over time following cessation of the noise exposure. The amount of threshold shift just after exposure is called the initial threshold shift. If the threshold shift eventually returns to zero (*i.e.*, the threshold returns to the pre-exposure value), it is called temporary threshold shift (TTS) (Southall *et al.*, 2007).

Researchers have studied TTS in certain captive odontocetes and pinnipeds exposed to strong sounds (reviewed in Southall *et al.*, 2007). However, there has been no specific documentation of TTS let alone permanent hearing damage, *i.e.*, permanent threshold shift (PTS), in free-ranging marine mammals exposed to sequences of airgun pulses during realistic field conditions.

Temporary Threshold Shift—TTS is the mildest form of hearing impairment that can occur during exposure to a strong sound (Kryter, 1985). While experiencing TTS, the hearing threshold rises and a sound must be stronger in order to be heard. At least in terrestrial mammals, TTS can last from minutes or hours to (in cases of strong TTS) days. For sound exposures at or somewhat above the TTS threshold, hearing sensitivity in both terrestrial and marine

mammals recovers rapidly after exposure to the noise ends. Few data on sound levels and durations necessary to elicit mild TTS have been obtained for marine mammals, and none of the published data concern TTS elicited by exposure to multiple pulses of sound. Available data on TTS in marine mammals are summarized in Southall *et al.* (2007). Table 1 (above) presents the distances from the Langseth's airguns at which the received energy level (per pulse, flat-weighted) would be expected to be greater than or equal to 180 dB re 1 μ Pa (rms).

To avoid the potential for injury, NMFS (1995, 2000) concluded that cetaceans should not be exposed to pulsed underwater noise at received levels exceeding 180 dB re 1 μ Pa (rms). NMFS believes that to avoid the potential for permanent physiological damage (Level A harassment), cetaceans should not be exposed to pulsed underwater noise at received levels exceeding 180 dB re 1 μ Pa (rms). The 180 dB level is a shutdown criterion applicable to cetaceans, as specified by NMFS (2000); these levels were used to establish the EZs. NMFS also assumes that cetaceans exposed to levels exceeding 160 dB re 1 μ Pa (rms) may experience Level B harassment.

Researchers have derived TTS information for odontocetes from studies on the bottlenose dolphin and beluga. For the one harbor porpoise tested, the received level of airgun sound that elicited onset of TTS was lower (Lucke *et al.*, 2009). If these results from a single animal are representative, it is inappropriate to assume that onset of TTS occurs at similar received levels in all odontocetes (*cf.* Southall *et al.*, 2007). Some cetaceans apparently can incur TTS at considerably lower sound exposures than are necessary to elicit TTS in the beluga or bottlenose dolphin.

For baleen whales, there are no data, direct or indirect, on levels or properties of sound that are required to induce TTS. The frequencies to which baleen whales are most sensitive are assumed to be lower than those to which odontocetes are most sensitive, and natural background noise levels at those low frequencies tend to be higher. As a result, auditory thresholds of baleen whales within their frequency band of best hearing are believed to be higher (less sensitive) than are those of odontocetes at their best frequencies (Clark and Ellison, 2004). From this, it is suspected that received levels causing TTS onset may also be higher in baleen whales (Southall *et al.*, 2007). For this proposed study, L-DEO expects no cases of TTS given the strong likelihood

that baleen whales would avoid the approaching airguns (or vessel) before being exposed to levels high enough for TTS to occur.

In pinnipeds, TTS thresholds associated with exposure to brief pulses (single or multiple) of underwater sound have not been measured. Initial evidence from more prolonged (non-pulse) exposures suggested that some pinnipeds (harbor seals in particular) incur TTS at somewhat lower received levels than do small odontocetes exposed for similar durations (Kastak *et al.*, 1999, 2005; Ketten *et al.*, 2001). The TTS threshold for pulsed sounds has been indirectly estimated as being an SEL of approximately 171 dB re 1 μ Pa²-s (Southall *et al.*, 2007) which would be equivalent to a single pulse with a received level of approximately 181 to 186 dB re 1 μ Pa (rms), or a series of pulses for which the highest rms values are a few dB lower. Corresponding values for California sea lions and northern elephant seals are likely to be higher (Kastak *et al.*, 2005).

Permanent Threshold Shift—When PTS occurs, there is physical damage to the sound receptors in the ear. In severe cases, there can be total or partial deafness, whereas in other cases, the animal has an impaired ability to hear sounds in specific frequency ranges (Kryter, 1985). There is no specific evidence that exposure to pulses of airgun sound can cause PTS in any marine mammal, even with large arrays of airguns. However, given the possibility that mammals close to an airgun array might incur at least mild TTS, there has been further speculation about the possibility that some individuals occurring very close to airguns might incur PTS (*e.g.*, Richardson *et al.*, 1995, p. 372ff; Gedamke *et al.*, 2008). Single or occasional occurrences of mild TTS are not indicative of permanent auditory damage, but repeated or (in some cases) single exposures to a level well above that causing TTS onset might elicit PTS.

Relationships between TTS and PTS thresholds have not been studied in marine mammals, but are assumed to be similar to those in humans and other terrestrial mammals. PTS might occur at a received sound level at least several dBs above that inducing mild TTS if the animal were exposed to strong sound pulses with rapid rise time—see Appendix B(6) of L-DEO's EA. Based on data from terrestrial mammals, a precautionary assumption is that the PTS threshold for impulse sounds (such as airgun pulses as received close to the source) is at least 6 dB higher than the TTS threshold on a peak-pressure basis,

and probably greater than six dB (Southall *et al.*, 2007).

Given the higher level of sound necessary to cause PTS as compared with TTS, it is considerably less likely that PTS would occur. Baleen whales generally avoid the immediate area around operating seismic vessels, as do some other marine mammals.

Stranding and Mortality—Marine mammals close to underwater detonations of high explosives can be killed or severely injured, and the auditory organs are especially susceptible to injury (Ketten *et al.*, 1993; Ketten, 1995). However, explosives are no longer used for marine waters for commercial seismic surveys or (with rare exceptions) for seismic research; they have been replaced entirely by airguns or related non-explosive pulse generators. Airgun pulses are less energetic and have slower rise times, and there is no specific evidence that they can cause serious injury, death, or stranding even in the case of large airgun arrays. However, the association of strandings of beaked whales with naval exercises involving mid-frequency active sonar and, in one case, an L-DEO seismic survey (Malakoff, 2002; Cox *et al.*, 2006), has raised the possibility that beaked whales exposed to strong “pulsed” sounds may be especially susceptible to injury and/or behavioral reactions that can lead to stranding (*e.g.*, Hildebrand, 2005; Southall *et al.*, 2007). Appendix B(6) of L-DEO’s EA provides additional details.

Specific sound-related processes that lead to strandings and mortality are not well documented, but may include:

- (1) Swimming in avoidance of a sound into shallow water;
- (2) A change in behavior (such as a change in diving behavior) that might contribute to tissue damage, gas bubble formation, hypoxia, cardiac arrhythmia, hypertensive hemorrhage or other forms of trauma;
- (3) A physiological change such as a vestibular response leading to a behavioral change or stress-induced hemorrhagic diathesis, leading in turn to tissue damage; and
- (4) Tissue damage directly from sound exposure, such as through acoustically mediated bubble formation and growth or acoustic resonance of tissues. Some of these mechanisms are unlikely to apply in the case of impulse sounds. However, there are indications that gas-bubble disease (analogous to “the bends”), induced in supersaturated tissue by a behavioral response to acoustic exposure, could be a pathologic mechanism for the strandings and mortality of some deep-diving cetaceans exposed to sonar. However, the

evidence for this remains circumstantial and associated with exposure to naval mid-frequency sonar, not seismic surveys (Cox *et al.*, 2006; Southall *et al.*, 2007).

Seismic pulses and mid-frequency sonar signals are quite different, and some mechanisms by which sonar sounds have been hypothesized to affect beaked whales are unlikely to apply to airgun pulses. Sounds produced by airgun arrays are broadband impulses with most of the energy below one kHz. Typical military mid-frequency sonar emits non-impulse sounds at frequencies of two to 10 kHz, generally with a relatively narrow bandwidth at any one time. A further difference between seismic surveys and naval exercises is that naval exercises can involve sound sources on more than one vessel. Thus, it is not appropriate to assume that there is a direct connection between the effects of military sonar and seismic surveys on marine mammals. However, evidence that sonar signals can, in special circumstances, lead (at least indirectly) to physical damage and mortality (*e.g.*, Balcomb and Claridge, 2001; NOAA and USN, 2001; Jepson *et al.*, 2003; Fernández *et al.*, 2004, 2005; Hildebrand 2005; Cox *et al.*, 2006) suggests that caution is warranted when dealing with exposure of marine mammals to any high-intensity “pulsed” sound.

There is no conclusive evidence of cetacean strandings or deaths at sea as a result of exposure to seismic surveys, but a few cases of strandings in the general area where a seismic survey was ongoing have led to speculation concerning a possible link between seismic surveys and strandings. Suggestions that there was a link between seismic surveys and strandings of humpback whales in Brazil (Engel *et al.*, 2004) were not well founded (IAGC, 2004; IWC, 2007). In September 2002, there was a stranding of two Cuvier’s beaked whales (*Ziphius cavirostris*) in the Gulf of California, Mexico, when the L-DEO vessel R/V *Maurice Ewing* was operating a 20 airgun (8,490 in³) array in the general area. The link between the stranding and the seismic surveys was inconclusive and not based on any physical evidence (Hogarth, 2002; Yoder, 2002). Nonetheless, the Gulf of California incident plus the beaked whale strandings near naval exercises involving use of mid-frequency sonar suggests a need for caution in conducting seismic surveys in areas occupied by beaked whales until more is known about effects of seismic surveys on those species (Hildebrand, 2005). No injuries of beaked whales are

anticipated during the proposed study because of:

(1) The high likelihood that any beaked whales nearby would avoid the approaching vessel before being exposed to high sound levels, and

(2) Differences between the sound sources operated by L-DEO and those involved in the naval exercises associated with strandings.

Non-auditory Physiological Effects—Non-auditory physiological effects or injuries that theoretically might occur in marine mammals exposed to strong underwater sound include stress, neurological effects, bubble formation, resonance, and other types of organ or tissue damage (Cox *et al.*, 2006; Southall *et al.*, 2007). Studies examining such effects are limited. However, resonance effects (Gentry, 2002) and direct noise-induced bubble formations (Crum *et al.*, 2005) are implausible in the case of exposure to an impulsive broadband source like an airgun array. If seismic surveys disrupt diving patterns of deep-diving species, this might perhaps result in bubble formation and a form of the bends, as speculated to occur in beaked whales exposed to sonar. However, there is no specific evidence of this upon exposure to airgun pulses.

In general, very little is known about the potential for seismic survey sounds (or other types of strong underwater sounds) to cause non-auditory physical effects in marine mammals. Such effects, if they occur at all, would presumably be limited to short distances and to activities that extend over a prolonged period. The available data do not allow identification of a specific exposure level above which non-auditory effects can be expected (Southall *et al.*, 2007), or any meaningful quantitative predictions of the numbers (if any) of marine mammals that might be affected in those ways. Marine mammals that show behavioral avoidance of seismic vessels, including most baleen whales and some odontocetes, are especially unlikely to incur non-auditory physical effects.

Potential Effects of Other Acoustic Devices

MBES

L-DEO will operate the Kongsberg EM 122 MBES from the source vessel during the planned study. Sounds from the MBES are very short pulses, occurring for two to 15 ms once every five to 20 s, depending on water depth. Most of the energy in the sound pulses emitted by this MBES is at frequencies near 12 kHz, and the maximum source level is 242 dB re 1 μ Pa (rms). The beam is narrow (1 to 2°) in fore-aft extent and

wide (150°) in the cross-track extent. Each ping consists of eight (in water greater than 1,000 m deep) or four (in water less than 1,000 m deep) successive fan-shaped transmissions (segments) at different cross-track angles. Any given mammal at depth near the trackline would be in the main beam for only one or two of the nine segments. Also, marine mammals that encounter the Kongsberg EM 122 are unlikely to be subjected to repeated pulses because of the narrow fore-aft width of the beam and will receive only limited amounts of pulse energy because of the short pulses. Animals close to the ship (where the beam is narrowest) are especially unlikely to be ensonified for more than one 2 to 15 ms pulse (or two pulses if in the overlap area). Similarly, Kremser *et al.* (2005) noted that the probability of a cetacean swimming through the area of exposure when an MBES emits a pulse is small. The animal would have to pass the transducer at close range and be swimming at speeds similar to the vessel in order to receive the multiple pulses that might result in sufficient exposure to cause TTS.

Navy sonars that have been linked to avoidance reactions and stranding of cetaceans: (1) Generally have longer pulse duration than the Kongsberg EM 122; and (2) are often directed close to horizontally versus more downward for the MBES. The area of possible influence of the MBES is much smaller—a narrow band below the source vessel. Also, the duration of exposure for a given marine mammal can be much longer for naval sonar. During L-DEO's operations, the individual pulses will be very short, and a given mammal would not receive many of the downward-directed pulses as the vessel passes by. Possible effects of an MBES on marine mammals are outlined below.

Masking—Marine mammal communications will not be masked appreciably by the MBES signals given the low duty cycle of the echosounder and the brief period when an individual mammal is likely to be within its beam. Furthermore, in the case of baleen whales, the MBES signals (12 kHz) do not overlap with the predominant frequencies in the calls, which would avoid any significant masking.

Behavioral Responses—Behavioral reactions of free-ranging marine mammals to sonars, echosounders, and other sound sources appear to vary by species and circumstance. Observed reactions have included silencing and dispersal by sperm whales (Watkins *et al.*, 1985), increased vocalizations and no dispersal by pilot whales

(*Globicephala melas*) (Rendell and Gordon, 1999), and the previously-mentioned beachings by beaked whales. During exposure to a 21 to 25 kHz "whale-finding" sonar with a source level of 215 dB re 1 μ Pa, gray whales reacted by orienting slightly away from the source and being deflected from their course by approximately 200 m (Frankel, 2005). When a 38 kHz echosounder and a 150 kHz acoustic Doppler current profiler were transmitting during studies in the Eastern Tropical Pacific, baleen whales showed no significant responses, while spotted and spinner dolphins were detected slightly more often and beaked whales less often during visual surveys (Gerrodette and Pettis, 2005).

Captive bottlenose dolphins and a beluga whale exhibited changes in behavior when exposed to 1 s tonal signals at frequencies similar to those that will be emitted by the MBES used by L-DEO, and to shorter broadband pulsed signals. Behavioral changes typically involved what appeared to be deliberate attempts to avoid the sound exposure (Schlundt *et al.*, 2000; Finneran *et al.*, 2002; Finneran and Schlundt, 2004). The relevance of those data to free-ranging odontocetes is uncertain, and in any case, the test sounds were quite different in duration as compared with those from an MBES.

Very few data are available on the reactions of pinnipeds to echosounder sounds at frequencies similar to those used during seismic operations. Hastie and Janik (2007) conducted a series of behavioral response tests on two captive gray seals to determine their reactions to underwater operation of a 375 kHz multibeam imaging echosounder that included significant signal components down to 6 kHz. Results indicated that the two seals reacted to the signal by significantly increasing their dive durations. Because of the likely brevity of exposure to the MBES sounds, pinniped reactions are expected to be limited to startle or otherwise brief responses of no lasting consequences to the animals.

Hearing Impairment and Other Physical Effects—Given recent stranding events that have been associated with the operation of naval sonar, there is concern that mid-frequency sonar sounds can cause serious impacts to marine mammals (see above). However, the MBES proposed for use by L-DEO is quite different than sonar used for Navy operations. Pulse duration of the MBES is very short relative to the naval sonar. Also, at any given location, an individual marine mammal would be in the beam of the MBES for much less time given the generally downward

orientation of the beam and its narrow fore-aft beamwidth; Navy sonar often uses near-horizontally-directed sound. Those factors would all reduce the sound energy received from the MBES rather drastically relative to that from naval sonar.

NMFS believes that the brief exposure of marine mammals to one pulse, or small numbers of signals, from the MBES is not likely to result in the harassment of marine mammals.

SBP

L-DEO will also operate a SBP from the source vessel during the proposed survey. Sounds from the SBP are very short pulses, occurring for one to four ms once every second. Most of the energy in the sound pulses emitted by the SBP is at 3.5 kHz, and the beam is directed downward. The SBP on the *Langseth* has a maximum source level of 204 dB re 1 μ Pa.

Kremser *et al.* (2005) noted that the probability of a cetacean swimming through the area of exposure when a bottom profiler emits a pulse is small—even for an SBP more powerful than that on the *Langseth*—if the animal was in the area, it would have to pass the transducer at close range in order to be subjected to sound levels that could cause TTS.

Masking—Marine mammal communications will not be masked appreciably by the SBP signals given the directionality of the signal and the brief period when an individual mammal is likely to be within its beam.

Furthermore, in the case of most baleen whales, the SBP signals do not overlap with the predominant frequencies in the calls, which would avoid significant masking.

Behavioral Responses—Marine mammal behavioral reactions to other pulsed sound sources are discussed above, and responses to the SBP are likely to be similar to those for other pulsed sources if received at the same levels. However, the pulsed signals from the SBP are considerably weaker than those from the MBES. Therefore, behavioral responses are not expected unless marine mammals are very close to the source.

Hearing Impairment and Other Physical Effects—It is unlikely that the SBP produces pulse levels strong enough to cause hearing impairment or other physical injuries even in an animal that is (briefly) in a position near the source. The SBP is usually operated simultaneously with other higher-power acoustic sources, including airguns. Many marine mammals will move away in response to the approaching higher-power sources or the vessel itself before

the mammals would be close enough for there to be any possibility of effects from the less intense sounds from the SBP.

Acoustic Release Signals

The acoustic release transponder used to communicate with the OBSs uses frequencies 9 to 13 kHz. These signals will be used very intermittently. It is unlikely that the acoustic release signals would have a significant effect on marine mammals through masking, disturbance, or hearing impairment. Any effects likely would be negligible given the brief exposure at presumably low levels.

The potential effects to marine mammals described in this section of the document do not take into consideration the proposed monitoring and mitigation measures described later in this document (see the "Proposed Mitigation" and "Proposed Monitoring and Reporting" sections) which, as noted are designed to effect the least practicable adverse impact on affected marine mammal species and stocks.

Anticipated Effects on Marine Mammal Habitat

The proposed seismic survey will not result in any permanent impact on habitats used by the marine mammals in the proposed survey area, including the food sources they use (*i.e.* fish and invertebrates), and there will be no physical damage to any habitat. While it is anticipated that the specified activity may result in marine mammals avoiding certain areas due to temporary ensonification, this impact to habitat is temporary and reversible and was considered in further detail earlier in this document, as behavioral modification. The main impact associated with the proposed activity will be temporarily elevated noise levels and the associated direct effects on marine mammals, previously discussed in this notice.

A total of approximately 21 OBSs will be deployed during the proposed study. Scripps LC4x4 OBSs will be used; this type of OBS has a volume of approximately 1 m³, with an anchor that consists of a large piece of steel grating (approximately 1 m²). OBS anchors will be left behind upon equipment recovery. Although OBS placement will disrupt a very small area of seafloor habitat and could disturb benthic invertebrates, the impacts are expected to be localized and transitory.

Anticipated Effects on Fish

One reason for the adoption of airguns as the standard energy source for marine seismic surveys is that, unlike

explosives, they have not been associated with large-scale fish kills. However, existing information on the impacts of seismic surveys on marine fish populations is limited (see Appendix D of L-DEO's EA). There are three types of potential effects of exposure to seismic surveys: (1) Pathological, (2) physiological, and (3) behavioral. Pathological effects involve lethal and temporary or permanent sub-lethal injury. Physiological effects involve temporary and permanent primary and secondary stress responses, such as changes in levels of enzymes and proteins. Behavioral effects refer to temporary and (if they occur) permanent changes in exhibited behavior (*e.g.*, startle and avoidance behavior). The three categories are interrelated in complex ways. For example, it is possible that certain physiological and behavioral changes could potentially lead to an ultimate pathological effect on individuals (*i.e.*, mortality).

The specific received sound levels at which permanent adverse effects to fish potentially could occur are little studied and largely unknown. Furthermore, the available information on the impacts of seismic surveys on marine fish is from studies of individuals or portions of a population; there have been no studies at the population scale. The studies of individual fish have often been on caged fish that were exposed to airgun pulses in situations not representative of an actual seismic survey. Thus, available information provides limited insight on possible real-world effects at the ocean or population scale.

Hastings and Popper (2005), Popper (2009), and Popper and Hastings (2009a,b) provided recent critical reviews of the known effects of sound on fish. The following sections provide a general synopsis of the available information on the effects of exposure to seismic and other anthropogenic sound as relevant to fish. The information comprises results from scientific studies of varying degrees of rigor plus some anecdotal information. Some of the data sources may have serious shortcomings in methods, analysis, interpretation, and reproducibility that must be considered when interpreting their results (see Hastings and Popper, 2005). Potential adverse effects of the program's sound sources on marine fish are noted.

Pathological Effects—The potential for pathological damage to hearing structures in fish depends on the energy level of the received sound and the physiology and hearing capability of the species in question (see Appendix D L-DEO's EA). For a given sound to result in hearing loss, the sound must exceed, by some substantial amount, the hearing

threshold of the fish for that sound (Popper, 2005). The consequences of temporary or permanent hearing loss in individual fish on a fish population are unknown; however, they likely depend on the number of individuals affected and whether critical behaviors involving sound (*e.g.*, predator avoidance, prey capture, orientation and navigation, reproduction, *etc.*) are adversely affected.

Little is known about the mechanisms and characteristics of damage to fish that may be inflicted by exposure to seismic survey sounds. Few data have been presented in the peer-reviewed scientific literature. As far as L-DEO and NMFS know, there are only two papers with proper experimental methods, controls, and careful pathological investigation implicating sounds produced by actual seismic survey airguns in causing adverse anatomical effects. One such study indicated anatomical damage, and the second indicated TTS in fish hearing. The anatomical case is McCauley *et al.* (2003), who found that exposure to airgun sound caused observable anatomical damage to the auditory maculae of pink snapper (*Pagrus auratus*). This damage in the ears had not been repaired in fish sacrificed and examined almost two months after exposure. On the other hand, Popper *et al.* (2005) documented only TTS (as determined by auditory brainstem response) in two of three fish species from the Mackenzie River Delta. This study found that broad whitefish (*Coregonus nasus*) exposed to five airgun shots were not significantly different from those of controls. During both studies, the repetitive exposure to sound was greater than would have occurred during a typical seismic survey. However, the substantial low-frequency energy produced by the airguns [less than 400 Hz in the study by McCauley *et al.* (2003) and less than approximately 200 Hz in Popper *et al.* (2005)] likely did not propagate to the fish because the water in the study areas was very shallow (approximately nine m in the former case and less than two m in the latter). Water depth sets a lower limit on the lowest sound frequency that will propagate (the "cutoff frequency") at about one-quarter wavelength (Urick, 1983; Rogers and Cox, 1988).

Wardle *et al.* (2001) suggested that in water, acute injury and death of organisms exposed to seismic energy depends primarily on two features of the sound source: (1) The received peak pressure and (2) the time required for the pressure to rise and decay. Generally, as received pressure

increases, the period for the pressure to rise and decay decreases, and the chance of acute pathological effects increases. According to Buchanan *et al.* (2004), for the types of seismic airguns and arrays involved with the proposed program, the pathological (mortality) zone for fish would be expected to be within a few meters of the seismic source. Numerous other studies provide examples of no fish mortality upon exposure to seismic sources (Falk and Lawrence, 1973; Holliday *et al.*, 1987; La Bella *et al.*, 1996; Santulli *et al.*, 1999; McCauley *et al.*, 2000a,b, 2003; Bjarti, 2002; Thomsen, 2002; Hassel *et al.*, 2003; Popper *et al.*, 2005; Boeger *et al.*, 2006).

Some studies have reported, some equivocally, that mortality of fish, fish eggs, or larvae can occur close to seismic sources (Kostyuchenko, 1973; Dalen and Knutsen, 1986; Booman *et al.*, 1996; Dalen *et al.*, 1996). Some of the reports claimed seismic effects from treatments quite different from actual seismic survey sounds or even reasonable surrogates. However, Payne *et al.* (2009) reported no statistical differences in mortality/morbidity between control and exposed groups of capelin eggs or monkfish larvae. Saetre and Ona (1996) applied a 'worst-case scenario' mathematical model to investigate the effects of seismic energy on fish eggs and larvae. They concluded that mortality rates caused by exposure to seismic surveys are so low, as compared to natural mortality rates, that the impact of seismic surveying on recruitment to a fish stock must be regarded as insignificant.

Physiological Effects—Physiological effects refer to cellular and/or biochemical responses of fish to acoustic stress. Such stress potentially could affect fish populations by increasing mortality or reducing reproductive success. Primary and secondary stress responses of fish after exposure to seismic survey sound appear to be temporary in all studies done to date (Sverdrup *et al.*, 1994; Santulli *et al.*, 1999; McCauley *et al.*, 2000a,b). The periods necessary for the biochemical changes to return to normal are variable and depend on numerous aspects of the biology of the species and of the sound stimulus (see Appendix D of L-DEO's EA).

Behavioral Effects—Behavioral effects include changes in the distribution, migration, mating, and catchability of fish populations. Studies investigating the possible effects of sound (including seismic survey sound) on fish behavior have been conducted on both uncaged and caged individuals (e.g., Chapman and Hawkins, 1969; Pearson *et al.*, 1992;

Santulli *et al.*, 1999; Wardle *et al.*, 2001; Hassel *et al.*, 2003). Typically, in these studies fish exhibited a sharp startle response at the onset of a sound followed by habituation and a return to normal behavior after the sound ceased.

In general, any adverse effects on fish behavior or fisheries attributable to seismic testing may depend on the species in question and the nature of the fishery (season, duration, fishing method). They may also depend on the age of the fish, its motivational state, its size, and numerous other factors that are difficult, if not impossible, to quantify at this point, given such limited data on effects of airguns on fish, particularly under realistic at-sea conditions.

Anticipated Effects on Fisheries

It is possible that the *Langseth's* streamers may become entangled with various types of fishing gear. Salmon, cod, rockfish, and sablefish fisheries will be operating at the time of the seismic project in the western GOA (ADF&G, 2010). L-DEO will employ avoidance tactics as necessary to prevent conflict. It is not expected that L-DEO's operations will have a significant impact on commercial fisheries in the western GOA. Nonetheless, L-DEO will minimize the potential to have a negative impact on the fisheries by avoiding areas where fishing is actively underway.

There is general concern about potential adverse effects of seismic operations on fisheries, namely a potential reduction in the "catchability" of fish involved in fisheries. Although reduced catch rates have been observed in some marine fisheries during seismic testing, in a number of cases the findings are confounded by other sources of disturbance (Dalen and Raknes, 1985; Dalen and Knutsen, 1986; Lokkeborg, 1991; Skalski *et al.*, 1992; Engas *et al.*, 1996). In other airgun experiments, there was no change in catch per unit effort (CPUE) of fish when airgun pulses were emitted, particularly in the immediate vicinity of the seismic survey (Pickett *et al.*, 1994; La Bella *et al.*, 1996). For some species, reductions in catch may have resulted from a change in behavior of the fish, e.g., a change in vertical or horizontal distribution, as reported in Slotte *et al.* (2004).

Anticipated Effects on Invertebrates

The existing body of information on the impacts of seismic survey sound on marine invertebrates is very limited. However, there is some unpublished and very limited evidence of the potential for adverse effects on invertebrates, thereby justifying further

discussion and analysis of this issue. The three types of potential effects of exposure to seismic surveys on marine invertebrates are pathological, physiological, and behavioral. Based on the physical structure of their sensory organs, marine invertebrates appear to be specialized to respond to particle displacement components of an impinging sound field and not to the pressure component (Popper *et al.*, 2001; see also Appendix E of L-DEO's EA).

The only information available on the impacts of seismic surveys on marine invertebrates involves studies of individuals; there have been no studies at the population scale. Thus, available information provides limited insight on possible real-world effects at the regional or ocean scale. The most important aspect of potential impacts concerns how exposure to seismic survey sound ultimately affects invertebrate populations and their viability, including availability to fisheries.

Literature reviews of the effects of seismic and other underwater sound on invertebrates were provided by Moriyasu *et al.* (2004) and Payne *et al.* (2008). The following sections provide a synopsis of available information on the effects of exposure to seismic survey sound on species of decapod crustaceans and cephalopods, the two taxonomic groups of invertebrates on which most such studies have been conducted. The available information is from studies with variable degrees of scientific soundness and from anecdotal information. A more detailed review of the literature on the effects of seismic survey sound on invertebrates is provided in Appendix E of L-DEO's EA.

Pathological Effects—In water, lethal and sub-lethal injury to organisms exposed to seismic survey sound appears to depend on at least two features of the sound source: (1) The received peak pressure; and (2) the time required for the pressure to rise and decay. Generally, as received pressure increases, the period for the pressure to rise and decay decreases, and the chance of acute pathological effects increases. For the type of airgun array planned for the proposed program, the pathological (mortality) zone for crustaceans and cephalopods is expected to be within a few meters of the seismic source, at most; however, very few specific data are available on levels of seismic signals that might damage these animals. This premise is based on the peak pressure and rise/decay time characteristics of seismic airgun arrays currently in use around the world.

Some studies have suggested that seismic survey sound has a limited pathological impact on early developmental stages of crustaceans (Pearson *et al.*, 1994; Christian *et al.*, 2003; DFO, 2004). However, the impacts appear to be either temporary or insignificant compared to what occurs under natural conditions. Controlled field experiments on adult crustaceans (Christian *et al.*, 2003, 2004; DFO, 2004) and adult cephalopods (McCauley *et al.*, 2000a,b) exposed to seismic survey sound have not resulted in any significant pathological impacts on the animals. It has been suggested that exposure to commercial seismic survey activities has injured giant squid (Guerra *et al.*, 2004), but the article provides little evidence to support this claim.

Physiological Effects—Physiological effects refer mainly to biochemical responses by marine invertebrates to acoustic stress. Such stress potentially could affect invertebrate populations by increasing mortality or reducing reproductive success. Primary and secondary stress responses (*i.e.*, changes in haemolymph levels of enzymes, proteins, *etc.*) of crustaceans have been noted several days or months after exposure to seismic survey sounds (Payne *et al.*, 2007). The periods necessary for these biochemical changes to return to normal are variable and depend on numerous aspects of the biology of the species and of the sound stimulus.

Behavioral Effects—There is increasing interest in assessing the possible direct and indirect effects of seismic and other sounds on invertebrate behavior, particularly in relation to the consequences for fisheries. Changes in behavior could potentially affect such aspects as reproductive success, distribution, susceptibility to predation, and catchability by fisheries. Studies investigating the possible behavioral effects of exposure to seismic survey sound on crustaceans and cephalopods have been conducted on both uncaged and caged animals. In some cases, invertebrates exhibited startle responses (*e.g.*, squid in McCauley *et al.*, 2000a,b). In other cases, no behavioral impacts were noted (*e.g.*, crustaceans in Christian *et al.*, 2003, 2004; DFO 2004). There have been anecdotal reports of reduced catch rates of shrimp shortly after exposure to seismic surveys; however, other studies have not observed any significant changes in shrimp catch rate (Andriguetto-Filho *et al.*, 2005). Similarly, Parry and Gason (2006) did not find any evidence that lobster catch rates were affected by

seismic surveys. Any adverse effects on crustacean and cephalopod behavior or fisheries attributable to seismic survey sound depend on the species in question and the nature of the fishery (season, duration, fishing method).

Proposed Mitigation

In order to issue an Incidental Take Authorization (ITA) under Section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and the availability of such species or stock for taking for certain subsistence uses.

L-DEO has based the mitigation measures described herein, to be implemented for the proposed seismic survey, on the following:

(1) Protocols used during previous L-DEO seismic research cruises as approved by NMFS;

(2) Previous IHA applications and IHAs approved and authorized by NMFS; and

(3) Recommended best practices in Richardson *et al.* (1995), Pierson *et al.* (1998), and Weir and Dolman, (2007).

To reduce the potential for disturbance from acoustic stimuli associated with the activities, L-DEO and/or its designees has proposed to implement the following mitigation measures for marine mammals:

- (1) Proposed exclusion zones;
- (2) Power-down procedures;
- (3) Shut-down procedures;
- (4) Ramp-up procedures; and
- (5) Special procedures for situations and species of concern.

Planning Phase—The PIs worked with L-DEO and NSF to identify potential time periods to carry out the survey taking into consideration key factors such as environmental conditions (*i.e.*, the seasonal presence of marine mammals, sea turtles, and sea birds), weather conditions, and equipment. The survey was previously scheduled for September, 2010; however after further consideration, it was viewed as not a viable operational option because of the strong possibility of not being able to carry out the science mission under potential weather conditions in the region at that time of year. Also, the late June to early August cruise avoids the peak in humpback abundance (late August to early September) and the peak of the marine mammal harvest (generally September to December, with a reduction in hunting effort in summer).

Reducing the size of the energy source was also considered, but it was decided that the 6,600 in³, 36 airgun array is necessary to penetrate through the seafloor to accurately delineate the geologic features and to achieve the primary scientific objectives of the program. A large source that is rich in relatively low-frequency seismic energy is required to penetrate to depths greater than 20 to 30 km (10.8 to 16.2 nmi) and image the deep fault that causes earthquakes off Alaska. By towing this source configuration at 12 m below the sea surface, the lower frequencies are enhanced. If a smaller source were used, it would inhibit the deep imaging of the fault zone, thus preventing the scientists' ability to carry out their research as proposed and meet their objectives. Similarly, the proposed combination of OBSs and hydrophone streamers are needed to record seismic returns from deep in the earth and determine the depth and geometry of the fault zone, thus meeting the scientific objectives.

Proposed Exclusion Zones—Received sound levels have been determined by empirical corrected measurements for the 36 airgun array, and a L-DEO model was used to predict the EZs for the single 1900LL 40 in³ airgun, which will be used during power-downs. Results were recently reported for propagation measurements of pulses from the 36 airgun array in two water depths (approximately 1,600 m and 50 m [5,249 to 164 ft]) in the Gulf of Mexico in 2007 to 2008 (Tolstoy *et al.*, 2009). It would be prudent to use the empirical values that resulted to determine EZs for the airgun array. Results of the propagation measurements (Tolstoy *et al.*, 2009) showed that radii around the airguns for various received levels varied with water depth. As no measurements were made in intermediate depth water, values halfway between the deep and shallow-water measurements were used. In addition, propagation varies with array tow depth. The depth of the array was different in the Gulf of Mexico calibration study (6 m [19.7 ft]) than in the proposed survey in the GOA (12 m); thus, correction factors have been applied to the distances reported by Tolstoy *et al.* (2009). The correction factors used were the ratios of the 160, 180, and 190 dB distances from the modeled results for the 6,600 in³ airgun array towed at 6 m versus 12 m.

Measurements were not reported for a single airgun, so model results will be used. The L-DEO model does not allow for bottom interactions, and thus is most directly applicable to deep water and to relatively short ranges. A detailed

description of the modeling effort is predicted in Appendix A of the EA.

Based on the corrected propagation measurements (airgun array) and modeling (single airgun), the distances from the source where sound levels are predicted to be 190, 180, and 160 dB re 1 μ Pa (rms) were determined (see Table 1 above). The 180 and 190 dB radii are shut-down criteria applicable to cetaceans and pinnipeds, respectively, as specified by NMFS (2000); these levels were used to establish the EZs. If the PSVO detects marine mammal(s) within or about to enter the appropriate EZ, the airguns will be powered-down (or shut-down, if necessary) immediately.

Power-down Procedures—A power-down involves decreasing the number of airguns in use to one airgun, such that the radius of the 180 dB (or 190 dB) zone is decreased to the extent that marine mammals are no longer in or about to enter the EZ. A power-down of the airgun array can also occur when the vessel is moving from one seismic line to another. During a power-down for mitigation, L-DEO will operate one airgun. The continued operation of one airgun is intended to alert marine mammals to the presence of the seismic vessel in the area. In contrast, a shut-down occurs when the *Langseth* suspends all airgun activity.

If the PSVO detects a marine mammal outside the EZ, but it is likely to enter the EZ, L-DEO will power-down the airguns before the animal is within the EZ. Likewise, if a mammal is already within the EZ, when first detected L-DEO will power-down the airguns immediately. During a power-down of the airgun array, L-DEO will also operate the 40 in³ airgun. If a marine mammal is detected within or near the smaller EZ around that single airgun (Table 1), L-DEO will shut-down the airgun (see next section).

Following a power-down, L-DEO will not resume airgun activity until the marine mammal has cleared the EZ. L-DEO will consider the animal to have cleared the EZ if:

- a PSVO has visually observed the animal leave the EZ, or
- a PSVO has not sighted the animal within the EZ for 15 min for species with shorter dive durations (*i.e.*, small odontocetes or pinnipeds), or 30 min for species with longer dive durations (*i.e.*, mysticetes and large odontocetes, including sperm, killer, and beaked whales).

During airgun operations following a power-down (or shut-down) whose duration has exceeded the time limits specified previously, L-DEO will ramp-

up the airgun array gradually (see Shut-down and Ramp-up Procedures).

Shut-down Procedures—L-DEO will shut down the operating airgun(s) if a marine mammal is seen within or approaching the EZ for the single airgun. L-DEO will implement a shut-down:

- (1) If an animal enters the EZ of the single airgun after L-DEO has initiated a power-down; or
- (2) if an animal is initially seen within the EZ of the single airgun when more than one airgun (typically the full airgun array) is operating.

L-DEO will not resume airgun activity until the marine mammal has cleared the EZ, or until the PSVO is confident that the animal has left the vicinity of the vessel. Criteria for judging that the animal has cleared the EZ will be as described in the preceding section.

Ramp-up Procedures—L-DEO will follow a ramp-up procedure when the airgun array begins operating after a specified period without airgun operations or when a power-down has exceeded that period. USGS proposes that, for the present cruise, this period would be approximately nine min. This period is based on the 180 dB radius (1,100 m) for the 36 airgun array towed at a depth of 12 m in relation to the minimum planned speed of the *Langseth* while shooting (7.4 km/hr). L-DEO has used similar periods (approximately 8 to 10 min) during previous L-DEO surveys.

Ramp-up will begin with the smallest airgun in the array (40 in³). Airguns will be added in a sequence such that the source level of the array will increase in steps not exceeding six dB per five min period over a total duration of approximately 35 min. During ramp-up, the Protected Species Observers (PSOs) will monitor the EZ, and if marine mammals are sighted, L-DEO will implement a power-down or shut-down as though the full airgun array were operational.

If the complete EZ has not been visible for at least 30 min prior to the start of operations in either daylight or nighttime, L-DEO will not commence the ramp-up unless at least one airgun (40 in³ or similar) has been operating during the interruption of seismic survey operations. Given these provisions, it is likely that the airgun array will not be ramped-up from a complete shut-down at night or in thick fog, because the outer part of the safety zone for that array will not be visible during those conditions. If one airgun has operated during a power-down period, ramp-up to full power will be permissible at night or in poor visibility,

on the assumption that marine mammals will be alerted to the approaching seismic vessel by the sounds from the single airgun and could move away. L-DEO will not initiate a ramp-up of the airguns if a marine mammal is sighted within or near the applicable EZs during the day or close to the vessel at night.

Special Procedures for Situations and Species of Concern—L-DEO will implement special mitigation procedures as follows:

- The airguns will be shut-down immediately if ESA-listed species for which no takes are being requested (*i.e.*, North Pacific right, sei, blue, and beluga whales) are sighted at any distance from the vessel. Ramp-up will only begin if the whale has not been seen for 30 min.
- Concentrations of humpback, fin, and/or killer whales will be avoided if possible, and the array will be powered-down if necessary. For purposes of this proposed survey, a concentration or group of whales will consist of three or more individuals visually sighted that do not appear to be traveling (*e.g.*, feeding, socializing, *etc.*).

- Seismic operations in Chignik Bay will be conducted from nearshore to offshore waters.

- Avoidance of areas where subsistence fishers are fishing, if requested (or viewed as necessary).

NMFS has carefully evaluated the applicant's proposed mitigation measures and has considered a range of other measures in the context of ensuring that NMFS prescribes the means of effecting the least practicable adverse impact on the affected marine mammal species and stocks and their habitat. NMFS's evaluation of potential measures included consideration of the following factors in relation to one another:

- (1) The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals;

- (2) The proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and

- (3) The practicability of the measure for applicant implementation.

Based on NMFS's evaluation of the applicant's proposed measures, as well as other measures considered by NMFS or recommended by the public, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable adverse impacts on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an ITA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth "requirements pertaining to the monitoring and reporting of such taking." The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for IHAs must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the action area.

Monitoring

L-DEO proposes to sponsor marine mammal monitoring during the proposed project, in order to implement the proposed mitigation measures that require real-time monitoring, and to satisfy the anticipated monitoring requirements of the IHA. L-DEO's proposed Monitoring Plan is described below this section. L-DEO understands that this monitoring plan will be subject to review by NMFS, and that refinements may be required. The monitoring work described here has been planned as a self-contained project independent of any other related monitoring projects that may be occurring simultaneously in the same regions. L-DEO is prepared to discuss coordination of its monitoring program with any related work that might be done by other groups insofar as this is practical and desirable.

Vessel-based Visual Monitoring

PSVOs will be based aboard the seismic source vessel and will watch for marine mammals near the vessel during daytime airgun operations and during any ramp-ups at night. PSVOs will also watch for marine mammals near the seismic vessel for at least 30 min prior to the start of airgun operations after an extended shut-down (*i.e.*, greater than approximately 9 min for this proposed cruise). When feasible, PSVOs will conduct observations during daytime periods when the seismic system is not operating for comparison of sighting rates and behavior with and without airgun operations and between acquisition periods. Based on PSVO observations, the airguns will be powered-down or shut-down when marine mammals are observed within or about to enter a designated EZ. The EZ is a region in which a possibility exists of adverse effects on animal hearing or other physical effects.

During seismic operations in the western GOA, at least four PSOs (PSVO and/or PSAO) will be based aboard the *Langseth*. L-DEO will appoint the PSOs with NMFS's concurrence. Observations will take place during ongoing daytime operations and nighttime ramp-ups of the airguns. During the majority of seismic operations, two PSVOs will be on duty from the observation tower to monitor marine mammals near the seismic vessel. Use of two simultaneous PSVOs will increase the effectiveness of detecting animals near the source vessel. However, during meal times and bathroom breaks, it is sometimes difficult to have two PSVOs on effort, but at least one PSVO will be on duty. PSVO(s) will be on duty in shifts of duration no longer than 4 hrs.

Two PSVOs will also be on visual watch during all nighttime ramp-ups of the seismic airguns. A third PSAO will monitor the PAM equipment 24 hours a day to detect vocalizing marine mammals present in the action area. In summary, a typical daytime cruise would have scheduled two PSVOs on duty from the observation tower, and a third PSAO on PAM. Other crew will also be instructed to assist in detecting marine mammals and implementing mitigation requirements (if practical). Other crew will also be instructed to assist in detecting marine mammals and implementing mitigation requirements. Before the start of the seismic survey, the crew will be given additional instruction on how to do so.

The *Langseth* is a suitable platform for marine mammal observations. When stationed on the observation platform, the eye level will be approximately 21.5 m (70.5 ft) above sea level, and the PSVO will have a good view around the entire vessel. During daytime, the PSVOs will scan the area around the vessel systematically with reticle binoculars (*e.g.*, 7 x 50 Fujinon), Big-eye binoculars (25 x 150), and with the naked eye. During darkness, night vision devices (NVDs) will be available (ITT F500 Series Generation 3 binocular-image intensifier or equivalent), when required. Laser range-finding binoculars (Leica LRF 1200 laser rangefinder or equivalent) will be available to assist with distance estimation. Those are useful in training observers to estimate distances visually, but are generally not useful in measuring distances to animals directly; that is done primarily with the reticles in the binoculars.

When marine mammals are detected within or about to enter the designated EZ, the airguns will immediately be powered-down or shut-down if necessary. The PSVO(s) will continue to

maintain watch to determine when the animal(s) are outside the EZ by visual confirmation. Airgun operations will not resume until the animal is confirmed to have left the EZ, or if not observed after 15 min for species with shorter dive durations (small odontocetes and pinnipeds) or 30 min for species with longer dive durations (mysticetes and large odontocetes, including sperm, killer, and beaked whales).

Passive Acoustic Monitoring (PAM)

PAM will complement the visual monitoring program, when practicable. Visual monitoring typically is not effective during periods of poor visibility or at night, and even with good visibility, is unable to detect marine mammals when they are below the surface or beyond visual range. Acoustical monitoring can be used in addition to visual observations to improve detection, identification, and localization of cetaceans. The acoustic monitoring will serve to alert visual observers (if on duty) when vocalizing cetaceans are detected. It is only useful when marine mammals call, but it can be effective either by day or by night, and does not depend on good visibility. It will be monitored in real time so that the PSVOs can be advised when cetaceans are detected.

The PAM system consists of hardware (*i.e.*, hydrophones) and software. The "wet end" of the system consists of a towed hydrophone array that is connected to the vessel by a tow cable. The tow cable is 250 m (820.2 ft) long, and the hydrophones are fitted in the last 10 m (32.8 ft) of cable. A depth gauge is attached to the free end of the cable, and the cable is typically towed at depths less than 20 m (65.6 ft). The array will be deployed from a winch located on the back deck. A deck cable will connect from the winch to the main computer laboratory where the acoustic station, signal conditioning, and processing system will be located. The acoustic signals received by the hydrophones are amplified, digitized, and then processed by the Pamguard software. The system can detect marine mammal vocalizations at frequencies up to 250 kHz.

One Protected Species Acoustic Observer (PSAO, an expert bioacoustician in addition to the four PSVOs), with primary responsibility for PAM, will be onboard the *Langseth*. The towed hydrophones will ideally be monitored by the PSAO 24 hours per day while at the proposed seismic survey area during airgun operations, and during most periods when the *Langseth* is underway while the airguns

are not operating. However, PAM may not be possible if damage occurs to the array or back-up systems during operations. The primary PAM streamer on the *Langseth* is a digital hydrophone streamer. Should the digital streamer fail, back-up systems should include an analog spare streamer and a hull-mounted hydrophone. One PSAO will monitor the acoustic detection system by listening to the signals from two channels via headphones and/or speakers and watching the real-time spectrographic display for frequency ranges produced by cetaceans. The PSAO monitoring the acoustical data will be on shift for one to six hours at a time. All PSOs are expected to rotate through the PAM position, although the expert PSAO will be on PAM duty more frequently.

When a vocalization is detected while visual observations are in progress, the PSAO will contact the PSVO immediately, to alert him/her to the presence of cetaceans (if they have not already been seen), and to allow a power-down or shut-down to be initiated, if required. When bearings (primary and mirror-image) to calling cetacean(s) are determined, the bearings will be related to the PSVO(s) to help him/her sight the calling animal. The information regarding the call will be entered into a database. Data entry will include an acoustic encounter identification number, whether it was linked with a visual sighting, date, time when first and last heard and whenever any additional information was recorded, position and water depth when first detected, bearing if determinable, species or species group (e.g., unidentified dolphin, sperm whale), types and nature of sounds heard (e.g., clicks, continuous, sporadic, whistles, creaks, burst pulses, strength of signal, etc.), and any other notable information. The acoustic detection can also be recorded for further analysis.

PSVO Data and Documentation

PSVOs will record data to estimate the numbers of marine mammals exposed to various received sound levels and to document apparent disturbance reactions or lack thereof. Data will be used to estimate numbers of animals potentially 'taken' by harassment (as defined in the MMPA). They will also provide information needed to order a power-down or shut-down of the airguns when a marine mammal is within or near the EZ. Observations will also be made during daytime periods when the *Langseth* is underway without seismic operations. In addition to transits to, from, and through the study area, there will also

be opportunities to collect baseline biological data during the deployment and recovery of OBSs.

When a sighting is made, the following information about the sighting will be recorded:

1. Species, group size, age/size/sex categories (if determinable), behavior when first sighted and after initial sighting, heading (if consistent), bearing and distance from seismic vessel, sighting cue, apparent reaction to the airguns or vessel (e.g., none, avoidance, approach, paralleling, etc.), and behavioral pace.

2. Time, location, heading, speed, activity of the vessel, sea state, visibility, and sun glare.

The data listed under (2) will also be recorded at the start and end of each observation watch, and during a watch whenever there is a change in one or more of the variables.

All observations and power-downs or shut-downs will be recorded in a standardized format. Data will be entered into an electronic database. The accuracy of the data entry will be verified by computerized data validity checks as the data are entered and by subsequent manual checking of the database. These procedures will allow initial summaries of data to be prepared during and shortly after the field program, and will facilitate transfer of the data to statistical, graphical, and other programs for further processing and archiving.

Results from the vessel-based observations will provide:

1. The basis for real-time mitigation (airgun power-down or shut-down).
2. Information needed to estimate the number of marine mammals potentially taken by harassment, which must be reported to NMFS.
3. Data on the occurrence, distribution, and activities of marine mammals in the area where the seismic study is conducted.
4. Information to compare the distance and distribution of marine mammals relative to the source vessel at times with and without seismic activity.
5. Data on the behavior and movement patterns of marine mammals seen at times with and without seismic activity.

L-DEO will submit a report to NMFS and NSF within 90 days after the end of the cruise. The report will describe the operations that were conducted and sightings of marine mammals near the operations. The report will provide full documentation of methods, results, and interpretation pertaining to all monitoring. The 90-day report will summarize the dates and locations of seismic operations, and all marine

mammal sightings (dates, times, locations, activities, associated seismic survey activities). The report will also include estimates of the number and nature of exposures that could result in "takes" of marine mammals by harassment or in other ways.

L-DEO will report all injured or dead marine mammals (regardless of cause) to NMFS as soon as practicable. The report should include the species or description of the animal, the condition of the animal, location, time first found, observed behaviors (if alive) and photo or video, if available. In the unanticipated event that any taking of a marine mammal in a manner prohibited by the proposed IHA occurs, such as an injury, serious injury, or mortality, and is judged to result from the proposed activities, the operator will immediately report the incident to the Chief of the Permits, Conservation, and Education Division, Office of Protected Resources, NMFS. The operator will postpone the proposed activities until NMFS is able to review the circumstances of the take. NMFS will work with the operator to determine whether modifications in the activities are appropriate and necessary, and notify the operator that they may resume sound source operations.

Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, the MMPA defines "harassment" as "any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breeding, nursing, breeding, feeding, or sheltering [Level B harassment]."

Only take by Level B harassment is anticipated and proposed to be authorized as a result of the proposed marine geophysical survey in the western GOA. Acoustic stimuli (i.e., increased underwater sound) generated during the operation of the seismic airgun array may have the potential to cause marine mammals in the survey area to be exposed to sounds at or greater than 160 dB or cause temporary, short-term changes in behavior. There is no evidence that the planned activities could result in injury, serious injury, or mortality within the specified geographic area for which L-DEO seeks the IHA. The required mitigation and monitoring measures will minimize any potential risk for injury, serious injury, or mortality.

The following sections describe L-DEO's methods to estimate take by incidental harassment and present the applicant's estimates of the numbers of marine mammals that could be affected during the proposed seismic program. The estimates are based on a consideration of the number of marine mammals that could be disturbed appreciably by operations with the 36 airgun array to be used during approximately 2,553 km of survey lines in the western GOA.

L-DEO assumes that, during simultaneous operations of the airgun array and the other sources, any marine mammals close enough to be affected by the MBES and SBP would already be affected by the airguns. However, whether or not the airguns are operating simultaneously with the other sources, marine mammals are expected to exhibit no more than short-term and inconsequential responses to the MBES and SBP given their characteristics (e.g., narrow, downward-directed beam) and other considerations described previously. Such reactions are not considered to constitute "taking" (NMFS, 2001). Therefore, L-DEO provides no additional allowance for animals that could be affected by sound sources other than airguns.

There are several sources of systematic data on the numbers and distributions of marine mammals in the coastal and nearshore areas of the GOA, but there are fewer data for offshore areas. Zerbini *et al.* (2003, 2006, 2007) conducted vessel-based surveys in the northern and western GOA from the Kenai Peninsula to the central Aleutian Islands during July to August 2001 to 2003. These surveys included all of the coastal and nearshore areas of the currently proposed study area. Killer whales were the principal target of the surveys, but the abundance and distribution of fin, humpback, and minke whales were also reported. Waite (2003) conducted vessel-based surveys in the northern and western GOA from Prince William Sound to approximately 160° West off the Alaska Peninsula during June 26 to July 15, 2003 (Waite, 2003); cetaceans recorded included small odontocetes, beaked whales, and mysticetes. The eastern part of the surveys by Zerbini *et al.* were confined to waters less than 1,000 m deep with most effort in depths less than 100 m, and all of Waite's survey was confined to waters less than 1,000 m deep with most effort in depths 100 to 1,000 m.

Dahlheim *et al.* (2000) conducted aerial surveys of the nearshore waters from Bristol Bay to Dixon Entrance for harbor porpoises; southeast Alaska was surveyed during June 1 to 26, 1993.

Dahlheim and Towell (1994) conducted vessel-based surveys of Pacific white-sided dolphins in the inland waterways of Southeast Alaska during April to May, June or July, and September to early October of 1991 to 1993. In a report on a seismic cruise in southeast Alaska from Dixon Entrance to Kodiak Island during August to September, 2004, MacLean and Koski (2005) included density estimates of cetaceans and pinnipeds for each of three depth ranges (<100 m, 100 to 1,000 m, and >1,000 m) during non-seismic periods. Hauser and Holst (2009) reported density estimates during non-seismic periods for all marine mammals sighted during a September to early October seismic cruise in southeast Alaska for each of the same three depth ranges as MacLean and Koski (2005). Rone *et al.* (2010) conducted surveys of the nearshore and offshore GOA during April, 2009 and provided estimates of densities of humpback and fin whales and provided maps with sightings of other species.

Most surveys for pinnipeds in Alaska waters have estimated the number of animals at haul-out sites, not in the water (e.g., Loughlin, 1994; Sease *et al.*, 2001; Withrow and Cesarone, 2002; Sease and York, 2003). The Department of the Navy (DON) (2009) estimated monthly in-water densities of several species of pinnipeds in the offshore GOA based on shore counts and biological (mostly breeding) information. To our knowledge, the only direct information available on at-sea densities of pinnipeds in and near the proposed survey area was provided by MacLean and Koski (2005) and Hauser and Holst (2009).

Table 2 (Table 5 of the EA) gives the estimated average (best) and maximum densities of marine mammals expected to occur in the waters of the central and western GOA. L-DEO used the densities reported by MacLean and Koski (2005) and Hauser and Holst (2009), and those calculated from effort and sightings in Dahlheim and Towell (1994) and Waite (2003) have been corrected for both detectability and availability bias using correction factors from Dahlheim *et al.* (2000) and Barlow and Forney (2007). Detectability bias is associated with diminishing sightability with increasing lateral distance from the trackline. Availability bias refers to the fact that there is less-than-100% probability of sighting an animal that is present along the survey trackline $f(0)$, and it is measured by $g(0)$.

Table 2 (Table 5 of the EA) incorporates the densities from the aforementioned studies plus those from the following surveys. L-DEO included

the killer whale and mysticete densities from the easternmost blocks surveyed by Zerbini *et al.* (2006, 2007), and the harbor porpoise densities for the Kodiak and Alaska Peninsula survey areas from Table 3 of Dahlheim and Towell (1994). Maps of effort and sightings in Waite (2003) and Zerbini *et al.* (2006, 2007) were used to roughly allocate effort and sightings between water less than 100 m and 100 to 1,000 m deep. Offshore effort and maps of sightings in the offshore stratum of Rone *et al.* (2010) were used to calculate densities for water depths greater than 1,000 m. Densities of Steller sea lion, northern fur seals, and northern elephant seals in water depths greater than 1,000 m were taken from DON (2009; Appendix E, Table 5) for July, and those in water depths less than 1,000 m are from MacLean and Koski (2005) and Hauser and Holst (2009).

There is some uncertainty about the representativeness of the data and the assumptions used in the calculations below for three main reasons:

(1) The timing of most of the survey effort (17,806 km [9,614.5 nmi]) (i.e., one of the surveys of Dahlheim and Towell [1994] and the surveys of Dahlheim *et al.* (2000), Waite [2003], MacLean and Koski (2005), and Zerbini *et al.* [2006, 2007]) overlaps the timing of the proposed survey, but some survey effort (4,693 km [2,534 nmi])—(i.e., two of the surveys of Dahlheim and Towell [1994] and the surveys of Rone *et al.* [2010] and Hauser and Holst [2009]) was earlier (April or June) or later (September to October) than the proposed July to August survey;

(2) Surveys by MacLean and Koski (2005), Hauser and Holst (2009), and Dahlheim and Towell (1994) were conducted primarily in southeast Alaska (east of the proposed study area); and

(3) Only the MacLean and Koski (2005), Hauser and Holst (2009), and Rone *et al.* (2010) surveys included depths greater than 1,000 m, whereas approximately 53% of the proposed line-km are in water depths greater than 1,000 m. However, the densities are based on a considerable survey effort (22,500 km [12,149 nmi], including 17,806 km [9,614.5 nmi] in months that overlap the proposed survey period), and the approach used here is believed to be the best available approach.

Also, to provide some allowance for these uncertainties, "maximum estimates" as well as "best estimates" of the densities present and numbers potentially affected have been derived. Best estimates of density are effort-weighted mean densities from all previous surveys, whereas maximum estimates of density come from the individual survey that provided the

highest density. For pinnipeds in deep water where only one density was available (DON, 2009), that density was used as the best estimate and the maximum is 1.5x the best estimate.

For one species, the Dall's porpoise, density estimates in the original reports are much higher than densities expected during the proposed survey, because this porpoise is attracted to vessels. L-DEO estimates for Dall's porpoises are from vessel-based surveys without seismic activity; they are overestimates possibly by a factor of 5x, given the tendency of this species to approach vessels (Turnock and Quinn, 1991). Noise from the airgun array during the proposed survey is expected to at least reduce and possibly eliminate the tendency of this porpoise to approach the vessel. Dall's porpoises are tolerant of small airgun sources (MacLean and Koski, 2005) and tolerated higher sound levels than other species during a large-array survey (Bain and Williams, 2006); however, they did respond to that and another large airgun array by moving away (Calambokidis and Osmeck, 1998; Bain and Williams, 2006). Because of the probable overestimates, the best and maximum estimates for Dall's porpoises shown in Table 2 (Table 3 of the IHA application) are one-quarter of the reported densities. In fact, actual densities are probably slightly lower than that.

L-DEO's estimates of exposures to various sound levels assume that the proposed surveys will be fully completed including the contingency line; in fact, the ensonified areas calculated using the planned number of line-km have been increased by 25% to accommodate lines that may need to be repeated, equipment testing, etc. As is typical during offshore ship surveys, inclement weather and equipment malfunctions are likely to cause delays and may limit the number of useful line-kilometers of seismic operations that can be undertaken. Furthermore, any marine mammal sightings within or near the designated EZs will result in the power-down or shut-down of seismic operations as a mitigation measure. Thus, the following estimates of the numbers of marine mammals potentially exposed to sound levels of 160 dB re 1 μ Pa (rms) are precautionary and probably overestimate the actual numbers of marine mammals that might be involved. These estimates also assume that there will be no weather, equipment, or mitigation delays, which is highly unlikely.

L-DEO estimated the number of different individuals that may be exposed to airgun sounds with received levels greater than or equal to 160 dB re

1 μ Pa (rms) on one or more occasions by considering the total marine area that would be within the 160 dB radius around the operating airgun array on at least one occasion and the expected density of marine mammals. The number of possible exposures (including repeated exposures of the same individuals) can be estimated by considering the total marine area that would be within the 160 dB radius around the operating airguns, including areas of overlap. In the proposed survey, the seismic lines are widely spaced in the survey area, so few individual marine mammals would be exposed more than once during the survey. The area including overlap is only 1.3 times the area excluding overlap. Thus, few individual marine mammals would be exposed more than once during the survey. Moreover, it is unlikely that a particular animal would stay in the area during the entire survey.

For each depth stratum, the number of different individuals potentially exposed to received levels greater than or equal to 160 re 1 μ Pa (rms) was calculated by multiplying:

(1) The expected species density, either "mean" (*i.e.*, best estimate) or "maximum", times

(2) The anticipated area to be ensonified to that level during airgun operations excluding overlap.

The area expected to be ensonified was determined by entering the planned survey lines into a MapInfo GIS, using the GIS to identify the relevant areas by "drawing" the applicable 160 dB buffer (see Table 1 of the IHA application) around each seismic line, and then calculating the total area within the buffers. Areas of overlap (because of lines being closer together than the 160 dB radius) were limited and included only once when estimating the number of individuals exposed.

Applying the approach described above, approximately 49,679 km² (14,841.1 nmi²) (approximately 62,098 km² [18,104.9 nmi²] including the 25% contingency) would be within the 160 dB isopleth on one or more occasions during the survey. For less than 100 m, 100 to 1,000 m, and greater than 1,000 m depth ranges, the areas would be 32,451 km² (9,487.4 nmi²) (40,564 km² [11,826.6 nmi²] including the 25% contingency), 8,612 km² (2,510.9 nmi²) (10,765 km² [3,138.6 nmi²]), and 8,616 km² (2,512 nmi²) (10,769 km² [3,139.7 nmi²]), respectively. Because this approach does not allow for turnover in the marine mammal populations in the study area during the course of the survey, the actual number of individuals exposed could be underestimated in some cases. However, the conservative

(*i.e.*, probably overestimated) densities used to calculate the numbers exposed may offset this. In addition, the approach assumes that no cetaceans will move away from or toward the trackline as the *Langseth* approaches in response to increasing sound levels prior to the time the levels reach 160 dB, which will result in overestimates for those species known to avoid seismic vessels.

Table 3 (Table 4 of the IHA application) shows the best and maximum estimates of the number of different individual marine mammals that potentially could be exposed to greater than or equal to 160 dB re 1 μ Pa (rms) during the seismic survey if no animals moved away from the survey vessel. The requested take authorization, given in Table 3 (the far right column of Table 4 of the IHA application), is based on the best estimates rather than the maximum estimates of the numbers exposed, because there was little uncertainty associated with the method of estimating densities. For cetacean species not listed under the ESA that could occur in the study area but were not sighted in the surveys from which density estimates were calculated—gray whale, Risso's dolphin, short-finned pilot whale, and Stejneger's beaked whale—the average group size has been used to request take authorization. For ESA-listed cetacean species unlikely to be encountered during the study (North Pacific right, sei, blue, and beluga whales), the requested takes are zero.

The "best estimate" of the number of individual cetaceans that could be exposed to seismic sounds with received levels greater than or equal to 160 dB re 1 μ Pa (rms) during the proposed survey is 4,392 (see Table 4 of the IHA application) for all three depth ranges combined. That total includes 1,824 humpback whales, 60 minke whales, 598 fin whales, 5 sperm whales, 12 Cuvier's beaked whales, 4 Baird's beaked whales, 127 Pacific white-sided dolphins, 415 killer whales, and 180 harbor porpoises which would represent 8.7%, 0.2%, 3.7%, 0.1%, 0.1%, 0.1%, 0.1%, 4.9%, and 0.1% of the regional populations, respectively. After humpback whales, Dall's porpoises are expected to be the most common species in the study area; the best estimate of the number of Dall's porpoises that could be exposed is 1,167 or about 0.1% of the regional population. This may be a slight overestimate because the estimated densities are slight overestimates. Estimates for other species are lower. The "maximum estimates" total 12,625 cetaceans for the three depth ranges combined.

“Best estimates” of 270 Steller sea lions and 218 harbor seals could be exposed to airgun sounds with received levels greater than or equal to 160 dB re 1 μ Pa (rms). These estimates represent 0.3% of the Steller sea lion regional population and less than 0.1% of the

harbor seal regional population. The estimated numbers of pinnipeds that could be exposed to received levels greater than or equal to 160 dB re 1 μ Pa (rms) are probably overestimates of the actual numbers that will be affected. Northern fur seals and northern

elephant seals are at their rookeries in August. No take has been requested for North Pacific right, sei, and blue whales, beluga whales, Northern elephant seals, Northern fur seals, or California sea lions because they are unlikely to be encountered in the proposed study area.

TABLE 3—ESTIMATES OF THE POSSIBLE NUMBERS OF MARINE MAMMALS EXPOSED TO DIFFERENT SOUND LEVELS \geq 160 dB DURING L-DEO'S PROPOSED SEISMIC SURVEY IN THE WESTERN GOA DURING JUNE TO AUGUST, 2011

| Species | Estimated number of individuals exposed to sound levels \geq 160 dB re 1 μ Pa (Best ¹) | Estimated number of individuals exposed to sound levels \geq 160 dB re 1 μ Pa (Maximum ¹) | Requested take authorization | Approximate percent of regional population ² (Best) |
|-----------------------------------|--|---|------------------------------|--|
| Mysticetes: | | | | |
| North Pacific right whale | 0 | 0 | 0 | 0 |
| Gray whale | NA | NA | ³ 6 | NA |
| Humpback whale | 1,824 | 3,458 | 1,824 | 8.8 |
| Minke whale | 60 | 308 | 60 | 0.2 |
| Sei whale | 0 | 0 | 0 | 0 |
| Fin whale | 598 | 2,166 | 598 | 3.7 |
| Blue whale | 0 | 0 | 0 | 0 |
| Odontocetes: | | | | |
| Sperm whale | 5 | 21 | 5 | < 0.1 |
| Cuvier's beaked whale | 12 | 19 | 12 | 0.1 |
| Baird's beaked whale | 4 | 6 | 4 | 0.1 |
| Stejneger's beaked whale | 0 | 0 | ³ 15 | 0 |
| Beluga whale | 0 | 0 | 0 | 0 |
| Pacific white-sided dolphin | 127 | 348 | 127 | < 0.1 |
| Risso's dolphin | 0 | 0 | ³ 33 | 0 |
| Killer whale | 415 | 2,292 | 415 | 4.9 |
| Short-finned pilot whale | 0 | 0 | ³ 50 | NA |
| Harbor porpoise | 180 | 2,050 | 180 | 0.1 |
| Dall's porpoise | 1,167 | 1,957 | 1,167 | 0.1 |
| Pinnipeds | | | | |
| Northern fur seal | 0 | 0 | 0 | 0 |
| Steller sea lion | 270 | 365 | 270 | 0.3 |
| California sea lion | NA | NA | NA | NA |
| Harbor seal | 218 | 299 | 218 | 0.1 |
| Northern elephant seal | 0 | 0 | 0 | 0 |

¹ Best and maximum estimates are based on densities from Table 3 (Table 4 of the IHA application) and ensonified areas (including 25% contingency) for 160 dB of 40,564 km², 10,765 km², and 10,770 km² for <100 m, 100 to 1,000 m, and >1,000 m depth ranges, respectively.

² Regional population size estimates are from Table 2 (see Table 2 of the IHA application); NA means not available.

³ Requested takes for species not sighted in surveys from which densities were derived are based on group size.

Encouraging and Coordinating Research

L-DEO and NSF will coordinate the planned marine mammal monitoring program associated with the seismic survey in the western GOA with other parties that may have an interest in the area and/or be conducting marine mammal studies in the same region during the proposed seismic survey. L-DEO and NSF will coordinate with applicable U.S. Federal, State, and Borough agencies, and will comply with their requirements. Actions of this type that are underway include (but are not limited to) the following:

- Coordination with the Alaska Department of Fish and Game concerning fisheries issues in state waters.
- Contact Alaska Native Harbor Seal Commission, the Aleut Marine Mammal Commission, and the Alaska Sea Otter

and Steller Sea Lion Commission with regard to potential concerns about interactions with fisheries and subsistence hunting.

- Contact USFWS regarding concerns about possible impacts on sea otters and critical habitat (for ESA).

- Contact USFWS avian biologists (Kathy Kuletz and Tim Bowman) regarding potential interaction with seabirds (for ESA).

- Contact Mike Holley, U.S. Army Corps of Engineers (ACOE), to confirm that no permits will be required by the ACOE for the proposed survey.

- A Coastal Project Questionnaire and Certification statement will be submitted with a copy of the EA to the State of Alaska to confirm that the project is in compliance with state and local Coastal Management Programs.

- Contact the National Weather Service (NWS; Jack Endicott) about the

survey with regard to the location of NWS buoys in the survey area and the proposed tracklines.

- Contact the logistics coordinator of the local commercial fish processor, to ensure that there will be minimal interference with the local salmon fishery.

Negligible Impact and Small Numbers Analysis and Determination

NMFS has defined “negligible impact” in 50 CFR 216.103 as “* * * an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.”

Based on the analysis contained herein, of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the

mitigation and monitoring measures, NMFS, on behalf of the Secretary, preliminarily finds that L-DEO's activities would result in the incidental take of marine mammals, by Level B harassment only, and that the total taking from the marine seismic survey in the western GOA would have a negligible impact on the affected species or stocks of marine mammals.

For reasons stated previously in this document, the specified activities associated with the marine seismic survey are not likely to cause TTS, PTS, or other non-auditory injury, serious injury, or death, and no such take is anticipated or proposed to be authorized, and the potential for temporary or permanent hearing impairment is very low and will be minimized through the incorporation of the proposed monitoring and mitigation measures.

In making a negligible impact determination, NMFS evaluated factors such as:

- (1) The number of anticipated injuries, serious injuries, or mortalities;
- (2) The number, nature, and intensity, and duration of Level B harassment (all relatively limited); and
- (3) The context in which the takes occur (*i.e.*, impacts to areas of significance, impacts to local populations, and cumulative impacts when taking into account successive/ contemporaneous actions when added to baseline data);
- (4) The status of stock or species of marine mammals (*i.e.*, depleted, not depleted, decreasing, increasing, stable, impact relative to the size of the population);
- (5) Impacts on habitat affecting rates of recruitment/survival; and
- (6) The effectiveness of monitoring and mitigation measures.

As mentioned previously, NMFS estimates that 16 species of marine mammals under its jurisdiction could be potentially affected by Level B harassment over the course of the IHA. For each species, these numbers are small (each, one percent or less, except for humpback [8.8%], fin [3.7%], and killer [4.9%] whales) relative to the regional population size.

No injuries, serious injuries, or mortalities are anticipated to occur as a result of the L-DEO's planned marine seismic survey, and none are proposed to be authorized. Only short-term behavioral disturbance is anticipated to occur due to the brief and sporadic duration of the survey activities. No mortality or injury is expected to occur, and due to the nature, degree, and context of behavioral harassment anticipated, the activity is not expected

to impact rates of recruitment or survival.

NMFS has preliminarily determined, provided that the aforementioned mitigation and monitoring measures are implemented, that the impact of conducting a marine geophysical survey in the western GOA, June to August, 2011, may result, at worst, in a temporary modification in behavior and/or low-level physiological effects (Level B harassment) of small numbers of certain species of marine mammals.

While behavioral modifications, including temporarily vacating the area during the operation of the airgun(s), may be made by these species to avoid the resultant acoustic disturbance, the availability of alternate areas within these areas and the short and sporadic duration of the research activities, have led NMFS to preliminarily determine that this action will have a negligible impact on the species in the specified geographic region.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the mitigation and monitoring measures, NMFS preliminarily finds that L-DEO's planned research activities, will result in the incidental take of small numbers of marine mammals, by Level B harassment only, and that the total taking from the marine seismic survey will have a negligible impact on the affected species or stocks.

Impact on Availability of Affected Species or Stock for Taking for Subsistence Uses

Section 101(a)(5)(D) also requires NMFS to determine that the authorization will not have an unmitigable adverse effect on the availability of marine mammal species or stocks for subsistence use. There are no relevant subsistence uses of marine mammals in the study area (offshore waters of the western GOA) that implicate MMPA Section 101(a)(5)(D).

Endangered Species Act

Of the species of marine mammals that may occur in the proposed survey area, several are listed as endangered under the ESA, including the North Pacific right, humpback, sei, fin, blue, and sperm whales, as well as the Cook Inlet DPS of beluga whales and the western stock of Steller sea lions. The eastern stock of Steller sea lions is listed as threatened. Critical habitat for the North Pacific right whale and Steller sea lion is also found within the proposed survey area. Under Section 7 of the ESA, NSF has initiated formal consultation

with the NMFS, Office of Protected Resources, Endangered Species Division, on this proposed seismic survey. NMFS's Office of Protected Resources, Permits, Conservation and Education Division, has initiated formal consultation under Section 7 of the ESA with NMFS's Office of Protected Resources, Endangered Species Division, to obtain a Biological Opinion evaluating the effects of issuing the IHA on threatened and endangered marine mammals and, if appropriate, authorizing incidental take. NMFS will conclude formal Section 7 consultation prior to making a determination on whether or not to issue the IHA. If the IHA is issued, NSF and L-DEO, in addition to the mitigation and monitoring requirements included in the IHA, will be required to comply with the Terms and Conditions of the Incidental Take Statement corresponding to NMFS's Biological Opinion issued to both NSF and NMFS's Office of Protected Resources.

National Environmental Policy Act (NEPA)

With its complete application, L-DEO provided NMFS a draft EA analyzing the direct, indirect, and cumulative environmental impacts of the proposed specified activities on marine mammals including those listed as threatened or endangered under the ESA. The EA, prepared by LGL on behalf of L-DEO is entitled "Environmental Assessment of a Marine Geophysical Survey by the R/V *Marcus G. Langseth* in the western Gulf of Alaska, July-August 2011." Prior to making a final decision on the IHA application, NMFS will either prepare an independent EA, or, after review and evaluation of the L-DEO EA for consistency with the regulations published by the Council of Environmental Quality (CEQ) and NOAA Administrative Order 216-6, Environmental Review Procedures for Implementing the National Environmental Policy Act, adopt the L-DEO EA and make a decision of whether or not to issue a Finding of No Significant Impact (FONSI).

Proposed Authorization

NMFS proposes to issue an IHA to L-DEO for conducting a marine geophysical survey in the western GOA, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. The duration of the IHA would not exceed one year from the date of its issuance.

Information Solicited

NMFS requests interested persons to submit comments and information

concerning this proposed project and NMFS' preliminary determination of issuing an IHA (see **ADDRESSES**). 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: May 2, 2011.

James H. Lecky,

*Director, Office of Protected Resources,
National Marine Fisheries Service.*

[FR Doc. 2011-11152 Filed 5-5-11; 8:45 am]

BILLING CODE 3510-22-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to the Procurement List.

SUMMARY: The Committee is proposing to add services to the Procurement List that will be provided by nonprofit agencies employing persons who are blind or have other severe disabilities.

Comments Must Be Received on or Before: 6/6/2011.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202-3259.

FOR FURTHER INFORMATION CONTACT OR TO SUBMIT COMMENTS CONTACT: Barry S. Lineback, *Telephone:* (703) 603-7740, *Fax:* (703) 603-0655, or e-mail CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(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 services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

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. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will provide the services to the Government.

2. If approved, the action will result in authorizing small entities to provide the 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. 46-48c) in connection with the services proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

End of Certification

The following services are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Services

Service Type/Location: Dining Facility Attendant and Cook Support Service, Army 7th Special Forces Group, Building 4570, Eglin AFB, FL.

NPA: Lakeview Center, Inc., Pensacola, FL.

Contracting Activity: Dept of the Army, W6QM Ft Bragg Contr Ctr, Fort Bragg, NC.

For this project, the DOD contracting activity specifically identified its requirement as Dining Facility Attendant (DFA) and Cook Support Service in its Performance Work Statement (PWS). The dining facility (DFAC) associated with this service requirement is newly constructed and will be under the control and military management of the 7th Special Forces Group. Food service personnel assigned to the Group will operate and manage the DFAC and will be augmented by contractor-provided DFA.

The PWS describes the DFA service tasks as preparation of vegetables, dining room service (prepare, maintain, clean dining areas; clean condiment containers; clean spills and remove soiled dinnerware; clean dining room tables, chairs, booths; clean dining room walls, baseboards, window ledges, doors, doorframes, ceiling fans, pictures, wall art, artificial plants, light fixtures, etc); buss and replace tray carts during meal serving periods; service and maintain patron self-service area; clean and sanitize food service equipment, utensil cleaning, and dishwashing; clean pots, pans, utensils, storage shelves, and racks; facility maintenance and sanitation; and provide trash and garbage service.

Because the 7th Special Forces Group is a deployable, combat unit, it may be absent from Eglin AFB as its mission and training dictates. Cook support will be required when troop strength is under 75% due to training/deployment/re-deployment. At a minimum, cook support will augment 25% of the military manpower at all times, but is not anticipated to exceed 50% of the required military manpower. The military will retain management and operational control during deployments as a Government (civil service) contracting officer's representative will assume those duties. At no time will the AbilityOne nonprofit agency contractor be responsible for the management and operational control of the DFAC.

Service Type/Location: Custodial and Grounds Service, White Sands Missile Range, NM.

NPA: Tresco, Inc., Las Cruces, NM.

Contracting Activity: Dept of the Army, W6QM White Sands Doc, White Sands Missile Range, NM.

Service Type/Location: Janitorial/Custodial Service, San Francisco Maritime National Historical Park, Building E, Lower Fort Mason, San Francisco, CA.

NPA: Toolworks, Inc., San Francisco, CA.

Contracting Activity: Dept of the Interior, National Park Service, Pacific West Region, Oakland, CA.

Service Type/Location: Facilities Maintenance Service, Department of Public Works, Fort Knox, KY.

NPA: NISH, Vienna, VA (Prime), Lakeview Center, Pensacola, FL (Subcontractor).

Contracting Agency: Mission And Installation Contracting Command Center, Fort Knox, KY.

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2011-11099 Filed 5-5-11; 8:45 am]

BILLING CODE 6353-01-P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting Notice

TIME AND DATE: Wednesday, May 11, 2011; 10 a.m.-11 a.m.

PLACE: Hearing Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, Maryland.

STATUS: Closed to the Public.

MATTER TO BE CONSIDERED

Compliance Status Report

The Commission staff will brief the Commission on the status of compliance matters. For a recorded message containing the latest agenda information, call (301) 504-7948.

CONTACT PERSON FOR MORE INFORMATION: Todd A. Stevenson, Office of the

Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504-7923.

Dated: May 3, 2011.

Todd A Stevenson,
Secretary.

[FR Doc. 2011-11217 Filed 5-4-11; 4:15 pm]

BILLING CODE 6355-01-P

COORDINATING COUNCIL ON JUVENILE JUSTICE AND DELINQUENCY PREVENTION

[OJP (OJJDP) Docket No. 1549]

Meeting of the Coordinating Council on Juvenile Justice and Delinquency Prevention

AGENCY: Coordinating Council on Juvenile Justice and Delinquency Prevention.

ACTION: Notice of meeting.

SUMMARY: The Coordinating Council on Juvenile Justice and Delinquency Prevention (Council) announces its May 2011 meeting.

DATES: Monday, May 23, from 2:30 to 5 p.m.

ADDRESSES: The meeting will take place in the third floor main conference room at the U.S. Department of Justice, Office of Justice Programs, 810 7th St., NW., Washington, DC 20531.

FOR FURTHER INFORMATION CONTACT: Visit the Web site for the Coordinating Council at <http://www.juvenilecouncil.gov> or contact Robin Delany-Shabazz, Designated Federal Official, by telephone at 202-307-9963 [Note: this is not a toll-free telephone number], or by e-mail at Robin.Delany-Shabazz@usdoj.gov. The meeting is open to the public.

SUPPLEMENTARY INFORMATION: The Coordinating Council on Juvenile Justice and Delinquency Prevention, established pursuant to Section 3(2)(A) of the Federal Advisory Committee Act (5 U.S.C. App. 2) will meet to carry out its advisory functions under Section 206 of the Juvenile Justice and Delinquency Prevention Act of 2002, 42 U.S.C. 5601, *et seq.* Documents such as meeting announcements, agendas, minutes, and reports will be available on the Council's Web page, <http://www.JuvenileCouncil.gov>, where you may also obtain information on the meeting.

Although designated agency representatives may attend, the Council membership is composed of the Attorney General (Chair), the Administrator of the Office of Juvenile

Justice and Delinquency Prevention (Vice Chair), the Secretary of Health and Human Services (HHS), the Secretary of Labor, the Secretary of Education, the Secretary of Housing and Urban Development, the Director of the Office of National Drug Control Policy, the Chief Executive Officer of the Corporation for National and Community Service, and the Assistant Secretary of Homeland Security for U.S. Immigration and Customs Enforcement. The nine additional members are appointed by the Speaker of the House of Representatives, the Senate Majority Leader, and the President of the United States. Other federal agencies take part in Council activities including the Departments of Agriculture, Defense, the Interior, and the Substance and Mental Health Services Administration of HHS.

Meeting Agenda

The preliminary agenda for this meeting includes: (a) A presentation from the Council of State Governments on their statewide analysis of Texas school records and the relationship between school discipline and juvenile justice; (b) presentations from Child Trends on effective approaches to school discipline and from the Liberty LEADS college preparatory program for at-risk youth; (c) an update on the Consolidated Report of the Council's Issue Teams; and (d) agency announcements and updates.

Registration

For security purposes, members of the public who wish to attend the meeting must pre-register online at <http://www.juvenilecouncil.gov> no later than Wednesday, May 18, 2011. Should problems arise with web registration, call Daryl Dunston at 240-221-4343 or send a request to register to Mr. Dunston. Include name, title, organization or other affiliation, full address and phone, fax and e-mail information and send to his attention either by fax to 301-945-4295, or by e-mail to ddunston@edjassociates.com. [Note: these are not toll-free telephone numbers.] Additional identification documents may be required. Space is limited.

Note: Photo identification will be required for admission to the meeting.

Written Comments: Interested parties may submit written comments and questions by Wednesday, May 18, 2011, to Robin Delany-Shabazz, Designated Federal Official for the Coordinating Council on Juvenile Justice and Delinquency Prevention, at Robin.Delany-Shabazz@usdoj.gov. The

Coordinating Council on Juvenile Justice and Delinquency Prevention expects that the public statements presented will not repeat previously submitted statements.

May 2, 2011.

Jeff Slowikowski,
Acting Administrator.

[FR Doc. 2011-11032 Filed 5-5-11; 8:45 am]

BILLING CODE 4410-18-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2558-029]

Vermont Marble Power Division of Omya Inc.; Notice of Application Accepted for Filing, Soliciting Motions to Intervene and Protests, Ready for Environmental Analysis, and Soliciting Comments, Recommendations, Preliminary Terms and Conditions, and Preliminary Fishway Prescriptions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 2558-029.

c. *Date filed:* March 31, 2010.

d. *Applicant:* Vermont Marble Power Division of Omya Inc.

e. *Name of Project:* Otter Creek Hydroelectric Project.

f. *Location:* The existing project is located on Otter Creek in Addison and Rutland counties, Vermont. The project does not affect federal lands.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)-825(r)

h. *Applicant Contact:* Todd Allard, Operations Engineer, Vermont Marble Power Division of Omya Inc., 9987 Carver Road, Suite 300, Cincinnati, OH 45242; Telephone (513) 387-4344.

i. *FERC Contact:* Aaron Liberty, Telephone (202) 502-6862, and e-mail aaron.liberty@ferc.gov.

j. The deadline for filing motions to intervene and protests, comments, recommendations, preliminary terms and conditions, and preliminary prescriptions is August 30, 2011, and reply comments are due October 14, 2011.

Motions to intervene, protests, comments, recommendations, preliminary terms and conditions, and preliminary fishway prescriptions may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site <http://www.ferc.gov/docs-filing/>

efiling.asp. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll free at 1-866-208-3676, or for TTY, (202) 502-8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing and is now ready for environmental analysis.

l. The Otter Creek Project consists of three developments with a combined installed capacity of 18.1 megawatts (MW). The project produces an average annual generation of 67,258 megawatt-hours. Vermont Marble Power uses the energy from the project to serve its retail customers in the towns of Proctor and Pittsford, Vermont and to serve its affiliated industrial operations within Omya Inc.

On November 23, 2010, the Commission issued an order approving transfer of licenses and substitution of applicant which approved the transfer of the existing license for the Otter Creek Hydroelectric Project from Vermont Marble Power to Central Vermont Public Service Corporation (133 FERC ¶ 62,171 [2010]). Ordering Paragraph (D) of the order provides that the approval of the transfer is contingent upon, among other things, transfer of the title of the properties under license, transfer of all project files, and delivery of all license instruments to Central Vermont Public Service. On April 15, 2011, Vermont Marble Power and Central Vermont Public Service jointly indicated that they would not be able to fulfill the requirements of Ordering Paragraph (D) until June 30, 2011. On April 29, 2011, the Commission issued an order granting Vermont Marble Power and Central Vermont Public

Service an extension of time until June 30, 2011 for filing the requirements of Ordering Paragraph (D).

The Proctor development, located at river mile 64.2, consists of: (1) An existing 13-foot-high, 128-foot-long dam with a 3-foot-high inflatable flashboard system; (2) an existing 92-acre reservoir with a storage capacity of 275 acre-feet at a normal maximum water surface elevation of 469.5 feet mean sea level (M.S.L.); (3) a gated-forebay intake structure approximately 14 feet deep by 115 feet long with a maximum width of 48 feet; (4) two intakes with two penstocks: A 9-foot-diameter, 460-foot-long, riveted steel penstock that decreases to 8 feet diameter; and a 7-foot-diameter, 500-foot-long, spiral welded steel penstock; (5) an original concrete and brick masonry powerhouse measuring 100 by 33 feet containing four vertical shaft turbines: Three 750-kilowatt (kW) units and one 1,680-kW unit with a combined maximum hydraulic capacity of 565 cubic feet per second (cfs); (6) an additional steel structure measuring 28 by 48 feet attached to the original powerhouse containing one 3,000-kW vertical shaft unit with a maximum hydraulic capacity of 325 cfs; (7) generator leads; (8) a 0.48/4.16-kilovolt (kV) single phase transformer; (9) a 0.48/46-kV step-up transformer; (10) three winding transformer banks; and (11) appurtenant facilities.

The Beldens development, located at river mile 23, consists of: (1) Two existing concrete dams on either side of a ledge/bedrock island with 2.5-foot-high wooden flashboards: A 15-foot-high, 56-foot-long dam (west) and a 24-foot-high, 57-foot-long dam (east); (2) an existing 22-acre reservoir with a storage capacity of 253 acre-feet at a normal maximum water surface elevation of 282.52 feet M.S.L.; (3) two intakes equipped with trash racks: A 79-foot-long intake and a 35-foot-long intake with a 95-foot-long sluiceway; (4) a 12-foot-diameter, 30-foot-long steel penstock that bifurcates into two 10-foot-diameter sections, each leading to an original powerhouse; (5) a 12-foot-diameter, 45-foot-long concrete penstock that leads to a newer powerhouse; (6) an original concrete and masonry powerhouse measuring 40 by 44 feet containing a 800-kW vertical shaft unit and 949-kW vertical shaft unit with a combined maximum hydraulic capacity of 650 cfs; (7) a second, newer concrete powerhouse measuring 40 by 75 feet containing a 4,100-kW vertical shaft unit with a maximum hydraulic capacity of 1,350 cfs; (8) generator leads; (9) a 2.4/46-kV step-up transformer bank; and (10) appurtenant facilities.

The Huntington Falls development, located at river mile 21, consists of: (1) An existing 31-foot-high, 187-foot-long concrete dam with a 2.5-foot-high inflatable flashboard system; (2) an existing 23-acre reservoir with a storage capacity of 234 acre-feet at a normal maximum water surface elevation of 218.1 feet M.S.L.; (3) two intakes equipped with trash racks: A 40-foot-long intake and a 24-foot-long intake; (4) three penstocks: Two 10-foot-diameter, 30-foot-long steel penstocks leading to an original powerhouse, and a 12-foot-diameter, 75-foot-long concrete penstock leading to a newer powerhouse; (5) an original brick masonry powerhouse measuring 42 by 60 feet containing a 600-kW vertical shaft unit and a 800-kW vertical shaft unit with a combined maximum hydraulic capacity of 660 cfs; (6) a second, newer powerhouse measuring 40 by 75 feet containing a 4,100-kW vertical shaft unit with a maximum hydraulic capacity of 1,350 cfs; (7) generator leads; (8) a 2.4/46-kV step-up transformer bank; and (9) appurtenant facilities.

Currently, the Proctor development operates in a modified run-of-river mode, with infrequent diversions at the direction of Independent System Operator-New England, while the Beldens and Huntington Falls developments operate in a run-of-river mode. The Proctor development provides a continuous downstream minimum flow of 100 cfs or inflow to the development, whichever is less, with minimum flows from April through mid-June equal to at least 50 percent of project inflows. A bypassed reach minimum flow of 5 cfs is released at the Beldens development through an opening in the flashboards along the west dam. A bypassed reach minimum flow of 15 cfs is released at the Huntington Falls development via a minimum flow gate at the right abutment of the dam.

The dams and existing project facilities described above are currently owned by Vermont Marble Power. Vermont Marble Power does not propose any changes to project facilities or operations. However, as noted above, the license for the project is currently being transferred to Central Vermont Public Service Corporation. Vermont Marble Power proposes to implement measures to enhance recreation facilities in the project area.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding

the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

Register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

All filings must (1) bear in all capital letters the title "PROTEST", "MOTION TO INTERVENE", "COMMENTS," "REPLY COMMENTS," "RECOMMENDATIONS," "PRELIMINARY TERMS AND CONDITIONS," or "PRELIMINARY FISHWAY PRESCRIPTIONS;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

o. Procedural Schedule:

The application will be processed according to the following revised Hydro Licensing Schedule. As noted in item (l) above, the current license is being transferred to Central Vermont Public Service Corporation. The revised schedule takes into consideration the timeline for completing the transfer. Revisions to the schedule may be made as appropriate.

| Milestone | Target date |
|--|--------------------|
| Filing of recommendations, preliminary terms and conditions, and preliminary fishway prescriptions | August 30, 2011. |
| Commission issues EA | December 28, 2011. |
| Comments on EA | January 27, 2012. |
| Modified terms and conditions | February 26, 2012. |

p. Final amendments to the application must be filed with the Commission no later than July 31, 2011.

q. A license applicant must file no later than August 30, 2011: (1) A copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying agency received the request; or (3) evidence of waiver of water quality certification.

Dated: May 2, 2011.

Kimberly D. Bose,
Secretary.
[FR Doc. 2011-11088 Filed 5-5-11; 8:45 am]

BILLING CODE 6717-01-P

supply of Reactive Power and Voltage Control from Generation Sources Service under Schedule 2 of the PJM Interconnection, L.L.C. open access transmission tariff, as provided by Buckeye's Greenville generating plant.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the

"eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: 5 p.m. Eastern Time on May 20, 2011.

Dated: May 2, 2011.

Kimberly D. Bose,
Secretary.
[FR Doc. 2011-11089 Filed 5-5-11; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL11-36-000]

Buckeye Power, Inc.; Notice of Filing

Take notice that on April 29, 2011, pursuant to section 207(a)(5) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 382.207 (a)(5) (2010), Buckeye Power, Inc. (Buckeye) filed a petition for acceptance or approval of its monthly revenue requirement for its contribution to the

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11-3459-000]

NRG Solar Roadrunner LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of NRG

Solar Roadrunner LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability, is May 23, 2011.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: May 2, 2011.

Kimberly D. Bose,
Secretary.

[FR Doc. 2011-11085 Filed 5-5-11; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11-3467-000]

Blue Chip Energy LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Blue Chip Energy LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability, is May 23, 2011.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail

FERCOnlineSupport@ferc.gov or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: May 2, 2011.

Kimberly D. Bose,
Secretary.

[FR Doc. 2011-11087 Filed 5-5-11; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11-3460-000]

Bayonne Energy Center, LLC; Supplemental Notice that Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Bayonne Energy Center, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 23, 2011.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the

Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: May 2, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011-11086 Filed 5-5-11; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2662-012-CT; Project No. 12968-001-CT]

FirstLight Hydro Generating Company, City of Norwich Dept. of Public Utilities; Notice of Meeting

a. *Date and Time of Meeting:* Tuesday, May 17, 2011 from 10 a.m. to 12 p.m. EDT.

b. *Place:* Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

c. *FERC Contact:* Janet Hutzal, (202) 502-8675 or janet.hutzal@ferc.gov.

d. *Purpose of meeting:* Commission staff will meet with FirstLight Hydro Generating Company and the City of Norwich Dept. of Public Utilities to discuss the requirements of a supporting design report needed for the Scotland Hydroelectric Project (P-2662-012 and P-12968-001, respectively).

e. All local, State, and Federal agencies, tribes, and interested parties are hereby invited to participate, and teleconference will be available to those who cannot attend in person. Please contact Janet Hutzal at 202-502-8675 or via email at janet.hutzal@ferc.gov by the close of business on Thursday, May 12, 2011 to attend via teleconference.

Dated: May 2, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011-11084 Filed 5-5-11; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9302-8]

Agency Information Collection Activities OMB Responses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This document announces the Office of Management and Budget (OMB) responses to Agency Clearance requests, in compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

FOR FURTHER INFORMATION CONTACT: Rick Westlund (202) 566-1682, or e-mail at westlund.rick@epa.gov and please refer to the appropriate EPA Information Collection Request (ICR) Number.

SUPPLEMENTARY INFORMATION:

OMB Responses to Agency Clearance Requests

OMB Approvals

EPA ICR Number 0983.12; NSPS for Equipment Leaks of VOC in Petroleum Refineries; 40 CFR part 60, subparts A, GGG and GGGa; was approved on 04/12/2011; OMB Number 2060-0067; expires on 04/30/2014; Approved without change.

EPA ICR Number 1643.07; Application Requirements for the Approval and Delegation of Federal Air Toxics Programs to State, Territorial, Local, and Tribal Agencies (Renewal); 40 CFR part 63, subpart E; was approved on 04/12/2011; OMB Number 2060-0264; expires on 04/30/2014; Approved without change.

EPA ICR Number 1080.13; NESHAP for Benzene Emission from Benzene Storage Vessels and Coke By Product Recovery Plants; 40 CFR part 61, subparts A and L; was approved on 04/12/2011; OMB Number 2060-0185; expires on 04/30/2014; Approved without change.

EPA ICR Number 1136.10; NSPS for VOC Emissions from Petroleum Refinery Wastewater Systems; 40 CFR part 60, subparts A and QQQ; was approved on 04/12/2011; OMB Number 2060-0172; expires on 04/30/2014; Approved without change.

EPA ICR Number 1764.05; National Volatile Organic Compound Emission Standards for Consumer Products; 40

CFR part 59, subpart C; was approved on 04/12/2011; OMB Number 2060-0348; expires on 04/30/2014; Approved without change.

EPA ICR Number 2383.02; NESHAP for Gold Mine Ore Processing; 40 CFR part 63, subparts A and EEEEEEE; was approved on 04/12/2011; OMB Number 2060-0659; expires on 04/30/2014; Approved without change.

EPA ICR Number 2274.03; NESHAP for Clay Ceramics Manufacturing, Glass Manufacturing and Secondary Nonferrous Metals Processing Area Sources; 40 CFR part 63, subparts A, RRRRRR, SSSSSS and TTTTTT; was approved on 04/12/2011; OMB Number 2060-0606; expires on 04/30/2014; Approved without change.

EPA ICR Number 2227.03; NSPS for Stationary Spark Ignition Internal Combustion Engines; 40 CFR part 60, subparts A and JJJJ; was approved on 04/12/2011; OMB Number 2060-0610; expires on 04/30/2014; Approved without change.

EPA ICR Number 1854.07; The Consolidated Air Rule (CAR) for the Synthetic Organic Chemical Manufacturing Industry (SOCMI) (Renewal); 40 CFR part 60, subparts A, Ka, Kb, VV, VVa, DDD, III, NNN and RRR; 40 CFR part 61, subparts A, BB, Y and V; 40 CFR part 63, subparts A, F, G, H and I; and 40 CFR part 65; was approved on 04/12/2011; OMB Number 2060-0443; expires on 04/30/2014; Approved without change.

EPA ICR Number 2369.02; NSPS for Sewage Sludge Incinerators; 40 CFR part 60, subpart LLLL; was approved on 04/12/2011; OMB Number 2060-0658; expires on 04/30/2014; Approved without change.

Comment Filed

EPA ICR Number 1856.07; NESHAP for Primary Lead Smelting; in 40 CFR part 63, subparts A and TTT; OMB filed comment on 04/12/2011.

Dated: May 3, 2011.

John Moses,

Director, Collections Strategies Division.

[FR Doc. 2011-11132 Filed 5-5-11; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9302-5; Docket ID No. EPA-HQ-ORD-2011-0051]

Draft Integrated Science Assessment for Lead (Pb)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing the availability of a document titled, "First External Review Draft Integrated Science Assessment for Lead" (EPA/600/R-10/075A). This draft document was prepared by the National Center for Environmental Assessment (NCEA) within EPA's Office of Research and Development as part of the review of the national ambient air quality standards (NAAQS) for lead (Pb).

EPA is releasing this draft document to seek review by the Clean Air Scientific Advisory Committee (CASAC) and the public (meeting date and location to be specified in a separate **Federal Register** Notice). The draft document does not represent and should not be construed to represent any final EPA policy, viewpoint, or determination. EPA will consider any timely public comments submitted in response to this notice when revising the document.

DATES: The public comment period begins May 6, 2011, and ends July 5, 2011. Comments must be received on or before July 5, 2011.

ADDRESSES: The "First External Review Draft Integrated Science Assessment for Lead" will be available primarily via the Internet on the National Center for Environmental Assessment's home page under the Recent Additions and Publications menus at <http://www.epa.gov/ncea>. A limited number of CD-ROM or paper copies will be available. Contact Ms. Debbie Wales by phone (919-541-4731), fax (919-541-5078), or e-mail (wales.deborah@epa.gov) to request either of these, and please provide your name, your mailing address, and the document title, "First External Review Draft Integrated Science Assessment for Lead" (EPA/600/R-10/075A) to facilitate processing of your request.

FOR FURTHER INFORMATION CONTACT: For technical information, contact Dr. Ellen Kirrane, NCEA; telephone: 919-541-1340; facsimile: 919-541-2985; or e-mail: kirrane.ellen@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Information About the Document

Two sections of the Clean Air Act (CAA) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. section 7408) directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants. The Administrator is to list those air pollutants that in her "judgment, cause

or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;" "the presence of which in the ambient air results from numerous or diverse mobile or stationary sources;" and "for which * * * [the Administrator] plans to issue air quality criteria * * *." Air quality criteria are intended to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air * * *." 42 U.S.C. 7408(b). Under section 109 (42 U.S.C. 7409) the Administrator is to establish national ambient air quality standards (NAAQS) for each pollutant for which EPA has issued criteria. Section 109(d)(1) requires periodic review and, if appropriate, revision of existing air quality criteria to reflect advances in scientific knowledge on the effects of the pollutant on public health or welfare. EPA is also to revise the NAAQS, if appropriate, based on the revised air quality criteria. Section 109(d)(2) requires that an independent scientific review committee "shall complete a review of the criteria * * * and the national primary and secondary ambient air quality standards * * * and shall recommend to the Administrator any new * * * standards and revisions of existing criteria and standards as may be appropriate . * * ." Since the early 1980's, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC).

Under the current NAAQS review process, EPA reviews the scientific basis for the NAAQS by preparing an Integrated Science Assessment (ISA) and supplementary materials (formerly called an Air Quality Criteria Document). On February 26, 2010 (75 FR 8934), EPA formally initiated its current review of the air quality criteria for Pb, requesting the submission of recent scientific information on specified topics. A workshop was held on May 10-11, 2010 (75 FR 20843) to discuss policy-relevant science to inform EPA's planning for the Pb NAAQS review. Following the workshop, a draft of EPA's "Integrated Review Plan for the National Ambient Air Quality Standards for Lead" (EPA-452/D-11-001) was made available in late March, 2011 for public comment and consultation with CASAC. It will be discussed by the CASAC via a publicly accessible teleconference consultation on May 5, 2011 (76 FR 21346). In December 2010, EPA held a workshop (75 FR 69078) to discuss, with invited

scientific experts, preliminary draft materials prepared during the ongoing development of the Pb ISA.

The first external review draft ISA for Pb will be discussed at a public meeting for review by CASAC, and public comments received will be provided to the CASAC review panel. A future **Federal Register** notice will inform the public of the exact date and time of that CASAC meeting.

II. How To Submit Technical Comments to the Docket at www.regulations.gov

Submit your comments, identified by Docket ID No. EPA-HQ-ORD-2011-0051, by one of the following methods:

- www.regulations.gov: Follow the on-line instructions for submitting comments.
- *E-mail*: ORD.Docket@epa.gov.
- *Fax*: 202-566-1753.
- *Mail*: Office of Environmental Information (OEI) Docket (Mail Code: 2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. The phone number is 202-566-1752.
- *Hand Delivery*: The OEI Docket is located in the EPA Headquarters Docket Center, Room 3334, EPA West Building, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is 202-566-1744. Such deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

If you provide comments by mail or hand delivery, please submit three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

Instructions: Direct your comments to Docket ID No. EPA-HQ-ORD-2011-0051. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked "late," and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at <http://www.regulations.gov>, including any personal information provided, unless a comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information through <http://www.regulations.gov> or e-mail

that you consider to be CBI or otherwise protected. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

Docket: 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. Publicly available docket materials are generally available either electronically in <http://www.regulations.gov> or in hard copy at the OEI Docket in the EPA Headquarters Docket Center; however, certain materials, such as copyrighted material, are publicly available only in hard copy.

Dated: April 21, 2011.

Darrell A. Winner,

Acting Director, National Center for Environmental Assessment.

[FR Doc. 2011-11140 Filed 5-5-11; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-8996-8]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564-1399 or <http://www.epa.gov/compliance/nepa/>.

Weekly Receipt of Environmental Impact Statements

Filed 04/25/2011 through 04/29/2011
Pursuant to 40 CFR 1506.9

Notice

In accordance with Section 309(a) of the Clean Air Act, EPA is required to make its comments on EISs issued by other Federal agencies public. Historically, EPA met this mandate by publishing weekly notices of availability of EPA comments, which includes a brief summary of EPA's comment letters, in the **Federal Register**. Since February 2008, EPA has included its comment letters on EISs on its Web site at: <http://www.epa.gov/compliance/nepa/eisdata.html>. Including the entire EIS comment letters on the Web site satisfies the Section 309(a) requirement to make EPA's comments on EISs available to the public. Accordingly, on March 31, 2010, EPA discontinued the publication of the notice of availability of EPA comments in the **Federal Register**.

EIS No. 20110133, Final EIS, NPS, FL, Programmatic—Coral Reef Restoration Plan, Implementation, Biscayne National Park, Homestead, FL, Wait Period Ends: 06/06/2011, **Contact:** Mark Lewis 305-230-1144.

EIS No. 20110134, Final Supplement, USFS, CA, Gemmill Thin Project, Updated Information on Four Alternatives, Chanchellula Late-Successional Reserve, Shasta-Trinity National Forest, Trinity County, CA, Review Period Ends: 06/06/2011, **Contact:** Joshua Wilson 530-226-2422.

EIS No. 20110135, Draft EIS, USFS, SD, Pactola Project Area, Proposes to Implement Multiple Resource Management Actions, Mystic Ranger District, Black Hills National Forest, Pennington County, SD, Comment Period Ends: 06/20/2011, **Contact:** Katie Van Alstyne 605-343-1567.

EIS No. 20110136, Final EIS, USFS, NM, Rinconada Communication Site, Designation of Site to Serve Present and Future High Power Communication Needs and to Permit the Development of a Radio Transmission Facility within Site, Mt. Taylor Ranger District, Cibola National Forest, Cibola County, NM, Review Period Ends: 06/06/2011, **Contact:** Keith Baker 505-346-3870.

EIS No. 20110137, Draft EIS, USFS, CA, Pettijohn Late-Successional Reserve Habitat Improvement and Fuels Reduction Project, Implementation, Trinity River Management, Trinity Unit of the Shasta-Trinity National Recreation Area, Trinity County, CA, Comment Period Ends: 06/20/2011, **Contact:** Keli M. McElroy 530-226-2354.

EIS No. 20110138, Draft Supplement, USACE, 00, Fargo-Moorhead

Metropolitan Area Flood Risk Management, To Documents the Analysis of Alternatives Developed to Reduce Flood Risk, Red River of the North Basin, ND and MN, Comment Period Ends: 06/20/2011, **Contact:** Aaron M. Snyder 651-290-5489.
EIS No. 20110139, Final EIS, USFS, CO, White River National Forest Travel Management Plan, Updated Information for the Preferred Alternative, To Accommodate and Balance Transportation Needs, Implementation, Eagle, Garfield, Gunnison, Mesa, Moffat, Pitkin, Rio Blanco, Routt and Summit Counties, CO, Review Period Ends: 06/06/2011, **Contact:** Wendy Jo Haskins 970-945-3303.

Amended Notices

EIS No. 20110090, Draft EIS, USFS, MN, Federal Hardrock Mineral Prospecting Permits Project, To Conduct Mineral Exploration Drilling and Geophysical Activities on the Superior National Forest, Cook, Lake, St. Louis and Koochiching Counties, MIN, Comment Period Ends: 06/30/2011, **Contact:** Loretta Cartner 218-626-4382.

Revision to FR Notice Published 04/01/2011: Extending Comment Period from 05/16/2011 to 06/30/2011.

EIS No. 20110115, Final EIS, BLM, NV, Genesis Project, Proposes Expansion of Existing Mine Pits and Development of the Bluestar Ridge Open Pit Mine, Newmont Mining Corporation, Eureka County, NV, Review Period Ends: 05/16/2011, **Contact:** Kirk Laird 775-753-0272.

Revision to FR Notice Published 04/15/2011: Correction to the Review Period from 05/09/2011 to 05/16/2011.

EIS No. 20110117, Final EIS, BLM, CA, First Solar Desert Sunlight Solar Farm (DSSF) Project, Proposing To Develop a 550-Megawatt Photovoltaic Solar Project, Also Proposes to Facilitate the Construction and Operation of the Red Bluff Substation, California Desert Conservation Area (CDCA) Plan, Riverside County, CA, Review Period Ends: 05/16/2011, **Contact:** Allison Shaffer 760-833-7104.

Revision to FR Notice Published 04/15/2011: Correction to the Review Period from 05/09/2011 to 05/16/2011.

EIS No. 20110118, Final EIS, DOI, WA, Cle Elum Dam Fish Passage Facilities and Fish Reintroduction Project, To Restore Connectivity, Biodiversity, and Natural Production of Anadromous Salmonids, Kittitas County, WA, Review Period Ends: 05/16/2011, **Contact:** Jim Taylor 208-378-5081.

Revision to FR Notice Published 04/15/2011: Correction to the Review Period from 05/08/2011 to 05/16/2011.

EIS No. 20110119, Final EIS, USFS, CA, Kings River Experimental Watershed Forest Health and Research Project, Implementation, Sierra National Forest, High Sierra Ranger District, Fresno County, CA, Review Period Ends: 05/16/2011, Contact: Judi Tapia 559-297-0706 Ext. 4938.

Revision to FR Notice Published 04/15/2011: Correction to the Review Period from 05/09/2011 to 05/16/2011.

Dated: May 3, 2011.

Robert W. Hargrove,
Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2011-11118 Filed 5-5-11; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2011-0399; FRL-8872-8]

FIFRA Scientific Advisory Panel; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: There will be a 4-day meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) to consider and review a set of scientific issues related to the Re-Evaluation of Human Health Effects of Atrazine: Review of Non-Cancer Effects, Drinking Water Monitoring Frequency, and Cancer Epidemiology.

DATES: The meeting will be held on July 26-29, 2011, from approximately 8:30 a.m. to 5 p.m.

Comments. The Agency encourages that written comments be submitted by July 12, 2011 and requests for oral comments be submitted by July 19, 2011. However, written comments and requests to make oral comments may be submitted until the date of the meeting, but anyone submitting written comments after July 12, 2011 should contact the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**. For additional instructions, see Unit I.C. of the **SUPPLEMENTARY INFORMATION**.

Nominations. Nominations of candidates to serve as ad hoc members of FIFRA SAP for this meeting should be provided on or before May 20, 2011.

Webcast. This meeting may be webcast. Please refer to the FIFRA SAP's

Web site, <http://www.epa.gov/scipoly/SAP> for information on how to access the webcast. Please note that the webcast is a supplementary public process provided only for convenience. If difficulties arise resulting in webcasting outages, the meeting will continue as planned.

Special accommodations. For information on access or services for individuals with disabilities, and to request accommodation of a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

ADDRESSES: The meeting will be held at the Environmental Protection Agency, Conference Center, Lobby Level, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA 22202.

Comments. Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2011-0399, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-2011-0399. If your comments contain any information that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting your comments. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line 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 regulations.gov or e-

mail. The regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. 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, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

Nominations, requests to present oral comments, and requests for special accommodations. Submit nominations to serve as ad hoc members of FIFRA SAP, requests for special seating accommodations, or requests to present oral comments to the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Joseph Bailey, DFO, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; **telephone number:** (202) 564-2045; **fax number:** (202) 564-8382; **e-mail address:** bailey.joseph@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA), FIFRA, and the Food Quality Protection Act of 1996 (FQPA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

When submitting comments, remember to:

1. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

2. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

3. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

4. Describe any assumptions and provide any technical information and/or data that you used.

5. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

6. Provide specific examples to illustrate your concerns and suggest alternatives.

7. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

8. Make sure to submit your comments by the comment period deadline identified.

C. How may I participate in this meeting?

You may participate in this meeting by following the instructions in this unit. To ensure proper receipt by EPA, it is imperative that you identify docket ID number EPA-HQ-OPP-2011-0399 in the subject line on the first page of your request.

1. *Written comments.* The Agency encourages that written comments be submitted, using the instructions in **ADDRESSES**, no later than July 12, 2011, to provide FIFRA SAP the time necessary to consider and review the written comments. Written comments

are accepted until the date of the meeting, but anyone submitting written comments after July 12, 2011 should contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**. Anyone submitting written comments at the meeting should bring 30 copies for distribution to the FIFRA SAP.

2. *Oral comments.* The Agency encourages that each individual or group wishing to make brief oral comments to the FIFRA SAP submit their request to the DFO listed under **FOR FURTHER INFORMATION CONTACT** no later than July 19, 2011, in order to be included on the meeting agenda. Requests to present oral comments will be accepted until the date of the meeting and, to the extent that time permits, the Chair of FIFRA SAP may permit the presentation of oral comments at the meeting by interested persons who have not previously requested time. The request should identify the name of the individual making the presentation, the organization (if any) the individual will represent, and any requirements for audiovisual equipment (e.g., overhead projector, 35 mm projector, chalkboard). Oral comments before FIFRA SAP are limited to approximately 5 minutes unless prior arrangements have been made. In addition, each speaker should bring 30 copies of his or her comments and presentation slides for distribution to the FIFRA SAP at the meeting.

3. *Seating at the meeting.* Seating at the meeting will be open and on a first-come basis.

4. *Request for nominations to serve as ad hoc members of FIFRA SAP for this meeting.* As part of a broader process for developing a pool of candidates for each meeting, FIFRA SAP staff routinely solicits the stakeholder community for nominations of prospective candidates for service as ad hoc members of FIFRA SAP. Any interested person or organization may nominate qualified individuals to be considered as prospective candidates for a specific meeting. Individuals nominated for this meeting should have expertise in one or more of the following areas: Risk assessment, environmental epidemiology, exposure assessment (particularly pesticide applicators), mammary gland development, mode of action analysis (particularly those with MOA framework experience), frameworks to evaluate human relevance, prostate development, pharmacokinetics, physiologically-based pharmacokinetic modeling, neuroendocrinology, hormone-mediated health effects, HPA axis (corticosterone), reproductive/developmental biology and environmental sampling and statistical modeling. Nominees should

be scientists who have sufficient professional qualifications, including training and experience, to be capable of providing expert comments on the scientific issues for this meeting. Nominees should be identified by name, occupation, position, address, and telephone number. Nominations should be provided to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before May 20, 2011. The Agency will consider all nominations of prospective candidates for this meeting that are received on or before this date. However, final selection of ad hoc members for this meeting is a discretionary function of the Agency.

The selection of scientists to serve on FIFRA SAP is based on the function of the panel and the expertise needed to address the Agency's charge to the panel. No interested scientists shall be ineligible to serve by reason of their membership on any other advisory committee to a Federal department or agency or their employment by a Federal department or agency except the EPA. Other factors considered during the selection process include availability of the potential panel member to fully participate in the panel's reviews, absence of any conflicts of interest or appearance of lack of impartiality, independence with respect to the matters under review, and lack of bias. Although financial conflicts of interest, the appearance of lack of impartiality, lack of independence, and bias may result in disqualification, the absence of such concerns does not assure that a candidate will be selected to serve on FIFRA SAP. Numerous qualified candidates are identified for each panel. Therefore, selection decisions involve carefully weighing a number of factors including the candidates' areas of expertise and professional qualifications and achieving an overall balance of different scientific perspectives on the panel. In order to have the collective breadth of experience needed to address the Agency's charge for this meeting, the Agency anticipates selecting approximately 15 ad hoc scientists.

FIFRA SAP members are subject to the provisions of 5 CFR part 2634, Executive Branch Financial Disclosure, as supplemented by the EPA in 5 CFR part 6401. In anticipation of this requirement, prospective candidates for service on the FIFRA SAP will be asked to submit confidential financial information which shall fully disclose, among other financial interests, the candidate's employment, stocks and bonds, and where applicable, sources of research support. The EPA will evaluate the candidate's financial disclosure

form to assess whether there are financial conflicts of interest, appearance of a lack of impartiality or any prior involvement with the development of the documents under consideration (including previous scientific peer review) before the candidate is considered further for service on FIFRA SAP. Those who are selected from the pool of prospective candidates will be asked to attend the public meetings and to participate in the discussion of key issues and assumptions at these meetings. In addition, they will be asked to review and to help finalize the meeting minutes. The list of FIFRA SAP members participating at this meeting will be posted on the FIFRA SAP Web site at <http://epa.gov/scipoly/sap> or may be obtained from the OPP Regulatory Public Docket at <http://www.regulations.gov>.

II. Background

A. Purpose of FIFRA SAP

FIFRA SAP serves as the primary scientific peer review mechanism of EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and is structured to provide scientific advice, information and recommendations to the EPA Administrator on pesticides and pesticide-related issues as to the impact of regulatory actions on health and the environment. FIFRA SAP is a Federal advisory committee established in 1975 under FIFRA that operates in accordance with requirements of the Federal Advisory Committee Act. FIFRA SAP is composed of a permanent panel consisting of seven members who are appointed by the EPA Administrator from nominees provided by the National Institutes of Health and the National Science Foundation. FIFRA, as amended by FQPA, established a Science Review Board consisting of at least 60 scientists who are available to the SAP on an ad hoc basis to assist in reviews conducted by the SAP. As a peer review mechanism, FIFRA SAP provides comments, evaluations and recommendations to improve the effectiveness and quality of analyses made by Agency scientists. Members of FIFRA SAP are scientists who have sufficient professional qualifications, including training and experience, to provide expert advice and recommendation to the Agency.

B. Public Meeting

EPA is undertaking a re-evaluation of the human health effects of atrazine. The human health re-evaluation has involved three SAP meetings in 2010 and one in 2011. The first meeting was

held in February 2010 during which the Agency presented its preliminary reviews of several atrazine epidemiology studies on birth outcomes and described a project plan to evaluate atrazine epidemiology data from the Agricultural Health Study (<http://aghealth.nci.nih.gov/>). The second meeting in April 2010 SAP meeting focused on:

1. A preliminary review of experimental toxicology studies from laboratory mammals and *in vitro* studies and recent advancements in understanding atrazine's mode of action along with;

2. Statistical and modeling approaches for evaluating monitoring frequency in community water systems (CWS). The September 2010 meeting built on the scientific analysis and SAP feedback from the April meeting. Specifically, the Agency presented scientific analyses on an empirical approach for estimating internal dosimetry, and calculation of benchmark dose estimates for purposes of deriving points of departure. In addition, EPA presented a general strategy for designing a monitoring study to characterize drinking water exposures and discussed different methods for analyzing and interpreting monitoring data collected at different sampling frequencies. The September 2010 meeting also provided proposals for updating the critical durations of exposure based on the new science, and a preliminary evaluation of potential susceptibility of the young. In addition, the September 2010 meeting included evaluation of non-cancer epidemiology studies, a weight of the evidence evaluation of the non-cancer epidemiology studies with experimental laboratory studies, and a proposal to use the non-cancer epidemiology studies qualitatively in evaluating the human relevance of experimental toxicology findings.

The July 2011 SAP meeting will build on the scientific analyses and SAP feedback from the previous three SAP meetings by proposing a conceptual framework for the evaluation of atrazine human health non-cancer effects. This proposed conceptual framework will integrate information on mode of action and adverse outcome pathways, potentially susceptible life stages/subpopulations, drinking water exposure, internal dosimetry, and water monitoring sampling uncertainty. The Agency will solicit comment on the overall integrative approach proposed for atrazine along with technical considerations for each scientific component. To illustrate the conceptual framework, a case study will be

provided that demonstrates an approach for estimating non-cancer risk to atrazine based on an internal dose metric for temporally, spatially, and demographically explicit information. The Agency will use feedback received from the SAP at the July 2011 meeting as it completes the scientific analysis for determining whether or not adjustments may be necessary in the sampling frequency of CWS monitoring. The evaluation of non-cancer effects will include studies available up through April 29, 2010.

In the 2003 Interim Reregistration Eligibility Decision (IRED) for atrazine, the Agency noted that it would convene another SAP meeting concerning atrazine and its possible association with carcinogenic effects, particularly as new information from the National Cancer Institute's (NCI) Agricultural Health Study (AHS) is made available. The Agency believes it is appropriate at this time to re-evaluate the cancer epidemiology literature on atrazine in a SAP meeting; EPA notes that the evidence of atrazine carcinogenicity based upon experimental animal data were evaluated by the SAP in April 2010. As such, at the July 2011 meeting, the Agency will provide a preliminary review of cancer epidemiology studies and a draft weight of the evidence (WOE) analysis on cancer that integrates mode of action, experimental toxicology information, and epidemiology. This draft WOE analysis will follow the Draft Framework for Incorporating Epidemiologic and Human Incident Data in Health Risk Assessment, which was reviewed by the SAP in February 2010. The Agency will include epidemiological studies on the cancer effects of atrazine available up through April 29, 2010. The Agricultural Health Study is anticipated to be published in spring 2011 and will be part of this review given that this study is considered to be a pivotal line of evidence.

At the February 2010 SAP, the Agency presented a proposed plan for a collaborative project with investigators from the AHS to evaluate approaches for estimating exposure to pesticide applicators. At the July 2011 meeting, the Agency will discuss the status of the collaborative project (which includes a case study involving atrazine) and solicit comment from the Panel on the overall direction of the project and the methods development aspects of this effort. This project is part of a larger effort by OPP to improve the incorporation of epidemiology in human health risk assessment. The feedback from the SAP may not be used for atrazine risk assessment *per se* but

will inform EPA's continued efforts to improve risk assessment approaches and methodologies.

C. FIFRA SAP Documents and Meeting Minutes

EPA's background paper, related supporting materials, charge/questions to FIFRA SAP, FIFRA SAP composition (i.e., members and ad hoc members for this meeting), and the meeting agenda will be available by late June. In addition, the Agency may provide additional background documents as the materials become available. You may obtain electronic copies of these documents, and certain other related documents that might be available electronically, at <http://www.regulations.gov> and the FIFRA SAP homepage at <http://www.epa.gov/scipoly/sap>.

FIFRA SAP will prepare meeting minutes summarizing its recommendations to the Agency approximately 90 days after the meeting. The meeting minutes will be posted on the FIFRA SAP Web site or may be obtained from the OPP Regulatory Public Docket at <http://www.regulations.gov>.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: April 27, 2011.

Frank Sanders,

Director, Office of Science Coordination and Policy.

[FR Doc. 2011-11027 Filed 5-5-11; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9302-7]

Science Advisory Board Staff Office; Notification of a Public Teleconference of the Chartered Science Advisory Board

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Science Advisory Board (SAB) Staff Office announces a public teleconference of the chartered SAB on June 6, 2011 to conduct a quality review of a draft SAB report entitled "SAB Review of EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments."

DATES: The public teleconference will be held on June 6, 2011, from 12 p.m. to 4 p.m. (Eastern Time).

ADDRESSES: The public teleconference will be conducted by telephone only.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing to obtain general information concerning the public teleconference may contact Ms. Stephanie Sanzone, Designated Federal Officer (DFO), EPA Science Advisory Board via e-mail at sanzone.stephanie@epa.gov, telephone/voice mail (202) 564-2067, or fax (202) 565-2098. General information concerning the EPA Science Advisory Board can be found on the EPA Web site at <http://www.epa.gov/sab>.

SUPPLEMENTARY INFORMATION: The SAB was established pursuant to the Environmental Research, Development, and Demonstration Authorization Act (ERDAA), codified at 42 U.S.C. 4365, to provide independent scientific and technical advice to the EPA Administrator on the technical basis for Agency positions and regulations. The SAB is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2. Pursuant to FACA and EPA policy, notice is hereby given that the SAB will hold a public teleconference to conduct a quality review of a draft report entitled "SAB Review of EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments." The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Background: The SAB was asked to review and provide advice to EPA on a draft report, entitled "EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments." To conduct this review, the SAB Staff Office requested public nominations of experts (73 FR 61114) and formed the *ad hoc* SAB Dioxin Review Panel. The Panel held face-to-face public meetings on July 13-15, 2010 (75 FR 28805) and October 27-29, 2010 (75 FR 57779), and follow-up public teleconference meetings on March 1 and March 2, 2011 (76 FR 6784) to review EPA's draft document. The SAB will conduct a quality review of the Panel's draft report, "SAB Review of EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments." Background information about this SAB advisory activity can be found on the SAB Web site at http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/Dioxin%20Reasst%20-%202008-2011?OpenDocument.

Availability of Meeting Materials: The agenda and other materials in support of the teleconference will be placed on the

SAB Web site at <http://www.epa.gov/sab> in advance of the teleconference.

Procedures for Providing Public Input: Public comment for consideration by EPA's federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office.

Federal advisory committees and panels, including scientific advisory committees, provide independent advice to EPA. Members of the public can submit comments for a federal advisory committee to consider as it develops advice for EPA. Input from the public to the SAB will have the most impact if it provides specific scientific or technical information or analysis for SAB panels to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comment should contact the Designated Federal Officer directly. **Oral Statements:** Individuals or groups requesting an oral presentation will be limited to five minutes. Those interested in being placed on the public speakers list for the June 6, 2011, teleconference should contact Ms. Sanzone at the contact information provided above no later than May 27, 2011. **Written Statements:** Written statements should be supplied to the DFO via e-mail at the contact information noted above by May 27, 2011, for the teleconference so that the information may be made available to the Panel members for their consideration. Written statements should be supplied in one of the following electronic formats: Adobe Acrobat PDF, MS Word, MS PowerPoint, or Rich Text files in IBM-PC/Windows 98/2000/XP format. It is the SAB Staff Office general policy to post written comments on the Web page for the advisory meeting or teleconference. Submitters are requested to provide an unsigned version of each document because the SAB Staff Office does not publish documents with signatures on its Web sites. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the SAB Web site. Copyrighted material will not be posted without explicit permission of the copyright holder.

Accessibility: For information on access or services for individuals with disabilities, please contact Ms. Sanzone at (202) 564-2067 or sanzone.stephanie@epa.gov. To request accommodation of a disability, please

contact Ms. Sanzone preferably at least ten days prior to the teleconference to give EPA as much time as possible to process your request.

Dated: April 26, 2011.

Anthony Maciorowski,
Deputy Director, EPA Science Advisory Staff Office.

[FR Doc. 2011-11129 Filed 5-5-11; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-R07-SFUND-2011-0339 FRL-9302-2]

Proposed CERCLA Administrative "Cost Recovery" Settlement; the Doe Run Resources Corporation

AGENCY: Environmental Protection Agency.

ACTION: Notice; request for public comment.

SUMMARY: In accordance with Section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended ("CERCLA"), 42 U.S.C. 9622(i), notice is hereby given of a proposed administrative settlement for recovery of past response costs concerning the Big River Mine Tailings Superfund Site, St. Francois Mining Area, St. Francois County, Missouri with the following settling party: The Doe Run Resources Corporation. The settlement requires the settling party to pay \$208,990, to the Hazardous Substance Superfund. The settlement includes a covenant not to sue the settling party pursuant to Section 107(a) of CERCLA, 42 U.S.C. 9607(a). For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the settlement. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate. The Agency's response to any comments received will be available for public inspection at: Desloge Public Library, 209 North Desloge Drive, Desloge, Missouri 63601; and St. Francois County Health Department, 1025 West Main, Park Hills, Missouri 63601; and Environmental Protection Agency, Region VII Docket Room, 901 North Fifth Street, Kansas City, KS 66101.

DATES: Comments must be submitted on or before June 6, 2011.

ADDRESSES: The proposed settlement is available for public inspection at the Environmental Protection Agency,

Region VII Docket Room, 901 North Fifth Street, Kansas City, KS 66101. A copy of the proposed settlement may be obtained from Kathy Robinson, Regional Hearing Clerk, Environmental Protection Agency, Region VII, 901 North Fifth Street, Kansas City, KS 66101, 913-551-7567. Comments should reference the Big River Mine Tailings Superfund Site, St. Francois County, Missouri, and EPA Docket No. CERCLA-07-2011-0003, and should be addressed to Kathy Robinson, Regional Hearing Clerk, Environmental Protection Agency, Region VII, 901 North Fifth Street, Kansas City, KS 66101.

FOR FURTHER INFORMATION CONTACT:

Jason Gunter, Remedial Project Manager, Superfund Division, Environmental Protection Agency, Region VII, 901 North Fifth Street, Kansas City, KS 66101, gunter.jason@epa.gov or at 913-551-7358.

Dated: April 21, 2011.

Cecilia Tapia,

Director, Superfund Division, Region 7.

[FR Doc. 2011-10997 Filed 5-5-11; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2011-0005; FRL-8870-3]

Pesticide Products; Registration Applications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of applications to register new uses for pesticide products containing currently registered active ingredients, pursuant to the provisions of section 3(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. EPA is publishing this Notice of such applications, pursuant to section 3(c)(4) of FIFRA.

DATES: Comments must be received on or before June 6, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number specified within the table below, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number specified for the pesticide of interest as shown in the registration application summaries. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line 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 [regulations.gov](http://www.regulations.gov) or e-mail. The [regulations.gov](http://www.regulations.gov) Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. 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, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP

Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: A contact person is listed at the end of each registration application summary and may be contacted by telephone or e-mail. The mailing address for each contact person listed is: Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, and Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

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

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 in this unit could also be affected. The North American Industrial Classification System (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 person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that

is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number). If you are commenting in a docket that addresses multiple products, please indicate to which registration numbers your comment applies.
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. Registration Applications

EPA received applications as follows to register pesticide products containing currently registered active ingredients pursuant to the provisions of section 3(c) of FIFRA, and is publishing this Notice of such applications pursuant to section 3(c)(4) of FIFRA. Notice of receipt of these applications does not imply a decision by the Agency on the applications.

1. *Registration Number/File Symbol:* 264-830 and 264-831. *Docket Number:* EPA-HQ-OPP-2011-0087. *Company name and address:* Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. *Active ingredient:* Spirodiclofen. *Proposed Uses:* Acerola, atemoya, biriba, cherimoya, custard apple, feijoa, jaboticaba, guava, ilama, longan, lychee, passionfruit, pulasan, soursop, spanish lime, starfruit, sugar apple, wax jambu,

rambutan, and persimmon. *Contact:* Rita Kumar, Registration Division, (703) 308-8291, kumar.rita@epa.gov.

2. *Registration Number/File Symbol:* 59639-173, 59639-150, and 59639-151. *Docket Number:* EPA-HQ-OPP-2010-0217. *Company name and address:* Valent, U.S.A. Corp., P.O. Box 8025, Walnut Creek, CA 94596-8025. *Active ingredient:* Clothianidin. *Proposed Use:* Terrestrial use on rice. *Contact:* Marianne Lewis, Registration Division, (703) 308-8043, lewis.marianne@epa.gov.

3. *Registration Number/File Symbol:* 10163-GEE. *Docket Number:* EPA-HQ-OPP-2006-0075. *Company name and address:* Gowan Company, 370 Main St., Yuma, AZ 85364. *Active ingredient:* Fenazaquin. *Proposed Use:* Alfalfa; avocado; beans, dry; beans, succulent; berry group; citrus group; corn, field; corn, sweet; cotton; cucurbits; fruiting vegetables, field and greenhouse; grapes; hops; mint; pome fruit group; stonefruit group; strawberries; tree nut group. *Contact:* Daniel Peacock, Registration Division, (703) 305-5407, peacock.dan@epa.gov.

4. *Registration Number/File Symbol:* 71693-1. *Docket Number:* EPA-HQ-OPP-2011-0305. *Company name and address:* Arizona Cotton Research and Protection Council, 3721 East Wier Avenue, Phoenix, AZ 85040-2933. *Active ingredient:* *Aspergillus favus* AF36. *Proposed Use:* Pistachio. *Contact:* Shanaz Bacchus, Biopesticides and Pollution Prevention Division, (703) 308-8097, bacchus.shanaz@epa.gov.

List of Subjects

Environmental protection, Pesticides and pest.

Dated: April 20, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2011-10441 Filed 5-5-11; 8:45 am]

BILLING CODE 6560-50-P

EXPORT-IMPORT BANK OF THE UNITED STATES

Notice of Open Meeting of the Advisory Committee of the Export-Import Bank of the United States (Ex-Im Bank)

SUMMARY: The Advisory Committee was established by Public Law 98-181, November 30, 1983, to advise the Export-Import Bank on its programs and to provide comments for inclusion in the reports of the Export-Import Bank of the United States to Congress.

Time and Place: Tuesday, May 17 from 11 a.m. to 3 p.m. A break for lunch

will be at the expense of the attendee. Security processing will be necessary for reentry into the building. The meeting will be held at Em-Im Bank in the Main Conference Room 1143, 811 Vermont Avenue, NW., Washington, DC 20571.

Agenda: Agenda items include a briefing of the Advisory Committee members on the status of the Bank's activities, the competitiveness report and progress reports from the various subcommittees.

Public Participation: The meeting will be open to public participation, and the last 10 minutes will be set aside for oral questions or comments. Members of the public may also file written statement(s) before or after the meeting. If you plan to attend, a photo ID must be presented at the guard's desk as part of the clearance process into the building, and you may contact Susan Houser to be placed on an attendee list. If any person wishes auxiliary aids (such as a sign language interpreter) or other special accommodations, please contact, prior to May 13, 2011, Susan Houser, Room 1273, 811 Vermont Avenue, NW., Washington, DC 20571, *Voice:* (202) 565-3232.

FOR FURTHER INFORMATION CONTACT: Susan Houser, Room 1273, 811 Vermont Avenue, NW., Washington, DC 20571, (202) 565-3232.

Jonathan Cordone,

Senior Vice President and General Counsel.

[FR Doc. 2011-10920 Filed 5-5-11; 8:45 am]

BILLING CODE 6690-01-M

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Being Submitted for Review and Approval to the Office of Management and Budget (OMB)

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burden and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520), the Federal Communications Commission invites the general public and other Federal agencies to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility;

(b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information collection burden for small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before July 5, 2011. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202-395-5167 or the Internet at *Nicholas_A_Fraser@omb.eop.gov*; and to the Federal Communications Commission's PRA mailbox (*e-mail address: PRA@fcc.gov*). Include in the e-mail the OMB control number of the collection as shown in the **SUPPLEMENTARY INFORMATION** section below, or if there is no OMB control number, the Title as shown in the **SUPPLEMENTARY INFORMATION** section. If you are unable to submit your comments by e-mail, contact the person listed below to make alternate arrangements.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Judith B. Herman at 202-418-0214 or via the Internet at *Judith-B.Herman@fcc.gov*.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-0411.

Title: Procedures for Formal Complaints Filed Against Common Carriers.

Form No.: FCC Form 485.

Type of Review: Revision of a currently approved collection.

Respondents: Individuals or household, business or other for-profit, not-for-profit institutions and state, local or tribal government.

Number of Respondents: 20 respondents.

Number of Responses: 301 responses.

Estimated Time per Response: 4.5 hours.

Frequency of Response:

Recordkeeping, on occasion reporting, and third party disclosure requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 154(i), 154(j), 206, 207, 208, 209, 301, 303, 304, 309, 316, 332, and 1302.

Total Annual Burden: 1,349 hours.

Total Annual Cost: \$1,847,600.

Privacy Act Impact Assessment: As noted on Form OMB 83-I, the information collection requirements may affect individuals or households. As required by the Privacy Act of 1974, as amended, 5 U.S.C. 552a, and OMB regulations, M-03-22 (September 22, 2003), the FCC has completed both a system of records, FCC/EB-3, "Investigations and Hearings," and a Privacy Impact Assessment (PIA), to cover the collection, maintenance, use, and disposal of all personally identifiable information PII that may be submitted as part of a formal complaint filed against a common carrier:

(a) The system of records notice (SORN) was last published in the **Federal Register** on April 6, 2006 (65 FR 17234, 17238), and is posted on the FCC's Privacy Act webpage at: <http://www.fcc.gov/omd/privacyact/records-systems.html>.

(b) The Privacy Impact Assessment was completed on May 22, 2009, and is posted on the FCC's Privacy Act webpage at: http://www.fcc.gov/omd/privacyact/System_of_records/pia-investigations-hearings.pdf.

Nature and Extent of Confidentiality: 47 CFR 1.731 provides for confidential treatment of materials disclosed or exchanged during the course of formal complaint proceedings when those materials have been identified by the disclosing party as proprietary or confidential. In the rare case in which a producing party believes that section 1.731 will not provide adequate protection for its asserted confidential material, it may request either that the opposing party consent to greater protection, or that the staff supervising the proceeding order greater protection.

Needs and Uses: Sections 206-209 of the Communications Act of 1934, as amended (the "Act"), provide the statutory framework for the Commission's rules for resolving formal complaints against common carriers. Section 208(a) authorizes complaints by any person "complaining of anything done or omitted to be done by any common carrier" subject to the provisions of the Act. Section 208(a) states that if a carrier does not satisfy a

complaint or there appears to be any reasonable ground for investigating the complaint, the Commission shall “investigate the matters complained of in such manner and by such means as it shall deem proper.” Certain categories of complaints are subject to a statutory deadline for resolution. *See, e.g.*, 47 U.S.C. 208(b)(1) (imposing a five-month deadline for complaints challenging the “lawfulness of a charge, classification, regulation, or practice”).

Formal complaint proceedings before the Commission are similar to civil litigation in federal district court. In fact, under section 207 of the Act, a party claiming to be damaged by a common carrier, may file its complaint with the Commission or in any district court of the United States, “but such person shall not have the right to pursue both such remedies” (47 U.S.C. 207). The Commission has promulgated rules (the “Formal Complaint Rules”) to govern its formal complaint proceedings that are similar in many respects to the Federal Rules of Civil Procedure. *See* 47 CFR 1.720–1.736. These rules require the submission of information from the parties necessary to create a record on which the Commission can decide complex legal and factual issues. As described in section 1.720 of the Commission’s rules, formal complaint proceedings are resolved on a written record consisting of a complaint, answer or response, and joint statement of stipulated facts, disputed facts and key legal issues, along with all associated affidavits, exhibits and other attachments.

This collection of information includes the process for submitting a formal complaint. The Commission uses this information to determine the sufficiency of complaints and to resolve the merits of disputes between the parties. Orders issued by the Commission in formal complaint proceedings are based upon evidence and argument produced by the parties in accordance with the Formal Complaint Rules. If the information were not collected, the Commission would not be able to resolve common carrier-related complaint proceedings, as required by section 208 of the Act.

The Commission is requesting a revision of this collection to ensure consistent Commission processes for resolving all voice and data roaming disputes where a complaint is the appropriate procedural vehicle. To do so, the Commission is adopting, for data roaming complaints, most of the procedural complaint processes currently available for resolving voice roaming disputes. Specifically, the Commission is extending, as applicable,

the procedural rules in the Commission’s Part I, Subpart E rules, 47 CFR 1.716–1.718, 1.720, 1.721, and 1.723–1.735, to disputes arising out of the data roaming rules.

The Commission finds that it is in the public interest to ensure a consistent Commission process for resolving both voice and data roaming complaints. Moreover, some roaming disputes will involve both data and voice and are likely to have factual issues common to both types of roaming. This approach allows a party to bring a single proceeding to address such a dispute, rather than having to bifurcate the matter and initiate two separate proceedings under two different sets of procedures. This, in turn, will be more efficient for the parties involved, as well as for the Commission, and should result in faster resolution of such disputes.

Federal Communications Commission.

Bulah P. Wheeler,

Deputy Manager.

[FR Doc. 2011–10222 Filed 5–5–11; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501–3520. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission’s burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information

collection burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a currently valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before July 5, 2011. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202–395–5167 or via e-mail to Nicholas_A.Fraser@omb.eop.gov and to the Federal Communications Commission via e-mail to PRA@fcc.gov and Cathy.Williams@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Cathy Williams on (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0288.

Title: Special Temporary Authority (Cable Television Relay Stations), 47 CFR 78.33.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business and other for-profit entities.

Number of Respondents and Responses: 35 respondents and 35 responses.

Estimated Time per Response: 4 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained Section 154(i) of the Communications Act of 1934, as amended.

Total Annual Burden: 140 hours.

Total Annual Costs: \$5,250.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Impact Assessment(s): No impacts.

Needs and Uses: 47 CFR 78.33 permits cable television relay station (CARS) operators to file informal requests for special temporary authority (STA) to install and operate equipment in a manner different than the way normally authorized in the station

license. The special temporary authority also may be used by cable operators to conduct field surveys to determine necessary data in connection with a formal application for installation of a radio system, or to conduct equipment, program, service, and path tests.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2011-11021 Filed 5-5-11; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501-3520. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology, and (e) ways to further reduce the information collection burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control

number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a currently valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before July 5, 2011. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202-395-5167 or via e-mail to Nicholas_A_Fraser@omb.eop.gov and to the Federal Communications Commission via e-mail to PRA@fcc.gov and Cathy.Williams@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Cathy Williams on (202) 418-2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-0288.

Title: Special Temporary Authority (Cable Television Relay Stations), 47 CFR 78.33.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business and other for-profit entities.

Number of Respondents and

Responses: 35 respondents and 35 responses.

Estimated Time per Response: 4 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained Section 154(i) of the Communications Act of 1934, as amended.

Total Annual Burden: 140 hours.

Total Annual Costs: \$5,250.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Impact Assessment(s): No impacts.

Needs and Uses: 47 CFR 78.33 permits cable television relay station (CARS) operators to file informal

requests for special temporary authority (STA) to install and operate equipment in a manner different than the way normally authorized in the station license. The special temporary authority also may be used by cable operators to conduct field surveys to determine necessary data in connection with a formal application for installation of a radio system, or to conduct equipment, program, service, and path tests.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2011-11020 Filed 5-5-11; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL DEPOSIT INSURANCE CORPORATION

Update to Notice of Financial Institutions for Which the Federal Deposit Insurance Corporation Has Been Appointed Either Receiver, Liquidator, or Manager

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Update listing of financial institutions in liquidation.

SUMMARY: Notice is hereby given that the Federal Deposit Insurance Corporation (Corporation) has been appointed the sole receiver for the following financial institutions effective as of the Date Closed as indicated in the listing. This list (as updated from time to time in the **Federal Register**) may be relied upon as "of record" notice that the Corporation has been appointed receiver for purposes of the statement of policy published in the July 2, 1992 issue of the **Federal Register** (57 FR 29491). For further information concerning the identification of any institutions which have been placed in liquidation, please visit the Corporation Web site at <http://www.fdic.gov/bank/individual/failed/banklist.html> or contact the Manager of Receivership Oversight in the appropriate service center.

Dated: May 2, 2011.

Federal Deposit Insurance Corporation.

Pamela Johnson,

Regulatory Editing Specialist.

INSTITUTIONS IN LIQUIDATION V

[In alphabetical order]

| FDIC Ref. No. | Bank name | City | State | Date closed |
|---------------|--|---------------------|----------|-------------|
| 10359 | Community Central Bank | Mount Clemens | MI | 04/29/2011 |
| 10360 | Cortez Community Bank | Brooksville | FL | 04/29/2011 |
| 10361 | First Choice Community Bank | Dallas | GA | 04/29/2011 |
| 10362 | First National Bank of Central Florida | Winter Park | FL | 04/29/2011 |

INSTITUTIONS IN LIQUIDATION V—Continued

[In alphabetical order]

| FDIC Ref. No. | Bank name | City | State | Date closed |
|---------------|----------------------------|----------------|----------|-------------|
| 10363 | The Park Avenue Bank | Valdosta | GA | 04/29/2011 |

[FR Doc. 2011-11052 Filed 5-5-11; 8:45 am]

BILLING CODE 6714-01-P

FEDERAL LABOR RELATIONS AUTHORITY**Public Availability of Federal Labor Relations Authority FY 2010 Service Contract Inventory**

AGENCY: Federal Labor Relations Authority.

ACTION: Notice of Public Availability of FY 2010 Service Contract Inventories.

SUMMARY: In accordance with Section 743 of Division C of the Consolidated Appropriations Act of 2010 (Pub. L. 111-117), the Federal Labor Relations Authority (FLRA) is publishing this notice to advise the public of the availability of the FY 2010 Service Contract inventory. This inventory provides information on service contract actions over \$25,000 that were made in FY 2010. The information is organized by function to show how contracted resources are distributed throughout the agency. The inventory has been developed in accordance with guidance issued on November 5, 2010 by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). OFPP's guidance is available at <http://www.whitehouse.gov/sites/default/files/omb/procurement/memo/service-contract-inventories-guidance-11052010.pdf>. The FLRA has posted its inventory and a summary of the inventory on the FLRA homepage at the following link: http://www.flra.gov/webfm_send/487.

FOR FURTHER INFORMATION CONTACT:

Questions regarding the service contract inventory should be directed to Dennis Dorsey, Director, Administrative Services Division, Federal Labor Relations Authority, at (202) 218-7764.

Dated: May 3, 2011.

Sonna Stampone,

Executive Director, Federal Labor Relations Authority.

[FR Doc. 2011-11139 Filed 5-5-11; 8:45 am]

BILLING CODE 6727-01-P

FEDERAL MARITIME COMMISSION**Sunshine Act Meeting**

AGENCY HOLDING THE MEETING: Federal Maritime Commission.

TIME AND DATE: May 11, 2011—10 a.m.

PLACE: 800 North Capitol Street, NW., First Floor Hearing Room, Washington, DC.

STATUS: A portion of the meeting will be in Open Session; the remainder of the meeting will be held in Closed Session.

MATTERS TO BE CONSIDERED:**Open Session**

1. Staff Update on Implementation of the NVOCC Tariff Publication Exemption.

2. Staff Update on Trade Conditions.

3. *Fact Finding No. 27:* Potentially Unlawful, Unfair or Deceptive Ocean Transportation Practices Related to the Movement of Household Goods or Personal Property in U.S.-Foreign Oceanborne Trades—Discussion of Fact Finding Officer's Final Report and Recommendations.

Closed Session

1. Staff Briefing and Discussion on Trends in Filed Service Contracts: Indexes, Service Terms, and Dispute Resolution.

2. Staff Briefing and Discussion on the Ministry of Transport of the People's Republic of China Request for Adjustment of NVOCC Bond Rider for China Trades.

CONTACT PERSON FOR MORE INFORMATION: Karen V. Gregory, Secretary, (202) 523-5725.

Karen V. Gregory,

Secretary.

[FR Doc. 2011-11219 Filed 5-4-11; 4:15 pm]

BILLING CODE 6730-01-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 May 23, 2011.

A. Federal Reserve Bank of Atlanta (Clifford Stanford, Vice President) 1000 Peachtree Street, NE., Atlanta, Georgia 30309:

1. Ranjeet Singh Sidhu, Kuala Lumpur, Malaysia; to acquire control of Hometown Community Bancshares, and thereby indirectly acquire control of Hometown Community Bank, both in Braselton, Georgia.

B. Federal Reserve Bank of San Francisco (Kenneth Binning, Vice President, Applications and Enforcement) 101 Market Street, San Francisco, California 94105-1579:

1. Larry Dale Williams, Boise, Idaho; to acquire control of Syringa Bancorp, and thereby indirectly acquire control of Syringa Bank, both in Boise, Idaho.

Board of Governors of the Federal Reserve System, May 3, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011-11080 Filed 5-5-11; 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 application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 2, 2011.

A. Federal Reserve Bank of Boston (Richard Walker, Community Affairs Officer) P.O. Box 55882, Boston, Massachusetts 02106-2204:

1. *Lowell Five Bancorp, MHC and Lowell Five Bancorp, Inc.*, both in Lowell, Massachusetts, to become a mutual bank holding company and a stock bank holding company, respectively, by acquiring all the voting shares of The Lowell Five Cents Savings Bank, Lowell, Massachusetts.

Board of Governors of the Federal Reserve System, May 3, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011-11081 Filed 5-5-11; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension

AGENCY: Federal Trade Commission ("Commission" or "FTC").

ACTION: Notice.

SUMMARY: The information collection requirements described below will be submitted to the Office of Management and Budget ("OMB") for review, as required by the Paperwork Reduction Act ("PRA"). The FTC is seeking public comments on its proposal to extend through September 30, 2014 the current Paperwork Reduction Act clearance for information collection requirements contained in its Funeral Industry Practice Rule ("Funeral Rule" or "Rule"). That clearance expires on September 30, 2011.

DATES: Comments must be submitted on or before July 5, 2011.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "Paperwork Comment: FTC File No. P084401" on your comment, and file your comment online at <https://ftcpublish.commentworks.com/ftc/funeralrulepra> by following the instructions on the Web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex J), 600 Pennsylvania Avenue, NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the proposed information requirements for the Funeral Rule should be addressed to Craig Tregillus, Attorney, Division of Marketing Practices, Bureau of Consumer Protection, Federal Trade Commission, Room H-288, 600 Pennsylvania Ave., NW., Washington, DC 20580, (202) 326-2970.

SUPPLEMENTARY INFORMATION: Under the PRA, 44 U.S.C. 3501-3521, federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. "Collection of information" means agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3), 5 CFR 1320.3(c). As required by section 3506(c)(2)(A) of the PRA, the FTC is providing this opportunity for public comment before requesting that OMB extend the existing paperwork clearance for the Funeral Rule, 16 CFR Part 453 (OMB Control Number 3084-0025).

The Funeral Rule ensures that consumers who are purchasing funeral goods and services have access to accurate itemized price information so they can purchase only the funeral goods and services they want or need. In particular, the Rule requires a funeral provider to: (1) Give consumers a copy they can keep of the funeral provider's General Price List ("GPL") that itemizes the goods and services they offer; (2) show consumers their Casket Price List ("CPL") and their Outer Burial Container Price List ("OBCPL") at the outset of any discussion of those items or their prices, and in any event before showing consumers caskets or burial containers; (3) provide price information from their price lists over the telephone; and (4) give consumers a Statement of Funeral Goods and Services Selected ("SFGSS") after determining the funeral

arrangements with the consumer (the "arrangements conference"). The Rule requires that funeral providers disclose this information to consumers and maintain records to facilitate enforcement of the Rule.

The estimated burden associated with the collection of information required by the Rule is 19,902 hours for recordkeeping, 101,076 hours for disclosures, and 39,804 hours for training, for a total of 160,782 hours. This estimate is based on the number of funeral providers (approximately 19,902),¹ the number of funerals per year (approximately 2.4 million),² and the time needed to fulfill the information collection tasks required by the Rule.

Recordkeeping: The Rule requires that funeral providers retain copies of price lists and statements of funeral goods and services selected by consumers. Based on a maximum average burden of one hour per provider per year for this task, the total burden for the 19,902 providers is 19,902 hours. This estimate is lower than FTC staff's 2008 estimate of 20,300 hours due to a decrease in the number of funeral providers.

Disclosure: As noted above, the Rule requires that funeral providers: (1) Maintain current price lists for funeral goods and services, (2) provide written documentation of the funeral goods and services selected by consumers making funeral arrangements, and (3) provide information about funeral prices in response to telephone inquiries.

1. Maintaining current price lists requires that funeral providers revise their price lists from time to time throughout the year to reflect price changes. Staff estimates, consistent with its current clearance, that this task requires a maximum average burden of two and one-half hours per provider per year. Thus, the total burden for 19,902 providers is 49,755 hours.

2. Staff retains its prior estimate that 13% of funeral providers prepare written documentation of funeral goods

¹ The estimated number of funeral providers is from 2010 data provided on the National Funeral Directors Association ("NFDA") Web site (see <http://www.nfda.org/about-funeral-service/trends-and-statistics.html>).

² The estimated number of funerals conducted annually is derived from the National Center for Health Statistics ("NCHS"), <http://www.cdc.gov/nchs/>. According to NCHS, 2,436,682 deaths occurred in the United States in 2009, the most recent year for which final data is available. See National Vital Statistics Reports, vol. 59, no. 4 "Preliminary Data for 2009," available at http://www.cdc.gov/nchs/data/nvsr/nvsr59/nvsr59_04.pdf. Staff believes this is a conservative estimate because not all remains go to a funeral provider covered by the Rule (e.g., remains sent directly to a crematory that does not sell urns; remains donated to a medical school, etc.).

and services selected by consumers solely because the Rule mandates this disclosure. The original rulemaking record indicated that 87% of funeral providers provided written documentation of funeral arrangements, even absent the Rule's requirements.³

According to the rulemaking record, the 13% of funeral providers who did not provide written documentation prior to enactment of the Rule are typically the smallest funeral homes. The written documentation requirement can be satisfied through the use of a standard form, an example of which the FTC has provided to all funeral providers in its compliance guide.⁴ Based on an estimate that these smaller funeral homes arrange, on average, approximately twenty funerals per year and that it would take each of them about three minutes to record prices for each consumer on the standard form, FTC staff estimates that the total burden associated with the written documentation requirement is one hour per provider, for a total of 2,587 hours [(19,902 funeral providers × 13%) × (20 statements per year × 3 minutes per statement)].

3. The Funeral Rule also requires funeral providers to answer telephone inquiries about the provider's offerings or prices. Information received in 2002 from the NFDA indicates that only about 12% of funeral purchasers make telephone inquiries, with each call lasting an estimated ten minutes.⁵ Thus, assuming that the average purchaser who makes telephone inquiries places one call per funeral to determine prices,⁶ the estimated burden is 48,734 hours (2,436,682 funerals per year × 12% × 10 minutes per inquiry). This burden likely will decline over time as consumers increasingly rely on the Internet for funeral price information.

³ In a 2002 public comment, the NFDA asserted that nearly every funeral home had been providing consumers with some kind of final statement in writing even before the Rule took effect. Nonetheless, in an abundance of caution, staff continues to retain its prior estimate based on the original rulemaking record.

⁴ The compliance guide is available at <http://business.ftc.gov/documents/bus05-complying-funeral-rule>.

⁵ No more recent information thus far has been available. The Commission invites submission of more recent data or studies on this subject.

⁶ Although consumers who pre-plan their own arrangements may comparison shop and call more than one funeral home for pricing and other information, consumers making "at need" arrangements after a death are less likely to take the time to seek pricing information from more than one home. Many fail to seek any pricing information by telephone. Staff therefore believes that an average of one call per funeral is a conservative assumption.

In sum, the burden due to the Rule's disclosure requirements totals 101,076 hours (49,755 + 2,587 + 48,734).

Training: In addition to the recordkeeping and disclosure-related tasks noted above, funeral homes may also have training requirements specifically attributable to the Rule. Staff believes that annual training burdens associated with the Rule should be minimal because Rule compliance is generally included in continuing education requirements for state licensing and voluntary certification programs. Staff estimates that, industry-wide, funeral homes would incur no more than 39,804 hours related to training specific to the Rule each year. This estimate is consistent with staff's assumption for the current clearance that an "average" funeral home consists of approximately five employees (full-time and part-time employment combined), but with no more than four of them having tasks specifically associated with the Funeral Rule. Staff retains its estimate that each of the four employees (three directors and a clerical receptionist) per firm would each require one-half hour, at most, per year, for such training.⁷ Thus, total estimated time for training is 39,804 hours (4 employees per firm × ½ hour × 19,902 providers).

Labor costs: Labor costs are derived by applying appropriate hourly cost figures to the burden hours described above. The hourly rates used below are averages.

Clerical personnel, at an estimated hourly rate of \$15,⁸ can perform the recordkeeping tasks required under the Rule. Based on the estimated hours burden of 19,902 hours, estimated labor cost for recordkeeping is \$298,530.

⁷ Funeral homes, depending on size and/or other factors, may be run by as few as one owner, manager, or other funeral director to multiple directors at various compensation levels. Extrapolating from past NFDA survey input, staff has theorized an "average" funeral home of approximately five employees, with management personnel and a clerical receptionist being those who would require training for Funeral Rule compliance. Staff conservatively assumes that the "average" home would consist of an owner/manager, funeral director/embalmer, and, as further sub-classified by the NFDA, a "funeral director only." In addition to that, staff assumes the home would also have one clerical receptionist. Compliance training for other employees (e.g., drivers, maintenance personnel) would be inapplicable.

⁸ Based on the "National Compensation Survey: Occupational Wages in the United States, 2009," U.S. Department of Labor, Bureau of Labor Statistics (June 2010) ("BLS National Compensation Survey"), available at <http://www.bls.gov/ncs/ocs/sp/nctb1346.pdf> <http://www.bls.gov/ncs/ocs/sp/nctb10910.pdf>. Clerical estimates are derived from the above source data, rounded upward, for "receptionist and information clerks."

The two and one-half hours required of each provider, on average, to update price lists should consist of approximately one and one-half hours of managerial or professional time, at an estimated \$35 per hour,⁹ and one hour of clerical time, at \$15 per hour, for a total of \$67.50 per provider [((\$35 per hour × 1.5 hours) + (\$15 per hour × 1 hour)]. Thus, the estimated total labor cost burden for maintaining price lists is \$1,343,385 (\$67.50 per provider × 19,902 providers).

The incremental cost to the 13% of small funeral providers who would not otherwise supply written documentation of the goods and services selected by the consumer, as previously noted, is 2,587 hours. Assuming managerial or professional time for these tasks at approximately \$35 per hour, the associated labor cost would be \$90,545 (2,587 hours × \$35 per hour).

As previously noted, staff estimates that 48,734 hours of managerial or professional time is required annually to respond to telephone inquiries about prices.¹⁰ The cost of 48,734 hours of managerial or professional time for responding to telephone inquiries about prices at \$35 per hour, is \$1,705,690 (48,734 hours × \$35 per hour).

Based on past consultations with funeral directors, FTC staff estimates that funeral homes will require no more than two hours of training of licensed and non-licensed funeral home staff to comply with the Funeral Rule,¹¹ with four employees of varying types each spending one-half hour on training. Consistent with past assumptions stated above,¹² paired with updated estimates, the Commission is assuming that three funeral directors, at hourly wages of \$35, \$23, and \$20,¹³ respectively, as

⁹ The hourly rate is derived from the median annual salary of a funeral home owner/manager, found in the 2010 NFDA Member Compensation Survey. See <http://www.nfda.org/news-a-events/all-press-releases/2289-nfda-releases-results-of-2010-member-compensation-survey.html>. Dividing the median annual salary an assumed 2,000 hour work year yields the hourly rate, albeit broadly rounded upward to \$35.

¹⁰ Although some funeral providers may permit staff who are not funeral directors to provide price information by telephone, the great majority reserve that task to a licensed funeral director.

¹¹ Rule compliance is generally included in continuing education requirements for licensing and voluntary certification programs. Moreover, as noted above, the FTC provides its compliance guide to all funeral providers at no cost, and it is available on the FTC Web site. See *supra* note 4. Additionally, the NFDA provides online guidance for compliance with the Rule: <http://www.nfda.org/onlinelearning-ftc.html>.

¹² See note 7 and accompanying text.

¹³ The hourly rates are derived from median annual salaries of a funeral home owner/manager, funeral director/embalmer, and "funeral director

well as one clerical or administrative staff member, at \$15 per hour, require such training, for a total burden of 39,804 hours (19,902 funeral homes \times 2 hours total per establishment), and \$925,443 $[(\$35 + \$23 + \$20 + \$15) \times \frac{1}{2} \text{ hour per employee} \times 19,902 \text{ funeral homes}]$.

The total labor cost of the three disclosure requirements imposed by the Funeral Rule is \$3,139,620 (\$1,343,385 + \$90,545 + \$1,705,690). The total labor cost for recordkeeping is \$298,530. The total labor cost for disclosures, recordkeeping, and training is \$4,363,593 (\$3,139,620 for disclosures + \$298,530 for recordkeeping + \$925,443 for training).

Capital or other non-labor costs: The Rule imposes minimal capital costs and no current start-up costs. The Rule first took effect in 1984 and the revised Rule took effect in 1994, so funeral providers should already have in place necessary equipment to carry out tasks associated with Rule compliance. Moreover, most funeral homes already have access, for other business purposes, to the ordinary office equipment needed for compliance, so the Rule likely imposes minimal additional capital expense.

Compliance with the Rule, however, does entail some expense to funeral providers for printing and duplication of required disclosures. Assuming that one copy of the GPL is provided to consumers for each funeral or cremation conducted, at \$.25 per copy, as required by the Rule,¹⁴ this would amount to 2,436,682 copies per year at a cumulative industry cost of \$624,171 (2,436,682 funerals per year¹⁵ \times \$.25 per price list). In addition, the funeral providers that furnish consumers with an SFGSS solely because of the Rule's mandate will incur additional printing and copying costs. Assuming that those 2,587 providers (19,902 funeral providers \times 13%) use the standard two-page form SFGSS shown in the compliance guide, at twenty-five cents per copy, at an average of twenty funerals per year, the added cost burden would be \$12,935 (2,587 providers \times 20 funerals per year \times \$.25). Thus,

only" found in the 2010 NFDA Member Compensation Survey. See <http://www.nfda.org/news-a-events/all-press-releases/2289-nfda-releases-results-of-2010-member-compensation-survey.html>. Hourly rates were then determined by dividing those salaries by an assumed 2,000 hour work year, then rounded.

¹⁴ Although copies of the CPL and OBCPL must be shown to consumers, the Rule does not require that they be given to consumers. Thus, the cost of printing a single copy of these two disclosures to show consumers is de minimis, and is not included in this estimate of printing costs.

¹⁵ See note 2 and accompanying text.

estimated non-labor costs total \$637,106.

Request for Comment

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before July 5, 2011. Write "Paperwork Comment: FTC File No. P084401" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at <http://www.ftc.gov/os/publiccomments.shtml>. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment doesn't include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment doesn't include any sensitive health information, like medical records or other individually identifiable health information. In addition, don't include any "[t]rade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential * * *," as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c). Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online, or to send them to the Commission by courier or overnight service. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/funeralrulepra>, by following the instructions on the web-based form. If this Notice appears at <http://www.regulations.gov/#/home>, you also

may file a comment through that Web site.

If you file your comment on paper, write "Paperwork Comment: FTC File No. P084401" on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex J), 600 Pennsylvania Avenue, NW., Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at <http://www.ftc.gov> to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before July 5, 2011. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

The FTC invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including 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.

Willard K. Tom,
General Counsel.

[FR Doc. 2011-11053 Filed 5-5-11; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a decision to designate a class of employees from the Linde Ceramics Plant in Tonawanda, New York, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On April 21, 2011, the Secretary of HHS designated the following class of employees as an addition to the SEC:

All Atomic Weapons Employees who worked at the Linde Ceramics Plant in Tonawanda, New York, from January 1, 1954 through December 31, 1969, for a number of work days aggregating at least 250 work days, occurring either solely under this employment, or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.

This designation will become effective on May 21, 2011, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C-46, Cincinnati, OH 45226, Telephone 877-222-7570. Information requests can also be submitted by e-mail to DCAS@CDC.GOV.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2011-11094 Filed 5-5-11; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Blood Safety and Availability

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the Advisory Committee on Blood Safety and Availability (ACBSA) will hold a meeting. The meeting will be open to the public.

DATES: The meeting will take place Tuesday, June 7, and Wednesday June 8, 2011, from 8:30 a.m. to 5 p.m.

ADDRESSES: National Institute of Health, Building 31, Conference Room 6, Bethesda, MD 20892.

FOR FURTHER INFORMATION CONTACT: Mr. James Berger, Associate Public Health Advisor for Blood, Organ and Tissue Safety, Office of the Assistant Secretary for Health, Department of Health and Human Services, 1101 Wootton Parkway, Suite 250, Rockville, MD 20852, (240) 453-8803, Fax (240) 453-8456, e-mail ACBSA@hhs.gov.

SUPPLEMENTARY INFORMATION: The ACBSA shall provide advice to the Secretary through the Assistant Secretary for Health. The Committee shall advise on a range of policy issues to include: (1) Definition of public health parameters around safety and availability of the blood supply and blood products, (2) broad public health, ethical and legal issues related to transfusion, and transplantation safety, and (3) the implications for safety and availability of various economic factors affecting product cost and supply.

In keeping with its established mission, the Committee will also be asked to review and provide comments to the Department on two World Health Assembly (WHA) resolutions related to transfusion, and transplantation safety. http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R22-en.pdf On June 7, 2011, the Committee will be asked to review the WHA 63.22 on human organ and tissue transplantation and if appropriate, make recommendations on areas of enhanced safety. Specifically areas of collecting data including adverse events and reactions on the practices, safety, quality, efficacy, epidemiology and ethics of donations and transplantation will be considered as it relates to safety. Concerns for a globally consistent coding system for human cells, tissues and organs to facilitate national and international traceability of materials of human origin for transplantation will be solicited. In addition, the Committee will be asked for comments or recommendations on developing and promoting international best practices.

On June 8, 2011, the Committee will be asked to review and comment on WHA 63.12 regarding the availability, safety and quality of blood products. http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R12-en.pdf Specifically the Committee will be asked to review the current status of safe and rational use of blood products in patient blood management and assess the current status in the U.S.

In addition, the Committee will be asked to comment on the areas of safety and sustainability of providing blood and blood products that should be addressed by the Committee in future meetings.

The public will have the opportunity to present their views to the Committee during a public comment session scheduled for June 7, 2011. Comments will be limited to five minutes per speaker and must be pertinent to the discussion. Pre-registration is required for participation in the public comment session. Any member of the public who would like to participate in this session is encouraged to contact the Executive Secretary at his/her earliest convenience to register for time (limited to 5 minutes) and registration must be prior to close of business on June 3, 2011. If it is not possible to provide 30 copies of the material to be distributed, then individuals are requested to provide a minimum of one (1) copy of the document(s) to be distributed prior to 11:30 a.m. Eastern Daylight Time on June 6, 2011. It is also requested that any member of the public who wishes to provide comments to the Committee utilizing electronic data projection to submit the necessary material to the Executive Secretary prior to the close of business on June 6, 2011. Electronic comments must adhere to disability accessibility guidelines (Section 508 compliance).

Dated: May 3, 2011.

James J. Berger,

Associate Public Health Advisor for Blood, Organ and Tissue Safety.

[FR Doc. 2011-11128 Filed 5-5-11; 8:45 am]

BILLING CODE 4150-41-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office of the Surgeon General of the United States Public Health Service.

ACTION: Notice.

SUMMARY: In accordance with Section 10(a) of the Federal Advisory Committee Act, Public Law 92-463, as amended (5 U.S.C. App.), notice is hereby given that a web meeting is scheduled to be held for the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health (the "Advisory Group"). The web meeting will be open to the public. Information about the Advisory

Group can be obtained by accessing the following Web site: <http://www.healthcare.gov/center/councils/nphpphc/index.html>.

DATES: May 24, 2011, 12 p.m.–2:30 p.m.

ADDRESSES: The meeting will be held online via WebEx software. For detailed instructions about how to make sure that your windows computer and browser is set up for WebEx and to register for the meeting, please send an e-mail to prevention.council@hhs.gov.

FOR FURTHER INFORMATION CONTACT:

Office of the Surgeon General, 200 Independence Ave., SW.; Hubert H. Humphrey Building, Room 701H; Washington, DC 20001; 202–205–9517; prevention.council@hhs.gov.

SUPPLEMENTARY INFORMATION: On June 10, 2010, the President issued Executive Order 13544 to comply with the statutes under Section 4001 of the Patient Protection and Affordable Care Act, Public Law 111–148. This legislation mandated that the Advisory Group was to be established within the Department of Health and Human Services. The charter for the Advisory Group was established by the Secretary of Health and Human Services on June 23, 2010; the charter was filed with the appropriate Congressional committees and Library of Congress on June 24, 2010. The Advisory Group has been established as a non-discretionary Federal advisory committee.

The Advisory Group has been established to provide recommendations and advice to the National Prevention, Health Promotion and Public Health Council (the “Council”). The Advisory Group shall provide assistance to the Council in carrying out its mission.

The Advisory Group membership shall consist of not more than 25 non-Federal members to be appointed by the President. The membership shall include a diverse group of licensed health professionals, including integrative health practitioners who have expertise in (1) worksite health promotion; (2) community services, including community health centers; (3) preventive medicine; (4) health coaching; (5) public health education; (6) geriatrics; and (7) rehabilitation medicine. On January 26, 2011, the President appointed 13 individuals to serve as members of the Advisory Group, and on April 8th, 2011 he named two new members. This will be the second meeting of the Advisory Group. The Web format will allow the Advisory Group to meet prior to the release of the National Prevention and Health Promotion Strategy.

Public participation during the Web meeting is limited. Members of the

public who wish to attend the Web meeting must register by 12 p.m. EST May 19, 2011. Individuals should notify the designated contact to register for public attendance at prevention.council@hhs.gov. The public will have opportunity to provide electronic written comments to the Advisory Group on May 24, 2011 during the Web meeting. Any member of the public who wishes to have printed material distributed to the Advisory Group for this scheduled Web meeting should submit material to the designated point of contact for the Advisory Group no later than May 17, 2011, 5 p.m. EST.

Dated: April 28, 2011.

Corinne M. Graffunder,

Designated Federal Officer, Advisory Group on Prevention, Health Promotion, and Integrative and Public Health, Office of the Surgeon General

[FR Doc. 2011–11130 Filed 5–5–11; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Decision To Evaluate a Petition To Designate a Class of Employees From the Y–12 Plant in Oak Ridge, TN, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice as required by 42 CFR 83.12(e) of a decision to evaluate a petition to designate a class of employees from the Y–12 Plant in Oak Ridge, TN, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000. The initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: Y–12 Plant.

Location: Oak Ridge, TN.

Job Titles and/or Job Duties: All workers potentially exposed to radioactive materials.

Period of Employment: January 1, 1948 through December 31, 1957.

FOR FURTHER INFORMATION CONTACT:

Stuart L. Hinnfeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 877–222–7570. Information requests can also

be submitted by e-mail to DCAS@CDC.GOV.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2011–11096 Filed 5–5–11; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health (ABRWH or Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), and pursuant to the requirements of 42 CFR 83.15(a), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Board Public Meeting Times and Dates (All times are Central Time):

8:15 a.m.–3:45 p.m., May 24, 2011.

8:15 a.m.–5 p.m., May 25, 2011.

8:15 a.m.–10:30 a.m., May 26, 2011.

Public Comment Times and Dates (All times are Central Time):

6 p.m.–7 p.m. *, May 24, 2011.

5:30 p.m.–7 p.m. *, May 25, 2011.

Please note that the public comment periods may end prior to the times indicated, following the last call for comments.

Members of the public who wish to provide public comments should plan to attend public comment sessions at the start times listed.

Place: Crowne Plaza St. Louis-Downtown, 200 North 4th Street, St. Louis, Missouri 63102; *Telephone:* 314–621–8200; *Fax:* 314–621–8073. The USA toll-free dial-in number is 1–866–659–0537, pass code 9933701.

Status: Open to the public, limited only by the space available. The meeting space accommodates approximately 150 people.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program (EEOICP) Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines which have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add

classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2011.

Purpose: This Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy (DOE) facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters To Be Discussed: The agenda for the Advisory Board meeting includes: NIOSH Program Update; Department of Labor (DOL) Program Update; DOE Program Update; NIOSH Program Evaluation; HHS Proposed Rule to Amend Probability of Causation Guidelines Regarding Chronic Lymphocytic Leukemia (42 CFR pt. 81); Savannah River Site Work Group Update; Feed Materials Production Center Work Group Update; Weldon Spring Work Group Update; *SEC petitions for:* Piqua Organic Moderated Reactor (1963–1966), Sandia National Laboratory (1957–1962), Hanford (Plutonium Finishing Plant, 1987–1989), General Electric (Evendale, Ohio); SEC Petition Status Updates; Subcommittee and Work Group Reports; Board Work Sessions, and an Administrative Session.

The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted in accordance with the redaction policy provided below. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

Policy on Redaction of Board Meeting Transcripts (Public Comment): (1) If a person making a comment gives his or her name, no attempt will be made to redact that name. (2)

NIOSH will take reasonable steps to ensure that individuals making public comment are aware of the fact that their comments (including their name, if provided) will appear in a transcript of the meeting posted on a public Web site. *Such reasonable steps include:* (a) A statement read at the start of each public comment period stating that transcripts will be posted and names of speakers will not be redacted; (b) A printed copy of the statement mentioned in (a) above will be displayed on the table where individuals sign up to make public comments; (c) A statement such as outlined in (a) above will also appear with the agenda for a Board Meeting when it is posted on the NIOSH Web site; (d) A statement such as in (a) above will appear in the **Federal Register** Notice that announces Board and Subcommittee meetings. (3) If an individual in making a statement reveals personal information (e.g., medical information) about themselves that information will not usually be redacted. The NIOSH Freedom of Information Act (FOIA) coordinator will, however, review such revelations in accordance with the FOIA and the Federal Advisory Committee Act (FACA) and if deemed appropriate, will redact such information. (4) All disclosures of information concerning third parties will be redacted. (5) If it comes to the attention of the Designated Federal Officer that an individual wishes to share information with the Board but objects to doing so in a public forum, the DFO will work with that individual, in accordance with the FACA, to find a way that the Board can hear such comments.

Contact Person for More Information: Theodore Katz, M.P.A., Executive Secretary, NIOSH, CDC, 1600 Clifton Road, Mailstop E-20, Atlanta Georgia 30333, *telephone:* (513) 533-6800, *toll free:* 1 (800)CDC-INFO, *e-mail:* dcas@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Dated: April 29, 2011.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2011-11076 Filed 5-5-11; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No. 0970-0278]

Submission for OMB Review; Comment Request; Reunification Procedures for Unaccompanied Alien Children

Description

Following the passage of the 2002 Homeland Security Act (Pub. L. 107-296), the Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), is charged with the care and placement of unaccompanied alien children in Federal custody, and implementing a policy for the release of these children, when appropriate, upon the request of suitable sponsors while awaiting immigration proceedings. In order for ORR to make determinations regarding the release of these children, the potential sponsors must meet certain conditions pursuant to section 462 of the Homeland Security Act and the *Flores v. Reno Settlement Agreement* No. CV85 4544-RJK (C.D. Cal. 1997). The proposed information collection requests information to be utilized by ORR for determining the suitability of a sponsor/respondent for the release of a minor from ORR custody. The proposed instruments are the Sponsors Agreement to Conditions of Release, Verification of Release, Family Reunification Packet, and the Authorization for Release of Information.

Respondents: Sponsors requesting release of unaccompanied alien.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Verification of Release (UAC) | 4,595 | 1 | 0.25 | 1148.75 |
| Authorization for Release of Information (Sponsor) | 4,595 | 1 | 0.25 | 1,148.75 |
| Family Reunification Packet (Sponsor) | 4,595 | 1 | 1 | 4,595 |
| Sponsors Agreement to Conditions of Release (Sponsor) | 4,595 | 1 | 0.25 | 1,148.75 |
| Verification of Release (Case Worker) | 4,595 | 1 | 0.25 | 1,148.75 |
| Authorization for Release of Information (Case Worker) | 4,595 | 1 | 0.25 | |
| Family Reunification Packet (Case Worker) | 4,595 | 1 | 1 | 4,595 |
| Sponsors Agreement to conditions of Release (Case Worker) | 4,595 | 1 | 0.25 | 1148.75 |

Estimated Total Annual Burden Hours: 16,082.50.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address:* infocollection@acf.hhs.gov.

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-7285, *E-mail:*

OIRA_SUBMISSION@OMB.EOP.GOV.

Attn: Desk Officer for the Administration for Children and Families.

Dated: March 29, 2011.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011-11046 Filed 5-5-11; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Continued Tracking of Families in the Head Start Impact Study.

OMB No.: 0970-0229.

Description: The Administration for Children and Families (ACF) of the Department of Health and Human Services (HHS), is requesting comments on plans to collect information from children and families in the Head Start Impact Study. In anticipation of the possibility of conducting a follow-up for this study in early adulthood, this effort will collect information necessary to identify respondents' current location, as well as other basic information about the parents' whereabouts and future contacts, should the follow-up study be continued. A limited set of items will also be collected to gather information from parents about their children's well-being, including whether they have been retained in grade, are receiving special education services, how well they are faring in school, and how they behave. This information will be collected annually, with the goal of ensuring continued high response rates in future follow-up data collections.

The Head Start Impact Study was a longitudinal study that involved approximately 5,000 first time enrolled

three- and four-year old preschool children across 84 nationally representative grantee/delegate agencies (in communities where there were more eligible children and families than can be served by the program.) The participating children were randomly assigned to either a Head Start group (that could enroll in Head Start services) or a control group (that could not enroll in Head Start services but could enroll in other available services selected by their parents). Data collection for the study began in fall of 2002 and extended through spring 2008, through the children's 3rd grade year. Tracking of these children and families has continued through spring 2011.

It is the intention of the Administration for Children and Families to continue to examine outcomes for this sample of children and families when the children reach early adulthood. In order to ensure that participants can be located for that future study, location and contact information will be collected from parents or guardians in the spring of 2012, 2013, 2014, 2015, and 2016. The tracking updates will primarily be conducted over the telephone with in-person follow-up as necessary. Tracking updates will take about 20 minutes to complete.

Respondents:

ANNUAL BURDEN ESTIMATES

| Instrument | Annual number of respondents | Number of responses per respondent | Average burden hours per response | Total annual burden hours |
|--------------------------|------------------------------|------------------------------------|-----------------------------------|---------------------------|
| Tracking Interview | 4,667 | 1 | 2/3 | 1,556 |

Estimated Total Annual Burden Hours: 1,556.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. E-mail address: OPREinfocollection@acf.hhs.gov. All

requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to

comments and suggestions submitted within 60 days of this publication.

Dated: May 2, 2011.

Seth F. Chamberlain

Reports Clearance Officer.

[FR Doc. 2011-11100 Filed 5-5-11; 8:45 am]

BILLING CODE 4184-22-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****[Docket No. FDA-2010-N-0555]****Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Device Tracking****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by June 6, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *Fax:* 202-395-7285, or e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0442. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleman, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, Daniel.Gittleman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices; Device Tracking—21 CFR Part 821 OMB Control Number 0910-0442—Extension

Section 211 of the Food and Drug Administration Modernization Act (FDAMA) (Pub. L. 105-115) became effective on February 19, 1998. FDAMA amended the previous medical device tracking provisions under section 519(e)(1) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i(e)(1) and (e)(2)) and were added by the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101-629). Unlike the tracking provisions under SMDA, which required tracking of any medical device meeting certain criteria, FDAMA allows FDA discretion in applying tracking provisions to medical devices meeting certain criteria and provides that tracking requirements for medical devices can be imposed only after FDA issues an order. In the **Federal Register** of February 8, 2002 (67 FR 5943), FDA issued a final rule that conformed existing tracking regulations to changes in tracking provisions effected by FDAMA under part 821 (21 CFR part 821).

Section 519(e)(1) of the FD&C Act, as amended by FDAMA, provides that FDA may require by order that a manufacturer adopt a method for tracking a class II or III medical device, if the device meets one of the three following criteria: (1) The failure of the device would be reasonably likely to have serious adverse health consequences, (2) the device is intended to be implanted in the human body for more than 1 year (referred to as a “tracked implant”), or (3) the device is life-sustaining or life-supporting (referred to as a “tracked l/s-l/s device”) and is used outside a device user facility.

Tracked device information is collected to facilitate identifying the current location of medical devices and patients possessing those devices, to the extent that patients permit the collection of identifying information.

Manufacturers and FDA (where necessary) use the data to: (1) Expedite the recall of distributed medical devices that are dangerous or defective and (2) facilitate the timely notification of patients or licensed practitioners of the risks associated with the medical device.

In addition, the regulations include provisions for: (1) Exemptions and variances; (2) system and content requirements for tracking; (3) obligations of persons other than device manufacturers, *e.g.*, distributors; records and inspection requirements; (4) confidentiality; and (5) record retention requirements.

Respondents for this collection of information are medical device manufacturers, importers, and distributors of tracked implants or tracked l/s-l/s devices used outside a device user facility. Distributors include multiple and final distributors, including hospitals.

The annual hourly burden for respondents involved with medical device tracking is estimated to be 604,279 hours per year. The burden estimates cited in tables 1, 2, and 3 of this document are based on the number of device tracking orders issued in the last 3 years.

This regulation also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by Office of Management and Budget under the PRA (44 U.S.C. 3501-3520). The collections of information found in §§ 821.2(b), 821.25(e), and 821.30(e) have been approved under OMB control number 0910-0183.

In the **Federal Register** of November 12, 2010 (75 FR 69447), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

| 21 CFR section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response (in hours) | Total hours |
|---------------------------|-----------------------|------------------------------------|------------------------|--|-------------|
| 821.1(d) | 1 | 1 | 1 | 1 | 1 |
| 821.2 and 821.30(e) | 1 | 1 | 1 | 1 | 1 |
| 821.25(a) | 12 | 1 | 12 | 76 | 912 |
| 821.25(d) | 1 | 1 | 1 | 1 | 1 |
| Total | | | | | 915 |

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

TABLE 2—ESTIMATED AVERAGE ANNUAL RECORDKEEPING BURDEN ¹

| 21 CFR section | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping (in hours) | Total hours |
|------------------------------|-------------------------|------------------------------------|----------------------|---|-------------|
| 821.25(b) | 12 | 46,260 | 555,120 | 1 | 555,120 |
| 821.25(c) ² | 12 | 1 | 12 | 63 | 756 |
| 821.25(c)(3) | 12 | 1,124 | 13,488 | 1 | 13,488 |
| Total | | | | | 569,364 |

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

² One time burden.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

| 21 CFR section | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure (in hours) | Total hours |
|----------------------------|-----------------------|--------------------------------------|--------------------------|--|-------------|
| 821.30(a) and (b) | 17,000 | 1 | 17,000 | 1 | 17,000 |
| 821.30(c)(2) and (d) | 17,000 | 1 | 17,000 | 1 | 17,000 |
| Total | | | | | 34,000 |

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

Dated: May 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-11072 Filed 5-5-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0275]

Agency Information Collection Activities; Proposed Collection; Comment Request; Certification To Accompany Drug, Biological Product, and Device Applications or Submissions (Form FDA 3674)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the requirements for certain FDA applications or submissions to be accompanied by a certification, Form

FDA 3674, to ensure all applicable statutory requirements have been met.

DATES: Submit either electronic or written comments on the collection of information by July 5, 2011.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the Office of Management and Budget (OMB) control number 0910-0616. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150-400B, Rockville, MD 20850, 301-796-3794, jonnalynn.capezzuto@fda.hhs.gov.

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. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies

to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed extension of an existing collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed extension of the collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Certification To Accompany Drug, Biological Product, and Device Applications or Submissions (Form FDA 3674)—(OMB Control Number 0910-0616)—Extension

The information required under section 402(j)(5)(B) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(5)(B)) is submitted in the form of

a certification, Form FDA 3674, which accompanies applications and submissions currently submitted to FDA and is already approved by OMB. The OMB control numbers and expiration dates for submitting FDA 3674 under the following parts are: 21 CFR parts 312 and 314 (human drugs) are 0910–0014, expiring August 31, 2011, and 0910–0001, expiring May 31, 2011; 21 CFR parts 312 and 601 (biological products) are 0910–0014 and 0910–0338, expiring December 31, 2013; 21 CFR parts 807 and 814 (devices) are 0910–0120, expiring December 31, 2013, and 0910–0231, expiring December 31, 2013.

Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85) amended the PHS Act by adding section 402(j). The provisions require additional information to be submitted to the clinical trials data bank (ClinicalTrials.gov)¹ previously established by the National Institutes of Health/National Library of Medicine, including expanded information on clinical trials and information on the results of clinical trials. The provisions include responsibilities for FDA as well as several amendments to the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

One provision, section 402(j)(5)(B) of the PHS Act, requires that a certification accompany human drug, biological, and device product submissions made to FDA. Specifically, at the time of submission of an application under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 355, 360e, or 360j(m)), or under section 351 of the PHS Act (42 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), such application or submission must be accompanied by a certification, Form FDA 3674, that all applicable requirements of section 402(j) of the PHS Act have been met. Where available, such certification must include the appropriate National Clinical Trial (NCT) numbers.

The proposed extension of the collection of information is necessary to satisfy the previously mentioned statutory requirement.

The importance of obtaining these data relates to adherence to the legal requirements for submissions to the clinical trials registry and results data bank and ensuring that individuals and organizations submitting applications or

reports to FDA under the listed provisions of the FD&C Act or the PHS Act adhere to the appropriate legal and regulatory requirements for certifying to having complied with those requirements. The failure to submit the certification required by section 402(j)(5)(B) of the PHS Act, and the knowing submission of a false certification are both prohibited acts under section 301 of the FD&C Act (21 U.S.C. 331). Violations are subject to civil money penalties.

In January 2009, FDA issued “Guidance for Sponsors, Industry, Researchers, Investigators, and Food and Drug Administration Staff—Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007” available at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125335.htm>. This guidance identified the applications and submissions that FDA considered should be accompanied by the certification form, Form FDA 3674. The applications and submissions noted in the guidance are reflected in the burden analysis.

Investigational New Drug Applications

FDA’s Center for Drug Evaluation and Research (CDER) received 1,752 investigational new drug applications (INDs) and 11,769 clinical protocol IND amendments in Fiscal Year (FY) 2010. CDER anticipates that IND and clinical protocol amendment submission rates will remain at or near this level in the near future.

FDA’s Center for Biologics Evaluation and Research (CBER) received 281 new INDs and 1,471 clinical protocol IND amendments in FY 2010. CBER anticipates that IND and clinical protocol amendment submission rates will remain at or near this level in the near future.

The estimated total number of submissions (new INDs and new protocol submissions) subject to mandatory certification requirements under section 402(j)(5)(B) of the PHS Act, is 13,521 for CDER plus 1,752 for CBER, or 15,273 submissions per year. The minutes per response is the estimated number of minutes that a respondent would spend preparing the information to be submitted to FDA under section 402(j)(5)(B) of the PHS Act, including the time it takes to enter the necessary information on the form.

Based on its experience with current submissions, FDA estimates that

approximately 15.0 minutes on average would be needed per response for certifications which accompany IND applications and clinical protocol amendment submissions. It is assumed that most submissions to investigational applications will reference only a few protocols for which the sponsor/applicant/submitter has obtained a NCT number from ClinicalTrials.gov prior to making the submission to FDA. It is also assumed that the sponsor/applicant/submitter has electronic capabilities allowing them to retrieve the information necessary to complete the form in an efficient manner.

Marketing Applications/Submissions

In 2010, CDER and CBER received 165 new drug applications (NDA)/biologics license applications (BLA)/resubmissions and 1,483 NDA/BLA amendments for which certifications are needed. CDER and CBER received 191 efficacy supplements/resubmissions to previously approved NDAs/BLAs in FY 2010. CDER and CBER anticipate that new drug/biologic applications/resubmissions and efficacy supplement submission rates will remain at or near this level in the near future.

FDA’s Center for Devices and Radiological Health (CDRH) received a total of 892 new applications for premarket approvals (PMA), 510(k) submissions containing clinical information, PMA supplements, applications for humanitarian device exemptions (HDE) and amendments, for a total of 424 new applications/submissions in FY 2010. CDRH anticipates that application, amendment, supplement, and annual report submission rates will remain at or near this level in the near future.

FDA’s Office of Generic Drugs (OGD) received 854 abbreviated new drug applications (ANDAs) in FY 2010. OGD received 495 bioequivalence amendments/supplements FY 2010. OGD anticipates that application, amendment, and supplement submission rates will remain at or near this level in the near future.

Based on its experience reviewing NDAs, BLAs, PMAs, HDEs, 510(k)s, and ANDAs and experience with current submissions of Form FDA 3674, FDA estimates that approximately 45.0 minutes on average would be needed per response for certifications which accompany NDA, BLA, PMA, HDE, 510(k), and ANDA marketing applications and submissions. It is assumed that the sponsor/applicant/submitter has electronic capabilities allowing them to retrieve the information necessary to complete the form in an efficient manner.

¹ FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| FDA Center Activity | Number of respondents (investigational applications) | Number of respondents (marketing applications) | Number of responses per respondent | Total annual responses | Average burden per response (in hours) ² | Total hours |
|---|--|--|------------------------------------|------------------------|---|-------------|
| CDER | | | | | | |
| New Applications (IND) | 1,752 | | 1 | 1,752 | 15/60 | 438 |
| Clinical Protocol Amendments (IND) | 11,769 | | 1 | 11,769 | 15/60 | 2,943 |
| New Marketing Applications/Resubmissions (NDA/BLA) | | 157 | 1 | 157 | 45/60 | 118 |
| Clinical Amendments to Marketing Applications | | 1,466 | 1 | 1,466 | 45/60 | 1,100 |
| Efficacy Supplements/Resubmissions | | 166 | 1 | 166 | 45/60 | 125 |
| CBER | | | | | | |
| New Applications (IND) | 281 | | 1 | 281 | 15/60 | 70 |
| Clinical Protocol Amendments (IND) | 1,471 | | 1 | 1,471 | 15/60 | 368 |
| New Marketing Applications/Resubmissions | | 8 | 1 | 8 | 45/60 | 6 |
| Clinical Amendments to Marketing Applications | | 17 | 1 | 17 | 45/60 | 13 |
| Efficacy Supplements/Resubmissions (BLA only) | | 25 | 1 | 25 | 45/60 | 19 |
| CDRH | | | | | | |
| New Marketing Applications (includes PMAs, HDEs, Supplements and 510(k)s expected to contain clinical data) | | 892 | 1 | 892 | 45/60 | 669 |
| OGD | | | | | | |
| Original Applications | | 854 | 1 | 854 | 45/60 | 641 |
| BE Supplements/Amendments | | 495 | | | 45/60 | 372 |
| Total | | | | | | 6,882 |

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

² Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format “[number of minutes per response]/60”.

Dated: May 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–11073 Filed 5–5–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0126]

Guidance for Industry on the Submission of Summary Bioequivalence Data for Abbreviated New Drug Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry

entitled “Submission of Summary Bioequivalence Data for Abbreviated New Drug Applications.” The guidance is intended to assist abbreviated new drug application (ANDA) applicants in complying with the requirements in the final rule on the submission of bioequivalence data that published in the **Federal Register** in January 2009 (74 FR 2849, January 16, 2009). The final rule requires ANDA applicants to submit data from all bioequivalence studies (BE studies) the applicant conducts on a drug product formulation submitted for approval, including both studies that demonstrate and studies that fail to demonstrate that a generic product meets the current bioequivalence criteria. The guidance provides recommendations to applicants planning to include BE studies for submission in ANDAs and is applicable to BE studies conducted during both preapproval and postapproval periods.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Aida L. Sanchez, Center for Drug Evaluation and Research (HFD–650),

Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240-276-8782.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Submission of Summary Bioequivalence Data for ANDAs." The guidance provides recommendations to applicants planning to include BE studies for submission in ANDAs. The guidance provides information on the following subjects:

- Types of ANDA submissions covered by the regulations on BE studies;
- Recommended format for summary reports of BE studies; and
- Types of formulations the Agency considers to be the same drug product formulation for different dosage forms based on differences in composition.

The guidance is applicable to BE studies conducted for ANDAs during both preapproval and postapproval periods.

On April 17, 2009, FDA announced the availability of the draft version of this guidance (74 FR 17872). The public comment period closed on July 16, 2009. A few comments were received from the public, all of which the Agency considered carefully as it finalized the guidance and made appropriate changes. Changes to the guidance were minor and made to clarify statements in the draft guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on submission of summary bioequivalence data for ANDAs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This guidance refers to information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 314.94(a)(7), 314.96(a)(1), and 314.97 have been approved under OMB control number 0910-0630.

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: May 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-11102 Filed 5-5-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse And Alcoholism; Notice of Meeting.

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Alcohol Abuse and Alcoholism.

Date: June 8-9, 2011.

Closed: June 8, 2011, 5:30 p.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Open: June 9, 2011, 9 a.m. to 3 p.m.

Agenda: Presentation and other business of the council.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Contact Person: Abraham P. Bautista, PhD, Executive Secretary, National Institute on Alcohol Abuse & Alcoholism National Institutes of Health, 5635 Fishers Lane, Rm 2085, Rockville, Md 20852, 301-443-9737, bautistaa@mail.nih.gov.

Information is also available on the Institute's/Center's home page: silk.nih.gov/silk/niaaa1/about/roster.htm, where an agenda and any additional information for the meeting will be posted when available. (Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: May 2, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-11170 Filed 5-5-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group, Epidemiology, Prevention and Behavior Research Review Subcommittee.

Date: July 19, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Katrina L Foster, PhD, Scientific Review Administrator, National Institutes On Alcohol Abuse & Alcoholism National, Institutes Of Health, 5635 Fishers Lane, Rm. 3037, Rockville, Md 20852, 301–443–3037, katrina@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: May 2, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–11175 Filed 5–5–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Auditory and Somatosensory Pain Neuroscience.

Date: June 1–2, 2011.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: John Bishop, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, (301) 408–9664, bishopj@csr.nih.gov.

Name of Committee: Musculoskeletal, Oral And Skin Sciences Integrated Review Group, Oral, Dental and Craniofacial Sciences Study Section.

Date: June 2–3, 2011.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin Long Beach, 333 East Ocean Boulevard, Long Beach, CA 90802.

Contact Person: Yi-Hsin Liu, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–435–1781, liuyh@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Pathophysiology and Clinical Studies of Osteonecrosis of the Jaw.

Date: June 3, 2011.

Time: 12 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin Long Beach, 333 East Ocean Boulevard, Long Beach, CA 90802.

Contact Person: Yi-Hsin Liu, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–435–1781, liuyh@csr.nih.gov.

Name of Committee: Vascular and Hematology Integrated Review Group, Vascular Cell and Molecular Biology Study Section.

Date: June 6–7, 2011.

Time: 8 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: The Embassy Suites Chicago O' Hare, 5500 North River Road, Rosemont, IL 60018.

Contact Person: Anshumali Chaudhari, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892, (301) 435–1210, chaudhaa@csr.nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group, Infectious Diseases, Reproductive Health, Asthma and Pulmonary Conditions Study Section.

Date: June 6–7, 2011.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Avenue, NW., Washington, DC 20037.

Contact Person: Lisa Steele, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, 301–594–6594, steeleln@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR–11–044: Indo-US Collaborative Program on Low-Cost Medical Devices.

Date: June 8–9, 2011.

Time: 11 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: David R Filpula, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6181, MSC 7892, Bethesda, MD 20892, 301–435–2902, filpuladr@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, RM10–018: Technology Development for New Affinity Reagents Against the Human Proteome.

Date: June 15, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

Contact Person: Joseph D Mosca, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5158, MSC 7808, Bethesda, MD 20892, (301) 435–2344, moscajos@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: May 2, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–11177 Filed 5–5–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, NCI Tumor Microenvironment (TMEN.)

Date: June 29–July 1, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington DC North Hilton Hotel, 620 Perry Parkway, Gaithersburg, MD 20877.

Contact Person: Lalita D. Palekar, PhD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 7141, Bethesda, MD 20892, 301–496–7575, palekarl@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 29, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-11180 Filed 5-5-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Population-based Research Optimizing Screening through Personalized Regimens (PROSPR) for Cancer and Statistical Coordinating Center.

Date: June 15-17, 2011.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Adriana Stoica, PhD, Scientific Review Officer, Special Review & Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Ste 703, Rm 7072, Bethesda, MD 20892-8329, 301-594-1408, Stoicaa2@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 29, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-11179 Filed 5-5-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Board of Scientific Advisors.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Board of Scientific Advisors.

Date: June 20-21, 2011.

Time: June 20, 2011, 9 a.m. to 5 p.m.

Agenda: Director's Report: Ongoing and New Business; Reports of Program Review Group(s); and Budget Presentations.

Place: National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, Conference Rm. 10, Bethesda, MD 20892.

Time: June 21, 2011, 9 a.m. to 12 p.m.

Agenda: Reports of Special Initiatives; RFA and RFP Concept Reviews; and Scientific Presentations.

Place: National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, Conference Rm. 10, Bethesda, MD 20892.

Contact Person: Paulette S. Gray, PhD, Executive Secretary, Director, Division Of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Rm. 8001, Bethesda, MD 20892, 301-496-5147, grayp@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page:

deainfo.nci.nih.gov/advisory/bsa.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 2, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-11178 Filed 5-5-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, *Program Project:* Addiction.

Date: May 17-18, 2011.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting.)

Contact Person: Brian Hoshaw, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5181, MSC 7844, Bethesda, MD 20892, 301-435-1033, hoshawb@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 2, 2011.

Jennifer S. Spaeth,

*Director, Office of Federal Advisory
Committee Policy.*

[FR Doc. 2011–11176 Filed 5–5–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel, Review of Program Projects on Alcohol-Related Research. August 12, 2011.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Richard A Rippe, PhD, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Room 2109, Rockville, MD 20852, 301–443–8599, rippera@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: May 2, 2011.

Jennifer S. Spaeth,

*Director, Office of Federal Advisory
Committee Policy.*

[FR Doc. 2011–11171 Filed 5–5–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel, Biomarkers Indicative of Mitochondrial Dysfunction.

Date: June 1–3, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Durham Southpoint, 7007 Fayetteville Road, Durham, NC 27713.

Contact Person: Leroy Worth, PhD, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30/Room 3171, Research Triangle Park, NC 27709, (919) 541–0670, worth@niehs.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: April 29, 2011.

Jennifer S. Spaeth,

*Director, Office of Federal Advisory
Committee Policy.*

[FR Doc. 2011–11167 Filed 5–5–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Harbor Maintenance Fee

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; Extension and revision of an existing collection of information: 1651–0055.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the Harbor Maintenance Fee (CBP Forms 349 and 350). This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13).

DATES: Written comments should be received on or before July 5, 2011, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of International Trade, 799 9th Street, NW., 5th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 799 9th Street, NW., 5th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). 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: Harbor Maintenance Fee.

OMB Number: 1651-0055.

Form Number: CBP Forms 349 and 350.

Abstract: The Harbor Maintenance Fee (HMF) and Trust Fund is used for the operation and maintenance of certain U.S. channels and harbors by the Army Corps of Engineers. U.S. Customs and Border Protection (CBP) is required to collect the HMF from importers, domestic shippers, and passenger vessel operators using federal navigation projects. Commercial cargo loaded on or unloaded from a commercial vessel is subject to a port use fee of 0.125 percent of its value if the loading or unloading occurs at a port that has been designated by the Army Corps of Engineers. The HMF also applies to the total ticket value of embarking and disembarking passengers and on cargo admissions into a Foreign Trade Zone (FTZ).

CBP Form 349, *Harbor Maintenance Fee Quarterly Summary Report*, and CBP Form 350, *Harbor Maintenance Fee Amended Quarterly Summary Report* are completed by domestic shippers, foreign trade zones applicants, and passenger vessel operators and submitted with payment to CBP. CBP proposes to amend Form 349 to add the respondent's email address and fax number.

CBP uses the information collected on CBP Forms 349 and 350 to verify that the fee collected is timely and accurately submitted. These forms are authorized by the Water Resources Development Act of 1986 (26 U.S.C. 4461, *et seq.*) and provided for by 19 CFR 24.24, which also includes the list of designated ports. CBP Forms 349 and 350 are accessible at <http://www.cbp.gov/xp/cgov/toolbox/forms/> or they may be completed and filed electronically at <http://www.pay.gov>.

Current Actions: This submission is being made to extend the expiration date of this information collection with a change to the burden hours resulting from revised estimates of the number of responses. CBP also proposes to add the respondent's email address and fax number to Form 349. There are no proposed changes to CBP 350.

Type of Review: Extension (with change).

Affected Public: Businesses.

Estimated Number of Respondents: 575.

Estimated Number of Responses: 2,300.

Estimated Time per Respondent: 130 minutes.

Estimated Total Annual Burden Hours: 1,246.

Dated: May 2, 2011.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2011-11054 Filed 5-5-11; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5477-N-18]

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 7266, Washington, DC 20410; telephone (202) 708-1234; TTY number for the hearing- and speech-impaired (202) 708-2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800-927-7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless v. Veterans Administration*, No. 88-2503-OG (D DC).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to

HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for "off-site use only" recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Theresa Rita, Division of Property Management, Program Support Center, HHS, room 5B-17, 5600 Fishers Lane, Rockville, MD 20857; (301) 443-2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1-800-927-7588 for detailed instructions or write a letter to Mark Johnston at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.*, acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: *Coast Guard*: Commandant, United States Coast Guard, *Attn*: Jennifer Stomber, 2100 Second St., SW., Stop 7901, Washington, DC 20593-0001; (202) 475-5609 *Energy*: Mr. Mark Price, Department of Energy, Office of Engineering & Construction Management, MA-50, 1000 Independence Ave, SW., Washington, DC 20585: (202) 586-5422; *GSA*: Mr. Gordon Creed, Acting Deputy Assistant Commissioner, General Services Administration, Office of Property Disposal, 18th & F Streets, NW., Washington, DC 20405; (202) 501-0084; *Interior*: Mr. Michael Wright, Acquisition & Property Management, Department of the Interior, 1801 Pennsylvania Ave, NW., 4th Floor, Washington, DC 20006: (202) 208-5399; *Navy*: Mr. Albert Johnson, Director of Real Estate, Department of the Navy, Naval Facilities Engineering Command, Washington Navy Yard, 1330 Patterson Ave., SW., Suite 1000, Washington, DC 20374; (202) 685-9305; (These are not toll-free numbers).

Dated: April 28, 2011.

Mark R. Johnston,

Deputy Assistant Secretary for Special Needs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 05/06/2011

Suitable/Available Properties

Building

Kansas

MKC Outer Marker FAA Site
Generally South of 2400 Steele Road
Kansas City KS 64106
Landholding Agency: GSA
Property Number: 54201120007
Status: Surplus
GSA Number: 7-U-KS-0525
Comments: 60 sq. ft., current use: support building, public road easement

Ohio

LTC Dwite Schaffner
U.S. Army Reserve Center
1011 Gorge Blvd.
Akron OH 44310
Landholding Agency: GSA
Property Number: 54201120006
Status: Excess
GSA Number: 1-D-OH-836
Comments: 25,039 sq. ft., most recent use: Office; in good condition

Texas

Rattle Snake Scoring Ste.
1085 County Rd. 332
Pecos TX 79772
Landholding Agency: GSA

Property Number: 54201120005
Status: Excess
GSA Number: 7-D-TX-0604-AM
Comments: 8,396 sq. ft., most recent use: training site, previously reported by Air Force and deemed "unsuitable" because property was in a secured area and published in May 2009.

Unsuitable Properties

Building

Florida

Carpenter Storage Bldg.
600 8th Ave. S.E.
U.S.C.G. Station
St. Petersburg FL
Landholding Agency: Coast Guard
Property Number: 88201120003
Status: Unutilized
Reasons: Secured Area, Extensive deterioration
Massachusetts
4 Bldgs
USCG
Bourne MA 02542
Landholding Agency: Coast Guard
Property Number: 88201120002
Status: Excess
Directions: 5300, 5311, 5314, 5690
Reasons: Extensive deterioration
Michigan

ANT Admin Office/Storage
2509 Seminole Drive
Sault Ste Marie MI 49783
Landholding Agency: Coast Guard
Property Number: 88201120001
Status: Excess
Reasons: Secured Area, Extensive deterioration

Mississippi

NATR R-126-16 House, Barn
571 Palmetto Road
Tupelo MS 38801
Landholding Agency: Interior
Property Number: 61201120003
Status: Unutilized
Reasons: Extensive deterioration

New Mexico

10 Bldgs.
NSA
Los Alamos NM 87545
Landholding Agency: Energy
Property Number: 41201120001
Status: Excess
Directions: 15-0041, 15-0045, 15-0186, 15-0199, 15-0200, 15-0201, 15-0233, 15-0310, 15-0477, 15-0468
Reasons: Secured Area, Within airport runway clear zone

Pennsylvania

Bldg. 40 Qtr. A
NSA
Philadelphia PA
Landholding Agency: Navy
Property Number: 77201120001
Status: Excess
Reasons: Secured Area

Washington

Bldgs. 7 and 65
Naval Station Everett
Jim Creek Rd.

Arlington WA 98223
Landholding Agency: Navy
Property Number: 77201120002
Status: Excess
Reasons: Secured Area, Extensive deterioration
[FR Doc. 2011-10792 Filed 5-5-11; 8:45 am]
BILLING CODE 4210-67-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R2-ES-2011-N072; 20124-1113-0000-F5]

Endangered and Threatened Species Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications; request for public comment.

SUMMARY: The following applicants have applied for scientific research permits to conduct certain activities with endangered species under the Endangered Species Act of 1973, as amended (Act). The Act requires that we invite public comment on these permit applications.

DATES: To ensure consideration, written comments must be received on or before June 6, 2011.

ADDRESSES: Written comments should be submitted to the Chief, Endangered Species Division, Ecological Services, P.O. Box 1306, Room 6034, Albuquerque, NM 87103. Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act. Documents will be available for public inspection, by appointment only, during normal business hours at the U.S. Fish and Wildlife Service, 500 Gold Ave., SW., Room 6034, Albuquerque, NM. Please refer to the respective permit number for each application when submitting comments.

FOR FURTHER INFORMATION CONTACT: Susan Jacobsen, Chief, Endangered Species Division, P.O. Box 1306, Albuquerque, NM 87103; (505) 248-6920.

SUPPLEMENTARY INFORMATION:

Public Availability of Comments

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time.

While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Permit TE-37047A

Applicant: Sea World Parks and Entertainment, San Antonio, Texas.

Applicant requests a new permit for husbandry and holding of green sea turtles (*Chelonia mydas*), hawksbill sea turtles (*Eretmochelys imbricate*), Kemp's ridley sea turtles (*Lepidochelys kempi*), and leatherback sea turtles (*Dermochelys coriacea*) at Sea World Park in San Antonio, Texas.

Permit TE-067869

Applicant: Rhea Environmental Consulting, Mancos, Colorado.

Applicant requests a renewal to a current permit for research and recovery purposes to conduct presence/absence surveys for southwestern willow flycatcher (*Empidonax traillii extimus*) within Arizona, New Mexico, Colorado, and Utah.

Permit TE-150490

Applicant: John Maresh, Austin, Texas.

Applicant requests a renewal to a current permit for research and recovery purposes to conduct presence/absence surveys for golden-cheeked warbler (*Dendroica chrysoparia*) and black-capped vireo (*Vireo atricapilla*) within Texas.

Permit TE-063395

Applicant: Oklahoma Aquarium, Jenks, Oklahoma.

Applicant requests an amendment to a current permit for holding, husbandry, and educational display for two non-releasable green sea turtles (*Chelonia mydas*) at the Oklahoma Aquarium.

Permit TE-828640

Applicant: Harris Environmental Group, Tucson, Arizona.

Applicant requests a renewal to a current permit for research and recovery purposes to conduct presence/absence surveys for lesser long-nosed bat (*Leptonycteris yerbabuenae*), northern aplomado falcon (*Falco femoralis septentrionalis*), and southwestern willow flycatcher (*Empidonax traillii extimus*) within Arizona.

Permit TE-37484A

Applicant: Balcones Canyonlands National Wildlife Refuge, Marble Falls, Texas.

Applicant requests a new permit for research and recovery purposes to conduct presence/absence surveys for

black-capped vireo (*Vireo atricapilla*) and golden-cheeked warbler (*Dendroica chrysoparia*) within the refuge.

Permit TE-38725A

Applicant: Geo-Marine, Inc., Plano, Texas.

Applicant requests a new permit for research and recovery purposes to conduct presence/absence surveys for Louisiana black bear (*Ursus americanus luteolus*) and white bladderpod (*Lesquerella pallida*) within Texas.

Permit TE-38748A

Applicant: Carlotta Copper Company, Fort Collins, Colorado.

Applicant requests a new permit for research and recovery purposes to collect seeds, propagate, and create receiving areas for transplants of Arizona hedgehog cactus (*Echinocereus triglochidiatus var. arizonicus*) within Arizona.

Authority: 16 U.S.C. 1531 *et seq.*

Dated: April 18, 2011.

Joy E. Nicholopoulos,

Acting Regional Director, Southwest Region, Fish and Wildlife Service.

[FR Doc. 2011-11078 Filed 5-5-11; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLOR957000-L631000000-HD000: HAG11-0217]

Filing of Plats of Survey: Oregon/ Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The plats of survey of the following described lands are scheduled to be officially filed in the Bureau of Land Management Oregon/Washington State Office, Portland, Oregon, 30 days from the date of this publication.

Willamette Meridian

Oregon

T. 30 S., R. 11 W., accepted March 24, 2011
T. 28 S., R. 3 W., accepted March 24, 2011
T. 24 S., R. 6 E., accepted March 28, 2011
T. 14 S., R. 7 W., accepted March 28, 2011
T. 6 S., R. 11 E., accepted March 28, 2011
T. 23 S., R. 3 W., accepted April 6, 2011
T. 20 S., R. 6 W., accepted April 6, 2011
T. 29 S., R. 4 W., accepted April 6, 2011
T. 14 S., R. 1 W., accepted April 8, 2011
T. 24 S., R. 8 W., accepted April 8, 2011
T. 21 S., R. 9 W., accepted April 20, 2011
T. 30 S., R. 8 W., accepted April 22, 2011
T. 31 S., R. 6 W., accepted April 22, 2011
T. 30 S., R. 6 W., accepted April 22, 2011
T. 3 S., R. 44 E., accepted April 22, 2011

T. 31 S., R. 14 W., accepted April 22, 2011
T. 15 S., R. 1 W., accepted April 27, 2011
Washington
T. 12 N., R. 1 E., accepted March 28, 2011
T. 36 N., R. 33 E., accepted March 28, 2011
T. 16 N., R. 4 W., accepted April 22, 2011
T. 9 N., R. 27 E., accepted April 27, 2011

ADDRESSES: A copy of the plats may be obtained from the Land Office at the Bureau of Land Management, Oregon/Washington State Office, 333 S.W. 1st Avenue, Portland, Oregon 97204, upon required payment. A person or party who wishes to protest against a survey must file a notice that they wish to protest (at the above address) with the Oregon/Washington State Director, Bureau of Land Management, Portland, Oregon.

FOR FURTHER INFORMATION CONTACT: Kyle Hensley, (503) 808-6124, Branch of Geographic Sciences, Bureau of Land Management, 333 S.W. 1st Avenue, Portland, Oregon 97204. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

Fred O'Ferrall,

Chief, Branch of Land, Mineral, and Energy Resources.

[FR Doc. 2011-11083 Filed 5-5-11; 8:45 am]

BILLING CODE 4310-33-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLIDT000000.L11200000.DD0000.241A.00]

Notice of Public Meetings, Twin Falls District Resource Advisory Council, Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA), the Federal Advisory Committee Act of 1972 (FACA), and the Federal Lands Recreation Enhancement Act of 2004 (FLREA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Twin Falls District Resource Advisory Council (RAC) will meet as indicated below.

DATES: May 16, 2011. On May 16, 2011, the Twin Falls District RAC members will meet at the Best Western Sawtooth Inn at 2653 S. Lincoln Street, Jerome, Idaho. The meeting will begin at 6 p.m.

and end no later than 8 p.m. The public comment period for the RAC meeting will take place 6:15 p.m. to 6:45 p.m.

FOR FURTHER INFORMATION CONTACT:

Heather Tiel-Nelson, Twin Falls District, Idaho, 2536 Kimberly Road, Twin Falls, Idaho 83301, (208) 736-2352.

SUPPLEMENTARY INFORMATION: The 15-member RAC advises the Secretary of the Interior, through the Bureau of Land Management, on a variety of planning and management issues associated with public land management in Idaho. During the May 16th meeting, there will be information shared about the Proposed China Mountain Wind Project Draft Environmental Impact Statement.

More information is available at http://www.blm.gov/id/st/en/res/resource_advisory.3.html. RAC meetings are open to the public. For further information about the meeting, please contact Heather Tiel-Nelson, Public Affairs Specialist for the Twin Falls District, BLM at (208) 736-2352.

Dated: April 28, 2011.

Bill Baker,
District Manager.

[FR Doc. 2011-11098 Filed 5-5-11; 8:45 am]

BILLING CODE 4310-GG-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-759]

In the Matter of Certain Birthing Simulators and Associated Systems; Notice of Commission Determination Not To Review an Initial Determination Finding Both Respondents in Default; Request for Written Submissions on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination ("ID") (Order No. 5) of the presiding administrative law judge ("ALJ") finding both respondents in default and is requesting briefing on remedy, public interest, and bonding.

FOR FURTHER INFORMATION CONTACT: Jia Chen, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 708-4737. Copies of non-confidential documents filed in connection with this investigation are or will be available for

inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at <http://www.usitc.gov>. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <http://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on February 7, 2011, based on a complaint filed by Gaumard Scientific Company, Inc. of Miami, Florida. 76 FR 6632 (Feb. 7, 2011). The complaint, as amended, alleged violations of section 337 of the Tariff Act of 1930 (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 birthing simulators and associated systems by reason of infringement of various claims of United States Patent Nos. 6,503,087 and 7,114,954. The complaint named Shanghai Honglian Medical Instruments of China and Shanghai Evenk International Trading Co., Ltd. of China as respondents. The complaint and Notice of Investigation were served on respondents on February 1, 2011. No responses were received.

On March 4, 2011, the ALJ issued an order requiring respondents to show cause why they should not be held in default and judgment rendered against them for failing to respond to the complaint and notice of investigation. Respondents did not respond. On March 30, 2011, the ALJ issued the subject ID, finding both respondents in default pursuant to Commission Rule 210.16 (19 CFR 210.16) and terminating the above-referenced investigation. None of the parties petitioned for review of the ID.

The Commission has determined not to review the ID.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving

written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *In the Matter of Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. See Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Specifically, Complainant and the Commission investigative attorney are requested to respond to the following question: Does section 337(j)(3) (19 U.S.C. 1337(j)(3)) or any other statutory authority authorize the Commission to permit default respondents subject to an exclusion order under section 337(g)(1) to import infringing products under bond during the sixty (60) day Presidential review period? Please cite any relevant legislative history. Complainant and the Commission investigative attorney are also requested

to submit proposed remedial orders for the Commission's consideration. Complainant is also requested to state the dates that the patents expire and the HTSUS numbers under which the accused products are imported. The written submissions and proposed remedial orders must be filed no later than close of business on Thursday, May 12, 2011. Reply submissions must be filed no later than the close of business on Thursday, May 19, 2011. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document and 12 true copies thereof on or before the deadlines stated above with the Office of the Secretary. Any person desiring to submit a document to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 210.6. Documents for which confidential treatment by the Commission is sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

The authority for the Commission's determination is contained in section 337(g)(1) of the Tariff Act of 1930, as amended (19 U.S.C. 1337(g)(1)), and in sections 210.42–46 and 210.50 of the Commission's Rules of Practice and Procedure (19 CFR 210.42–46 and 210.50).

Issued: May 2, 2011.

By order of the Commission.

James R. Holbein,

Acting Secretary to the Commission.

[FR Doc. 2011–11075 Filed 5–5–11; 8:45 am]

BILLING CODE P

INTERNATIONAL TRADE COMMISSION

[USITC SE–11–012]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: May 16, 2011 at 11 a.m.

PLACE: Room 110, 500 E Street, SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: none.

2. Minutes.

3. Ratification List.

4. Vote in Inv. Nos. 701–TA–479 and 731–TA–1183–1184 (Preliminary) (Galvanized Steel Wire from China and Mexico). The Commission is currently scheduled to transmit its determinations to the Secretary of Commerce on or before May 16, 2011; Commissioners' opinions are currently scheduled to be transmitted to the Secretary of Commerce on or before May 23, 2011.

5. Vote in Inv. No. 731–TA–1185 (Preliminary) (Certain Steel Nails from the United Arab Emirates). The Commission is currently scheduled to transmit its determination to the Secretary of Commerce on or before May 16, 2011; Commissioners' opinions are currently scheduled to be transmitted to the Secretary of Commerce on or before May 23, 2011.

6. Vote in Inv. Nos. 731–TA–1186 and 1187 (Preliminary) (Certain Stilbenic Optical Brightening Agents from China and Taiwan). The Commission is currently scheduled to transmit its determinations to the Secretary of Commerce on or before May 16, 2011; Commissioners' opinions are currently scheduled to be transmitted to the Secretary of Commerce on or before May 23, 2011.

7. Outstanding action jackets: none.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

Issued: May 3, 2011.

By order of the Commission:

William R. Bishop,

Hearings and Meetings Coordinator.

[FR Doc. 2011–11227 Filed 5–4–11; 4:15 pm]

BILLING CODE 7020–02–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 11– 044]

Aerospace Safety Advisory Panel; Meeting

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of meeting; Correction.

Federal Register Citation of Previous Announcement: 76 FR 23339, Notice Number 11–043, dated April 26, 2011; and 76 FR 19147, Notice Number 11–030, dated April 6, 2011.

SUMMARY: The National Aeronautics and Space Administration published a notice in the **Federal Register** of April 26, 2011, announcing a meeting of the Aerospace Safety Advisory Panel

(ASAP) to take place on May 24, 2011, at the Kennedy Space Center, FL.

Correction: Date and time of ASAP public meeting remains the same: Tuesday, May 24, 2011, 11 a.m. to 1 p.m. Location has been moved to: NASA Headquarters, Room 9H40, 300 E. Street, SW., Washington, DC 20546. Agenda has been modified accordingly.

FOR FURTHER INFORMATION CONTACT: Ms. Kathy Dakon, ASAP Executive Director, National Aeronautics and Space Administration, Washington, DC 20546, (202) 358–0732.

SUPPLEMENTARY INFORMATION: The Aerospace Safety Advisory Panel will hold its 2nd Quarterly Meeting for 2011. This discussion is pursuant to carrying out its statutory duties for which the Panel reviews, identifies, evaluates, and advises on those program activities, systems, procedures, and management activities that can contribute to program risk. Priority is given to those programs that involve the safety of human flight.

The agenda will include: Updates on Safety and Mission Assurance; Safety Metrics; and Commercial Space.

The meeting will be open to the public up to the seating capacity of the room. Seating will be on a first-come basis. Photographs will only be permitted during the first 10 minutes of the meeting. During the first 30 minutes of the meeting, members of the public may make a 5-minute verbal presentation to the Panel on the subject of safety in NASA. To do so, please contact Ms. Susan Burch at susan.burch@nasa.gov or by telephone at (202) 358–0550 at least 48 hours in advance. Any member of the public is permitted to file a written statement with the Panel at the time of the meeting. Verbal presentations and written comments should be limited to the subject of safety in NASA. Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID, before receiving an access badge. Foreign nationals attending this meeting will be required to provide a copy of their passport, visa, or green card in addition to providing the following information no less than 10 working days prior to the meeting: Full name; gender; date/place of birth; citizenship; visa/green card information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee. To expedite admittance, attendees with U.S. citizenship can provide identifying information 3 working days in advance

by contacting Susan Burch via e-mail at susan.burch@nasa.gov or by telephone at (202) 358-0550.

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

May 2, 2011.

P. Diane Rausch,

*Advisory Committee Management Officer,
National Aeronautics and Space
Administration.*

[FR Doc. 2011-11028 Filed 5-5-11; 8:45 am]

BILLING CODE P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Advisory Committee on Presidential Library-Foundation Partnerships

AGENCY: National Archives and Records Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), the National Archives and Records Administration (NARA) announces a meeting of the Advisory Committee on Presidential Library-Foundation Partnerships. The meeting will be held to discuss the reorganization of the National Archives as they relate to Presidential Libraries, Social Media Initiatives, Processing of Presidential materials, and the Advancement of Library-Foundation Partnerships.

DATES: The meeting will be held on June 9, 2011 from 9 a.m. to 12 noon.

ADDRESSES: Hay-Adams Hotel Ballroom at 800 16th Street, NW., Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Sharon Fawcett, Assistant Archivist for Presidential Libraries, at the National Archives and Records Administration, 8601 Adelphi Road, College Park, Maryland 20740, telephone number (301) 837-3250. Contact the Presidential Libraries staff at Kathleen.mead@nara.gov.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public. Valet parking is available at the hotel and there are commercial parking lots and metered curb parking nearby. The Hay-Adams is convenient to the McPherson Square and Farragut West Metro stations.

Dated: May 3, 2011.

Mary Ann Hadyka,

Committee Management Officer.

[FR Doc. 2011-11207 Filed 5-5-11; 8:45 am]

BILLING CODE 7515-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC-2011-0092]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The NRC invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* NRC Form 536, "Operator Licensing Examination Data."

2. *Current OMB approval number:* 3150-0131.

3. *How often the collection is required:* Annually.

4. *Who is required or asked to report:* All holders of operating licenses for nuclear power reactors under the provision of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel, and all holders of or applicants for a limited work authorization, early site permits, or combined license issued under 10 CFR Part 52, "Licenses, Certifications and Approval for Nuclear Power Plants."

5. *The number of annual respondents:* 110.

6. *The number of hours needed annually to complete the requirement or request:* 110.

7. *Abstract:* The NRC is requesting renewal of its clearance to annually request all commercial power reactor licensees and applicants for an operating license to voluntarily send to the NRC: (1) Their projected number of candidates for initial operator licensing examinations; (2) the estimated dates of the examinations; (3) if the examinations will be facility developed or NRC developed; and (4) the estimated number of individuals that will participate in the Generic Fundamentals Examination (GFE) for that calendar

year. Except for the GFE, this information is used to plan budgets and resources in regard to operator examination scheduling in order to meet the needs of the nuclear power industry.

Submit, by July 5, 2011, comments that address the following questions

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

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 Web site: <http://www.nrc.gov/public-involve/doc-comment/omb/index.html>. The document will be available on the NRC Web 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-2011-0092. 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-2011-0092. Mail comments to NRC Clearance Officer, Tremaine Donnell (T-5F53), 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-5F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by telephone at 301-415-6258, or by e-mail to INFOCOLLECTS.Resource@NRC.GOV.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2011-11010 Filed 5-5-11; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC-2011-0053]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The NRC invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* Notice of Enforcement Discretion (NOEDs) for Operating Power Reactors and Gaseous Diffusion Plants (GDP) (NRC Enforcement Policy).

2. *Current OMB approval number:* 3150-0136.

3. *How often the collection is required:* On occasion.

4. *Who is required or asked to report:* Nuclear power reactor licensees and gaseous diffusion plant certificate holders.

5. *The number of annual respondents:* Approximately 11.

6. *The number of hours needed annually to complete the requirement or request:* 1,705.

7. *Abstract:* The NRC's Enforcement Policy addresses circumstances in which the NRC may exercise enforcement discretion. A specific type of enforcement discretion is designated as a NOED and relates to circumstances which may arise where a nuclear power plant licensee's compliance with a Technical Specification Limiting Condition for Operation or other license conditions would involve: (1) An unnecessary plant shutdown; (2) performance of testing, inspection, or system realignment that is inappropriate for the specific plant conditions; or (3) unnecessary delays in plant startup without a corresponding health and safety benefit. Similarly, for a gaseous diffusion plant, circumstances may arise where compliance with a Technical Safety Requirement or other condition would unnecessarily require a total plant shutdown, or, compliance would unnecessarily place the plant in a

condition where safety, safeguards, or security features were degraded or inoperable.

A licensee or certificate holder seeking the issuance of a NOED, must document the safety basis for the request, including: An evaluation of the safety significance and potential consequences of the proposed request, a description of proposed compensatory measures, a justification for the duration of the request, the basis for the licensee's or certificate holder's conclusion that the request does not have a potential adverse impact on the public health and safety, that there will be no adverse consequences to the environment, and any other information the NRC staff deems necessary before the NRC staff makes a decision whether to exercise discretion.

In addition, the NRC's Enforcement Policy includes a provision allowing licensees to voluntarily adopt fire protection requirements contained in the National Fire Protection Association Standard 805, "Performance Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants, 2001 Edition" (NFPA 805). Licensees who wish to implement the risk-informed process in NFPA 805 must submit a letter of intent (LOI) to the NRC. Licensees who wish to withdraw from the NFPA 805 risk-informed process must submit a letter of retraction.

Submit, by July 5, 2011, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the burden estimate accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

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 Web site: <http://www.nrc.gov/public-involve/doc-omment/omb/index.html>. The document will be available on the NRC Web 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-2011-0053. 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-2011-0053. Mail comments to NRC Clearance Officer, Tremaine Donnell (T-5F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Questions about the information collection requirements may be directed to the NRC Clearance Officer, Tremaine Donnell (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by telephone at 301-415-6258, or by email to INFOCOLLECTS.Resource@NRC.GOV.

For the Nuclear Regulatory Commission.
Tremaine Donnell,
NRC Clearance Officer, Office of Information Services.

[FR Doc. 2011-11110 Filed 5-5-11; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC-2011-0092]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The NRC invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* NRC Form 536, "Operator Licensing Examination Data."

2. *Current OMB approval number:* 3150-0131.

3. *How often the collection is required:* Annually.

4. *Who is required or asked to report:* All holders of operating licenses for nuclear power reactors under the

provision of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel, and all holders of or applicants for a limited work authorization, early site permits, or combined license issued under 10 CFR Part 52, "Licenses, Certifications and Approval for Nuclear Power Plants."

5. *The number of annual respondents:* 110.

6. *The number of hours needed annually to complete the requirement or request:* 110.

7. *Abstract:* The NRC is requesting renewal of its clearance to annually request all commercial power reactor licensees and applicants for an operating license to voluntarily send to the NRC: (1) Their projected number of candidates for initial operator licensing examinations; (2) the estimated dates of the examinations; (3) if the examinations will be facility developed or NRC developed; and (4) the estimated number of individuals that will participate in the Generic Fundamentals Examination (GFE) for that calendar year. Except for the GFE, this information is used to plan budgets and resources in regard to operator examination scheduling in order to meet the needs of the nuclear power industry.

Submit, by July 5, 2011, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the burden estimate accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

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 Web site: <http://www.nrc.gov/public-involve/doc-comment/omb/index.html>. The document will be available on the NRC Web 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-2011-0092. 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-2011-0092. Mail comments to NRC Clearance Officer, Tremaine Donnell (T-5F53), 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-5F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by telephone at 301-415-6258, or by e-mail to INFOCOLLECTS.Resource@NRC.GOV.

For the Nuclear Regulatory Commission.
Tremaine Donnell,
NRC Clearance Officer, Office of Information Services.

[FR Doc. 2011-11109 Filed 5-5-11; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC-2011-0053]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The NRC invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* Notice of Enforcement Discretion (NOEDs) for Operating Power Reactors and Gaseous Diffusion Plants (GDP) (NRC Enforcement Policy).
2. *Current OMB approval number:* 3150-0136.
3. *How often the collection is required:* On occasion.
4. *Who is required or asked to report:* Nuclear power reactor licensees and

gaseous diffusion plant certificate holders.

5. *The number of annual respondents:* Approximately 11.

6. *The number of hours needed annually to complete the requirement or request:* 1,705.

7. *Abstract:* The NRC's Enforcement Policy addresses circumstances in which the NRC may exercise enforcement discretion. A specific type of enforcement discretion is designated as a NOED and relates to circumstances which may arise where a nuclear power plant licensee's compliance with a Technical Specification Limiting Condition for Operation or other license conditions would involve: (1) An unnecessary plant shutdown; (2) performance of testing, inspection, or system realignment that is inappropriate for the specific plant conditions; or (3) unnecessary delays in plant startup without a corresponding health and safety benefit. Similarly, for a gaseous diffusion plant, circumstances may arise where compliance with a Technical Safety Requirement or other condition would unnecessarily require a total plant shutdown, or, compliance would unnecessarily place the plant in a condition where safety, safeguards, or security features were degraded or inoperable.

A licensee or certificate holder seeking the issuance of a NOED, must document the safety basis for the request, including: An evaluation of the safety significance and potential consequences of the proposed request, a description of proposed compensatory measures, a justification for the duration of the request, the basis for the licensee's or certificate holder's conclusion that the request does not have a potential adverse impact on the public health and safety, that there will be no adverse consequences to the environment, and any other information the NRC staff deems necessary before the NRC staff makes a decision whether to exercise discretion.

In addition, the NRC's Enforcement Policy includes a provision allowing licensees to voluntarily adopt fire protection requirements contained in the National Fire Protection Association Standard 805, "Performance Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants, 2001 Edition" (NFPA 805). Licensees who wish to implement the risk-informed process in NFPA 805 must submit a letter of intent (LOI) to the NRC. Licensees who wish to withdraw from the NFPA 805 risk-informed process must submit a letter of retraction.

Submit, by July 5, 2011, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the burden estimate accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

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 Web site: <http://www.nrc.gov/public-involve/doc-comment/omb/index.html>. The document will be available on the NRC Web 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-2011-0053. 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-2011-0053. Mail comments to NRC Clearance Officer, Tremaine Donnell (T-5F53), 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-5F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by telephone at 301-415-6258, or by e-mail to INFOCOLLECTS.Resource@NRC.GOV.

For the Nuclear Regulatory Commission,
Tremaine Donnell,
NRC Clearance Officer, Office of Information Services.

[FR Doc. 2011-11011 Filed 5-5-11; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2011-0071; Docket No. 50-382]

Entergy Operations, Inc.; Biweekly Notice; Notice of Issuance of Amendment to Facility Operating License; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of issuance of amendment; correction.

SUMMARY: This document corrects a notice appearing in the **Federal Register** on April 5, 2011 (76 FR 18806) that incorrectly excluded the date of a supplement to the amendment request. This action is necessary to correct a missing date on the notice of issuance of amendment.

FOR FURTHER INFORMATION CONTACT: Nageswaran Kalyanam, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone (301) 415-1480, e-mail: kaly.kalyanam@nrc.gov.

SUPPLEMENTARY INFORMATION: On page 18806, appearing near the top of the first column under the subheading "Date of amendment request," fourth line, it is corrected to read from "January 4 and March 7, 2011" to "January 4, March 7, and March 18, 2011".

Dated in Rockville, Maryland, this 27th day of April 2011.

For the Nuclear Regulatory Commission,
Nageswaran Kalyanam,
Project Manager, Plant Licensing Branch IV, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2011-11107 Filed 5-5-11; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-243; NRC-2010-0044]

Nextera Energy Seabrook, LLC; Notice of Withdrawal of Application for Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission or NRC) has granted the request of NextEra Energy Seabrook, LLC (the licensee), to withdraw its January 27, 2011, application for proposed amendment to Facility Operating License No. NPF-86 for Seabrook Station, Unit No. 1 (Seabrook), located in Rockingham County, New Hampshire.

The proposed amendment would have revised Seabrook Technical

Specification Sections 6.7.6.k and 6.8.1.7 to allow an alternate repair criteria during inspection of the steam generators. The amendment application dated January 27, 2011, is available in the Agencywide Documents Access and Management System (ADAMS) Accession No. ML110330202.

The Commission had previously issued a Notice of Consideration of Issuance of Amendment published in the **Federal Register** on March 1, 2011 (76 FR 11291), and March 22, 2011 (76 FR 16009). However, by letter dated April 19, 2011, (ADAMS Accession No. ML11112A024) the licensee withdrew the proposed change.

For further details with respect to this action, see the application for amendment dated January 27, 2011, and the licensee's letter dated April 19, 2011, which withdrew the application for license amendment. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the internet at the NRC Web site, <http://www.nrc.gov/reading-rm/adams.html>. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1-800-397-4209, or 301-415-4737 or by email to pdr.resource@nrc.gov.

Dated at Rockville, Maryland, this 2nd day of May 2011.

For the Nuclear Regulatory Commission.

G. Edward Miller,
Project Manager, Plant Licensing Branch I-2, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2011-11114 Filed 5-5-11; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2009-0481]

Draft Regulatory Guide: Reissuance and Availability

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Reissuance and Availability of Draft Regulatory Guide, DG-1217 "Protection Against Turbine Missiles."

SUMMARY: On November 2, 2009 (74 FR 56672), the U.S. Nuclear Regulatory

Commission (NRC) published a notice of issuance and availability of Draft Regulatory Guide (DG)—1217, “Protection Against Turbine Missiles.” The guide is being reissued to allow further public review and comment following additional changes to the document.

FOR FURTHER INFORMATION CONTACT:

Simon Sheng, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–2280, e-mail Simon.Sheng@nrc.gov or R.A. Jervey, telephone: 301–251–7404, e-mail Richard.Jervey@nrc.gov

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is reissuing for public comment a draft guide in the agency’s “Regulatory Guide” series. This series was developed to describe and make available to the public such information as methods that are acceptable to the NRC staff for implementing specific parts of the NRC’s regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

General Design Criterion 4, “Environmental and Dynamic Effects Design Bases,” of Appendix A, “General Design Criteria for Nuclear Power Plants,” to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities,” requires, in part, that structures, systems, and components important to safety be appropriately protected against the effects of missiles that might result from equipment failures. Failures that could occur in the large steam turbines of the main turbine-generator sets have the potential for producing large high-energy missiles.

This guide describes methods acceptable to the NRC staff for protecting structures, systems, and components (SSCs) against missiles resulting from turbine failure by the appropriate orientation and placement of the turbine-generator set, the management of the probability of turbine missile generation, and the use of missile barriers. The guide also identifies SSCs to be considered in designing protection from turbine missiles.

The draft regulatory guide (DG) is temporarily identified by its task number, DG–1217, which should be mentioned in all related correspondence. DG–1217 is proposed Revision 2 of Regulatory Guide 1.115,

Revision 1, dated July 1977, “Protection Against Turbine Missiles.” DG–1217 was previously issued for comment November 2, 2009 (74 FR 56672). The draft guide is being reissued to allow further public review and comment following additional changes to the document. DG–1217 now identifies that applicants who choose to use a risk informed approach to demonstrate adequate protection against turbine missiles would be considered on a case-by-case basis. Additionally, DG–1217 uses the term ‘essential’, instead of the term ‘safety related’ to define affected SSCs.

Previously received public comments and the staff’s consideration may be reviewed electronically under the NRC’s Agencywide Documents Access and Management System (ADAMS) Accession Number ML101660585.

II. Further Information

The NRC staff is soliciting comments on DG–1217. Comments may be accompanied by relevant information or supporting data and should mention DG–1217 in the subject line. Comments submitted in writing or in electronic form will be made available to the public in their entirety through the NRC’s Agencywide Documents Access and Management System (ADAMS).

ADDRESSES: You may submit comments by any one of the following methods. Please include Docket ID NRC–2009–0481 in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking website www.regulations.gov. 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.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

Federal Rulemaking Web site: Go to <http://www.regulations.gov> and search for documents filed under Docket ID NRC–2009–0481. Address questions about NRC dockets to Carol Gallagher 301–492–3668; e-mail Carol.Gallagher@nrc.gov.

Mail comments to: Cindy K. Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of

Administration, *Mail Stop:* TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by fax to RADB at 301–492–3446.

You can access publicly available documents related to this notice using the following methods:

NRC’s Public Document Room (PDR): The public may examine and copy for a fee publicly available documents at the NRC’s PDR, Room O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

NRC’s Agencywide Documents Access and Management System (ADAMS): Publicly available documents created or received at the NRC are available electronically at the NRC’s Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this page, the public can gain entry into ADAMS, which provides text and image files of NRC’s public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC’s PDR reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to pdr.resource@nrc.gov. The Regulatory Analysis is available electronically under ADAMS Accession Number ML103350166.

Comments would be most helpful if received by June 3, 2011. Comments received after that date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

Electronic copies of DG–1217 are available through the NRC’s public Web site under Draft Regulatory Guides in the “Regulatory Guides” collection of the NRC’s Electronic Reading Room at <http://www.nrc.gov/reading-rm/doc-collections/>. Electronic copies are also available in ADAMS (<http://www.nrc.gov/reading-rm/adams.html>), under Accession No. ML103350136.

Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

Dated: Dated at Rockville, Maryland, this 28th day of April, 2011.

For the Nuclear Regulatory Commission.

Harriet Karagiannis,

Acting Chief, Regulatory Guide Development Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2011–11108 Filed 5–5–11; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 030-02278; NRC-2011-0086]

Curators of the University of Missouri, Columbia, MO, Pickard Hall; License Amendment Request, Opportunity To Provide Comments, Request a Hearing and To Petition for Leave To Intervene

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of amendment and opportunity to provide comments, request a hearing, and to petition for leave to intervene.

DATES: Submit comments by July 5, 2011. Requests for a hearing or leave to intervene must be filed by July 5, 2011.

ADDRESSES: Please include Docket ID NRC-2011-0086 in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site, <http://www.regulations.gov>. 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.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed. You may submit comments by any one of the following methods:

- *Federal Rulemaking Web Site:* Go to <http://www.regulations.gov> and search for documents filed under Docket ID NRC-2011-0086. Address questions about NRC dockets to Carol Gallagher, telephone: 301-492-3668; e-mail: Carol.Gallagher@nrc.gov.

- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB-05-B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

- *Fax comments to:* RADB at 301-492-3446.

You can access publicly available documents related to this notice using the following methods:

- *NRC's Public Document Room (PDR):* The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, O1-F21,

One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* Publicly available documents created or received at the NRC are available online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The Request for Pickard Hall Alternate Decommissioning Schedule is available electronically under ADAMS Accession Number ML110540477.

- *Federal Rulemaking Web site:* Public comments and supporting materials related to this notice can be found at <http://www.regulations.gov> by searching on Docket ID: NRC-2011-0086.

FOR FURTHER INFORMATION CONTACT:

Katie Streit, Project Manager, Materials Control, ISFSI, and Decommissioning Branch, Division of Nuclear Materials Safety, Region III, U.S. Nuclear Regulatory Commission, Lisle, IL 60532. Telephone: 630-829-9621; fax number: 630-515-1259; e-mail: Katherine.Streit@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Nuclear Regulatory Commission (NRC) has received, by letter dated February 17, 2011, a license amendment application from the Curators of the University of Missouri (licensee) requesting an alternate schedule for decommissioning of Pickard Hall located at the University of Missouri campus in Columbia, Missouri. (ADAMS Accession Number ML110540477) Specifically, the amendment would authorize an alternative schedule for submission of a decommissioning plan pursuant to 10 Code of Federal Regulations (CFR) Part 30.36 (g)(2), to allow for delay in beginning decommissioning due to the educational, cultural, and historical value of the facility.

An NRC administrative review, documented in a letter to Curators of the University of Missouri dated March 21, 2011, found the application acceptable to begin a technical review. (ADAMS Accession Number ML11081A022) If the NRC approves the request, the approval will be documented in an amendment to NRC License No.24-

00513-32. However, before approving the proposed amendment, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended, and the NRC's regulations. These findings will be documented in a Safety Evaluation Report and an Environmental Assessment.

II. Opportunity To Request a Hearing

Requirements for hearing requests and petitions for leave to intervene are found in 10 CFR 2.309, "Hearing Requests, Petitions to Intervene, Requirements for Standing, and Contentions." Interested persons should consult 10 CFR Part 2, section 2.309, which is available at the NRC's Public Document Room (PDR), located at O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852 (or call the PDR at 800-397-4209 or 301-415-4737). NRC regulations are also accessible online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>.

III. Petitions for Leave To Intervene

Any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding and how that interest may be affected by the results of the proceeding. The petition must provide the name, address, and telephone number of the petitioner and specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order that may be entered in the proceeding on the petitioner's interest.

A petition for leave to intervene must also include a specification of the contentions that the petitioner seeks to have litigated in the hearing. For each contention, the petitioner must provide a specific statement of the issue of law or fact to be raised or controverted, as well as a brief explanation of the basis for the contention. Additionally, the petitioner must demonstrate that the issue raised by each contention is within the scope of the proceeding and is material to the findings the NRC must make to support the granting of a license amendment in response to the application. The petition must also include a concise statement of the

alleged facts or expert opinions which support the position of the petitioner and on which the petitioner intends to rely at hearing, together with references to the specific sources and documents on which the petitioner intends to rely. Finally, the petition must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact, including references to specific portions of the application for amendment that the petitioner disputes and the supporting reasons for each dispute, or, if the petitioner believes that the application for amendment fails to contain information on a relevant matter as required by law, the identification of each failure and the supporting reasons for the petitioner's belief. Each contention must be one that, if proven, would entitle the petitioner to relief.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with NRC regulations, policies, and procedures. The Atomic Safety and Licensing Board will set the time and place for any prehearing conferences and evidentiary hearings, and the appropriate notices will be provided.

Non-timely petitions for leave to intervene and contentions, amended petitions, and supplemental petitions will not be entertained absent a determination by the Commission, the Atomic Safety and Licensing Board or a Presiding Officer that the petition should be granted and/or the contentions should be admitted based upon a balancing of the factors specified in 10 CFR 2.309(c)(1)(i)-(viii).

A State, county, municipality, Federally recognized Indian Tribe, or agencies thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(d)(2). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by July 5, 2011. The petition must be filed in accordance with the filing instructions in section IV of this document, and should meet the requirements for petitions for leave to intervene set forth in this section, except that State and Federally recognized Indian tribes do not need to address the standing requirements in 10 CFR 2.309(d)(1) if

the facility is located within its boundaries. The entities listed above could also seek to participate in a hearing as a nonparty pursuant to 10 CFR 2.315(c).

Any person who does not wish, or is not qualified, to become a party to this proceeding may request permission to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of position on the issues, but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to such limits and conditions as may be imposed by the Atomic Safety and Licensing Board. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission by July 5, 2011.

IV. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule (72 FR 49139, August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the Internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten (10) days prior to the filing deadline, the participant should contact the Office of the Secretary by e-mail at hearing.docket@nrc.gov, or by telephone at 301-415-1677, to request (1) a digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the

Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/apply-certificates.html>. System requirements for accessing the E-Submittal server are detailed in NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through EIE, users will be required to install a Web browser plug-in from the NRC Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The E-Filing system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they

can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the "Contact Us" link located on the NRC Web site at <http://www.nrc.gov/site-help/e-submittals.html>, by e-mail at MSHD.Resource@nrc.gov, or by a toll-free call at 866-672-7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

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constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Petitions for leave to intervene must be filed no later than 60 days from May 6, 2011. Non-timely filings will not be entertained absent a determination by the presiding officer that the petition or request should be granted or the contentions should be admitted, based on a balancing of the factors specified in 10 CFR 2.309(c)(1)(i)-(viii).

Dated at Lisle, Illinois, this 13th day of April 2011.

For the Nuclear Regulatory Commission.

Christine Lipa,

Chief, Materials Control, ISFSI, and Decommissioning Branch, Division of Nuclear Materials Safety, Region III.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-64373/April 29, 2011]

Order Making Fiscal Year 2012 Annual Adjustments to Section 31 Fee Rates

I. Background

Section 31 of the Securities Exchange Act of 1934 ("Exchange Act") requires each national securities exchange and national securities association to pay transaction fees to the Commission.¹ Specifically, Section 31(b) requires each national securities exchange to pay to the Commission fees based on the aggregate dollar amount of sales of certain securities transacted on the exchange.² Section 31(c) requires each national securities association to pay to the Commission fees based on the aggregate dollar amount of sales of certain securities transacted by or through any member of the association other than on an exchange.³

The Investor and Capital Markets Fee Relief Act ("Fee Relief Act")⁴ amended Section 31 of the Exchange Act to require the Commission to make annual adjustments to the fee rates applicable under this section for each of the fiscal years 2003 through 2011, and one final adjustment to fix the fee rates under these sections for fiscal year 2012 and beyond.⁵

¹ 15 U.S.C. 78ee.

² 15 U.S.C. 78ee(b).

³ 15 U.S.C. 78ee(c).

⁴ Public Law 107-123, 115 Stat. 2390 (2002).

⁵ See 15 U.S.C. 77f(b)(5), 77f(b)(6), 78m(e)(5), 78m(e)(6), 78n(g)(5), 78n(g)(6), 78ee(j)(1), and 78ee(j)(3). Section 31(j)(2) of the Exchange Act, 15 U.S.C. 78ee(j)(2), also requires the Commission, in

II. Fiscal Year 2012 Annual Adjustment to the Fee Rates Applicable Under Sections 31(b) and (c) of the Exchange Act

Section 31(b) of the Exchange Act requires each national securities exchange to pay the Commission a fee at a rate, as adjusted by our order pursuant to Section 31(j)(1),⁶ which currently is \$19.20 per million of the aggregate dollar amount of sales of specified securities transacted on the exchange. Similarly, Section 31(c) requires each national securities association to pay the Commission a fee at the same adjusted rate on the aggregate dollar amount of sales of specified securities transacted by or through any member of the association otherwise than on an exchange. Section 31(j)(1) requires the Commission to make annual adjustments to the fee rates applicable under Sections 31(b) and (c) for each of the fiscal years 2003 through 2011.⁷ Section 31(j)(3) requires the Commission to make one final adjustment for fiscal year 2012.⁸

Section 31(j)(3) specifies the method for determining the annual adjustment for fiscal year 2012. Specifically, the Commission must adjust the rates under Sections 31(b) and (c) to a "uniform adjusted rate that, when applied to the baseline estimate of the aggregate dollar amount of sales for fiscal year 2012, is reasonably likely to produce aggregate fee collections under [Section 31] in

specified circumstances, to make a mid-year adjustment to the fee rates under Sections 31(b) and (c) of the Exchange Act in fiscal years 2002 through 2011.

⁶ Order Making Fiscal Year 2011 Annual Adjustments to the Fee Rates Applicable under Section 6(b) of the Securities Act of 1933 and Sections 13(e), 14(g), 31(b) and 31(c) of the Securities Exchange Act of 1934, Rel. No. 33-9122 (April 29, 2010), 75 FR 24757 (May 5, 2010).

⁷ The annual adjustments, as well as the mid-year adjustments required in specified circumstances under Section 31(j)(2) in fiscal years 2002 through 2011, are designed to adjust the fee rates in a given fiscal year so that, when applied to the aggregate dollar volume of sales for the fiscal year, they are reasonably likely to produce total fee collections under Section 31 equal to the "target offsetting collection amount" specified in Section 31(l)(1) for that fiscal year.

⁸ The final adjustment for fiscal year 2012 is designed to adjust the fee rate in 2012 and subsequent years so that, when applied to the aggregate dollar volume of sales for fiscal year 2012, it is reasonably like to produce total fee collections under Section 31 equal to the "target offsetting collection amount" for fiscal year 2011. Note, however, that Section 31 will be amended by the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank Act") effective on the later of October 1, 2011 or the date of enactment of an Act making a regular appropriation to the Commission for fiscal year 2012. Once the amendments become effective, the Commission will be required to make a new adjustment to the fee rates under Section 31 for fiscal year 2012 and subsequent fiscal years.

fiscal year 2012 (including assessments collected under [Section 31(d)]) that are equal to the target offsetting collection amount for fiscal year 2011.”

Section 31(j)(1) specifies that the “target offsetting collection amount” for fiscal year 2011 is \$1,321,000,000. Section 31(j)(2) defines the “baseline estimate of the aggregate dollar amount of sales” as “the baseline estimate of the aggregate dollar amount of sales of securities * * * to be transacted on each national securities exchange and by or through any member of each national securities association (otherwise than on a national securities exchange) during fiscal year 2012 as determined by the Commission, after consultation with the Congressional Budget Office and the Office of Management and Budget. * * *”

To make the baseline estimate of the aggregate dollar amount of sales for fiscal year 2012, the Commission is using the same methodology it developed in consultation with the CBO and OMB to project dollar volume for purposes of prior fee adjustments.⁹ Using this methodology, the Commission calculates the baseline estimate of the aggregate dollar amount of sales for fiscal year 2012 to be \$85,673,432,736,834. Based on this estimate, and an estimated collection of \$27,453 in assessments on security futures transactions under Section 31(d) in fiscal year 2012, the uniform adjusted rate for fiscal year 2012 is \$15.10 per million.¹⁰

III. Effective Dates of the Annual Adjustments

Section 31(j)(4)(A) of the Exchange Act provides that the fiscal year 2012 annual adjustments to the fee rates applicable under Sections 31(b) and (c) of the Exchange Act shall take effect on the later of October 1, 2011, or 30 days after the date on which a regular appropriation to the Commission for fiscal year 2012 is enacted.

It is important to note, however, that Section 991 of the Dodd-Frank Act amends Section 31 of the Exchange Act effective on the later of October 1, 2011 or the date of enactment of an Act

making a regular appropriation to the Commission for fiscal year 2012. Once, the amendments become effective, new lapse in appropriations provisions will apply such that, if a regular appropriation to the Commission for fiscal year 2012 is not enacted on or before October 1, 2011, the new fee rates will not become effective until 60 days after the date such a regular appropriation is enacted.

Moreover, once the amendments to Section 31 become effective, the Commission will be required to make a new adjustment to the fee rates under Section 31 for fiscal year 2012. The new fee rates will be determined no later than 30 days after the date on which an Act making a regular appropriation to the Commission for fiscal year 2012 is enacted,¹¹ and they will become effective on the later of October 1, 2011 or 60 days after the date such a regular appropriation is enacted.

As a result of these amendments, if a regular appropriation to the Commission for fiscal year 2012 is not enacted on or before October 1, 2011, the fee rate adjustments under this order will never become effective. Rather the fee rate adjustments for fiscal year 2012 will be determined in accordance with the amendments to Section 31 made by the Dodd-Frank Act and will become effective 60 days after the date such a regular appropriation is enacted.

IV. Conclusion

Accordingly, pursuant to Section 31 of the Exchange Act,¹²

It is hereby ordered that, if a regular appropriation to the Commission for fiscal year 2012 is enacted on or before October 1, 2011, the fee rates applicable under Sections 31(b) and (c) of the Exchange Act shall be \$15.10 per million effective on the later of October 1, 2011, or 30 days after the date on which a regular appropriation to the Commission for fiscal year 2012 is enacted.

By the Commission.

Cathy H. Ahn,
Deputy Secretary.

Appendix A

With the passage of the Investor and Capital Markets Relief Act, Congress has, among other things, established a target amount of monies to be collected from fees charged to investors based on

the value of their transactions. This appendix provides the formula for determining such fees, which the Commission adjusts annually, and may adjust semi-annually.¹³ In order to maximize the likelihood that the amount of monies targeted by Congress will be collected, the fee rate must be set to reflect projected dollar transaction volume on the securities exchanges and certain over-the-counter markets over the course of the year. As a percentage, the fee rate equals the ratio of the target amounts of monies to the projected dollar transaction volume.

For 2012, the Commission has estimated dollar transaction volume by projecting forward the trend established in the previous decade. More specifically, dollar transaction volume was forecasted for months subsequent to March 2011, the last month for which the Commission has data on transaction volume.

The following sections describe this process in detail.

A. Baseline Estimate of the Aggregate Dollar Amount of Sales for Fiscal Year 2012

First, calculate the average daily dollar amount of sales (ADS) for each month in the sample (March 2001—March 2011). The monthly aggregate dollar amount of sales (exchange plus certain over-the-counter markets) is presented in column C of Table B.

Next, calculate the change in the natural logarithm of ADS from month to month. The average monthly percentage growth of ADS over the entire sample is 0.0074 and the standard deviation is 0.123. Assuming the monthly percentage change in ADS follows a random walk, calculating the expected monthly percentage growth rate for the full sample is straightforward. The expected monthly percentage growth rate of ADS is 1.5%.

Now, use the expected monthly percentage growth rate to forecast total dollar volume. For example, one can use the ADS for March 2011 (\$282,580,668,926) to forecast ADS for April 2011 (\$286,849,029,708 = \$282,580,668,926 × 1.015).¹⁴ Multiply by the number of trading days in April 2011 (20) to obtain a forecast of the total dollar volume for the month (\$5,736,980,594,157). Repeat the

⁹ Appendix A explains how we determined the “baseline estimate of the aggregate dollar amount of sales” for fiscal year 2012 using our methodology, and then shows the purely arithmetical process of calculating the fiscal year 2012 annual adjustment based on that estimate. The appendix also includes the data used by the Commission in making its “baseline estimate of the aggregate dollar amount of sales” for fiscal year 2012.

¹⁰ The calculation of the adjusted fee rate assumes that the current fee rate of \$19.20 per million will apply through October 31, 2012, due to the operation of the effective date provision contained in Section 31(j)(4)(A) of the Exchange Act.

¹¹ In the event an Act making a regular appropriation to the Commission for fiscal year 2012 is enacted more than 30 days prior to October 1, 2011, the Commission will need to defer making a new adjustment until October 1, 2011, because the amendments requiring the new adjustment will not be effective until that date.

¹² 15 U.S.C. 77f(b), 78m(e), 78n(g), and 78ee(j).

¹³ Congress requires that the Commission make a mid-year adjustment to the fee rate if four months into the fiscal year it determines that its forecasts of aggregate dollar volume are reasonably likely to be off by 10% or more.

¹⁴ The value 1.015 has been rounded. All computations are done with the unrounded value.

method to generate forecasts for subsequent months.

The forecasts for total dollar volume are in column G of Table A. The following is a more formal (mathematical) description of the procedure:

1. Divide each month's total dollar volume (column C) by the number of trading days in that month (column B) to obtain the average daily dollar volume (ADS, column D).

2. For each month t , calculate the change in ADS from the previous month as $\Delta_t = \log(ADS_t/ADS_{t-1})$, where $\log(x)$ denotes the natural logarithm of x .

3. Calculate the mean and standard deviation of the series $\{\Delta_1, \Delta_2, \dots, \Delta_{120}\}$. These are given by $\mu = 0.0074$ and $\sigma = 0.123$, respectively.

4. Assume that the natural logarithm of ADS follows a random walk, so that Δ_s and Δ_t are statistically independent for any two months s and t .

5. Under the assumption that Δ_t is normally distributed, the expected value

of ADS_t/ADS_{t-1} is given by $\exp(\mu + \sigma^2/2)$, or on average $ADS_t = 1.015 \times ADS_{t-1}$.

6. For April 2011, this gives a forecast ADS of $1.015 \times \$282,580,668,926 = \$286,849,029,708$. Multiply this figure by the 20 trading days in April 2011 to obtain a total dollar volume forecast of \$5,736,980,594,157.

7. For May 2011, multiply the April 2011 ADS forecast by 1.015 to obtain a forecast ADS of \$291,181,863,773. Multiply this figure by the 21 trading days in May 2011 to obtain a total dollar volume forecast of \$6,114,819,139,242.

8. Repeat this procedure for subsequent months.

B. Using the Forecasts From A to Calculate the New Fee Rate

1. Use Table A to estimate fees collected for the period 10/1/11 through 10/31/11. The projected aggregate dollar amount of sales for this period is \$6,590,802,501,369. Projected fee collections at the current fee rate of 0.0000192 are \$126,543,408.

2. Estimate the amount of assessments on securities futures products collected during 10/1/11 and 9/30/12 to be \$27,453 by projecting a 1.5% monthly increase from a base of \$1,960 in March 2011.

3. Subtract the amounts \$126,543,408 and \$27,453 from the target offsetting collection amount set by Congress of \$1,321,000,000 leaving \$1,194,429,139 to be collected on dollar volume for the period 11/1/11 through 9/30/12.

4. Use Table A to estimate dollar volume for the period 11/1/11 through 9/30/12. The estimate is \$79,082,630,235,466. Finally, compute the fee rate required to produce the additional \$1,194,429,139 in revenue. This rate is \$1,194,429,139 divided by \$79,082,630,235,466 or 0.0000151036.

5. Round the result to the seventh decimal point, yielding a rate of .0000151 (or \$15.10 per million).

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Table A. Estimation of baseline of the aggregate dollar amount of sales.

Fee rate calculation.

| | |
|--|------------|
| a. Baseline estimate of the aggregate dollar amount of sales, 10/1/11 to 10/31/11 (\$Millions) | 6,590,803 |
| b. Baseline estimate of the aggregate dollar amount of sales, 11/1/11 to 9/30/12 (\$Millions) | 79,082,630 |
| c. Estimated collections in assessments on securities futures products in FY 2012 (\$Millions) | 0.027 |
| d. Implied fee rate $((\$1,321,000,000 - 0.0000192 * a - c) / b)$ | \$15.10 |

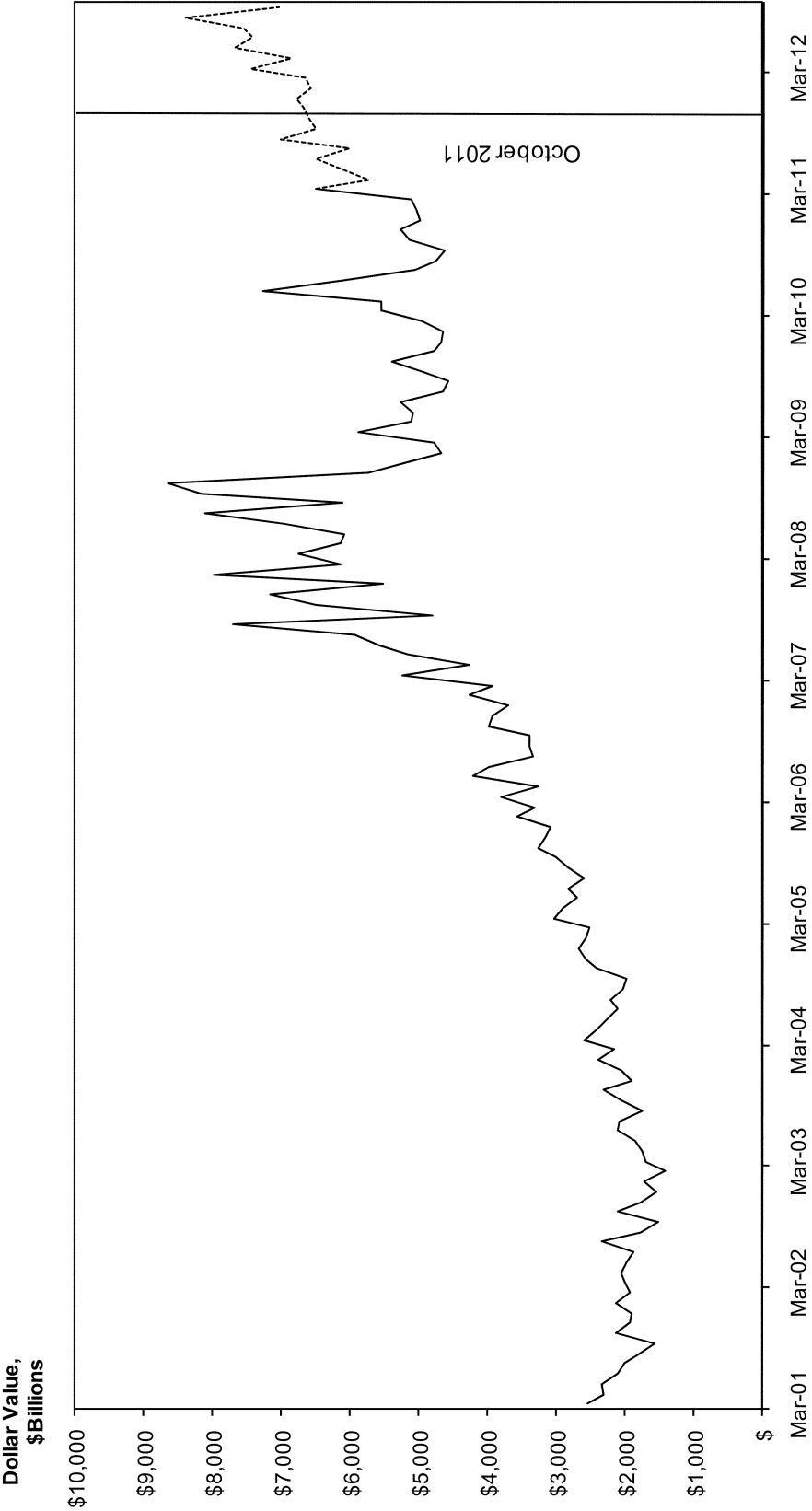
Data

| (A) Month | (B) # of Trading Days in Month | (C) Aggregate Dollar Amount of Sales | (D) Average Daily Dollar Amount of Sales (ADS) | (E) Change in LN of ADS | (F) Forecast ADS | (G) Forecast Aggregate Dollar Amount of Sales |
|--------------|--------------------------------------|--|---|-------------------------------|---------------------|--|
| Mar-01 | 22 | 2,554,419,085,113 | 116,109,958,414 | - | | |
| Apr-01 | 20 | 2,324,349,507,745 | 116,217,475,387 | 0.001 | | |
| May-01 | 22 | 2,353,179,388,303 | 106,962,699,468 | -0.083 | | |
| Jun-01 | 21 | 2,111,922,113,236 | 100,567,719,678 | -0.062 | | |
| Jul-01 | 21 | 2,004,384,034,554 | 95,446,858,788 | -0.052 | | |
| Aug-01 | 23 | 1,803,565,337,795 | 78,415,884,252 | -0.197 | | |
| Sep-01 | 15 | 1,573,484,946,383 | 104,898,996,426 | 0.291 | | |
| Oct-01 | 23 | 2,147,238,873,044 | 93,358,211,871 | -0.117 | | |
| Nov-01 | 21 | 1,939,427,217,518 | 92,353,677,025 | -0.011 | | |
| Dec-01 | 20 | 1,921,098,738,113 | 96,054,936,906 | 0.039 | | |
| Jan-02 | 21 | 2,149,243,312,432 | 102,344,919,640 | 0.063 | | |
| Feb-02 | 19 | 1,928,830,595,585 | 101,517,399,768 | -0.008 | | |
| Mar-02 | 20 | 2,002,216,374,514 | 100,110,818,726 | -0.014 | | |
| Apr-02 | 22 | 2,062,101,866,506 | 93,731,903,023 | -0.066 | | |
| May-02 | 22 | 1,985,859,756,557 | 90,266,352,571 | -0.038 | | |
| Jun-02 | 20 | 1,882,185,380,609 | 94,109,269,030 | 0.042 | | |
| Jul-02 | 22 | 2,349,564,490,189 | 106,798,385,918 | 0.126 | | |
| Aug-02 | 22 | 1,793,429,904,079 | 81,519,541,095 | -0.270 | | |
| Sep-02 | 20 | 1,518,944,367,204 | 75,947,218,360 | -0.071 | | |
| Oct-02 | 23 | 2,127,874,947,972 | 92,516,302,086 | 0.197 | | |
| Nov-02 | 20 | 1,780,816,458,122 | 89,040,822,906 | -0.038 | | |
| Dec-02 | 21 | 1,561,092,215,646 | 74,337,724,555 | -0.180 | | |
| Jan-03 | 21 | 1,723,698,830,414 | 82,080,896,686 | 0.099 | | |
| Feb-03 | 19 | 1,411,722,405,357 | 74,301,179,229 | -0.100 | | |
| Mar-03 | 21 | 1,699,581,267,718 | 80,932,441,320 | 0.085 | | |
| Apr-03 | 21 | 1,759,751,025,279 | 83,797,667,870 | 0.035 | | |
| May-03 | 21 | 1,871,390,985,678 | 89,113,856,461 | 0.062 | | |
| Jun-03 | 21 | 2,122,225,077,345 | 101,058,337,016 | 0.126 | | |
| Jul-03 | 22 | 2,100,812,973,956 | 95,491,498,816 | -0.057 | | |
| Aug-03 | 21 | 1,766,527,686,224 | 84,120,366,011 | -0.127 | | |
| Sep-03 | 21 | 2,063,584,421,939 | 98,265,924,854 | 0.155 | | |
| Oct-03 | 23 | 2,331,850,083,022 | 101,384,786,218 | 0.031 | | |
| Nov-03 | 19 | 1,903,726,129,859 | 100,196,112,098 | -0.012 | | |
| Dec-03 | 22 | 2,066,530,151,383 | 93,933,188,699 | -0.065 | | |
| Jan-04 | 20 | 2,390,942,905,678 | 119,547,145,284 | 0.241 | | |
| Feb-04 | 19 | 2,177,765,594,701 | 114,619,241,826 | -0.042 | | |
| Mar-04 | 23 | 2,613,808,754,550 | 113,643,858,893 | -0.009 | | |
| Apr-04 | 21 | 2,418,663,760,191 | 115,174,464,771 | 0.013 | | |
| May-04 | 20 | 2,259,243,404,459 | 112,962,170,223 | -0.019 | | |
| Jun-04 | 21 | 2,112,826,072,876 | 100,610,765,375 | -0.116 | | |
| Jul-04 | 21 | 2,209,808,376,565 | 105,228,970,313 | 0.045 | | |
| Aug-04 | 22 | 2,033,343,354,640 | 92,424,697,938 | -0.130 | | |
| Sep-04 | 21 | 1,993,803,487,749 | 94,943,023,226 | 0.027 | | |
| Oct-04 | 21 | 2,414,599,088,108 | 114,980,908,958 | 0.191 | | |
| Nov-04 | 21 | 2,577,513,374,160 | 122,738,732,103 | 0.065 | | |
| Dec-04 | 22 | 2,673,532,981,863 | 121,524,226,448 | -0.010 | | |
| Jan-05 | 20 | 2,581,847,200,448 | 129,092,360,022 | 0.060 | | |
| Feb-05 | 19 | 2,532,202,408,589 | 133,273,810,978 | 0.032 | | |
| Mar-05 | 22 | 3,030,474,897,226 | 137,748,858,965 | 0.033 | | |
| Apr-05 | 21 | 2,906,386,944,434 | 138,399,378,306 | 0.005 | | |
| May-05 | 21 | 2,697,414,503,460 | 128,448,309,689 | -0.075 | | |

| | | | | | | |
|--------|----|-------------------|-----------------|--------|--|--|
| Jun-05 | 22 | 2,825,962,273,624 | 128,452,830,619 | 0.000 | | |
| Jul-05 | 20 | 2,604,021,263,875 | 130,201,063,194 | 0.014 | | |
| Aug-05 | 23 | 2,846,115,585,965 | 123,744,155,912 | -0.051 | | |
| Sep-05 | 21 | 3,009,640,645,370 | 143,316,221,208 | 0.147 | | |
| Oct-05 | 21 | 3,279,847,331,057 | 156,183,206,241 | 0.086 | | |
| Nov-05 | 21 | 3,163,453,821,548 | 150,640,658,169 | -0.036 | | |
| Dec-05 | 21 | 3,090,212,715,561 | 147,152,986,455 | -0.023 | | |
| Jan-06 | 20 | 3,573,372,724,766 | 178,668,636,238 | 0.194 | | |
| Feb-06 | 19 | 3,314,259,849,456 | 174,434,728,919 | -0.024 | | |
| Mar-06 | 23 | 3,807,974,821,564 | 165,564,122,677 | -0.052 | | |
| Apr-06 | 19 | 3,257,478,138,851 | 171,446,217,834 | 0.035 | | |
| May-06 | 22 | 4,206,447,844,451 | 191,202,174,748 | 0.109 | | |
| Jun-06 | 22 | 3,995,113,357,316 | 181,596,061,696 | -0.052 | | |
| Jul-06 | 20 | 3,339,658,009,357 | 166,982,900,468 | -0.084 | | |
| Aug-06 | 23 | 3,410,187,280,845 | 148,269,012,211 | -0.119 | | |
| Sep-06 | 20 | 3,407,409,863,673 | 170,370,493,184 | 0.139 | | |
| Oct-06 | 22 | 3,980,070,216,912 | 180,912,282,587 | 0.060 | | |
| Nov-06 | 21 | 3,933,474,986,969 | 187,308,332,713 | 0.035 | | |
| Dec-06 | 20 | 3,715,146,848,695 | 185,757,342,435 | -0.008 | | |
| Jan-07 | 20 | 4,263,986,570,973 | 213,199,328,549 | 0.138 | | |
| Feb-07 | 19 | 3,946,799,860,532 | 207,726,308,449 | -0.026 | | |
| Mar-07 | 22 | 5,245,051,744,090 | 238,411,442,913 | 0.138 | | |
| Apr-07 | 20 | 4,274,665,072,437 | 213,733,253,622 | -0.109 | | |
| May-07 | 22 | 5,172,568,357,522 | 235,116,743,524 | 0.095 | | |
| Jun-07 | 21 | 5,586,337,010,802 | 266,016,048,133 | 0.123 | | |
| Jul-07 | 21 | 5,938,330,480,139 | 282,777,641,911 | 0.061 | | |
| Aug-07 | 23 | 7,713,644,229,032 | 335,375,836,045 | 0.171 | | |
| Sep-07 | 19 | 4,805,676,596,099 | 252,930,347,163 | -0.282 | | |
| Oct-07 | 23 | 6,499,651,716,225 | 282,593,552,879 | 0.111 | | |
| Nov-07 | 21 | 7,176,290,763,989 | 341,728,131,619 | 0.190 | | |
| Dec-07 | 20 | 5,512,903,594,564 | 275,645,179,728 | -0.215 | | |
| Jan-08 | 21 | 7,997,242,071,529 | 380,821,051,025 | 0.323 | | |
| Feb-08 | 20 | 6,139,080,448,887 | 306,954,022,444 | -0.216 | | |
| Mar-08 | 20 | 6,767,852,332,381 | 338,392,616,619 | 0.098 | | |
| Apr-08 | 22 | 6,150,017,772,735 | 279,546,262,397 | -0.191 | | |
| May-08 | 21 | 6,080,169,766,807 | 289,531,893,657 | 0.035 | | |
| Jun-08 | 21 | 6,962,199,302,412 | 331,533,300,115 | 0.135 | | |
| Jul-08 | 22 | 8,104,256,787,805 | 368,375,308,537 | 0.105 | | |
| Aug-08 | 21 | 6,106,057,711,009 | 290,764,652,905 | -0.237 | | |
| Sep-08 | 21 | 8,156,991,919,103 | 388,428,186,624 | 0.290 | | |
| Oct-08 | 23 | 8,644,538,213,244 | 375,849,487,532 | -0.033 | | |
| Nov-08 | 19 | 5,727,998,341,833 | 301,473,596,939 | -0.221 | | |
| Dec-08 | 22 | 5,176,041,317,640 | 235,274,605,347 | -0.248 | | |
| Jan-09 | 20 | 4,670,249,433,806 | 233,512,471,690 | -0.008 | | |
| Feb-09 | 19 | 4,771,470,184,048 | 251,130,009,687 | 0.073 | | |
| Mar-09 | 22 | 5,885,594,284,780 | 267,527,012,945 | 0.063 | | |
| Apr-09 | 21 | 5,123,665,205,517 | 243,984,057,406 | -0.092 | | |
| May-09 | 20 | 5,086,717,129,965 | 254,335,856,498 | 0.042 | | |
| Jun-09 | 22 | 5,271,742,782,609 | 239,624,671,937 | -0.060 | | |
| Jul-09 | 22 | 4,659,599,245,583 | 211,799,965,708 | -0.123 | | |
| Aug-09 | 21 | 4,582,102,295,783 | 218,195,347,418 | 0.030 | | |
| Sep-09 | 21 | 4,929,155,364,888 | 234,721,684,042 | 0.073 | | |
| Oct-09 | 22 | 5,410,025,301,030 | 245,910,240,956 | 0.047 | | |
| Nov-09 | 20 | 4,770,928,103,032 | 238,546,405,152 | -0.030 | | |
| Dec-09 | 22 | 4,688,555,303,171 | 213,116,150,144 | -0.113 | | |
| Jan-10 | 19 | 4,661,793,708,648 | 245,357,563,613 | 0.141 | | |
| Feb-10 | 19 | 4,969,848,578,023 | 261,570,977,791 | 0.064 | | |

| | | | | | | |
|--------|----|-------------------|-----------------|--------|-----------------|-------------------|
| Mar-10 | 23 | 5,563,529,823,621 | 241,892,601,027 | -0.078 | | |
| Apr-10 | 21 | 5,546,445,874,917 | 264,116,470,234 | 0.088 | | |
| May-10 | 20 | 7,260,430,376,294 | 363,021,518,815 | 0.318 | | |
| Jun-10 | 22 | 6,124,776,349,285 | 278,398,924,967 | -0.265 | | |
| Jul-10 | 21 | 5,058,242,097,334 | 240,868,671,302 | -0.145 | | |
| Aug-10 | 22 | 4,765,828,005,840 | 216,628,545,720 | -0.106 | | |
| Sep-10 | 21 | 4,640,722,344,586 | 220,986,778,314 | 0.020 | | |
| Oct-10 | 21 | 5,138,411,712,272 | 244,686,272,013 | 0.102 | | |
| Nov-10 | 21 | 5,279,700,881,901 | 251,414,327,710 | 0.027 | | |
| Dec-10 | 22 | 4,998,574,681,208 | 227,207,940,055 | -0.101 | | |
| Jan-11 | 20 | 5,043,391,121,345 | 252,169,556,067 | 0.104 | | |
| Feb-11 | 19 | 5,114,631,590,581 | 269,191,136,346 | 0.065 | | |
| Mar-11 | 23 | 6,499,355,385,307 | 282,580,668,926 | 0.049 | | |
| Apr-11 | 20 | | | | 286,849,029,708 | 5,736,980,594,157 |
| May-11 | 21 | | | | 291,181,863,773 | 6,114,819,139,242 |
| Jun-11 | 22 | | | | 295,580,144,987 | 6,502,763,189,725 |
| Jul-11 | 20 | | | | 300,044,861,925 | 6,000,897,238,491 |
| Aug-11 | 23 | | | | 304,577,018,091 | 7,005,271,416,102 |
| Sep-11 | 21 | | | | 309,177,632,153 | 6,492,730,275,209 |
| Oct-11 | 21 | | | | 313,847,738,160 | 6,590,802,501,369 |
| Nov-11 | 21 | | | | 318,588,385,785 | 6,690,356,101,486 |
| Dec-11 | 21 | | | | 323,400,640,553 | 6,791,413,451,608 |
| Jan-12 | 20 | | | | 328,285,584,084 | 6,565,711,681,687 |
| Feb-12 | 20 | | | | 333,244,314,338 | 6,664,886,286,769 |
| Mar-12 | 22 | | | | 338,277,945,858 | 7,442,114,808,879 |
| Apr-12 | 20 | | | | 343,387,610,022 | 6,867,752,200,434 |
| May-12 | 22 | | | | 348,574,455,297 | 7,668,638,016,529 |
| Jun-12 | 21 | | | | 353,839,647,499 | 7,430,632,597,469 |
| Jul-12 | 21 | | | | 359,184,370,052 | 7,542,871,771,086 |
| Aug-12 | 23 | | | | 364,609,824,257 | 8,386,025,957,901 |
| Sep-12 | 19 | | | | 370,117,229,559 | 7,032,227,361,619 |

Figure A.
Aggregate Dollar Amount of Sales Subject to Exchange Act Sections 31(b) and 31(c)¹
Methodology Developed in Consultation With OMB and CBO
(Dashed Line Indicates Forecast Values)



¹Forecasted line is not smooth because the number of trading days varies by month.

[FR Doc. 2011-10964 Filed 5-5-11; 8:45 am]

BILLING CODE 8011-01-C

SECURITIES AND EXCHANGE COMMISSION

[File No. 500-1]

Dijji Corp., Hydro Environmental Resources, Inc. (n/k/a EXIM Internet Group, Inc.), Hydrogen Power, Inc., and InsynQ, Inc.; Order of Suspension of Trading

May 4, 2011.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Dijji Corp. because it has not filed any periodic reports since the period ended December 31, 2005.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Hydro Environmental Resources, Inc. (n/k/a EXIM Internet Group, Inc.) because it has not filed any periodic reports since the period ended September 30, 2004.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Hydrogen Power, Inc. because it has not filed any periodic reports since the period ended September 30, 2007.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of InsynQ, Inc. because it has not filed any periodic reports since the period ended November 30, 2005.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies. Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. EDT on May 4, 2011 and terminating at 11:59 p.m. EDT on May 17, 2011.

By the Commission.

Jill M. Peterson,
Assistant Secretary.

[FR Doc. 2011-11187 Filed 5-4-11; 11:15 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-64376; File No. SR-BATS-2011-013]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Trading Hours of BATS Options for Certain Products

May 2, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act")¹ and Rule 19b-4 thereunder,² notice is hereby given that, on April 26, 2011, BATS Exchange, Inc. (the "Exchange" or "BATS") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposal to amend the Rules applicable to the BATS options market ("BATS Options") in order to allow certain products to trade on BATS Options until 4:15 p.m. Eastern Time.

The text of the proposed rule change is available at the Exchange's Web site at <http://www.batstrading.com>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**1. Purpose**

BATS Options currently allows trading in options contracts from 9:30 a.m. to 4 p.m. Eastern Time. The purpose of the proposed rule change is to amend BATS Rules in order to allow trading on BATS Options to 4:15 p.m. Eastern Time for specified products. Specifically, the Exchange proposes to amend Rules 21.2 and 29.10 to extend to 4:15 p.m. Eastern Time the trading hours for option contracts on Fund Shares, as defined in Rule 19.3(i), option contracts on exchange-traded notes including Index-Linked Securities, as defined in Rule 19.3(l), and option contracts on broad-based indexes, as defined in Rule 29.1(j). The Exchange's rules already permit listing of options on Fund Shares,³ Index-Linked Securities,⁴ and broad-based indices.⁵ However, the Exchange's rules currently require trading in all products to end at 4 p.m. Eastern Time, whereas other options exchanges permit trading to occur until 4:15 p.m. Eastern Time for the three product types specified in this filing.⁶

In addition to the proposed amendments to Rules 21.2(a) and 29.10(a), for the avoidance of doubt, the Exchange proposes to amend its Rule 21.2(b), which states that the hours during which transactions in options on individual stocks shall correspond to the normal business days and hours for business set forth in the rules of the primary market trading the securities underlying such options. As proposed, Rule 21.2(b) will make clear that the products specified in Rule 21.2(a) will be available for trading until 4:15 p.m. Eastern Time, notwithstanding any other language in the Rule.

The Exchange believes the proposed changes are necessary in order to ensure consistency in the trading of such products on BATS Options and other options exchanges.

2. Statutory Basis

The Exchange believes that its proposal is consistent with the requirements of the Act and the rules

³ See BATS Rule 19.3(i), which sets forth the listing criteria for Fund Shares.

⁴ See BATS Rule 19.3(l), which sets forth the listing criteria for Index-Linked Securities.

⁵ Chapter XXIX governs the listing and trading of options on an index. In particular, Rule 29.3 sets forth the listing requirements for options on broad-based indices.

⁶ See e.g., Nasdaq Options Market ("NOM") Chapter VI, Sec. 2 and NOM Chapter XIV, Sec. 10; see also ISE Rule 700(b)-(d).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.⁷ In particular, the proposal is consistent with Section 6(b)(5) of the Act,⁸ because it would promote just and equitable principles of trade, remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and, in general, protect investors and the public interest. In particular, the proposed rule change will allow the Exchange to provide a competitive marketplace for Exchange Users to trade options on Fund Shares, Index-Linked Securities and broad-based indices until 4:15 p.m. Eastern Time.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change imposes any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) by its terms, does not become operative for 30 days after the date of filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act⁹ and Rule 19b-4(f)(6) thereunder.¹⁰

A proposed rule change filed under Rule 19b-4(f)(6) normally does not become operative for 30 days after the date of filing.¹¹ However, Rule 19b-4(f)(6)(iii) permits the Commission to designate a shorter time if such action

is consistent with the protection of investors and the public interest. The Exchange requested that the Commission waive the 30-day operative delay, as specified in Rule 19b-4(f)(6)(iii),¹² which would make the rule change effective and operative upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because the proposed rule change does not raise any novel regulatory issues. The proposal is designed to align the Exchange's trading hours for options contracts on Fund Shares, exchange-traded notes including Index Linked Securities, and broad-based indexes to correspond with the trading hours for these products on certain other exchanges.¹³ Accordingly, the Commission designates the proposed rule change as operative upon filing with the Commission.¹⁴

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.¹⁵

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an e-mail to rule-comments@sec.gov. Please include File Number SR-BATS-2011-013 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-BATS-2011-013. This file

number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-BATS-2011-013 and should be submitted on or before May 27, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁶

Cathy H. Ahn,
Deputy Secretary.

[FR Doc. 2011-11082 Filed 5-5-11; 8:45 am]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #12540]

Guam Disaster #GU-00001 Declaration of Economic Injury

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Economic Injury Disaster Loan (EIDL) declaration for the Territory of Guam, dated 04/27/2011.

Incident: Compadres Mall Fire.
Incident Period: 01/28/2011.
Effective Date: 04/27/2011.
Eidl Loan Application Deadline Date: 01/27/2012.

ADDRESSES: Submit completed loan applications to: U.S. Small Business

⁷ 15 U.S.C. 78f(b).

⁸ 15 U.S.C. 78f(b)(5).

⁹ 15 U.S.C. 78s(b)(3)(A).

¹⁰ 17 CFR 240.19b-4(f)(6).

¹¹ 17 CFR 240.19b-4(f)(6)(iii). In addition, Rule 19b-4(f)(6)(iii) requires the self-regulatory organization to give the Commission notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹² 17 CFR 240.19b-4(f)(6)(iii).

¹³ See *supra* note 6.

¹⁴ For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹⁵ 15 U.S.C. 78s(b)(3)(C).

¹⁶ 17 CFR 200.30-3(a)(12).

Administration, Processing And Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT:

A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's EIDL declaration, applications for economic injury disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Area:

Guam.

Contiguous Counties:

None.

The Interest Rates are:

| | Percent |
|---|---------|
| Businesses and Small Agricultural Cooperatives Without Credit Available Elsewhere | 4.000 |
| Non-Profit Organizations Without Credit Available Elsewhere | 3.000 |

The number assigned to this disaster for economic injury is 125400.

The Territory which received an EIDL Declaration # is Guam.

(Catalog of Federal Domestic Assistance Number 59002)

April 27, 2011.

Karen G. Mills,
Administrator.

[FR Doc. 2011-11143 Filed 5-5-11; 8:45 am]

BILLING CODE 8025-01-P

SMALL BUSINESS ADMINISTRATION

National Federal Regulatory Enforcement Fairness Hearing Region III Regulatory Fairness Board

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice of open hearing of the Regional (Region III) Small Business Regulatory Fairness Board.

SUMMARY: The SBA, Office of the National Ombudsman is issuing this notice to announce the location, date and time of the National Federal Regulatory Enforcement Fairness Hearing. This hearing is open to the public.

DATES: The hearing will be held on Tuesday, May 24, 2011, from 9 a.m. to 1 p.m. (EST).

ADDRESSES: The hearing will be at the Horowitz Visual and Performing Arts

Center—Smith Theatre, Howard Community College, 10901 Little Patuxent Parkway, Columbia, MD 21044.

SUPPLEMENTARY INFORMATION: Pursuant to the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121), Sec. 222 and the Federal Advisory Committee Act, 5 U.S.C. Appendix 2, notice is hereby given that the U.S. Small Business Administration (SBA) Region III Regional Small Business Regulatory Fairness Board and the SBA Office of the National Ombudsman announces the hearing for Small Business Owners, Business Organizations, Trade Associations, Chambers of Commerce and related organizations serving small business concerns to report experiences regarding unfair or excessive Federal regulatory enforcement issues affecting their members. Free parking is available at the college. Anyone outside the Washington Metropolitan area planning to testify at the hearing, can use our toll-free teleconference number (ReadyTalk) by dialing (866) 740-1260 and the Access Code is 3212002#.

FOR FURTHER INFORMATION CONTACT: The hearing is open to the public; however, advance notice of attendance is requested. Anyone wishing to attend and/or make a presentation to Region III Regulatory Fairness Board must contact José Méndez by May 19, 2011, in writing, by fax or e-mail in order to be placed on the agenda. José Méndez, Case Management Specialist, SBA Headquarters, 409 3rd Street, SW., Suite 7125, Washington, DC, phone (202) 205-6178 and fax (202) 481-2707, e-mail: Jose.mendez@sba.gov. Additionally, if you need accommodations because of a disability or require additional information, please contact José Méndez.

For more information on the Office of the National Ombudsman, see our Web site at <http://www.sba.gov/ombudsman>.

Dated: April 29, 2011.

Dan Jones,

SBA Committee Management Officer.

[FR Doc. 2011-11145 Filed 5-5-11; 8:45 am]

BILLING CODE P

DEPARTMENT OF STATE

[Public Notice: 7403]

U.S. Department of State Advisory Committee on Private International Law (ACPIL); Notice of Public Meeting of Its Study Group on the Hague Convention on Choice of Court Agreements

The Office of the Assistant Legal Adviser for Private International Law, Department of State, hereby gives notice of a public meeting of the ACPIL Study Group on the Hague Convention on Choice of Court Agreements. The meeting will take place on June 15, 2011 from 9 a.m. to 2 p.m. EDT at the Department of State, Washington, DC. This is not a meeting of the full Advisory Committee. The Study Group will meet to discuss the draft Federal legislation that has been developed to implement the Convention. It is proposed that the Federal legislation would work in tandem with uniform State law, developed by the Uniform Law Commission, as may be enacted by individual States. Where a State did not enact the uniform State law, or in the event of any inconsistency between the Federal law and the uniform State law as enacted, the Federal law would apply. Prior to the Study Group meeting, we will send out the latest Federal and State drafts to all those who indicate that they intend to attend the meeting or participate by telephone or who otherwise express an interest in commenting on the draft Federal text.

Time and Place: The meeting will take place on June 15th from 9 a.m. to 2 p.m. EDT at the Office of the Assistant Legal Adviser for Private International Law, Department of State, Washington, DC. Participants should appear by 8:45 a.m. at the C Street gate to Navy Hill, corner of C Street, NW., and 23rd Street, NW.

Public Participation: This Study Group meeting is open to the public, subject to the capacity of the meeting room. Access to the meeting building is controlled; persons wishing to attend should contact Tricia Smeltzer or Niesha Toms of the Department of State Legal Adviser's Office at SmeltzerTK@state.gov or TomsNN@state.gov and provide your name, affiliation, e-mail address, and mailing address. Data from the public is requested pursuant to Public Law 99-399 (Omnibus Act of 1986) as amended; Public Law 107-56 (USA PATRIOT ACT); and Executive Order 13356. The primary purpose for collecting is to validate the identity of individuals who enter Department facilities. Please see the Privacy Impact Assessment for

VACS-D at <http://www.state.gov/documents/organization/100305.pdf> for additional information. Persons who cannot participate in the meeting but who wish to comment on the draft Federal implementing legislation are welcome to do so by e-mail to Keith Loken at lokenk@state.gov. A member of the public needing reasonable accommodation should advise the contact persons identified above not later than June 8th. Requests made after that date will be considered, but might not be able to be fulfilled. If you are unable to attend the public meeting in person and would like to participate by teleconferencing, please contact Tricia Smeltzer or Niesha Toms at 202-776-8420 to receive the conference call-in number and the relevant information.

Dated: April 28, 2011.

Keith Loken,

Assistant Legal Adviser, Office of Private International Law, Office of the Legal Adviser, Department of State.

[FR Doc. 2011-11120 Filed 5-5-11; 8:45 am]

BILLING CODE 4710-08-P

DEPARTMENT OF STATE

[Public Notice: 7399]

Overseas Security Advisory Council (OSAC) Meeting Notice

Closed Meeting

The Department of State announces a meeting of the U.S. State Department—Overseas Security Advisory Council on June 7 and 8. Pursuant to Section 10(d) of the Federal Advisory Committee Act (5 U.S.C. Appendix), 5 U.S.C. 552b(c)(4), and 5 U.S.C. 552b(c)(7)(E), it has been determined that the meeting will be closed to the public. The meeting will focus on an examination of corporate security policies and procedures and will involve extensive discussion of trade secrets and proprietary commercial information that is privileged and confidential, and will discuss law enforcement investigative techniques and procedures. The agenda will include updated committee reports, a global threat overview, and other matters relating to private sector security policies and protective programs and the protection of U.S. business information overseas.

For more information, contact Marsha Thurman, Overseas Security Advisory Council, U.S. Department of State, Washington, DC 20522-2008, phone: 571-345-2214.

Dated: April 20, 2011.

Jeffrey W. Culver,

Director of the Diplomatic Security Service, U.S. Department of State.

[FR Doc. 2011-11123 Filed 5-5-11; 8:45 am]

BILLING CODE 4710-24-P

OFFICE OF THE TRADE REPRESENTATIVE

Request for Comments on Possible Negotiations in the World Trade Organization To Expand the Information Technology Agreement, Including Its Product Coverage

AGENCY: Office of the United States Trade Representative.

ACTION: Notice and request for comments.

SUMMARY: The interagency Trade Policy Staff Committee (TPSC) is requesting comments from the public on whether the United States should undertake negotiations to expand the Information Technology Agreement (ITA) and, if so: (1) Which additional information and communications technology (ICT) products the United States should seek to include and provide duty-free treatment under the ITA, including both products that existed when the ITA was concluded in 1996 but that were not covered under the agreement as well as products that have been developed since then; and (2) which U.S. trading partners that are significant producers or consumers of ICT products that are not currently participants in the ITA the United States should seek to have join the ITA. The TPSC will consider public comments in formulating U.S. positions and objectives regarding possible negotiations to expand the ITA.

DATES: Public comments are due by noon, June 13, 2011.

FOR FURTHER INFORMATION CONTACT: Scott Pietan (Director for Industrial Trade Policy) or Mary Thornton (Director for Tariff Affairs), Office of Small Business, Market Access, and Industrial Competitiveness, Office of the United States Trade Representative (USTR), 600 17th St., NW., Washington, DC 20508, telephone (202) 395-5656, Fax (202) 395-9674.

SUPPLEMENTARY INFORMATION: Any amendments to the ITA resulting from negotiations to expand the agreement will be subject to approval by its current participants.

Background Information

In December 1996, United States and 36 other countries and separate customs territories reached agreement to

eliminate tariffs on a wide range of ICT products. The resulting agreement, the *Ministerial Declaration on Trade in Information Technology Products* (also termed the Information Technology Agreement, or ITA) was implemented under the auspices of the World Trade Organization (WTO). The number of ITA participants has since grown to 73, reflecting a significant increase in participation by developing countries, and currently representing approximately 97 percent of world trade in ITA products. However, many countries still remain outside of the agreement. *Current participants include:* Albania; Australia; Bahrain; Canada; China; Chinese Taipei; Costa Rica; Croatia; Dominican Republic; Egypt; El Salvador; European Union (on behalf of its 27 Member States); Georgia; Guatemala; Honduras; Hong Kong; Iceland; India; Indonesia; Israel; Japan; Jordan; Korea; Kuwait; Kyrgyz Republic; Macao; Malaysia; Mauritius; Moldova; Morocco; New Zealand; Nicaragua; Norway; Oman; Panama; Peru; Philippines; Saudi Arabia; Singapore; Switzerland and Liechtenstein; Thailand; Turkey; Ukraine; United Arab Emirates; United States; and Vietnam. Any WTO Member or any State or separate customs territory in the process of acceding to the WTO may become a participant in the ITA.

The ITA requires participants to eliminate import duties on covered products. The elimination of duties under the agreement has helped to generate substantial growth in ICT trade. Industry sources estimate that global trade in products currently covered under the ITA grew from \$1.2 trillion in 1996 to \$4.0 trillion in 2008.

The ITA currently covers computers and computer equipment, semiconductors and integrated circuits, computer software products, telecommunications equipment, semiconductor manufacturing equipment, and computer-based analytical instruments. The list of covered products has not been expanded since the ITA was concluded in 1996. Detailed information on the ITA, including the text of the agreement and its annexes specifying the products the agreement covers, can be found online at: http://www.wto.org/english/tratop_e/inftec_e/inftec_e.htm.

Comments From the Public

The TPSC, led by USTR, is considering a proposal by industry stakeholders to expand the scope of the ITA significantly to provide duty-free treatment for a broader range of products and encourage wider participation in the agreement.

Interested persons are invited to submit comments, by noon, June 13, 2011, on the desirability of engaging in negotiations to expand the ITA. Comments are invited in particular on: (1) Additional ICT products that the United States should seek to include under the ITA, and (2) U.S. trading partners that are significant producers or consumers of ICT products that are not currently participants in the ITA and that the United States should seek to have join the ITA. Comments on proposed additional ICT products may address products that existed when the ITA was concluded in 1996 but that were not covered under the agreement as well as products that have been developed since that time. Those comments should include a detailed description of the specific product(s) and, whenever appropriate, the six-digit (or 8-digit, where applicable) Harmonized System tariff classification number for the product(s) concerned. The TPSC requests this advice pursuant to 19 U.S.C. 2155.

Requirements for Submissions

All comments must be submitted in English and must identify (on the first page of the submission) the subject matter of the comment as the "Possible Expansion of the Information Technology Agreement." In order to be assured of consideration, comments should be submitted by noon, June 13, 2011.

In order to ensure the timely receipt and consideration of comments, USTR strongly encourages commenters to make on-line submissions, using the <http://www.regulations.gov> Web site. Comments should be submitted under the following docket: USTR-2011-0003. To find the docket, enter the docket number in the "Enter Keyword or ID" window at the <http://www.regulations.gov> home page and click "Search." The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice by selecting "Notices" under "Document Type" on the search-results page, and click on the link entitled "Submit a Comment." (For further information on using the <http://www.regulations.gov> Web site, please consult the resources provided on the Web site by clicking on the "Help" tab.)

The <http://www.regulations.gov> Web site provides the option of making submissions by filling in a comments field, or by attaching a document. USTR prefers submissions to be provided in an attached document. If a document is attached, it is sufficient to type "See attached" in the "Type comment &

Upload File" field. USTR prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If the submission is in an application other than those two, please indicate the name of the application in the "Comments" field.

For any comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters "BC." The top of any page containing business confidential information must be clearly marked "BUSINESS CONFIDENTIAL." Any person filing comments that contain business confidential information must also file in a separate submission a public version of the comments. The file name of the public version should begin with the character "P." The "BC" and "P" should be followed by the name of the person or entity submitting the comments. If a comment contains no business confidential information, the file name should begin with the character "P," followed by the name of the person or entity submitting the comment.

Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible please include any exhibits, annexes, or other attachments in the same file as the submission itself, not as separate files.

Public Inspection of Submissions

Comments will be placed in the docket and open to public inspection pursuant to 15 CFR 2006.13, except confidential business information exempt from public inspection in accordance with 15 CFR 2006.15. Comments may be viewed on the <http://www.regulations.gov> Web site by entering docket number USTR-2011-0003 in the search field on the home page.

USTR strongly urges submitters to file comments through [regulations.gov](http://www.regulations.gov), if at all possible. Any alternative arrangements must be made with Anita Kyler in advance of transmitting a comment. Ms. Kyler should be contacted at (202) 395-9665. General information concerning USTR is available at <http://www.ustr.gov>.

Donald W. Eiss,

Acting Chair, Trade Policy Staff Committee.

[FR Doc. 2011-11049 Filed 5-5-11; 8:45 am]

BILLING CODE 3190-W1-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE-2011-19]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number involved and must be received on or before May 26, 2011.

ADDRESSES: You may send comments identified by Docket Number FAA-2011-0442 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.

- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12-140, Washington, DC 20590.

- *Fax:* Fax comments to the Docket Management Facility at 202-493-2251.

- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477-78).

Docket: To read background documents or comments received, go to

<http://www.regulations.gov> at any time or to the Docket Management Facility in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: David Staples (202) 267-4058, Keira Jones (202) 267-4025, or Tyneka Thomas (202) 267-7626, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591. This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on May 2, 2011.

Pamela Hamilton-Powell,
Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA-2011-0442

Petitioner: Tatonduk Outfitters, Ltd.
d/b/a Everts Air Alaska

Section of 14 CFR Affected: 14 CFR 91.313(a) and (c)

Description of Relief Sought:

Tatonduk Outfitters, Ltd. d/b/a Everts Air Alaska, requests relief to operate restricted category Air Tractor AT-802 aircraft in intra-Alaska fuel hauling operations of Everts' owned or 3rd party (customer) owned fuel product pursuant to Everts' part 119 air carrier certificate and part 135 operations specifications.

[FR Doc. 2011-11003 Filed 5-5-11; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on the Proposed Klingle Valley Trail in Washington, DC

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA and Other Federal Agencies.

SUMMARY: This notice announces actions taken by the FHWA and other Federal agencies that are final within the meaning of 23 U.S.C. 139(l)(1). The actions relate to the proposed Klingle Valley Trail project in Northwest Washington, DC. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the project will be barred unless the claim is filed on or before [November 2, 2011]. If the

Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT:

Federal Highway Administration, *District of Columbia Division:* Mr. Michael Hicks, Environmental/Urban Engineer, 1990 K Street, NW., Suite 510, Washington, DC 20006-1103, (202) 219-3536; or *District Department of Transportation:* Austina Casey, Project Manager, Planning, Policy and Sustainability Administration, 55 M Street, SE., Suite 500, Washington, DC 20003, (202) 671-2740.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA and other Federal agencies have taken final agency actions subject to 23 U.S.C. 139(l)(1) by issuing licenses, permits, and approvals for the following project in Northwest Washington, DC: The Klingle Valley Trail project. The project includes construction of a multi-use trail facility within the 0.7 mile barricaded portion of Klingle Road between Porter Street, NW., and Cortland Place, NW.; including the restoration of Klingle Creek. The Federal Project number is 4168(011). The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Environmental Assessment (EA) for the project, approved on January 13, 2011, in the Finding of No Significant Impact (FONSI) issued on March 3, 2011, and in other documents in the FHWA project files. The Final EA, FONSI, and other project records are available by contacting the FHWA or DDOT at the addresses provided above. The Final EA and FONSI can be viewed and downloaded from the project Web site at <http://www.klingletrail.com>.

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321-4351]; Federal-Aid Highway Act [23 U.S.C. 109].
2. *Air:* Clean Air Act, 42 U.S.C. 7401-7671(q).
3. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303];
4. *Wildlife:* Endangered Species Act [16 U.S.C. 1531-1544 and Section 1536], Fish and Wildlife Coordination Act [16 U.S.C. 661-667(d)], Migratory Bird Treaty Act [16 U.S.C. 703-712], Magnuson-Stevenson Fishery Conservation and Management Act of

1976, as amended [16 U.S.C. 1801 *et seq.*].

5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)-11]; Archeological and Historic Preservation Act [16 U.S.C. 469-469(c)];

6. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000(d)-2000(d)(1)];

7. *Wetlands and Water Resources:* Clean Water Act, 33 U.S.C. 1251-1377 (Section 404, Section 401, Section 319);

8. E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources;

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1).

Issued on: May 3, 2011.

Joseph C. Lawson,
Division Administration, Federal Highway Administration, District of Columbia Division.
[FR Doc. 2011-11091 Filed 5-5-11; 8:45 am]

BILLING CODE 4910-22-P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA-2011-0028]

Notice of Request for Approval of an Information Collection

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice of request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Federal Transit Administration (FTA) to request the Office of Management and Budget (OMB) to approve the following information collection:

49 U.S.C. 5308—Clean Fuels Grant Program.

DATES: Comments must be submitted before July 5, 2011.

ADDRESSES: To ensure that your comments are not entered more than once into the docket, submit comments identified by the docket number by only one of the following methods:

1. *Web site:* www.regulations.gov. Follow the instructions for submitting comments on the U.S. Government

electronic docket site. (**Note:** The U.S. Department of Transportation's (DOT's) electronic docket is no longer accepting electronic comments.) All electronic submissions must be made to the U.S. Government electronic docket site at <http://www.regulations.gov>. Commenters should follow the directions below for mailed and hand-delivered comments.

2. *Fax:* 202-366-7951.

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

4. *Hand Delivery:* U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Docket Operations, M-30, West Building, Ground Floor, Room W12-140, Washington, DC 20590-0001 between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays.

Instructions: You must include the agency name and docket number for this notice at the beginning of your comments. Submit two copies of your comments if you submit them by mail. For confirmation that FTA has received your comments, include a self-addressed stamped postcard. Note that all comments received, including any personal information, will be posted and will be available to Internet users, without change, to <http://www.regulations.gov>. You may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000, (65 FR 19477), or you may visit <http://www.regulations.gov>.

Docket: For access to the docket to read background documents and comments received, go to <http://www.regulations.gov> at any time. Background documents and comments received may also be viewed at the U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Docket Operations, M-30, West Building, Ground Floor, Room W12-140, Washington, DC 20590-0001 between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: Vanessa Williams, Office of Program Management, (202) 366-4818, or *e-mail:* vanessa.williams@dot.gov.

SUPPLEMENTARY INFORMATION: Interested parties are invited to send comments regarding any aspect of this information collection, including: (1) The necessity and utility of the information collection for the proper performance of the functions of the FTA; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the collected information; and (4) ways to minimize the collection burden

without reducing the quality of the collected information. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection.

Title: 49 U.S.C. 5308—Clean Fuels Grant Program (*OMB Number: 2132-NEW*).

Background: The Section 5308 Clean Fuels Grant Program was initiated as a formula program under the Transportation Equity Act for the 21st Century (TEA-21) in June 1998. The program was reauthorized in August 2005 under the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU) as a grant program. The program supports the development and deployment of clean fuel and advanced propulsion technologies for transit buses by providing funds for clean fuel vehicles and facilities. To meet program oversight responsibilities, FTA needs information on the operations and performance of clean fuel technology buses to help assess the reliability, benefits and costs of these technologies compared to conventional vehicle technologies.

Respondents: State and local government and public transportation authorities located in areas designated as non-attainment or maintenance for ozone or carbon monoxide.

Estimated Annual Burden on Respondents: Approximately 45.6 hours for each respondent.

Estimated Total Annual Burden: 1,644 hours.

Frequency: Semi-annual.

Issued: May 2, 2011.

Ann M. Linnertz,

Associate Administrator for Administration.

[FR Doc. 2011-11029 Filed 5-5-11; 8:45 am]

BILLING CODE 4910-57-P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

May 2, 2011.

The Department of Treasury will submit the following public 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. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department

Clearance Officer, Department of the Treasury, Room 11000, 1750 Pennsylvania Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before June 6, 2011 to be assured of consideration.

Financial Crimes Enforcement Network (FinCEN)

OMB Number: 1506-xxxx.

Title: Bank Secrecy Act Suspicious Activity Report (BSA-SAR)

Abstract: FinCEN is fielding a new system of record to support the collection and Dissemination of BSA data to law enforcement and other regulatory agencies. The BSA-SAR is a new dynamic information collection tool that will serve as the principle collection instrument to be used by financial institutions to record and report suspicious activity.

Type of Review: New Collection.

Affected Public: Businesses and Organizations.

Burden Hours: 2,670,560.

Bureau Clearance Officer: Russell Stephenson (202) 354-6012, Department of the Treasury, Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183; (202) 354-6012.

OMB Reviewer: Shagufta Ahmed, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; (202) 395-7873.

Robert Dahl,

Treasury PRA Clearance Officer.

[FR Doc. 2011-11071 Filed 5-5-11; 8:45 am]

BILLING CODE 4810-02-P

DEPARTMENT OF THE TREASURY

Departmental Offices; Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)), this notice invites the general public and other public agencies to comment on a proposed information collection for which approval from the Office of Management and Budget (OMB) will be requested. The proposed collection would be an extension of a currently approved collection under OMB No. 1505-0218.

DATES: Written comments must be received on or before July 5, 2011 to be assured of consideration.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper

performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, 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 the use of appropriate automated, electronic, mechanical, or other technological 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.

Comments may be sent by e-mail to 1602Reports@treasury.gov. Responses to this notice will be summarized and included in the request for OMB approval and will also become a matter of public record.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the information collection should be directed

1602Reports@treasury.gov or by contacting Jean Whaley, Department of the Treasury, 1500 Pennsylvania Ave., NW., Rm. 2045, Washington, DC 20220; (202) 622-0637.

SUPPLEMENTARY INFORMATION:

OMB Number: 1505-0218.

Title: Grants to States for Low-Income Housing Projects in lieu of Tax Credits.

Type of Review: Extension.

Abstract: Authorized under the American Recovery and Reinvestment Act (ARRA) (Pub. L. 111-5), the Department of the Treasury implemented several provisions of the Act, more specifically Division B—Tax, Unemployment, Health, State Fiscal Relief, and Other Provisions. Among these components is a program which requires Treasury to make payments, in lieu of a tax credit, to state housing credit agencies. State housing credit agencies use the funds to make subawards to finance the construction or acquisition and rehabilitation of qualified low-income buildings. The collection of information is necessary to properly monitor compliance with program requirements.

Affected Public: State and Local Governments.

Estimated Number of Respondents: 55.

Estimated Total Annual Responses: 114.

Hours Per Response: 0.50.

Total Annual Burden Hours: 57.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2011-11077 Filed 5-5-11; 8:45 am]

BILLING CODE 4810-25-P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

Agency Information Collection Activities; Renewal Without Change of a Current Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: In order to comply with the requirements of the Paperwork Reduction Act (PRA) of 1995, FinCEN intends to submit the information collection addressed in this notice for a three-year extension of approval by the Office of Management and Budget (OMB). OMB Control Number 1506-0043 currently covers the information collection addressed in this notice. Prior to submission of the extension request, FinCEN is soliciting comment on those information collections in 31 CFR 1010.630, Prohibition on correspondent accounts for foreign shell banks; records concerning owners of foreign banks and agents for service of legal process.

DATES: Written comments should be received on or before July 5, 2011.

ADDRESSES: You may submit comments, identified by 1506-0043, by any of the following methods:

- *E-mail:* regcomments@fincen.gov. Include OMB Control Number 1506-0043 in the subject line of the message.
- *Mail:* Department of the Treasury, Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183. Include OMB Control Number 1506-0043 in the body of the text.

Instructions: It is preferable for comments to be submitted by electronic mail. Please submit comments by one method only. All submissions received must include the agency name and the OMB control number for this notice. All comments received will be posted without change to <http://www.fincen.gov> including any personal information provided.

Inspection of comments: Comments may be inspected, between 10 a.m. and 4 p.m., in the FinCEN reading room in Vienna, VA. Persons wishing to inspect the comments submitted must request an appointment with the Disclosure Officer by telephoning (703) 905-5034 (Not a toll free call).

FOR FURTHER INFORMATION CONTACT: The FinCEN Regulatory helpline at (800) 949-2732 and select Option 6.

SUPPLEMENTARY INFORMATION: The Bank Secrecy Act ("BSA"), Titles I and II of Public Law 91-508, as amended, codified at 12 U.S.C. 1829(b), 12 U.S.C. 1951-1959, and 31 U.S.C. *et seq.*, authorizes the Secretary of the Treasury, *inter alia*, to issue regulations requiring records and reports that are determined to have a high degree of usefulness in criminal, tax and regulatory matters. Title III of the USA PATRIOT Act of 2001, Public Law 107-56, included certain amendments to the anti-money laundering provisions of Title II of the BSA, 31 U.S.C. 5311 *et seq.*, which are intended to aid in the prevention, detection and prosecution of international money laundering and terrorist financing. Regulations implementing Title II of the BSA appear at 31 CFR Chapter X. The authority of the Secretary of the Treasury to administer Title II of the BSA has been delegated to the Director of FinCEN. The information collected and retained under the regulation addressed in this notice assist federal, state, and local law enforcement as well as regulatory authorities in the identification, investigation and prosecution of money laundering and other matters. In accordance with the requirements of the PRA of 1995, 44 U.S.C. 3506(c)(2)(A), and its implementing regulations, the following information is presented concerning the information collection below.

Title: Correspondent Accounts for Foreign Shell Banks; Recordkeeping and Termination of Correspondent Accounts for Foreign Banks (31 CFR 1010.630).

OMB Number: 1506-0043.

Abstract: Covered financial institutions are prohibited from maintaining correspondent accounts for foreign shell banks (31 CFR 1010.630(a)(1)). Covered financial institutions that maintain correspondent accounts for foreign banks must maintain records of owner(s) of the foreign bank and the name and address of a person residing in the United States who is authorized to accept service of legal process for the foreign bank. (31 CFR 1010.630(a)(2)). Covered financial institutions may satisfy these requirements by using the sample certification on the FinCEN Web site (<http://www.fincen.gov/forms/files/Certification%20Regarding%20Correspondent%20Accounts%20for%20Foreign%20Banks.pdf>) and re-certification (<http://www.fincen.gov/forms/files/Recertification%20Regarding>

*%20Correspondent%20Accounts
%20for%20Foreign%20Banks.pdf).*

Records of documents relied upon by a financial institution for purposes of 31 CFR 1010.630 must be maintained for at least five years after the date that the financial institution no longer maintains a correspondent account for such foreign bank (31 CFR 1010.630(e)).

Current Action: Renewal without change to the existing regulations.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or for profit institutions, and non-profit institutions.

Burden: It is estimated that 2,000 covered financial institutions maintain correspondent accounts with 9,000 foreign banks. The estimated average annual reporting burden associated with certification is 180,000 hours (9,000 respondents at 20 hours per respondent); the estimated average annual reporting burden associated with recertification is 45,000 hours (9,000

respondents at 5 hours per respondent); and the estimated average recordkeeping burden associated with section 1010.630(e) is 81,000 hours (9,000 respondents at 9 hours per recordkeeper). Total PRA burden for this OMB Control number is 306,000.

The following paragraph applies to the collection of information addressed in this notice. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Records required to be retained under the BSA must be retained for five years. Generally, information collected pursuant to the BSA is confidential, but may be shared as provided by law with regulatory and law enforcement authorities.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of

public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance and purchase of services to provide information.

Dated: May 2, 2011.

James H. Freis, Jr.,

Director, Financial Crimes Enforcement Network.

[FR Doc. 2011-11101 Filed 5-5-11; 8:45 am]

BILLING CODE 4810-02-P



FEDERAL REGISTER

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May 6, 2011

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 447

Medicare Program; Methods for Assuring Access to Covered Medicaid Services; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS 2328–P]

RIN 0938–AQ54

Medicaid Program; Methods for Assuring Access to Covered Medicaid Services

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would create a standardized, transparent process for States to follow as part of their broader efforts to “assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area” as required by section 1902(a)(30)(A) of the Social Security Act (the Act). This proposed rule would also recognize, as States have requested, electronic publication as an optional means of communicating State plan amendments (SPAs) proposed rate-setting policy changes to the public.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. July 5, 2011.

ADDRESSES: In commenting, please refer to file code CMS–2328–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–2328–P, P.O. Box 8016, Baltimore, MD 21244–8016. 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–2328–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document’s paperwork requirements by following the instructions at the end of the “Collection of Information Requirements” section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Jeremy Silanskis, (410) 786–1592.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as

they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. General Information

Title XIX of the Social Security Act (the Act) authorizes the Secretary of the Department of Health and Human Services (the Secretary) to provide grants to States to help finance programs furnishing medical assistance (State Medicaid programs) to specified groups of eligible individuals in accordance with an approved State plan. “Medical Assistance” is defined at section 1905(a) of the Act as payment for part or all of the cost of a list of specified care and services, or the care and services themselves, or both.

Federal law provides a broad framework for State Medicaid programs, within which States have considerable flexibility. Details concerning the scope of covered services, the groups of eligible individuals, the payment methodologies for covered services, and all other information necessary to assure that the plan can be a basis for Federal Medicaid funding must be set forth in the approved Medicaid State plan. To be approved by the Department of Health and Human Services, the Medicaid State plan must comply with requirements set forth in section 1902(a) of the Act, as implemented and interpreted in applicable regulations and guidance issued by CMS. The Secretary has delegated overall authority for the Federal Medicaid program, including State plan approval, to CMS.

Medicaid services are jointly funded by the Federal and State governments in accordance with section 1903(a) of the Act. Section 1903(a)(1) of the Act provides for payments to States of a percentage of expenditures under the approved State plan for covered medical assistance. For general medical assistance, the “Federal medical assistance percentage” (FMAP) varies among the States based on a formula set forth in section 1905(b) of the Act that takes into consideration State specific information under a formula set forth in section 1905(b) of the Act. Beginning in 2014, the Federal Government will assume all or a higher share of costs for certain beneficiaries made eligible under the Patient Protection and Affordable Care Act of 2010, (Pub. L.

111–148, enacted March 23, 2010) (the Affordable Care Act).

The Medicaid statute requires that States provide coverage to certain groups of individuals, and also requires that such coverage include certain minimum benefits. In addition, States may elect to cover other populations and benefits. In order to give meaning to coverage requirements and options, beneficiaries must have meaningful access to the health care items and services that are within the scope of the covered benefits, as required by section 1902(a)(30)(A) of the Act. Many factors affect whether beneficiaries have access to Medicaid services, including but not limited to, the beneficiaries' health care needs and characteristics, State or local service delivery models, procedures for enrolling and reimbursing qualified providers, the availability of providers in the community, and Medicaid service payment rates to providers.

States have broad flexibility under the Act to establish service delivery systems for covered health care items and services, to design the procedures for enrolling providers of such care, and to set the methods for establishing provider payment rates. For instance, many States provide medical assistance primarily through capitated managed care arrangements, while others use fee-for-service payment arrangements (with or without primary care case management). Increasingly, States are developing service delivery models that emphasize medical homes, health homes, or broader integrated care delivery systems to provide and coordinate medical services. The delivery system design and accompanying payment methodologies can significantly shape beneficiaries' abilities to access needed care by facilitating the availability of such care. In addition, the delivery system model and payment methodologies can improve access to care by making available care management teams, physician assistants, community care coordinators, telemedicine and telehealth, nurse help lines, health information technology and other methods for providing coordinated care and services and support in a setting and timeframe that meet beneficiary needs.

As State delivery system models have evolved, so too have their provider payment systems. Many States develop rates based on the costs of providing the service, a review of the amount paid by commercial payers in the private market, or as a percentage of rates paid under the Medicare program for equivalent services. Often, rates are updated based on specific trending

factors such as the Medicare Economic Index or a Medicaid trend factor that incorporates a State-determined inflation adjustment rate. Rates may include supplemental or incentive payments that encourage providers to serve Medicaid populations. For instance, some States have authorized Medicaid providers to receive supplemental payments for care coordination and care management, or for achieving certain specified quality measures.

The flexibility in designing service delivery systems and provider payment methodologies, as described above, is consistent with the requirement in section 1902(a)(30)(A) of the Act that State Medicaid plans must "provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan * * * as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the same extent that such care and services are available to the general population in the geographic area."

Consistent with the requirement in section 1902(a)(30)(A) of the Act to provide payment for care in an effective and efficient manner consistent with quality of care, States are empowered to seek the best value through their rate-setting policies and may tailor their access strategies to take into account local conditions including geographic disparities in the availability of providers and demand for particular services. Achieving best value has been a key strategy for some States that have attempted to reduce costs in the Medicaid program in these difficult fiscal times. We do not intend to impair States' ability to pursue that goal, or their ability to explore innovative approaches to providing services and lowering costs for other reasons. Indeed, the Secretary and CMS, including through the new Center for Medicare and Medicaid Innovation, is actively engaged in helping States achieve better value and better care while lowering per-person costs.

B. Discussion

Medicaid payment rate changes are a function of the State budget process in many States. We recognize that payment reductions or other adjustments to payment rates are legitimate tools to manage Medicaid program costs and achieve overall budget objectives. However, payment rate changes made

without consideration of the potential impact on access to care for Medicaid beneficiaries or without effective processes for assuring that the impact on access will be monitored, may lead to access problems. Payment rate changes are not in compliance with the Medicaid access requirements if they result in a denial of sufficient access to covered care and services.

Budget-driven payment changes have led to confusion about the analysis required to demonstrate compliance with Medicaid access requirements at section 1902(a)(30)(A) of the Act. States attempting to reduce Medicaid costs through payment rate changes have increasingly been faced with litigation challenging payment rate reductions as inconsistent with the access provisions of section 1902(a)(30)(A) of the Act. Resulting court decisions have not offered consistent approaches to compliance with the access requirement. These decisions have left States without clear and consistent guidelines and have subjected them to considerable uncertainty as they move forward in designing service delivery systems and payment methodologies.

For instance, the United States Court of Appeals for the Ninth Circuit Court, in *Orthopedic Hospital v. Belshe*, 102 F.3d 1481, 1496 (1997), cert. denied, 522 U.S. 1044 (1998) required the State agency to set provider payment rates that "bear a reasonable relationship" to provider costs, based on "responsible cost studies." This ruling was reaffirmed by the Ninth Circuit in *Independent Living v. Maxwell-Jolly*, 572 F.3d 644 (2009). In contrast, the United States Court of Appeals for the Seventh Circuit, in *The Methodist Hospitals, Inc. v. Sullivan*, 91 F.3d 1026, 1030 (1996) did not find any requirement for prior cost studies or other procedural requirements. While other Federal Courts of Appeals have also addressed the issue, there is no consensus among the circuits.

Significantly, in 2009, the Congress created the Medicaid and CHIP Payment and Access Commission (MACPAC) (Pub. L. 111–3, section 506) specifically to study and make recommendations on beneficiary access to care in Medicaid and the Children's Health Insurance Program (CHIP). With members appointed by the non-partisan U.S. Comptroller General, MACPAC reviewed 30 years of research and consulted extensively with key stakeholders to develop a recommendation on how to measure access to care for Medicaid beneficiaries. This recommendation was in MACPAC's first report to the Congress, published on March 15, 2011.

The MACPAC report sets out the three-part framework for analyzing access to care which, as we discuss below in this section of the proposed rule, we propose to adopt as part of a State-level review strategy. The MACPAC-recommended framework considers: (1) Enrollee needs; (2) the availability of care and providers; and (3) utilization of services.

In this proposed rule, we recognize that States must have some flexibility in designing the appropriate measures to demonstrate and monitor access to care, which reflects unique and evolving State service delivery models and service rate structures. At this point, a singular approach to meeting the statutory requirement under section 1902(a)(30)(A) of the Act could prove to be ineffective given current limitations on data, local variations in service delivery, beneficiary needs, and provider practice roles. For these reasons, we are proposing Federal guidelines to frame alternative approaches for States to demonstrate consistency with the access requirement using a standardized, transparent process, rather than setting nationwide standards. We are soliciting comments on this basic approach.

It is important to note that, if adopted, this proposed rule would not directly require States to adjust payment rates, nor to take any steps that would not be consistent with efficiency, economy, and quality of care. We believe that even if access issues are discovered as a result of the analysis that would be required under this rule, States may be able to resolve those issues through means other than increasing payment rates. Rather, these rules proposed to clarify that beneficiary access must be considered in setting and adjusting payment methodologies for Medicaid services. If a problem is identified, any number of steps might be appropriate, such as redesigning service delivery strategies, or improving provider enrollment and retention efforts. It has always been within the regulatory authority of CMS to make SPA approval decisions based on sufficiency of beneficiary service access and this proposed rule merely provides a more consistent and transparent way to gather and analyze the necessary information to support such reviews.

II. Proposed State Level Review Strategy for Compliance With Access Requirements

We are not aware of any standardized, transparent methodology that is broadly accepted to definitively measure access to health care and services. Partly as a result, there has been no prior Federal rulemaking or guidance previously on

this subject. As a consequence, in implementing their programs, States lack the guidance that they need to understand the types of information that they are expected to analyze and monitor in determining compliance with statutory access requirements. This issue has come to light recently, both in litigation and in our review of proposed Medicaid State plan amendments (SPAs) that would reduce provider payment rates. Two Governors and several State Medicaid directors have sought Federal guidance in this area, and the Congress, by establishing MACPAC, has also expressed its interest in promoting more information analysis and guidance with respect to these important matters. MACPAC's March report is significant in that it offers the first Congressionally-authorized expert recommendation on standards and methodologies for defining access to health care and health services.

We have a responsibility under the Act to ensure sufficient beneficiary access to covered services and are aware of the uncertainties and problems that arise for States in the absence of Federal guidance on methods and standards for States to demonstrate compliance with this requirement. At the same time, we are mindful that the landscape of health care delivery systems and associated payment methodologies is undergoing significant change, the relevant data are not always available, and that MACPAC, the entity established by the Congress to consider these issues, may adapt its first set of recommendations.

As such, the strategy we are now proposing is designed to allow for State and Federal review of beneficiary access to evolve over time and for States to implement effective and efficient approaches and solutions that are appropriate to their local and perhaps changing circumstances. The proposed strategy would be a consistent and ongoing State-level review to demonstrate sufficient beneficiary access to services covered under the Medicaid State plan that is not solely focused on provider payment rate changes and the State plan process, but assesses ongoing performance.

We note that section 1902(a)(30)(A) of the Act, and the requirements of this proposed rule, discuss access to care for all Medicaid services paid through a State plan under fee-for-service and do not extend to services provided through managed care arrangements. Managed care entities are subject to separate access review procedures that are set forth in 42 CFR part 438 to ensure network sufficiency and procedures for beneficiaries to obtain needed services. We are currently undertaking a review

of State managed care access standards and are considering future proposals to address access issues under managed care delivery systems. The access requirements under section 1902(a)(30)(A) of the Act, apply equally to States that are not changing provider payment rates and those that are. The proposed State reviews, however, will provide an analytic framework to consider the impact of any proposed Medicaid State plan rate reductions on service access.

More specifically, we propose to require States to determine appropriate data elements that focus on the MACPAC-recommended three-part framework, which include information on: Enrollee needs, availability of care and providers, and utilization of services. This and other information that the State believes to be relevant, will be periodically analyzed by States to demonstrate and monitor sufficient access to care. The data and analysis will be made available to the public and furnished to CMS as requested in the context of a SPA that reduces provider rates or restructures provider payments in circumstances that could result in access issues, or as part of ongoing program reviews.

The MACPAC-recommended framework does not focus on one particular data element, such as the relationship of provider payment rates to provider costs, but recognizes that access to covered services is affected by multiple factors. Though cost may be one consideration affecting access to care, there are other factors such as local market conditions, variable provider costs, administrative burden for providers, and demographic differences. Depending upon State circumstances, cost-based studies may not always be informative or necessary. In addition, because many State payment rates are not specifically calculated based on provider cost considerations, it can be burdensome and not particularly productive to rely solely on that one factor as a measure of access.

The proposed State-level review strategy would recognize an ongoing responsibility to conduct periodic reviews of compliance with access requirements for all Medicaid services and also a particular responsibility to review and monitor sustained service access after implementing a change in provider payment rates. While we are proposing to allow States some discretion to determine appropriate measures to demonstrate and monitor access to care within the three-part framework, this proposal provides consistent steps for States to follow in

demonstrating and monitoring Medicaid access.

To ensure continuing compliance review, we propose that States must conduct access reviews for a subset of services each calendar year and release the results through public records or a web site developed and maintained by the State, by January 1st of each year. We have chosen to base the requirement on the calendar year because State fiscal years vary. We note that States may issue the access reviews prior to, but no later than January 1 of each year, with the first review completed by no sooner than 12 months after the effective date of the final rule. States may determine the services that they will review each year, provided that each service is reviewed at least once every 5 years. The reviews must include the specific measures that the State used to analyze access to care by geographic location, discuss the measures in the context of the MACPAC three-part framework, discuss any issues with access that were discovered as a result of the review, and make a recommendation about the consistency with the requirements of section 1902(a)(30)(A) of the Act.

We propose that, prior to submission of a SPA to reduce rates or alter the structure of provider payment rates in circumstances that could result in access issues for a covered service, the State would need to submit information from an access review that had been conducted within the year prior to submission of the SPA as applicable. We are proposing this requirement so that CMS and the States will have the information necessary to assess consistency with section 1902(a)(30)(A) of the Act before a rate reduction or restructuring proposal is processed. Since it may be difficult to predict the impact that a provider rate reduction or restructuring of provider payments will have on access, we are also proposing that States develop special procedures to monitor access to services after such a change has been implemented. These procedures would result in a periodic review of State-determined indices that demonstrate sustained access to care that would be made available to CMS and the public.

To address potential issues that develop in service access, we are proposing that States implement an ongoing mechanism that allows beneficiary feedback. This feedback mechanism could be based on beneficiary hotlines or surveys, an ombudsman program, or other equivalent mechanisms. In addition, we are proposing that each State specify a process to address any access issues that are discovered through the ongoing

access reviews and monitoring, through a corrective action plan that would be submitted to CMS and would include specific steps and a timeline for State action to address such issues. As proposed under this proposed rule, States would need to submit their action plan to CMS within 90 days of discovering an access issue. Below, in section II.C. of this proposed rule, we offer some examples of actions that States may take to address access issues.

A. Data Measures To Demonstrate Sufficiency of Access

We propose to provide States with discretion in determining the appropriate data measures to demonstrate whether access is sufficient through access reviews and monitoring efforts in the context of the MACPAC-recommended framework. We are offering specific suggestions on trends and factors that States could use to measure enrollee needs, the availability of care and providers, and utilization, but we would allow States to develop alternative approaches and improve on these suggestions within each of these categories of required data. We are soliciting public comments on additional data measures that may be useful in measuring access in the context of the proposed framework and whether it is appropriate to require certain data measures as part of State access reviews.

We note at the outset that the data States would review under this rule will explicitly address Medicaid beneficiary access. However, the required statutory test is a comparison between Medicaid beneficiary access and access to medical services by the general population in the geographic area. While it is neither desirable nor feasible to require that States develop new data sources on general access to medical services, the data measures for Medicaid beneficiary fee-for-service access may, in some cases, require that States compare information from commercial insurance standards or Medicaid managed care. We welcome public comment on any existing data sources that address general access to medical services that might be relevant. In general, we are confident that the Medicaid data will implicitly address general access standards in the geographic area. For example, data on beneficiary experience and satisfaction will take into account expectations based on community standards, and the percentage of community providers enrolled and accepting Medicaid patients will necessarily indicate the availability of such providers in the community.

We believe the meeting of enrollee needs should be the primary driver to determine whether access to care is sufficient. Measurable data on the beneficiaries' experiences and needs, however, may be difficult for States to attain. States may need to rely upon qualitative information that is received through beneficiary surveys or other means, such as hotlines or beneficiary Ombudsman offices that some States may have in place, and may request that community-based organizations, primary care providers, hospitals, case management, and other providers assist in soliciting the information from beneficiaries. Once a State determines the most efficient means to reach beneficiaries, it has a number of options for data elements that could be significant in assessing whether their needs are met:

- Extent of knowledge that a service is covered by the Medicaid program;
- Success in scheduling a service appointment with a provider, including after hours as necessary;
- Satisfaction with the availability of service providers within a reasonable distance from home;
- Ability to obtain transportation to and from a scheduled appointment;
- Number and reasons for emergency room services received in the year;
- Number and reasons for missed appointments and means;
- Ability to either schedule an appointment or receive services in light of limited English language proficiency;
- Turnover in providers such as with homecare workers or personal care attendants; and
- Means and ability to seek help in scheduling service appointments.

The connection between the number of enrolled providers and the availability of services is seemingly obvious, but there are many qualifications that affect the meaningfulness of such data. It may be important to know the number of enrolled providers in relation to the overall number of providers in the community. And, in order to contribute to beneficiary access, it is significant to know whether enrolled providers have "open panels" which means that they are accepting Medicaid patients.

Data on the availability of care and providers is likely more easily obtainable by States, measurable and able to be monitored on a consistent basis. Many of the elements that we suggest below are likely available through current State information systems, while some of the information may require a survey of the providers within the State. With that in mind,

States could review the following data elements:

- The availability of care and services through Medicaid fee-for-service as compared to access standards established under Medicaid managed care;
- The availability of care and services through Medicaid fee-for-service as compared to commercial managed care or other commercial insurance access standards.
- The number of providers with open panels who are accepting new Medicaid patients;
- The extent to which timely follow-up visits occur after an emergency visit or inpatient stay;
- Provider Medicaid enrollment (with open panels) compared to licensed providers in the preceding rate year applicable to each covered service;
- Provider Medicaid enrollment compared to actual provider Medicaid participation (as measured by claims submitted) in the preceding rate year applicable to each covered service;
- Provider Medicaid enrollment (with open panels) compared to provider enrollment in one of the four largest commercial insurers in the State in the preceding rate year applicable to each covered service;
- Provider loss and retention in the preceding rate year applicable to each covered service;
- The average amount of time from provider application for enrollment to the approval of the provider agreement; and
- The average amount of time from provider claim submission to payment of the claim by the Medicaid agency.

Beneficiary service utilization data is relevant because changes in beneficiary service utilization can indicate access problems. In particular, drops in service utilization that coincide with payment changes may indicate access problems. In addition, patterns of beneficiaries obtaining access to care through hospital emergency rooms may be an indication of the access problems for certain categories of services.

Beneficiary utilization data is readily available through State information claims systems and relatively easy for States to review and monitor. For purposes of reviewing utilization, States could focus on Medicaid utilization of applicable covered Medicaid State plan services in the preceding rate year on a per capita basis and also take into account that some services apply to subsets of the population (such as pediatric services and obstetrics services). States could also look at avoidable emergency room visits and hospital admissions to determine if

there are issues with preventive hospital use that may suggest a corresponding access issue.

Consistent with the performance standard measures described under the Affordable Care Act, we are actively working, with input from State partners to develop a coordinated and streamlined data solution aimed at reducing redundancy, administrative burden, and to maximize business value. As we propose to have States review data to measure Medicaid access to care, we are mindful that our broader data improvement and streamlining efforts that aim to inform program performance and compliance may also be useful to States in informing access to care. As part of this proposed rule, we are asking States to consider how measures of access to care may align with current program oversight and review activities so that the access reviews build upon existing State data collection efforts that are used to improve overall program efficiency and quality. In addition, through our data efforts, we will work to identify and highlight data available within CMS and States that can inform the State access review under this proposed rule and monitor access on a national basis.

We also will offer States technical assistance in identifying available data resources and facilitate cross-State collaboration as they undertake the access review procedures proposed under this proposed rule. To initiate our technical assistance, we have worked with our Federal partners to develop a matrix of potential Federal and State data resources which may be helpful to States in developing their access reviews. These resources are listed below in section IV. of this proposed rule.

The resources presented in section IV. do not address each data element identified in this proposed rule and much of the data will need to be obtained from existing or developed State sources. We are soliciting public comments and suggestions on these and other existing sources of data that may help States inform their rate-setting policies and their efforts to ensure service access. We will also develop a standardized template for States to report and make publically available the data analysis identified under this proposed rule. The template will be designed to focus on the data elements that a State has reviewed to measure access to care within the MACPAC recommended framework, any issues that the State has identified as a result of the review, and the State agency's recommendation on the sufficiency of access to care based on the review. We

are soliciting public comments on the content of the access template and specifically, the important areas that States should address in their reviews. We believe the reviews should address, minimally, the data elements reviewed under the MACPAC recommended framework, including the information gathered on beneficiary experience, and the Medicaid payment rate comparison. However, we are interested in exploring additional topics that should be standardized through the template.

B. Public Process To Involve Stakeholders

In addition to the access rate review, we propose to require a public process that States would conduct prior to submitting State plan amendments that propose Medicaid provider payment rate reductions or changes in the provider payment structure. We are not prescribing a specific form for that public process, but we would require that the State describe the process that they have developed in their State plan. We are soliciting public comments on whether specific elements regarding that process should be required. We also encourage States to conduct the public process in any instance when the State data collection and monitoring process uncovers an access issue. The purpose of the public process would be to provide a meaningful opportunity for beneficiaries, providers, and other interested parties to provide input and feedback on the impact that the proposed rate reductions will have on efficiency, economy, and access to care, offer ideas to enhance service delivery models and other innovative solutions to address access issues, discuss strategies to encourage continued provider participation, and develop the procedures that States will use to monitor access to care after implementation of the proposed rate reductions.

We are proposing to require this public process in part because we have found that States that worked with affected stakeholders prior to implementing rate reductions often maintained a commitment from providers to continue to serve Medicaid beneficiaries. States have frequently held these discussions with the affected provider community. We are proposing that States also discuss the impact of proposed rate reductions with beneficiaries and other interested parties. As stated earlier in section II.A. of this proposed rule, we believe that beneficiaries' experiences in receiving services are a primary driver in determining the sufficiency of service access and it is important that their

views concerning changes that could directly affect their care be solicited.

Moreover, it is also important to have a public process that obtains feedback from all affected stakeholders because each may have unique approaches to mediating Medicaid service access issues, promoting provider participation in the program, and assuring the program operates in an efficient and economical way. As proposed, the public process requirements will solicit feedback from stakeholders in determining the monitoring and oversight procedures that a State will implement to ensure access is sustained after the implementation of a rate reduction.

C. Monitoring Access and Corrective Action To Address Access

As States review their service access data and monitor access after implementing rate reductions, it is important to have a process in place to address access issues that are uncovered through the new process. While we, through official compliance procedures, may address issues by requiring the State to develop a corrective action plan detailing action steps and timelines to address access issues, we are also proposing to allow States to identify access issues and submit a corrective action plan within 90 days of discovering the problem. When a State develops a corrective action plan on its own, we would not treat it as a finding of non-compliance, but as evidence of a good faith effort by the State to remain in compliance. Action plans may also be developed to improve the State's information base going forward, regardless of whether a particular access problem is identified.

While a corrective action plan may have longer term action steps, it should set a target for compliance with access requirements that is no longer than one year from the submittal of the plan to CMS. We are also encouraging States to work with stakeholders through the public process to develop monitoring indices to ensure sustained access to care and remediation plans that address known access issues. Stakeholders can provide valuable input and assistance in the identification and implementation of measurable efforts that could increase access as appropriate for their local health delivery infrastructure, service delivery system, and other factors.

The precise nature of needed corrective action depends on individual State circumstances. For instance, a State could submit action steps and a timeline to reduce administrative burdens on providers or to implement and oversee a program through which

beneficiaries receive assistance in finding a service appointment. We understand that some States have "ombudsman" programs to aid beneficiaries in finding service appointments as part of their managed care systems and we offer that these programs could serve as one step in alleviating fee-for-service access issues or could help pinpoint the access issues with great precision. Alternatively, or perhaps in addition, a State might seek to incentivize the development or expansion of clinics in underserved areas where access is of particular concern. States could also structure their service reimbursement rates to address particular geographic disparities in service access or to offer incentives for available evening and weekend appointments to working individuals who may not have flexible schedules to accommodate regular work hour appointments. A State could also review, modify or implement transportation, telemedicine or integrated models of care (such as health homes or primary care case management) policies that serve to make care available in efficient and effective ways.

In proposing to address access to care issues through any of these approaches, it would be important for States to describe their process for monitoring program effectiveness in improving or maintaining service access through use of these action steps so that the State will ultimately comply with the requirements at section 1902(a)(30)(A) of the Act.

D. Clarification and Electronic Publication of State Public Notice

In addition to establishing a framework for documenting access to covered Medicaid services, this proposed rule would update the public notice requirement in § 447.205 by recognizing electronic publication as a means to notify the public of payment policy changes. We are proposing this change at the request of States to relieve State burden. The current regulatory language, which requires publication in a State register similar to the **Federal Register**, the newspaper of widest circulation in each city with a population of 50,000 or more, or the newspaper of widest circulation in the State, if there is no city with a population of 50,000 or more, was drafted prior to widespread accessibility of the web and development of State government web sites and we are updating the regulation to consider electronic methods of publication.

We are also soliciting public comment on the use of the term "significant" in

§ 447.205(a). The current public notice regulation calls for notice of "significant" changes in methods and standards, which has resulted in some confusion among States in determining when it is appropriate to publish notice. Because the term "significant" is not defined, and because the impact of payment changes is not always objectively clear, States are not always clear on when it is appropriate to notify the public of changes to rate-setting methods and standards.

Longstanding CMS policy has been to require public notice for any change in payment methods and standards because there is no definable threshold for a "significant" change that can apply across services, service providers, beneficiaries and other stakeholders. A change that may be significant for one individual or group of stakeholders may not be significant to another. Therefore, the historic interpretation has been applied because it is important for providers, beneficiaries and stakeholders to be aware of all changes in State rate policies and evaluate how those changes impact the delivery of Medicaid services. In addition, given that the process for amending the approved State plan to change provider payment rates is somewhat complex, we do not believe that States go through that process for changes that are not significant.

We are soliciting public comments to determine if it is appropriate to clarify the public notice requirement at this time. One option to clarify the requirement is to remove the reference to significance and clarify that any changes in rates, methods and standards require public notice as has been consistent with CMS policy. We could also establish a threshold for significance.

III. Specific Proposed Regulatory Changes

A. Existing Authorities

Section 1902(a)(30)(A) of the Act requires that, in order to receive Federal Financial Participation (FFP), States must set Medicaid service payment rates that are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that services are available to Medicaid eligible individuals to the extent that they are available to the general population in the geographic area. The regulations located at 42 CFR part 447 subpart B (Payment Methods: General Provisions) sets forth the implementation requirements that States must follow when establishing Medicaid payment rates.

Regulations at § 447.203 establish certain documentation requirements that the State Medicaid agency must maintain and make available to the Department of Health and Human Services upon request. Specifically, for any increase in payment rates, the State Medicaid agency is required to record an estimate of the percentile of the range of customary charges to which the revised payment structure applies, a description of the methods used to make the estimate and an estimate of the composite average percentage increase of the revised payment rates of the preceding rates. This information is recorded in State manuals or other official files and applies to individual practitioner services.

As currently described, § 447.203 requires that States document a comparison of increased payment rates to customary charges and preceding rates at the time that the increase occurs and only for practitioner service rates. The documentation requirement does not contemplate rate decreases or include a process or timeframe for States to update the methodology and make a rate comparison using contemporary data. Further, the documentation process does not account for all Medicaid provider payments and could be interpreted to exclude payment increases for hospital, clinic, long-term care facilities, hospice, home health care, durable medical equipment, and other Medicaid service rates that encompass costs beyond practitioner services. Clearly, the regulation was intended to document potential overpayments for a subset of Medicaid service rates and is insufficient, in its current scope, to ensure the collection of information on efficiency, economy, and adequacy of current payment rates across all services and to measure service access.

Regulations at § 447.204 implement, in part, section 1902(a)(30)(A) of the Act by adopting into the CFR the statutory requirement for comparable general population service availability. The regulation replicates the statute, stating that payments must be sufficient to enlist enough providers to ensure that services under the plan are available to recipients at least to the extent that those services are available to the general public. However, the regulation does not provide additional guidance to States on standards to demonstrate sufficient access to Medicaid services. Without specific guidance, States have attempted to comply with this regulation through a variety of methods. As discussed in more detail in section III.A. of this proposed rule, these methods include: stated assurances,

public processes, and/or data reviews, each of which may not fully demonstrate that rates are sufficient to provide for Medicaid service access equivalent to service access available to the general public consistent with the statute.

Regulations at § 447.205 require, with certain exceptions, that the State agency provide public notice of any significant proposed change in methods and standards for setting Medicaid payment rates. Prior to the effective date of a change in methodology, which must be submitted to CMS for review through a Medicaid SPA, States are required to notify the public of the proposed change through publication of a public notice that is published in: a State register similar to the **Federal Register**, or the newspaper of widest circulation in each city with a population of 50,000 or more. If there is no city with a population of 50,000 or more within the State, the publication must be made in the newspaper of widest circulation within the State. The regulation specifies that the content of the public notice describe the proposed change in methods and standards, explain the reason for the change, identify the local agencies where the changes are available for public review, provide an address where comments may be sent and reviewed by the public, and give the location, date and time for any public hearings on the change. The public notice requirement is meant to notify stakeholders of rate-setting policy changes that have already been determined and does not require that States examine and provide the public with any information on the resulting impact on service access that the proposed changes may have once such changes have taken effect.

B. State Plan Review Process Changes

Since 2008, as more States sought to amend Medicaid State plan payment methodologies by instituting significant provider rate changes, we have requested that States provide information to help the agency determine that the changes to rates resulting from State plan amendments will continue to provide for access to care consistent with the Act and the implementing regulations. As part of the SPA review process, we requested this information either informally or through a formal request for additional information. Though we did not develop a standard set of questions for all SPA information requests, similar concerns over adherence to the provisions of § 447.204 were raised in many of the rate reduction SPA reviews. Without clear standards or processes for

determining sufficient rates that will maintain access and encourage provider participation, States were offered a variety of means to satisfy the statutory requirement.

Based on our current review methods, all States that propose to implement rate reductions through a SPA submittal, or change payment rate structures during the rate year, respond with a statement assuring that access would not be affected by the changes in the amendment. When asked for additional detail on the methodology that States used to determine compliance with the access requirement, only a few States indicated that they relied upon actual data to make the determination. Of the States that relied upon data, most focused on historical levels of provider enrollment and their belief that providers would not disenroll based on a reduction in payments. A few States also looked at rates as compared to cost, Medicare rates, or payment rates in surrounding States to determine the impact of the reductions. Some States noted that historic reductions had no discernible impact on provider participation and so they did not anticipate access issues as a result of additional reductions.

Nearly every State held a public meeting that invited some or all of the providers to discuss the proposed changes or at least held informal discussions with providers and policymakers. Approximately half of the States also included consumer groups and other affected stakeholders as part of the rate proposal hearings or discussions. Many of these public hearings, however, seemed focused on awareness of the coming rate changes, rather than a discussion on the potential impact to service access.

Finally, when asked how they intended to monitor the impact of the rate changes on access, a few States indicated that they would review data submitted to their Medicaid Management Information Systems to determine if services utilization or provider participation levels dropped after the changes were implemented. Some States have hotlines or other mechanisms to record consumer complaints, although it is not clear how widely known these mechanisms are among beneficiaries or how the complaints are considered or evaluated over time. The majority of States did not offer any plan to monitor the impact of the rate reduction on an on-going basis or to make rate adjustments or other changes based on the monitoring activities.

Absent data on the sufficiency of State efforts, including State plan rates, to

achieve access consistent with efficiency, economy, and quality and without a defined process for involving stakeholders in rate setting determinations, we have generally relied upon State assurances and these disparate State approaches to make decisions on proposed rate reduction SPAs. It should be noted that in one instance, we informed a State that based upon the persistent, widespread negative reaction by providers in response to a proposed significant rate reduction of an already low rate (by comparison to commercial rates and other State Medicaid rates for the same service), that we could not approve a reduction amendment as submitted because of concerns that Medicaid eligible individuals would no longer have adequate access to care. In a similar situation, where a State also failed to provide any information or analysis on whether the rate proposal would negatively impact access after the implementation of proposed reductions, we have denied the relevant SPAs.

We agree with MACPAC that it is more consistent with the statute to make such decisions in the context of a consistent framework for evaluating access, informative data and a transparent process that assures stakeholder involvement. Therefore, we are proposing clear guidelines on data collection efforts and public processes that all States must implement in order to demonstrate that rate-setting is informed by sustained access to services consistent with the requirements of section 1902(a)(30)(A) of the Act.

We are also proposing to require that States should submit to CMS, in support of State plan amendments that reduce payment rates or restructure provider payments in circumstance when the resulting changes could create access issues, an analysis based on access data collected during the prior year. The data itself would be available to CMS for review upon request.

C. Standards for CMS Review of Compliance With Access Requirements and State Plan Amendments Affecting Access

As discussed above, we are proposing a State-level ongoing access review process that will generate analysis and data concerning access issues, and will provide a framework for ongoing monitoring and corrective action. We would consider State compliance with these procedural requirements, including both the access review process and the need for identification of access issues and corrective action plans, to be essential to a demonstration of compliance when we review

proposed State plan amendments that affect access to services, such as provider payment reductions or restructuring. When a State has not complied with the access review requirements, we would not approve such a State plan amendment.

We have considered and declined to propose setting a single uniform Federal standard for reviewing substantive compliance with access requirements because we believe that determination of such compliance is very fact-specific and data-specific, taking into consideration local circumstances.

In our review of compliance with access requirements, we intend to focus on working with States to improve beneficiary access mindful of legitimate efforts to ensure that State policies are consistent with efficiency and economy, as well as to the potential advantages of innovative methods of service delivery, provider payment, and case management. However, we will have a perspective in reviewing State-level access reviews and underlying data that States themselves will not have. This is because we will have the advantage of having seen similar access reviews from other States and will recognize best practices and analytic methodologies based on that experience.

Federal review will be based on the statutory standard that the State must have methods and procedures “to assure that payments are consistent with efficiency, economy, and quality of care, and sufficient to enlist enough providers so that care and services under the plan are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.” We believe that application of this standard requires a review and analysis of data in light of local circumstances. Determinations of compliance will necessarily involve judgments as to how to weigh the data States develop on access measures, and at least without more experience and analysis we do not believe those judgments can be readily reduced to procedural or substantive formulas. We invite comment on possible national or State-specific access threshold tests, particularly given that the statutory requirement to measure access to care in relation to the availability of care and services to “the general population in the geographic area” suggests a State-specific CMS review.

In Federal oversight of State-level reviews to determine ongoing compliance with the statutory access requirement, we do not intend to develop independent analyses of beneficiary access to services, but instead will review State analyses to

ensure that the State-level review process operated to reasonably demonstrate substantive compliance with the access requirements. Our review will generally be limited to the issues of whether the State collected relevant data on each of the required elements, and reasonably analyzed that data to find substantive compliance with access requirements. While we intend to conduct a case-by-case review of these State-level reviews, we may also issue guidance on State-level review practices and may integrate such guidance into our Federal oversight review.

Such guidance may direct the State with respect to the analysis of the required data, and we may consider a State analysis to be deficient if those practices are not applied. For example, such guidance might inform States about how to appropriately weigh different types of data to ensure that the resulting analysis reflects overall access. If we conclude that a State-level review and analysis is deficient and therefore does not reasonably demonstrate compliance with the statutory access requirements, we intend to initiate a compliance process (which could involve requiring a corrective action plan pursuant to these regulations) or, for a pending SPA, we would disapprove the SPA. In that latter instance, we note that the State would have an opportunity during the reconsideration process to correct deficiencies in the State-level review and access analysis.

We note that Federal oversight of State reviews will likely be more stringent when the State proposes changes in provider payment of significant magnitude, or when we have other evidence, either through data or other sources, of an access problem.

While we are not proposing any single Federal standard for reviewing access issues, we are inviting public comment on whether there should be particular indicators that we would regard as an irreducible minimum standard. We have not proposed such a minimum standard for several reasons. First, it is not clear whether any particular indicator is going to be determinative of access issues in every circumstance. The access reviews will examine a number of indicators, and we believe they are best examined in the aggregate. In most cases, we believe that the different indicators that a State examines will confirm each other, but in some cases there may actually be a reason for a variation in the results that is based on a State-specific characteristic. In any case, we believe that the overall access review process should make serious

access problems obvious and easily addressed in a case-by-case review. We also invite comment from States and others on whether a single or small set of Federally determined indicators is preferable administratively to a broader set of State determined indicators.

IV. State Use of National Data Resources To Fulfill Proposed Data Requirements

As discussed previously in this proposed rule, we have worked closely with our partners within the Federal Government, the MACPAC, and a number of experts in an attempt to identify potential sources of data that States may use to fulfill their responsibilities under the proposal. We recognize that much of the information necessary to evaluate access may require States to use existing State data or develop or implement new resources, such as a beneficiary survey. We also recognize that data from different sources have distinct definitions, timeframes for collection, and therefore, challenge and limitations exist to trending data reliably. We are soliciting public comments on existing sources of data that States may use to ensure that they are fulfilling their responsibility to assure access to care and, if States are already analyzing data to measure access to care, that they share their sources and methods of data collection with other States either through public comment to this proposed rule or through MACPAC.

At the Federal level, the Health Resources and Services Administration (HRSA) publishes the Uniform Data System, which includes patient count, diagnosis and expense data at the grantee, State and national levels for HRSA's Federally Qualified Health Center grantees, which are funded under section 330 of the Public Health Service Act. This information is available at <http://www.hrsa.gov/data-statistics/health-center-data/index.html#what>. The HRSA also publishes State data on shortages in primary care, dental and mental health providers on the Health Areas Shortage Designation web site (<http://hpsafind.hrsa.gov/HPSASearch.aspx>). This information may be of particular use to States in targeting specific State locations where access problems are a known issue in that geographic area, without regard to payer. The Agency for Healthcare Research and Quality (AHRQ) has developed a Medical Expenditures Panel Survey, available at http://www.meps.ahrq.gov/mepsweb/data_stats/onsite_datacenter.jsp, which offers surveys of families and individuals, medical providers, and

employers to document cost and use of health care and health insurance coverage. The Centers for Disease Control and Prevention (CDC), produces the National Ambulatory Medical Care Survey, which describes data on utilization and the provision of ambulatory care services in hospital emergency and outpatient departments, (<http://www.cdc.gov/nchs/ahcd.htm>), and the National Health Interview Survey, which tracks health status and health care access: (<http://www.cdc.gov/nchs/nhis.htm>).

We publish a number of Medicare and Medicaid data measures through a contractor, the Research Data Assistance Center (RESDAC), (<http://www.resdac.org/>). In addition, we have developed the Medicare Current Beneficiary Survey, which States may find of use in developing surveys that track beneficiary experience (<https://www.cms.gov/>). States may also find the U.S. Census Bureau's Current Population Survey of use for developing beneficiary questionnaires, <http://www.census.gov/>.

For external resources, the State Health Access Data Assistance Center (SHADAC) Web site, <http://www.shadac.org/>, which includes access data measures for each State. Finally, as part of MACPAC's three part approach to measuring access to care, the Commission offers a number of useful survey resources that States may find helpful in their first published report to the Congress, which was issued on March 15, 2011, (<http://www.macpac.gov/reports/>).

We are working to improve upon Medicaid data collection and analyses more generally and will be soon reaching out to States to help us identify the data and measures that are most important to guide State and Federal administration of the Medicaid program. We believe these broader data and performance measures will ultimately provide new resources for States to use as they carry out their important responsibilities to assure access to care consistent with the principles of efficiency, economy, and quality of care.

V. Provisions of the Proposed Regulations

The provisions of this proposed rule aim to create a consistent national approach to analyze and document Medicaid service access that allows States to formulate their own processes, metrics, and approaches in light of the range of local factors and circumstances that influence access in their State. In addition, the provisions seek to clarify and modernize the public notice regulation. As discussed previously in

this proposed rule, we are proposing to address State processes for setting payment rates by amending existing regulations at § 447.203, § 447.204, and § 447.205. Together, these changes better inform States and CMS on beneficiary access as States develop their service delivery and payment policies and potentially implement initiatives to address access issues.

A. Documentation of Access to Care and Service Payment Rates

The proposed revisions at § 447.203(b) would require State Medicaid agencies to demonstrate access to care by considering: Enrollee needs, the availability of care and providers, and the utilization of services. We believe that the experiences of beneficiaries should be a primary determinant of whether access is sufficient and we are soliciting public comments that will serve to help States narrow the focus of the data review to core elements that will demonstrate sufficient access to care. If beneficiaries are able to gain access to care (as required by the Act as equivalent to the general population in a geographic area), then clearly the standards of the Act have been met regardless of other factors, including payment levels. However, if beneficiaries experience difficulty in scheduling service appointments or otherwise accessing needed care, then data on rates of provider participation and retention, analyses of care delivery systems, as well as other relevant factors, including levels of payment are important for States to review and potentially adjust.

We have structured this proposed rule to require that States collect information on each of three parts of the MACPAC-recommended framework, leaving States the discretion to determine which particular metrics they can and should examine. However, we are soliciting public comments as to whether the data review should be required on an ongoing basis if the beneficiary data demonstrates adequate access to care. In part, this may depend on how accurate the beneficiary data may be, and we are particularly interested in public comments on the most reliable ways to gather beneficiary input across diverse groups of people, some with significant physical and mental health problems, language and other barriers.

As proposed, States would be required to review these data elements on an ongoing basis and specifically with respect to an affected service prior to submitting a Medicaid SPA that proposes service payment rate reductions. In terms of the ongoing review, we are proposing that States

would develop a schedule for reviewing each covered service at least once every 5 years, looking at a subset of services each calendar year. We considered a mandatory schedule for all States to follow to promote cross State collaborations and so that comparative data would be available. For example, all States would examine access to physician services in year one, and hospital services in year two. However, in this proposed rule, we are allowing States the discretion to determine the timeline and the organization of the review in recognition of unique State delivery systems and to allow States to prioritize their reviews based on their own sense of urgency, potential issues, or anticipated rate modifications. Further, this proposed rule proposes that all States have some process in place to hear from beneficiaries on access issues, for example, beneficiary survey, a hotline, or an ombudsman that is either internal to the agency or a contracted community partner. In addition, in this proposed rule, we are proposing that States set procedures for their review that will be informed by a public process, to monitor sustained access to care after a rate reduction is implemented and submit a corrective action plan to CMS to address access issues within 90 days of their discovery.

The data collection requirements are discussed in the proposed regulation text at § 447.203(b)(1)(i) through (iii). These provisions would require States to review and make publically available, data trends and factors that measure: Enrollee needs, availability of care and providers, and utilization of services. Consistent with the statutory requirement, we have proposed that States review this data by State designated geographic location.

The proposed changes to the regulation text at § 447.203(b)(1)(iii)(B) would require that the review must include: (1) An estimate of the percentile which Medicaid payment represents of the estimate average customary provider charges; (2) an estimate of the percentile which Medicaid payment represents of one, or more, of the following: Medicare payment rates, the average commercial payment rates, or the applicable Medicaid allowable cost of the services, and (3) an estimate of the composite average percentage increase or decrease resulting from any proposed revision in payment rates. We have developed this list of comparable payment structures based on our experience in how States set rates and the availability of the data in the interest of easing the administrative burden associated with the data collection effort. In our

experience, most States set Medicaid rates based on one of the three above-noted structures to which we are requiring a comparison and the comparable data should be easily obtained. We believe that the payment comparisons are consistent with the MACPAC-recommended framework and particularly may be informative of the availability of providers, though as discussed, may not be the primary indicator or provider participation. We are soliciting public comments on these measures.

We have further clarified the regulation text, at § 447.203(b)(1)(iii)(B)(3), to state that the Medicaid payment rates must include both base and supplemental payments for Medicaid services. It is important to include supplemental payments because the supplements are tied to the provision of a Medicaid service and will more accurately reflect total provider reimbursement. Should States target a subset of providers with supplemental payments, this should be noted and the targeted amounts recorded in the methodology required at § 447.203(b)(1)(iii)(B). Since States often reimburse service providers according to different payment schedules based on governmental status, we have included a provision at § 447.203(b)(1)(iii)(C) that has States stratify the access review data by State government owned or operated, non-State government owned or operated and private providers. Presenting the data in this manner should inform States as to whether payments are consistent with efficiency, economy, and quality and sufficient to enlist providers consistent with the availability of care and services in the geographic area.

In the proposed regulation text at § 447.203(b)(1)(iii)(D), we have described the minimum content that must be included in the rate review. Specifically, we require that States describe the measures that were used to conduct the review and their relationship to enrollee needs, the availability of care and providers, service utilization and Medicaid payment rates as compared to other payment structures. We also require that States discuss any access issues that were discovered as a result of the review and the State agency's recommendation on the sufficiency of access to care based on the data review.

The proposed regulation text at § 447.203(b)(2) describe the timeframe for States to conduct the data review and make the information available to the public through accessible public records or web sites on an on-going basis for all covered services. We

propose such annual reviews begin no later than 2013, so that States would have the discretion to determine a timeframe to review each covered Medicaid service, as long as the State reviews a subset of services each year and each covered service is reviewed at least once every 5 years. We provided States this 5-year cycle to reduce the burden while accommodating the need for review to assure compliance with section 1902(a)(30)(A) of the Act.

Because of the need to demonstrate service access in the context of a payment rate reduction, we describe at § 447.203(b)(3)(i) that States will need to conduct its review relevant to the affected service prior to submission of a State plan amendment implementing a reduction. We believe this is appropriate so that States consider the impact that such proposals may have on access to care and demonstrate compliance with section 1902(a)(30)(A) of the Act. If the State has already reviewed access relating to the types of services that are subject to the rate reduction within 12 months prior to the proposed rate reduction, and maintains an ongoing monitoring mechanism with respect to beneficiary complaints, its review relative to the rate reduction can reference the previous review.

In order to ensure sustained access to care, we have included provisions at § 447.203(b)(3)(ii) that require States to develop ongoing monitoring procedures through which they periodically review indices to measure sustained access to care. The periodic reviews helps a State to fulfill its ongoing responsibility to assure access to covered services consistent with the Act and forms a solid, informed basis by which a State and CMS can consider how any proposed changes might impact access. Along with monitoring the review data, it is important for States to continue to engage beneficiaries to understand their concerns and access issues on an ongoing basis. We have proposed to require States to have a mechanism for beneficiary input on access to care, such as hotlines, surveys, ombudsman or other equivalent mechanisms, at § 447.203(b)(4). Additionally, proposed regulation text at § 447.203(b)(5) would institute a corrective action procedure requiring States to submit a remediation plan should access issues be discovered through the access review or monitoring processes. These requirements intend to ensure that States will oversee and address any future access concerns.

After careful consideration, we developed the data elements discussed in this provision based on coordination with our Federal partners, in light of the MACPAC-recommended three-part

approach, and in an effort to minimize the administrative burden associated with the requirement. Though we recognize that no methodology to gauge access to care is flawless, we believe that these measures are appropriate to inform whether the Medicaid access requirements are met and that the MACPAC-recommended framework has been developed after study and based on public and expert input. We are soliciting public comments and alternatives to the framework and data elements that we have proposed in this proposed rule, the timeline for the data review and the process for monitoring and remediating access issues.

We note that the data analysis activities are claimable as administrative claiming activities, and reimbursable at the general 50 percent FFP rate for administrative expenditures, insofar as they are necessary for the proper and efficient administration of the Medicaid State plan, as described at section 1903(a)(7) of the Act. More specifically, utilization review is identified as an allowable Medicaid administrative activity in guidance that we issued in a State Medicaid Director Letter dated December 20, 1994. We also believe that States may be collecting some of this information as part of current review efforts for various purposes, including program administration and oversight, quality activities, integrity and payment, and are likely to be collecting such information by 2014 as part of other performance standards and measures required under the Affordable Care Act.

B. Medicaid Provider Participation and Public Process To Inform Access to Care

Regulations at § 447.204 implement the statutory requirement that Medicaid rates must be consistent with efficiency, economy, and quality and sufficient to enlist enough providers so that services under the plan are available to beneficiaries at least to the extent that those services are available to the general population. As discussed, the sufficiency requirement has been difficult to measure due to lack of consistent data, variables in delivery systems, and inconsistent State approaches to involving stakeholders in the rate development process.

To address these issues, we are proposing to amend the regulation text at § 447.204(a)(1) through (a)(2) to require that States consider, when proposing to reduce or restructure Medicaid payment rates, the data collected through the proposed requirement at § 447.203 and undertake a public process that solicits input on the potential impact of the proposed

reduction of Medicaid service payment rates on beneficiary access to care. We have also clarified, at § 447.204(b) that we may disapprove a proposed rate reduction or restructuring SPA that does not include or consider the data review and a public process. As an alternative, we may take a compliance action, in accordance with regulation text at 42 CFR 430.35 in these instances.

C. Public Notice of Changes in Statewide Methods and Standards for Setting Payment Rates

We are also taking this opportunity to propose clarifying and modernizing changes the public notice requirement at § 447.205. The substance of the notice is not affected by this action. However, a few States have expressed confusion in the past as to when a notice is required insofar as the current regulation calls for notice of “significant” changes in payment methods and standards. At this time we are soliciting public comments on whether it is advisable to delete the term “significant” from the paragraph at § 447.205(a) and explicitly state that notice is required for any change in rates. Alternatively, we are soliciting comments on whether to adopt a threshold for significance and what that threshold might be.

Further, we are proposing to recognize electronic publication as an optional means of publishing payment notice. To do so, we are adding § 447.205(d)(iv), which would allow notice to be published on a web site developed and maintained by the single State Medicaid Agency or other responsible State agency that is accessible to the general public on the Internet.

Given the dynamic nature of electronic media, we are proposing the following requirements for Internet notices: The notices are published on a regular and known basis; the issued notice includes the date that it was released to the public on the web site, and that the content of the notice is not altered after the initial publication. Based on discussions with States, we believe this will reduce State costs and allow for a more efficient means to notify the public of changes to Medicaid payment methods and standards.

VI. 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 Regarding Documentation of Access to Care and Service Payment Rates (§ 447.203(b))

Section 447.203(b) would require that States review and make public information that demonstrates sufficient Medicaid access to care, through a review of: Enrollee needs, the availability of care and providers, utilization of services and service payment rates. States would also be required under this provision to monitor data and beneficiary input on an ongoing basis and address known access issues through corrective action. Through this proposed rule, we would provide States with the discretion to determine appropriate data sources that will be used to conduct the review. We believe that most of the data that will be used to inform access is available to States and may already be collected by States as part of Medicaid program reviews and payment rate-setting procedures. We also note that States would have flexibility to compare Medicaid rates to one or more of Medicare rates, commercial rates, or Medicaid cost, as may be appropriate to the service under review. The burden associated with these requirements would be time and effort associated with analyzing this information, making it available to the public, and periodically updating the information relative to activities States are already undertaking. We have attempted to mitigate any new burden associated with this section by identifying data that States are likely to currently possess, by identifying other data sources that might be informative to State access reviews, and by phasing in the broader service review over 5-year intervals.

1. Access to Care Review Timeline

Section 1902(a)(30)(A) of the Act requires that States ensure that access to care is available to Medicaid beneficiaries equivalent to care provided to the general population in a geographic area. Since this obligation is ongoing and service access may change over time, § 447.203(b)(2) requires that States conduct their reviews for a subset of services each calendar year and review all covered Medicaid services at least once every 5 years. States would have the discretion to determine the appropriate services to review each year over the 5-year period in order to manage their review priorities and resources. As an exception to the 5-year timeline, § 447.203(b)(3)(i) would require States to conduct the access review in the context of a SPA to reduce payment rates or restructure provider payments in circumstance when the resulting changes could create access issues prior to the submission of a SPA that implements the changes. In this way, States would consider the impact that such proposals may have on access to care and demonstrate compliance with section 1902(a)(30)(A) of the Act. States may complete this review within the prior 12 months of the SPA submission.

2. Access to Care Review Framework

The data analysis activities described under the proposal are claimable as administrative claiming activities, and reimbursable at the general 50 percent FFP rate for administrative expenditures, insofar as they are necessary for the proper and efficient administration of the Medicaid State plan, as described at section 1903(a)(7) of the Act. More specifically, utilization review is identified as an allowable Medicaid administrative activity in guidance that we issued in a State Medicaid Director Letter dated December 20, 1994. We also believe that States may be collecting some of this information as part of current review efforts for various purposes, including program administration and oversight, quality activities, integrity and payment, and are likely to be collecting such information by 2014 as part of other performance standards and measures required under the Affordable Care Act.

The provisions at § 447.203(b)(1) through (3) would require States to review and make publically available, data trends and factors that measure: Enrollee needs, availability of care and providers, utilization of services, and service payment information. Consistent with the statutory requirement, we have proposed that States review this data by

State designated geographic location. After careful consideration, we developed the review framework based on coordination with our Federal partners, in light of the MACPAC-recommended three-part approach, and in an effort to minimize the administrative burden associated with the requirement. Though we recognize that no methodology to gauge access to care is flawless, we believe that the framework, as supported by State data sources, are appropriate to inform whether the Medicaid access requirements are met.

Section 447.203(b)(1)(iii)(B) would require that the review include: (1) An estimate of the percentile which Medicaid payment represents of the estimate average customary provider charges; (2) an estimate of the percentile which Medicaid payment represents of one, or more, of the following: Medicare payment rates, the average commercial payment rates, or the applicable Medicaid allowable cost of the services; and (3) an estimate of the composite average percentage increase or decrease resulting from any proposed revision in payment rates. We have developed this list of comparable payment structures based on our experience in how States set rates and the availability of the data in the interest of easing the administrative burden associated with the data collection effort. In our experience, most States set Medicaid rates based on one of the three above-noted structures and the comparable data should be easily obtained. We believe that the payment comparisons are consistent with the MACPAC-recommended framework and particularly may be informative of the availability of providers, though as discussed, may not be the primary indicator or provider participation.

In § 447.203(b)(1)(iii)(B)(3), we clarified that both base and supplemental payments for Medicaid services must include supplemental payments because the supplements are tied to the provision of a Medicaid service and will more accurately reflect total provider reimbursement. Should States target a subset of providers with supplemental payments, this should be noted and the targeted amounts recorded in the methodology required at § 447.203(b)(1)(iii)(B).

Since States often reimburse service providers according to different payment schedules based on governmental status, we have included a provision at § 447.203(b)(1)(iii)(C) that has States stratify the access review data by State government owned or operated, non-State government owned or operated and private providers.

Presenting the data in this manner should inform States as to whether payments are consistent with efficiency, economy, and quality and sufficient to enlist providers consistent with the availability of care and services in the geographic area.

In § 447.203(b)(1)(iii)(D), we describe the minimum content that must be included in the rate review. Specifically, we require that States describe the measures that were used to conduct the review and their relationship to enrollee needs, the availability of care and providers, service utilization and Medicaid payment rates as compared to other payment structures. We also require that States discuss any access issues that were discovered as a result of the review and the State agency's recommendation on the sufficiency of access to care based on the data review.

Section 447.203(b)(2) describes the timeframe for States to conduct the data review and make the information available to the public through accessible public records or web sites on an on-going basis for all covered services. We propose such annual reviews begin no later than 2013, so that States would have the discretion to determine a timeframe to review each covered Medicaid service, as long as the State reviews a subset of services each year and each covered service is reviewed at least once every 5 years. We provided States this 5-year cycle to reduce the burden while accommodating the need for review to assure compliance with section 1902(a)(30)(A) of the Act.

We estimate that the requirements to review and make publically available, data trends and factors that measure: Enrollee needs, availability of care and providers, utilization of services, and Medicaid rate comparisons under § 447.203(b)(1) through (3) would affect all States. We have allowed States the flexibility to choose the services that they review annually based on available resources and State priorities. As such, we assume that States will conduct reviews in the context of rate reductions or restructuring payment rates as part of their annual ongoing reviews and we consider the burden associated with rate reduction reviews as part of the ongoing estimate burden.

An employee equivalent to the Federal Salary Classification of GS 13 Step 1 could be responsible for gathering review data and developing and publishing the content of the data review. An employee equivalent to the Federal Salary Classification of a GS 15 Step 1 would be responsible for overseeing and approving the data

review. We have taken these employee assumptions and utilized the corresponding employee hourly rates for the locality pay area of Washington, DC as published by the U.S. Office of Personnel Management, to calculate our

cost estimates. We have also calculated the cost by assuming that a State expends 36 percent of an employee's hourly wages on benefits for the employee. We have concluded that a 36 percent expenditure on benefits is an

appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our calculations are expressed in Tables 1 and 2.

TABLE 1—ACCESS DATA REVIEW: BURDEN PER STATE
[Annual]

| Proposed requirement | Employee equivalent | Burden hours | Employee hourly wage rate | Cost of employee benefits per hour | Cost per data review |
|--------------------------------------|---------------------|--------------|---------------------------|------------------------------------|----------------------|
| Gathering Review Data | GS 13 Step 1 | 160 | \$42.66 | \$15.35 | \$9,281.60 |
| Developing Content of Review | GS 13 Step 1 | 100 | 42.66 | 15.35 | 5,801.00 |
| Publishing Content of Review | GS 13 Step 1 | 40 | 42.66 | 15.35 | 2,320.40 |
| Reviewing and Approving Review | GS 15 Step 1 | 10 | 59.30 | 21.35 | 806.50 |
| Total Burden per State | | 310 | | | 18,209.50 |

TABLE 2—ACCESS DATA REVIEW: TOTAL BURDEN
[Annual]

| Anticipated number of State reviews | Total hours | Cost of review per State | Total cost estimate (\$) |
|-------------------------------------|-------------|--------------------------|--------------------------|
| 50 | 15,500 | \$18,209.50 | \$910,475.00 |

*B. ICRs Regarding Monitoring Access
(\$ 447.203(b)(3)(ii))*

Section 447.203(b)(3)(ii) would require States to develop ongoing monitoring procedures after reducing or restructuring payments through which they periodically review measures of sustained access to care for the affected service(s). The periodic reviews are intended to help a State fulfill its ongoing responsibility to assure access to covered services consistent with the Act and form a solid, informed basis by which a State and CMS can consider how any proposed changes might affect access. Along with monitoring the review data, it is important for States to

continue to engage beneficiaries to understand their concerns and access issues on an ongoing basis.

We estimate that the requirement under § 447.203(b)(3)(ii) would affect all States that implement a rate reduction or restructure payment rates. We are estimating that approximately 22 States will implement these rate changes based on the number of States that proposed such reductions in FY 2010. An employee equivalent to the Federal Salary Classification of a GS 13 Step 1 could develop the monitoring procedures and periodically review the monitoring results. An employee equivalent to the Federal Salary Classification of a GS 15 Step 1 would

be responsible for overseeing and approve the monitoring process. We have taken these employee assumptions and utilized the corresponding employee hourly rates for the locality pay area of Washington, DC as published by the U.S. Office of Personnel Management, to calculate our cost estimates. We have also calculated the cost by assuming that a State expends 36 percent of an employee's hourly wages on benefits for the employee. We have concluded that a 36 percent expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our calculations are expressed in Tables 3 and 4.

TABLE 3—ACCESS MONITORING PROCEDURES: BURDEN PER STATE
[Annual]

| Proposed requirement | Employee equivalent | Burden hours | Employee hourly wage rate | Cost of employee benefits per hour | Cost per data review |
|--|---------------------|--------------|---------------------------|------------------------------------|----------------------|
| Develop Monitoring Procedures | GS 13 Step 1 | 40 | \$42.66 | \$15.35 | \$2,320.40 |
| Periodically Review Monitoring Results | GS 13 Step 1 | 24 | 42.66 | 15.35 | 1,392.24 |
| Approve Monitoring Procedures | GS 15 Step 1 | 3 | 59.30 | 21.35 | 241.95 |
| Total Burden per State | | 67 | | | 3,954.59 |

TABLE 4—ACCESS MONITORING PROCEDURES: TOTAL BURDEN
[Annual]

| Anticipated number of State reviews | Total hours | Cost of review per State | Total cost estimate (\$) |
|-------------------------------------|-------------|--------------------------|--------------------------|
| 22 | 1,474 | \$3,954.59 | \$87,000.98 |

C. ICRs Regarding Beneficiary Feedback (§ 447.203(b)(4))

Section 447.203(b)(4) would require States to have a mechanism for obtaining beneficiary feedback on access to care, such as hotlines, surveys, ombudsman or other equivalent mechanisms.

We estimate that the requirement under § 447.203(b)(4) would affect all States that do not currently have a means of beneficiary feedback. Since we

currently do not know which States have implemented these mechanisms, we are assuming in our estimate that all States will need to develop new mechanisms. An employee equivalent to the Federal Salary Classification of a GS 9 Step 1 could develop and oversee the feedback effort. An employee equivalent to the Federal Salary Classification of a GS 15 Step 1 would be responsible for approving the feedback effort. We have taken these employee assumptions and utilized the corresponding employee

hourly rates for the locality pay area of Washington, DC as published by the U.S. Office of Personnel Management, to calculate our cost estimates. We have also calculated the cost by assuming that a State expends 36 percent of an employee's hourly wages on benefits for the employee. We have concluded that a 36 percent expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our calculations are expressed in Tables 5 and 6.

TABLE 5—BENEFICIARY FEEDBACK MECHANISM: BURDEN PER STATE
[Annual]

| Proposed requirement | Employee equivalent | Burden hours | Employee hourly wage rate | Cost of employee benefits per hour | Cost per data review |
|-----------------------------------|---------------------|--------------|---------------------------|------------------------------------|----------------------|
| Developing Feedback Effort | GS 9 Step 1 | 100 | \$24.74 | \$8.90 | \$3,364.00 |
| Monitoring Feedback Results | GS 9 Step 1 | 24 | 24.74 | 8.90 | 807.36 |
| Approve Feedback Effort | GS 15 Step 1 | 5 | 59.30 | 21.35 | 403.25 |
| Total Burden per State | | 129 | | | 4,574.61 |

TABLE 6—BENEFICIARY FEEDBACK MECHANISM: TOTAL BURDEN
[Annual]

| Anticipated number of State reviews | Total hours | Cost of review per State | Total cost estimate (\$) |
|-------------------------------------|-------------|--------------------------|--------------------------|
| 50 | 6,450 | \$4,574.61 | \$228,730.50 |

D. ICRs Regarding Corrective Action Plan (§ 447.203(b)(5))

Section 447.203(b)(5) would institute a corrective action procedure that requires States to submit to CMS a remediation plan should access issues be discovered through the access review or monitoring processes. The requirement is intended to ensure that States will oversee and address any future access concerns.

We estimate that the requirement under § 447.203(b)(5) would affect all States that identify access issues. We are estimating that approximately 10 States will identify access issues and submit corrective action plans to CMS. This is

a new requirement and we have no basis to determine how many States will identify access issues as they conduct the data reviews and monitoring activities. We assume that many States currently have mechanisms in place to monitor access to care and identify issues. However, we are careful not to under-estimate the burden associated with this provision and we believe that a maximum of 10 States may identify access issues per year. An employee equivalent to the Federal Salary Classification of a GS 13 Step 1 could identify issues that require corrective action and develop the plan to submit to CMS. An employee equivalent to the Federal Salary Classification of a GS 15

Step 1 would be responsible for review and approving the plan. We have taken these employee assumptions and utilized the corresponding employee hourly rates for the locality pay area of Washington, DC as published by the U.S. Office of Personnel Management, to calculate our cost estimates. We have also calculated the cost by assuming that a State expends 36 percent of an employee's hourly wages on benefits for the employee. We have concluded that a 36 percent expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our calculations are expressed in Tables 7 and 8.

TABLE 7—CORRECTIVE ACTION PLAN: BURDEN PER STATE
[Annual]

| Proposed requirement | Employee equivalent | Burden hours | Employee hourly wage rate | Cost of employee benefits per hour | Cost per data review |
|--------------------------------------|---------------------|--------------|---------------------------|------------------------------------|----------------------|
| Identifying Issues for Action | GS 13 Step 1 | 20 | \$42.66 | \$15.35 | \$1,160.20 |
| Developing the Corrective Plan | GS 13 Step 1 | 40 | 42.66 | 15.35 | 2,320.40 |
| Approve Corrective Plan | GS 15 Step 1 | 3 | 59.30 | 21.35 | 241.95 |
| Total Burden Per State | | 63 | | | \$3,722.55 |

TABLE 8—CORRECTIVE ACTION PLAN: TOTAL BURDEN
[Annual]

| Anticipated number of state reviews | Total hours | Cost of review per state | Total cost estimate (\$) |
|-------------------------------------|-------------|--------------------------|--------------------------|
| 10 | 630 | \$3,722.55 | \$37,225.50 |

E. ICRs Regarding Public Process to Engage Stakeholders (§ 447.204)

Section 447.204 implements the statutory requirement specifying that Medicaid rates must be consistent with efficiency, economy, and quality and must also be sufficient to enlist enough providers so that services under the plan are available to beneficiaries at least to the extent that those services are available to the general population. As discussed in section I. of this proposed rule, the sufficiency requirement has been difficult to measure due to lack of consistent data, variables in delivery systems, and inconsistent State approaches to involving stakeholders in the rate development process.

To address these issues, § 447.204(a)(1) and (a)(2) would require that States consider (when proposing to

reduce Medicaid payment rates) the data collected through § 447.203 and undertake a public process that solicits input on the potential impact of the proposed reduction or restructuring of Medicaid service payment rates on beneficiary access to care. We have also clarified, at § 447.204(b) that we may disapprove a proposed rate reduction or restructuring SPA that does not include or consider the data review and a public process. As an alternative, we may take a compliance action, in accordance with regulation text at § 430.35 in these instances.

We are estimating that approximately 22 States will implement these rate changes that would require a public process based on the number of States that proposed such reductions in FY 2010. An employee equivalent to the Federal Salary Classification of a GS 9

Step 1 could develop and oversee the public process effort. An employee equivalent to the Federal Salary Classification of a GS 15 Step 1 would be responsible for approving the public process effort. We have taken these employee assumptions and utilized the corresponding employee hourly rates for the locality pay area of Washington, DC as published by the U.S. Office of Personnel Management, to calculate our cost estimates. We have also calculated the cost by assuming that a State expends 36 percent of an employee's hourly wages on benefits for the employee. We have concluded that a 36 percent expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our calculations are expressed in Tables 9 and 10.

TABLE 9—PUBLIC PROCESS: BURDEN PER STATE

| Proposed requirement | Employee equivalent | Burden hours | Employee hourly wage rate | Cost of employee benefits per hour | Cost per data review |
|----------------------------------|---------------------|--------------|---------------------------|------------------------------------|----------------------|
| Develop the Public Process | GS 9 Step 1 | 20 | \$24.74 | \$8.90 | \$672.80 |
| Oversee the Public Process | GS 9 Step 1 | 40 | 24.74 | 8.90 | 1345.60 |
| Approve Public Process | GS 15 Step 1 | 3 | 59.30 | 21.35 | 241.95 |
| Total Burden Per State | | 63 | | | 2,260.35 |

TABLE 10—PUBLIC PROCESS: TOTAL BURDEN
[Annual]

| Anticipated number of state reviews | Total hours | Cost of review per state | Total cost estimate (\$) |
|-------------------------------------|-------------|--------------------------|--------------------------|
| 22 | 1,386 | \$2,260.35 | \$49,727.70 |

F. ICRs Regarding Public Notice of Changes in Statewide Methods and Standards for Setting Payment Rates (§ 447.205)

The proposed provisions at § 447.205 would clarify when States must issue public notice to providers and would allow for the electronic publication of

those notices. Section 447.205(d)(2)(iv)(A) through (C) would allow those notices to be published on the single State Medicaid Agency or other State developed and maintained web site that is accessible to the general public via the Internet.

The burden associated with developing and issuing public notice at

§ 447.205 is not affected by this proposed action since the revision would simply allow for an additional (in this case, electronic) means of notification. Consequently, we do not include the electronic notice activity in our burden analysis.

TABLE 11: Annual Recordkeeping and Reporting Requirements

| Regulation Section(s) | OMB Control No. | Number of Respondents | Number of Responses | Burden per Response (hours) | Total Annual Burden (hours) | Hourly Labor Cost of Reporting (\$) | Total Labor Cost of Reporting (\$) | Total Capital/Maintenance Costs (\$) | Total Cost (\$) |
|-----------------------|-----------------|-----------------------|---------------------|-----------------------------|-----------------------------|-------------------------------------|------------------------------------|--------------------------------------|-----------------|
| 447.203(b)(1) – (3) | 0938-NEW | 50 | 50 | 300 | 15,000 | 58.01 | 870,150 | 0 | 870,150 |
| Subtotal | | | | 10 | 500 | 80.65 | 40,325 | 0 | 40,325 |
| 447.203(b)(3)(ii) | 0938-NEW | 22 | 22 | 310 | 15,500 | – | 910,475 | 0 | 910,475 |
| Subtotal | | | | 64 | 1,408 | 58.01 | 81,678.08 | 0 | 81,678.08 |
| 447.203(b)(4) | 0938-NEW | 50 | 50 | 3 | 66 | 80.65 | 5,322.90 | 0 | 5,323.90 |
| Subtotal | | | | 67 | 1,474 | – | 87,000.98 | 0 | 87,000.98 |
| 447.203(b)(5) | 0938-NEW | 10 | 10 | 124 | 6,200 | 33.64 | 208,568 | 0 | 208,568 |
| Subtotal | | | | 5 | 250 | 80.65 | 20,162.50 | 0 | 20,162.50 |
| 447.203(b)(5) | 0938-NEW | 10 | 10 | 129 | 6,450 | – | 228,730.50 | 0 | 228,730.50 |
| Subtotal | | | | 60 | 600 | 58.01 | 34,806 | 0 | 34,806 |
| 447.204(a)(1) and (2) | 0938-NEW | 22 | 22 | 3 | 30 | 80.65 | 2,419.50 | 0 | 2,419.50 |
| Subtotal | | | | 63 | 630 | – | 37,225.50 | 0 | 37,225.50 |
| 447.204(a)(1) and (2) | 0938-NEW | 22 | 22 | 60 | 1,320 | 33.64 | 44,404.80 | 0 | 44,404.80 |
| Subtotal | | | | 3 | 66 | 80.65 | 5,322.90 | 0 | 5,322.90 |
| TOTAL | | 154 | 154 | 63 | 1,386 | – | 49,727.70 | 0 | 49,727.70 |
| | | | | 632 | 25,440 | -- | 131,3159.68 | 0 | 131,3159.68 |

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-2328-P Fax: (202) 395-6974; or Email: OIRA_submission@omb.eop.gov

VII. 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.

VIII. Regulatory Impact Statement

A. Statement of Need

This proposed rule would revise regulatory provisions in § 447.203 and § 447.204 to create a standardized, transparent process for States to follow as part of their broader efforts to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to the general population in the geographic area, as required by section 1902(a)(30)(A) of the Act. This proposed rule would also clarify and amend the regulations at § 447.205, which require States to issue public notice to their providers when changing Medicaid payment methods and standards. The proposed changes to the public notice requirement intend to alleviate confusion on when States must issue notice to providers and recognize electronic media as a means to issue the notices.

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 Order 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is

necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We do not believe that there is potential for this provision to surpass the threshold for economic significance because the proposed data analysis effort is generally consistent with current State oversight and review activities and States have flexibility within the reviews to use their existing data or build upon that data when reviewing access to care.

In fact, the guidance provided under the proposal intends to focus disparate State efforts in monitoring and overseeing data and beneficiary concerns, which offers a clear framework to comply with section 1902(a)(30)(A) of the Act. In the absence of Federal guidance, States have likely mispent resources in efforts to interpret and comply with section 1902(a)(30)(A) of the Act. We will also make every effort, in collaboration with State and Federal partners, to identify resources and tools that States may use to review and monitor access to care within their State Medicaid programs. In this proposed rule, we are soliciting public comments to begin identifying data sources and will continue to provide assistance as States develop their reviews and monitoring procedures.

We estimate that even if these data collection efforts were, in fact, totally new to a State and each State were to either bid a contract to gather and publish the data collection effort and public process required under this proposed rule or conduct the collection and public process with State agency resources, the economic effects would not surpass \$100 million or more in any 1 year.

Further, we are not requiring that States directly adjust payment rates as a result of the provisions of this proposed rule, nor to take any steps that would not be consistent with efficiency, economy, and quality of care. Rather, these rules propose to make clear that beneficiary access must be considered in setting and adjusting payment methodology for Medicaid services. If a problem is identified, any number of steps might be appropriate, such as redesigning service delivery strategies, or improving provider enrollment and retention efforts. It has always been within the regulatory authority of the CMS to make SPA approval decisions based on sufficiency of beneficiary

service access and this proposed rule merely provides a more consistent and transparent way to gather and analyze the necessary information to support such reviews.

The RFA requires agencies to analyze options for regulatory relief for 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 government jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$7.0 million to \$34.5 million in any 1 year. For details, see the Small Business Administration's Web site at <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2465b064ba6965cc1fbd2eae60854b11&rgn=div8&view=text&node=13:1.0.1.1.16.1.266.9&idno=13>. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we and the Secretary have determined that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 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 for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we and the Secretary have 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 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately \$136 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose costs above \$135 million or more on

State or local governments, the requirements of E.O. 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

C. Regulatory Alternatives Considered

This section provides an overview of regulatory alternatives that CMS considered for this proposed rule. In determining the appropriate approach to guide States in their efforts to meet the requirements of section 1902(a)(30)(A) of the Act and demonstrate sufficient access to Medicaid services, we consulted with State Medicaid directors, Federal agency policy officials and the MACPAC. Based, in part, on these discussions we arrived at the provisions proposed in this proposed rule, which seek to balance State obligations to meet the statutory requirement of section 1902(a)(30)(A) of the Act and potential new burden associated with the proposal. To achieve this balance, we have set forth a process that provides a framework for States to demonstrate access to Medicaid services using available data resources and in consideration of unique and evolving health care delivery systems. We have also emphasized the importance of considering beneficiary input in determining and monitoring access to Medicaid services throughout the process as discussed in this proposed rule.

1. Access Data Review

The process for documenting access to care and service payment rates described at § 447.203 would require States to publish access data reviews that discuss, as recommended by MACPAC, the extent to which enrollee needs are met, the availability of care and providers, and changes in beneficiary utilization of covered services. The review would also include a comparison of Medicaid payment rates to customary charges and Medicare, commercial payments, or provider cost. The reviews are to be conducted over 5-year periods for all services covered in a State's Medicaid State plan or, in the context of a State plan amendment proposal to reduce provider rates or restructure provider rates in circumstance that may negatively impact access to care, within 12 months of implementing the State plan amendment.

As an alternative to the MACPAC-recommended framework for reviewing access to care, we considered requiring States to report standard data measures to demonstrate sufficient access to care

and section 1902(a)(30)(A) of the Act. We also considered setting national access thresholds or requiring States to establish and demonstrate access thresholds. As we have highlighted throughout this proposed rule, there are no standardized, transparent methodologies for demonstrating access to care that would be appropriate to adopt at this time. A singular approach to demonstrating access may not consider differences in Medicaid benefits and State or local delivery models. For instance, the appropriate data to measure access to Medicaid long-term care services provided through personal care providers could be very different from data used to measure access to acute care services delivered in a hospital facility that offers outpatient care.

Rather than prescribe data measures that may not align with all services or set threshold standards, we have adopted the MACPAC-recommended framework, which sets forth a three-part review that applies across services and delivery systems and will allow States the flexibility to determine, through current or new data sources, appropriate measures of access to care. As States analyze their existing data sources and those that we identify through work with MACPAC and our Federal partners, we believe that States may arrive at best practices for determining sufficient Medicaid access to care which could be replicated across State delivery systems and will evolve with new approaches to delivering health care to Medicaid beneficiaries.

2. Access Review Timeframe and Monitoring Procedures

In this proposed rule, we are proposing that access data reviews be conducted over 5-year periods for all services covered in a State's Medicaid State plan or, in the context of a provider rate reduction or restructuring of provider rates that may negatively affect access to care, within 12 months of implementing the State plan amendment. We have arrived at the 5-year ongoing review to allow States to determine the best use of available State resources in conducting the access review and to prioritize the review in light of program changes or particular access concerns.

We considered requiring the review on an annual basis or a review period that is more frequent than 5 years. However, the burden associated with an annual review would likely be high and may not demonstrate any changes in access to care if the payment rates and service delivery systems remain stable. We believe that, absent rate reductions

or restructuring of payments, the 5-year review periods, combined with ongoing solicitation of information about access from beneficiaries, are sufficient to identify access issues that may occur over time, while also allowing the States the flexibility to prioritize the reviews. We also considered prescribing the services that States would be required to review each year so that there is national consistency in the access reviews. However, since the objective of this proposed rule is to provide States with a framework to demonstrate access to care consistent with section 1902(a)(30)(A) of the Act rather than to conduct a national study of access, we determined it appropriate to allow States the flexibility to choose which services to review each year based on their priorities.

This proposed rule would require that States develop monitoring procedures after implementing provider rate reductions or restructuring rates in ways that may negatively impact access to care. We require these monitoring procedures because the impact of rate changes on access to care may not be apparent at the time the changes are adopted. We considered not requiring States to monitor access after implementing the changes and to continue to rely on the 5-year reviews to ensure that access is maintained. However, we believe that it is important for States to identify and address access issues that arise from specific SPA actions, such as reimbursement rate reductions.

3. Beneficiary Input on Access to Care

The proposed changes to § 447.203 and § 447.204 emphasize the importance of involving beneficiaries in determining access issues and the impact that State rate changes will have on access to care. Specifically, we require that States implement an ongoing mechanism for beneficiary input on access to care (through hotlines, surveys, ombudsman, or another equivalent mechanism) and receive input from beneficiaries (and affected stakeholders) on the impact that proposed rates changes will have through a public process. We believe that beneficiaries' experiences in accessing Medicaid services is the most important indicator of whether access is sufficient and beneficiary input will be particularly informative in identifying access issues.

We also considered a requirement that States consult with beneficiaries when developing their corrective action plans in instances when the access data reviews or monitoring procedures identify access issues. While we

encourage States to solicit beneficiary input on corrective action plans, we did not make this a specific regulatory requirement and we leave this to the States' discretion to develop the corrective action plans as part of their current policy development methods.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, and Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services would amend 42 CFR chapter IV as set forth below:

PART 447—PAYMENTS FOR SERVICES

1. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart B—Payment Methods: General Provisions

2. Section 447.203 is amended by—

A. Revising the section heading.

B. Revising paragraph (b).

The revisions read as follows:

§ 447.203 Documentation of access to care and service payment rates.

* * * * *

(b) The agency must record and update, medical assistance access reviews for each covered benefit, in accordance with timeline describe in paragraph (c) of this section. Such reviews must be published or promptly made available upon request to the public and furnished, upon request, to CMS. The access reviews must include the items specified in this section, as well as trends and factors, which may vary by geographic location within the State, which will be used to inform State policies affecting access to Medicaid services, such as provider payment rates.

(1) *Access review data requirements.* States must document in their access review, using data trends and factors, an analysis that demonstrates sufficient access to care, considering, at a minimum:

(i) The extent to which enrollee needs are met;

(ii) The availability of care and providers; and

(iii) Changes in beneficiary utilization of covered services. The access review must also include the following information:

(A) *Beneficiary information.* Relevant beneficiary information as described in paragraph (b)(4) of this section.

(B) *Access review medicaid payment data.* The review must include all of the following:

(1) An estimate of the percentile, which Medicaid payment represents of the estimated average customary provider charges.

(2) An estimate of the percentile, which Medicaid payment represents of one, or more, of the following: Medicare payment rates, the average commercial payment rates, or the applicable Medicaid allowable cost of the services.

(3) An estimate of the composite average percentage increase or decrease resulting from any proposed revision in payment rates. The review must also include a description of the methods used to make the estimates described above. The data on Medicaid payment rates must include all base and supplemental payments to providers described under the Medicaid State plan.

(C) *Stratification requirement.* Data on provider payment rates in the access review must be stratified to the extent that payments vary by the following categories of providers: State government-owned or operated, non-State government owned or operated, privately owned or operated.

(D) *Content of the review.* The review must, at a minimum, describe: the specific measures that the State uses to analyze access to care, how the measures relate to the framework described in paragraph (b)(1) of this section, any issues with access that are discovered as a result of the review, and the State agency's recommendations on the sufficiency of access to care based on the review.

(2) *Access review timeframe.* Beginning January 1 of the year beginning no sooner than 12 months after the effective date of the final rule, for all covered services, the State agency must complete the access review on a State-determined timeframe, provided that:

(i) The State completes its reviews a subset of services each calendar year by January 1 of each year;

(ii) All covered services undergo a full review at least once every 5 years; and

(iii) The results of the review are made available to the public (which could include a web site developed and maintained by the single State agency or other responsible State agency), and to CMS upon request through public records.

(3) *Special provisions for proposed provider rate reductions or restructuring—*(i) *Compliance with*

access requirements. To demonstrate compliance with the access requirements at section 1902(a)(30)(A) of the Act, the State must submit with any State plan amendment that would reduce provider payment rates or restructure provider payments in circumstance when the changes could result in access issues, an access review described under paragraph (b)(1) of this section completed within the prior 12 months. That access review must demonstrate sufficient access for any service for which the State agency proposes to reduce payment rates or restructure provider payments in circumstance when the changes could result in access issues.

(ii) *Monitoring procedures.* A State must develop procedures to monitor continued access to care after implementation of State plan service rate reduction or payment restructuring. The procedures must define a periodic review of State determined indices that will serve to demonstrate sustained service access, consistent with efficiency, economy, and quality of care.

(4) *Mechanisms for ongoing input.* States must have ongoing mechanisms for beneficiary input on access to care (through hotlines, surveys, ombudsman or another equivalent mechanism), consistent with the access requirements and public process described in § 447.204 of this subpart. States must maintain a record of the volume and nature of the response to such input.

(5) *Addressing access questions and remediation of access issues.* If a State's access review or monitoring procedures determine access issues, regardless of whether the issue would indicate non-compliance with the statutory standard, the State agency is responsible for submitting a corrective action plan to CMS with specific steps and timelines to address the issue within 90 days of discovery. While the corrective action plan may include longer-term measures, the goal for remediation of the access deficiency should be no longer than 12 months.

3. Section 447.204 is revised to read as follows:

§ 447.204 Medicaid provider participation and public process to inform access to care.

(a) The agency's payments must be consistent with efficiency, economy, and quality of care and sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population. In reviewing payment sufficiency, States are required to consider, prior to the submission of

any State plan amendment that proposes to reduce or restructure Medicaid service payment rates:

(1) The data collected through the process described in § 447.203 of this subpart.

(2) Input from beneficiaries and affected stakeholders in determining the extent of beneficiary access to the affected services and the impact that the proposed rate change will have, if any, on continued service access. The State should maintain a record of the volume and nature of the response to such input.

(b) The State must submit to CMS with any such proposed State plan amendment, an analysis reflecting consideration of the information and procedure described in paragraph (a) of this section. If CMS determines that service rates are modified without such

an analysis, the agency may disapprove a proposed State plan amendment using the authority and procedures described at part 430 Subpart B of this title or may take a compliance action using the authority and procedures described at § 430.35 of this title.

4. Section 447.205 is amended by adding paragraph (d)(2)(iv) to read as follows:

§ 447.205 Public notice of changes in Statewide methods and standards for setting payment rates.

* * * * *

(d) * * *

(2) * * *

(iv) A web site developed and maintained by the single State agency or other responsible State agency that is accessible to the general public, provided that:

(A) The site is updated for bulletins on a regular and known basis (for example, the first day of each month);

(B) The issued notice includes the actual date it was released to the public on the web site; or

(C) The content of the issued notice is not modified after the initial publication.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program).

Dated: April 13, 2011.

Donald M. Berwick,
Administrator, Centers for Medicare & Medicaid Services.

Approved: April 27, 2011.

Kathleen Sebelius,
Secretary, Health and Human Services.

[FR Doc. 2011–10681 Filed 4–29–11; 4:15 pm]

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 424, and 455

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Disclosures of Ownership and Additional Disclosable Parties Information; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 424, and 455

[CMS-1351-P]

RIN 0938-AQ29

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Disclosures of Ownership and Additional Disclosable Parties Information

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

ACTION: Proposed rule.

SUMMARY: This proposed rule presents two options for updating the payment rates used under the prospective payment system for skilled nursing facilities (SNFs), for fiscal year 2012. In this context, it examines recent changes in provider behavior relating to the implementation of the Resource Utilization Groups, version 4 (RUG-IV) case-mix classification system and considers a possible recalibration of the case-mix indexes so that they more accurately reflect parity in expenditures between RUG-IV and the previous case-mix classification system. It also includes a discussion of a Non-Therapy Ancillary component and outlier research currently under development within CMS. In addition, this proposed rule discusses the impact of certain provisions of the Affordable Care Act. It proposes to require for fiscal year 2012 and subsequent fiscal years that the SNF market basket percentage change be reduced by the multi-factor productivity adjustment. It also proposes to require Medicare SNFs and Medicaid nursing facilities to disclose certain information to the Secretary of the United States Department of Health and Human Services (the Secretary) and other entities regarding the ownership and organizational structure of their facilities. Finally, it proposes certain changes relating to the payment of group therapy services and proposes new resident assessment policies.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 27, 2011.

ADDRESSES: In commenting, please refer to file code CMS-1351-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1351-P, P.O. Box 8016, Baltimore, MD 21244-8016.

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-1351-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. 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. Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments 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:

Sandra Bastinelli, (410) 786-3630 (for disclosure of ownership).
Penny Gershman, (410) 786-6643 (for information related to clinical issues).

John Kane, (410) 786-0557 (for information related to the development of the payment rates and case-mix indexes).
Kia Sidbury, (410) 786-7816 (for information related to the wage index).

Bill Ullman, (410) 786-5667 (for information related to level of care determinations, consolidated billing, and general information).

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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Abbreviations

In addition, because of the many terms to which we refer by abbreviation in this proposed rule, we are listing these abbreviations and their corresponding terms in alphabetical order below:

ABN Advance Beneficiary Notice
 AIDS Acquired Immune Deficiency Syndrome
 ARD Assessment Reference Date
 ASAP Assessment Submission and Processing
 BBA Balanced Budget Act of 1997, Public Law 105–33
 BBRA Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Public Law 106–113
 BIMS Brief Interview for Mental Status
 BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Public Law 106–554
 CAH Critical Access Hospital
 CBSA Core-Based Statistical Area
 CCR Cost-to-Charge Ratio
 CFR Code of Federal Regulations
 CMI Case-Mix Index
 CMS Centers for Medicare & Medicaid Services
 COT Change of Therapy
 EOT End of Therapy
 EOT–R End of Therapy—Resumption
 FQHC Federally Qualified Health Center
 FR Federal Register
 FY Fiscal Year
 GAO Government Accountability Office
 HAC Hospital-Acquired Condition
 HCC Hierarchical Condition Category
 HCPCS Healthcare Common Procedure Coding System
 HR–III Hybrid Resource Utilization Groups, Version 3
 IGI IHS (Information Handling Services) Global Insight, Inc.
 MDS Minimum Data Set
 MFP Multifactor Productivity
 MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275
 MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
 MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110–173
 MPAF Medicare PPS Assessment Form
 MSA Metropolitan Statistical Area
 NTA Non-Therapy Ancillary
 OMB Office of Management and Budget
 OMRA Other Medicare-Required Assessment
 ONTA Other Non-Therapy Ancillary

OSCAR Online Survey Certification and Reporting System
 PAC–PRD Post Acute Care Payment Reform Demonstration
 PECOS Medicare Provider Enrollment, Chain, and Ownership System
 PPS Prospective Payment System
 QIES Quality Improvement and Evaluation System
 RAI Resident Assessment Instrument
 RAVEN Resident Assessment Validation Entry
 RFA Regulatory Flexibility Act, Public Law 96–354
 RNP Routine NTA Bundled Payment
 RHC Rural Health Clinic
 RIA Regulatory Impact Analysis
 RTM Reimbursable Therapy Minutes
 RUG–III Resource Utilization Groups, Version 3
 RUG–IV Resource Utilization Groups, Version 4
 RUG–53 Refined 53–Group RUG–III Case-Mix Classification System
 SCHIP State Children's Health Insurance Program
 SNF Skilled Nursing Facility
 STM Staff Time Measurement
 STRIVE Staff Time and Resource Intensity Verification
 TNP Tiered Non-routine NTA Payment
 UMRA Unfunded Mandates Reform Act, Public Law 104–4

I. Background

Annual updates to the prospective payment system (PPS) rates for skilled nursing facilities (SNFs) are required by section 1888(e) of the Social Security Act (the Act), as added by section 4432 of the Balanced Budget Act of 1997 (BBA, Public Law 105–33, enacted on August 5, 1997), and amended by subsequent legislation as discussed elsewhere in this preamble. Our most recent annual update occurred in an update notice with comment period (75 FR 42886, July 22, 2010) that set forth updates to the SNF PPS payment rates for fiscal year (FY) 2011. We subsequently published a correction notice (75 FR 55801, September 14, 2010) with respect to those payment rate updates. We will respond to public comments which relate to the FY 2011 update notice, along with those relating to this current proposed rule, in the FY 2012 final rule.

A. Current System for Payment of Skilled Nursing Facility Services Under Part A of the Medicare Program

Section 4432 of the BBA amended section 1888 of the Act to provide for the implementation of a per diem PPS for SNFs, covering all costs (routine, ancillary, and capital-related) of covered SNF services furnished to beneficiaries under Part A of the Medicare program, effective for cost reporting periods beginning on or after July 1, 1998. In this proposed rule, we would update the

per diem payment rates for SNFs for FY 2012. Major elements of the SNF PPS include:

- *Rates.* As discussed in section I.G.1. of this proposed rule, we established per diem Federal rates for urban and rural areas using allowable costs from FY 1995 cost reports. These rates also included a “Part B add-on” (an estimate of the cost of those services that, before July 1, 1998, were paid under Part B but furnished to Medicare beneficiaries in a SNF during a Part A covered stay). We adjust the rates annually using a SNF market basket index, and we adjust them by the hospital inpatient wage index to account for geographic variation in wages. We also apply a case-mix adjustment to account for the relative resource utilization of different patient types. As further discussed in section I.G.1. of this proposed rule, for FY 2012 this adjustment will utilize the Resource Utilization Groups, version 4 (RUG–IV) case-mix classification, and will use information obtained from the required resident assessments using version 3.0 of the Minimum Data Set (MDS 3.0). (The resident assessment is approved under OMB# 0938–0739.) Additionally, as noted elsewhere in this preamble, the payment rates at various times have also reflected specific legislative provisions for certain temporary adjustments.

- *Transition.* Under sections 1888(e)(1)(A) and (e)(11) of the Act, the SNF PPS included an initial, three-phase transition that blended a facility-specific rate (reflecting the individual facility’s historical cost experience) with the Federal case-mix adjusted rate. The transition extended through the facility’s first three cost reporting periods under the PPS, up to and including the one that began in FY 2001. Thus, the SNF PPS is no longer operating under the transition, as all facilities have been paid at the full Federal rate effective with cost reporting periods beginning in FY 2002. As we now base payments entirely on the adjusted Federal per diem rates, we no longer include adjustment factors related to facility-specific rates for the coming FY.

- *Coverage.* The establishment of the SNF PPS did not change Medicare’s fundamental requirements for SNF coverage. However, because the case-mix classification is based, in part, on the beneficiary’s need for skilled nursing care and therapy, we have attempted, where possible, to coordinate claims review procedures with the existing resident assessment process and case-mix classification system. As further discussed in section II.E. of this proposed rule, in FY 2012, this

approach includes an administrative presumption that utilizes a beneficiary’s initial classification in one of the upper 52 RUGs of the 66-group RUG–IV case-mix classification system to assist in making certain SNF level of care determinations. In the July 30, 1999 final rule (64 FR 41670), we indicated that we would announce any changes to the guidelines for Medicare level of care determinations related to modifications in the case-mix classification structure (see section II.E. of this proposed rule for a more detailed discussion of the relationship between the case-mix classification system and SNF level of care determinations).

- *Consolidated Billing.* The SNF PPS includes a consolidated billing provision that requires a SNF to submit consolidated Medicare bills to its fiscal intermediary or Medicare Administrative Contractor for almost all of the services that its residents receive during the course of a covered Part A stay. In addition, this provision places with the SNF the Medicare billing responsibility for physical therapy, occupational therapy, and speech-language pathology services that the resident receives during a noncovered stay. The statute excludes a small list of services from the consolidated billing provision (primarily those of physicians and certain other types of practitioners), which remain separately billable under Part B when furnished to a SNF’s Part A resident. A more detailed discussion of this provision appears in section VII. of this proposed rule.

- *Application of the SNF PPS to SNF services furnished by swing-bed hospitals.* Section 1883 of the Act permits certain small, rural hospitals to enter into a Medicare swing-bed agreement, under which the hospital can use its beds to provide either acute or SNF care, as needed. For critical access hospitals (CAHs), Part A pays on a reasonable cost basis for SNF services furnished under a swing-bed agreement. However, in accordance with section 1888(e)(7) of the Act, these services furnished by non-CAH rural hospitals are paid under the SNF PPS, effective with cost reporting periods beginning on or after July 1, 2002. A more detailed discussion of this provision appears in section VIII. of this proposed rule.

B. Requirements of the Balanced Budget Act of 1997 (BBA) for Updating the Prospective Payment System for Skilled Nursing Facilities

Section 1888(e)(4)(H) of the Act requires that we provide for publication annually in the **Federal Register**:

1. The unadjusted Federal per diem rates to be applied to days of covered

SNF services furnished during the upcoming FY.

2. The case-mix classification system to be applied with respect to these services during the upcoming FY.

3. The factors to be applied in making the area wage adjustment with respect to these services.

Along with other revisions discussed later in this preamble, this proposed rule provides these required annual updates to the Federal rates.

C. The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA)

There were several provisions in the BBRA (Pub. L. 106–113, enacted on November 29, 1999) that resulted in adjustments to the SNF PPS. We described these provisions in detail in the SNF PPS final rule for FY 2001 (65 FR 46770, July 31, 2000). In particular, section 101(a) of the BBRA provided for a temporary 20 percent increase in the per diem adjusted payment rates for 15 specified groups in the original, 44-group Resource Utilization Groups, version 3 (RUG–III) case-mix classification system. In accordance with section 101(c)(2) of the BBRA, this temporary payment adjustment expired on January 1, 2006, upon the implementation of a refined, 53-group version of the RUG–III system, RUG–53 (see section I.G.1. of this proposed rule). We included further information on BBRA provisions that affected the SNF PPS in Program Memoranda A–99–53 and A–99–61 (December 1999).

Also, section 103 of the BBRA designated certain additional services for exclusion from the consolidated billing requirement, as discussed in section VII. of this proposed rule. Further, for swing-bed hospitals with more than 49 (but less than 100) beds, section 408 of the BBRA provided for the repeal of certain statutory restrictions on length of stay and aggregate payment for patient days, effective with the end of the SNF PPS transition period described in section 1888(e)(2)(E) of the Act. In the final rule for FY 2002 (66 FR 39562, July 31, 2001), we made conforming changes to the regulations at § 413.114(d), effective for services furnished in cost reporting periods beginning on or after July 1, 2002, to reflect section 408 of the BBRA.

D. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)

The BIPA (Pub. L. 106–554, enacted December 21, 2000) also included several provisions that resulted in adjustments to the SNF PPS. We described these provisions in detail in

the final rule for FY 2002 (66 FR 39562, July 31, 2001). In particular:

- Section 203 of the BIPA exempted CAH swing beds from the SNF PPS. We included further information on this provision in Program Memorandum A–01–09 (Change Request #1509), issued January 16, 2001, which is available online at <http://www.cms.gov/transmittals/downloads/a0109.pdf>.
- Section 311 of the BIPA revised the statutory update formula for the SNF market basket, and also directed us to conduct a study of alternative case-mix classification systems for the SNF PPS. In 2006, we submitted a report to the Congress on this study, which is available online at http://www.cms.gov/SNFPPS/Downloads/RC_2006_PC-PPSSNF.pdf.
- Section 312 of the BIPA provided for a temporary increase of 16.66 percent in the nursing component of the case-mix adjusted Federal rate for services furnished on or after April 1, 2001, and before October 1, 2002; accordingly, this add-on is no longer in effect. This section also directed the Government Accountability Office (GAO) to conduct an audit of SNF nursing staff ratios and submit a report to the Congress on whether the temporary increase in the nursing component should be continued. The report (GAO–03–176), which GAO issued in November 2002, is available online at <http://www.gao.gov/new.items/d03176.pdf>.
- Section 313 of the BIPA repealed the consolidated billing requirement for services (other than physical therapy, occupational therapy, and speech-language pathology services) furnished to SNF residents during noncovered stays, effective January 1, 2001. (A more detailed discussion of this provision appears in section VII. of this proposed rule.)
- Section 314 of the BIPA corrected an anomaly involving three of the RUGs that section 101(a) of the BBRA had designated to receive the temporary payment adjustment discussed above in section I.C. of this proposed rule. (As noted previously, in accordance with section 101(c)(2) of the BBRA, this temporary payment adjustment expired upon the implementation of case-mix refinements on January 1, 2006.)
- Section 315 of the BIPA authorized us to establish a geographic reclassification procedure that is specific to SNFs, but only after collecting the data necessary to establish a SNF wage index that is based on wage data from nursing homes. To date, this has proven to be unfeasible due to the volatility of existing SNF wage data and the significant amount of resources that

would be required to improve the quality of that data.

We included further information on several of the BIPA provisions in Program Memorandum A–01–08 (Change Request #1510), issued January 16, 2001, which is available online at <http://www.cms.gov/transmittals/downloads/a0108.pdf>.

E. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)

The MMA (Pub. L. 108–173, enacted on December 8, 2003) included a provision that resulted in a further adjustment to the SNF PPS. Specifically, section 511 of the MMA amended section 1888(e)(12) of the Act, to provide for a temporary increase of 128 percent in the PPS per diem payment for any SNF residents with Acquired Immune Deficiency Syndrome (AIDS), effective with services furnished on or after October 1, 2004. This special AIDS add-on was to remain in effect until “* * * the Secretary certifies that there is an appropriate adjustment in the case mix * * * to compensate for the increased costs associated with [such] residents * * *.” The AIDS add-on is also discussed in Program Transmittal #160 (Change Request #3291), issued on April 30, 2004, which is available online at <http://www.cms.gov/transmittals/downloads/r160cp.pdf>. In the SNF PPS final rule for FY 2010 (74 FR 40288, August 11, 2009), we did not address the certification of the AIDS add-on in that final rule’s implementation of the case-mix refinements for RUG–IV, thus allowing the temporary add-on payment created by section 511 of the MMA to remain in effect.

For the limited number of SNF residents that qualify for the AIDS add-on, implementation of this provision results in a significant increase in payment. For example, using FY 2009 data, we identified less than 3,500 SNF residents with a diagnosis code of 042 (Human Immunodeficiency Virus (HIV) Infection). For FY 2012, an urban facility with a resident with AIDS in RUG–IV group “HC2” would have a case-mix adjusted payment of \$400.01 (see Table 5) before the application of the MMA adjustment. After an increase of 128 percent, this urban facility would receive a case-mix adjusted payment of approximately \$912.02.

In addition, section 410 of the MMA contained a provision that excluded from consolidated billing certain services furnished to SNF residents by rural health clinics (RHCs) and Federally Qualified Health Centers (FQHCs). (Further information on this

provision appears in section VII of this proposed rule.)

F. The Affordable Care Act

On March 23, 2010, the Patient Protection and Affordable Care Act, Public Law 111–148, was enacted. Following the enactment of Public Law 111–148, the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted on March 30, 2010) amended certain provisions of Public Law 111–148 and certain sections of the Social Security Act and, in certain instances, included “freestanding” provisions (Pub. L. 111–148 and Pub. L. 111–152 are collectively referred to in this proposed rule as “the Affordable Care Act”). Section 10325 of the Affordable Care Act included a provision involving the SNF PPS. Section 10325 postponed the implementation of the RUG–IV case-mix classification system published in the FY 2010 SNF PPS final rule (74 FR 40288, August 11, 2009), requiring that the Secretary not implement the RUG–IV case-mix classification system before October 1, 2011. Notwithstanding this postponement of overall RUG–IV implementation, section 10325 further specified that the Secretary implement, effective October 1 2010, the changes related to concurrent therapy and the look-back period that were finalized as components of RUG–IV (see 74 FR 40315–19, 40322–24, August 11, 2009). As we noted in the FY 2011 SNF PPS update notice (75 FR 42889), implementing the particular combination of RUG–III and RUG–IV features specified in section 10325 of the Affordable Care Act would require developing a revised grouper, something that could not be accomplished by that provision’s effective date (October 1, 2010) without risking serious disruption to providers, suppliers, and State agencies. Accordingly, in the FY 2011 update notice (75 FR 42889), we announced our intention to proceed on an interim basis with implementation of the full RUG–IV case-mix classification system as of October 1, 2010, followed by a retroactive claims adjustment, using a hybrid RUG–III (HR–III) system reflecting the Affordable Care Act configuration, once we had developed a revised grouper that could accommodate it. In that update notice, we also invited public comment specifically on our plans for implementing section 10325 of the Affordable Care Act in this manner.

However, on December 15, 2010, the President signed H.R. 4994, the “Medicare and Medicaid Extenders Act of 2010” (Pub. L. 111–309), in which section 202 repeals section 10325 of the

Affordable Care Act. We will, therefore, leave in place permanently the implementation of the full RUG–IV system as of FY 2011, as finalized in the FY 2010 SNF PPS final rule (74 FR 40288). Moreover, as the repeal of section 10325 of the Affordable Care Act has now eliminated the need for a subsequent transition to the HR–III system, this also effectively renders moot any further discussion of public comments that we had invited on our planned implementation of that transition. In addition, we note that implementation of version 3.0 of the Minimum Data Set (MDS 3.0) has proceeded as originally scheduled, with an effective date of October 1, 2010. The MDS 3.0 RAI Manual and MDS 3.0 Item Set are published on the MDS 3.0 Training Materials Web site, at http://www.cms.gov/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp.

We note that a parity adjustment was applied to the RUG–53 nursing case-mix weights when the RUG–III system was initially refined in 2006, in order to ensure that the implementation of the refinements would not cause any change in overall payment levels (70 FR 45031, August 4, 2005). A detailed discussion of the parity adjustment in the specific context of the RUG–IV payment rates appears in the FY 2010 SNF PPS proposed rule (74 FR 22236–38, May 12, 2009) and final rule (74 FR 40338–40339, August 11, 2009), and in the FY 2011 update notice (75 FR 42892–42893).

Accordingly, as discussed above, effective October 1, 2010, we implemented and paid claims under the RUG–IV system that was finalized in the FY 2010 SNF PPS final rule. In section IV. of this proposed rule, we discuss certain ongoing Affordable Care Act initiatives that relate to SNFs, and in section V.A., we discuss proposed revisions involving section 6101 of the Affordable Care Act, regarding required disclosure of ownership and additional disclosable parties information.

G. Skilled Nursing Facility Prospective Payment—General Overview

We implemented the Medicare SNF PPS effective with cost reporting periods beginning on or after July 1, 1998. This methodology uses prospective, case-mix adjusted per diem payment rates applicable to all covered SNF services. These payment rates cover all costs of furnishing covered skilled nursing services (routine, ancillary, and capital-related costs) other than costs associated with approved educational activities and bad debts. Covered SNF services include

post-hospital services for which benefits are provided under Part A, as well as those items and services (other than physician and certain other services specifically excluded under the BBA) which, before July 1, 1998, had been paid under Part B but furnished to Medicare beneficiaries in a SNF during a covered Part A stay. A comprehensive discussion of these provisions appears in the May 12, 1998 interim final rule (63 FR 26252).

1. Payment Provisions—Federal Rate

The PPS uses per diem Federal payment rates based on mean SNF costs in a base year (FY 1995) updated for inflation to the first effective period of the PPS. We developed the Federal payment rates using allowable costs from hospital-based and freestanding SNF cost reports for reporting periods beginning in FY 1995. The data used in developing the Federal rates also incorporated an estimate of the amounts that would be payable under Part B for covered SNF services furnished to individuals during the course of a covered Part A stay in a SNF.

In developing the rates for the initial period, we updated costs to the first effective year of the PPS (the 15-month period beginning July 1, 1998) using a SNF market basket index, and then standardized for the costs of facility differences in case mix and for geographic variations in wages. In compiling the database used to compute the Federal payment rates, we excluded those providers that received new provider exemptions from the routine cost limits, as well as costs related to payments for exceptions to the routine cost limits. Using the formula that the BBA prescribed, we set the Federal rates at a level equal to the weighted mean of freestanding costs plus 50 percent of the difference between the freestanding mean and weighted mean of all SNF costs (hospital-based and freestanding) combined. We computed and applied separately the payment rates for facilities located in urban and rural areas. In addition, we adjusted the portion of the Federal rate attributable to wage-related costs by a wage index.

The Federal rate also incorporates adjustments to account for facility case-mix, using a classification system that accounts for the relative resource utilization of different patient types. The RUG–IV classification system uses beneficiary assessment data from the MDS 3.0 completed by SNFs to assign beneficiaries to one of 66 RUG–IV groups. The original RUG–III case-mix classification system used beneficiary assessment data from the MDS, version 2.0 (MDS 2.0) completed by SNFs to

assign beneficiaries to one of 44 RUG–III groups. Then, under incremental refinements that became effective on January 1, 2006, we added nine new groups—comprising a new Rehabilitation plus Extensive Services category—at the top of the RUG–III hierarchy. The May 12, 1998 interim final rule (63 FR 26252) included a detailed description of the original 44-group RUG–III case-mix classification system. A comprehensive description of the refined RUG–53 system appeared in the proposed and final rules for FY 2006 (70 FR 29070, May 19, 2005, and 70 FR 45026, August 4, 2005), and a detailed description of the current 66-group RUG–IV system appeared in the proposed and final rules for FY 2010 (74 FR 22208, May 12, 2009, and 74 FR 40288, August 11, 2009).

Further, in accordance with sections 1888(e)(4)(E)(ii)(IV) and (e)(5) of the Act, the Federal rates in this proposed rule reflect an update to the rates that we published in the update notice for FY 2011 (75 FR 42886, July 22, 2010) and the associated correction notice (75 FR 55801, September 14, 2010), equal to the full change in the SNF market basket index, adjusted by the forecast error correction, if applicable, and the Multifactor Productivity (MFP) adjustment for FY 2012. A more detailed discussion of the SNF market basket index and related issues appears in sections I.G.2. and VI. of this proposed rule.

2. FY 2012 Rate Updates Using the Skilled Nursing Facility Market Basket Index

Section 1888(e)(5) of the Act requires us to establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. We use the SNF market basket index, adjusted in the manner described below, to update the Federal rates on an annual basis. In the SNF PPS final rule for FY 2008 (72 FR 43425 through 43430, August 3, 2007), we revised and rebased the market basket, which included updating the base year from FY 1997 to FY 2004. The proposed FY 2012 market basket increase is 2.7 percent, which is based on IHS Global Insight, Inc. (IGI) first quarter 2011 forecast with historical data through fourth quarter 2010.

In addition, as explained in the final rule for FY 2004 (66 FR 46058, August 4, 2003) and in section VI.B. of this proposed rule, the annual update of the payment rates includes, as appropriate, an adjustment to account for market basket forecast error. As described in the final rule for FY 2008, the threshold

percentage that serves to trigger an adjustment to account for market basket forecast error is 0.5 percentage point effective for FY 2008 and subsequent years. This adjustment takes into account the forecast error from the most recently available FY for which there is final data, and applies whenever the difference between the forecasted and actual change in the market basket exceeds a 0.5 percentage point

threshold. For FY 2010 (the most recently available FY for which there is final data), the estimated increase in the market basket index was 2.2 percentage points, while the actual increase was 2.0 percentage points, resulting in the actual increase being 0.2 percentage point lower than the estimated increase. Accordingly, as the difference between the estimated and actual amount of change does not exceed the 0.5

percentage point threshold, the payment rates for FY 2012 do not include a forecast error adjustment. As we stated in the final rule for FY 2004 that first promulgated the forecast error adjustment (68 FR 46058, August 4, 2003), the adjustment will “* * * reflect both upward and downward adjustments, as appropriate.” Table 1 shows the forecasted and actual market basket amounts for FY 2010.

TABLE 1—DIFFERENCE BETWEEN THE FORECASTED AND ACTUAL MARKET BASKET INCREASES FOR FY 2010

| Index | Forecasted FY 2010 increase * | Actual FY 2010 increase ** | FY 2010 difference |
|-----------|----------------------------------|-------------------------------|--------------------|
| SNF | 2.2 | 2.0 | –0.2 |

* Published in **Federal Register**; based on second quarter 2009 IHS Global Insight Inc. forecast (2004-based index).

** Based on the first quarter 2011 IHS Global Insight forecast, with historical data through the fourth quarter 2010 (2004-based index).

Furthermore, effective FY 2012, as required by section 3401(b) of the Affordable Care Act, the market basket percentage is reduced by a productivity adjustment equal to “the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost-reporting period or other annual period)” (the MFP adjustment). As discussed in greater detail in section VI.C of this proposed rule, the proposed MFP adjustment for FY 2012 is 1.2 percent.

II. FY 2012 Annual Update of Payment Rates Under the Prospective Payment System for Skilled Nursing Facilities

A. Federal Prospective Payment System

This proposed rule sets forth a schedule of Federal prospective payment rates applicable to Medicare Part A SNF services beginning October 1, 2011. The schedule incorporates per diem Federal rates that provide Part A payment for almost all costs of services furnished to a beneficiary in a SNF during a Medicare-covered stay.

1. Costs and Services Covered by the Federal Rates

In accordance with section 1888(e)(2)(B) of the Act, the Federal rates apply to all costs (routine, ancillary, and capital-related) of covered SNF services other than costs associated with approved educational activities as defined in § 413.85. Under section 1888(e)(2)(A)(i) of the Act, covered SNF

services include post-hospital SNF services for which benefits are provided under Part A (the hospital insurance program), as well as all items and services (other than those services excluded by statute) that, before July 1, 1998, were paid under Part B (the supplementary medical insurance program) but furnished to Medicare beneficiaries in a SNF during a Part A covered stay. (These excluded service categories are discussed in greater detail in section V.B.2 of the May 12, 1998 interim final rule (63 FR 26295 through 26297)).

2. Methodology Used for the Calculation of the Federal Rates

The FY 2012 rates reflect an update using the latest market basket index, reduced by the MFP adjustment. The FY 2012 market basket increase factor is 2.7 percent, which as discussed in section VI.C of this proposed rule, is reduced by a 1.2 percent MFP adjustment. A complete description of the multi-step process used to calculate Federal rates initially appeared in the May 12, 1998 interim final rule (63 FR 26252), as further revised in subsequent rules. As explained above in section I.C of this proposed rule, under section 101(c)(2) of the BBRA, the previous temporary increases in the per diem adjusted payment rates for certain designated RUGs (as specified in section 101(a) of the BBRA and section 314 of the BIPA) are no longer in effect due to the implementation of case-mix refinements as of January 1, 2006. However, the temporary increase of 128 percent in the per diem adjusted payment rates for

SNF residents with AIDS, enacted by section 511 of the MMA, remains in effect.

We used the SNF market basket to adjust each per diem component of the Federal rates forward to reflect cost increases occurring between the midpoint of the Federal FY beginning October 1, 2010, and ending September 30, 2011, and the midpoint of the Federal FY beginning October 1, 2011, and ending September 30, 2012, to which the payment rates apply. In accordance with sections 1888(e)(4)(E)(ii)(IV) and (e)(5) of the Act, we update the payment rates for FY 2012 by a factor equal to the market basket index percentage increase, as discussed in sections I.G.2 and VI. of this proposed rule. As further explained in sections I.G.2 and VI. of this proposed rule, as applicable, we adjust the market basket index by the forecast error from the most recently available FY for which there is final data and apply this adjustment whenever the difference between the forecasted and actual change in the market basket exceeds a 0.5 percentage point threshold. In addition, as further explained in sections I.G.2 and VI. of this proposed rule, effective FY 2012 and each subsequent fiscal year, we are required to reduce the market basket percentage by the MFP adjustment. We further adjust the rates by a wage index budget neutrality factor, described later in this section. Tables 2 and 3 reflect the updated components of the unadjusted Federal rates for FY 2012, prior to adjustment for case-mix.

TABLE 2—FY 2012 UNADJUSTED FEDERAL RATE PER DIEM URBAN

| Rate component | Nursing— case-mix | Therapy— case-mix | Therapy— non-case-mix | Non-case-mix |
|-----------------------|----------------------|----------------------|--------------------------|--------------|
| Per Diem Amount | \$160.20 | \$120.68 | \$15.90 | \$81.76 |

TABLE 3—FY 2012 UNADJUSTED FEDERAL RATE PER DIEM RURAL

| Rate component | Nursing— case-mix | Therapy— case-mix | Therapy— non-case-mix | Non-case-mix |
|-----------------------|----------------------|----------------------|--------------------------|--------------|
| Per Diem Amount | \$153.07 | \$139.15 | \$16.97 | \$83.28 |

B. Case-Mix Adjustments

1. Background

Section 1888(e)(4)(G)(i) of the Act requires the Secretary to make an adjustment to account for case mix. The statute specifies that the adjustment is to reflect both a resident classification system that the Secretary establishes to account for the relative resource use of different patient types, as well as resident assessment and other data that the Secretary considers appropriate. In first implementing the SNF PPS (63 FR 26252, May 12, 1998), we developed the RUG—III case-mix classification system, which tied the amount of payment to resident resource use in combination with resident characteristic information. Staff time measurement (STM) studies conducted in 1990, 1995, and 1997 provided information on resource use (time spent by staff members on residents) and resident characteristics that enabled us not only to establish RUG—III, but also to create case-mix indexes (CMIs).

Although the establishment of the SNF PPS did not change Medicare's fundamental requirements for SNF coverage, there is a correlation between level of care and provider payment. One of the elements affecting the SNF PPS per diem rates is the case-mix adjustment derived from a classification system based on comprehensive resident assessments using the MDS. Case-mix classification is based, in part, on the beneficiary's need for skilled nursing care and therapy. The case-mix classification system uses clinical data from the MDS, and wage-adjusted staff time measurement data, to assign a case-mix group to each patient record that is then used to calculate a per diem payment under the SNF PPS. Because the MDS is a payment as well as a clinical document, we have provided extensive training on proper coding and the time frames for MDS completion in our Resident Assessment Instrument (RAI) Manual. For an MDS to be considered valid for use in determining payment, the MDS assessment must be

completed in compliance with the instructions in the RAI Manual in effect at the time the assessment is completed. For payment and quality monitoring purposes, the RAI Manual consists of both the Manual instructions and the interpretive guidance and policy clarifications posted on the appropriate MDS Web site at http://www.cms.gov/NursingHomeQualityInits/25_NHQIMDS30.asp.

The original RUG—III grouper logic was based on clinical data collected in 1990, 1995, and 1997. As discussed in the SNF PPS proposed rule for FY 2010 (74 FR 22208, May 12, 2009), we subsequently conducted a multi-year data collection and analysis under the Staff Time and Resource Intensity Verification (STRIVE) project to update the case-mix classification system for FY 2011. The resulting RUG—IV case-mix classification system reflected the data collected in 2006–2007 during the STRIVE project, and was finalized in the FY 2010 SNF PPS final rule (74 FR 40288, August 11, 2009) to take effect in FY 2011 concurrently with an updated new resident assessment instrument, the MDS 3.0, which collects the clinical data used for case-mix classification under RUG—IV.

Under the BBA, each update of the SNF PPS payment rates must include the case-mix classification methodology applicable for the coming Federal FY. As indicated in section I.G of this proposed rule, the payment rates set forth herein reflect the use of the RUG—IV case-mix classification system from October 1, 2011, through September 30, 2012.

2. Parity Adjustment

As discussed further below, we are considering two options for the CMIs that would be applied to the FY 2012 RUG—IV payment rates.

a. Option for Recalibration of the Parity Adjustment

As explained in the FY 2011 SNF PPS notice with comment period (75 FR 42886, 42892, July 22, 2010), we applied

an upward adjustment of 61 percent to the RUG—IV nursing CMIs to achieve parity between the RUG—53 and RUG—IV models, based on an analysis using final FY 2009 claims data. Our calculation of the parity adjustment used the most recent data available to estimate RUG—IV utilization. As we stated in the FY 2010 SNF PPS final rule (74 FR 40339), in the absence of actual RUG—IV utilization for FY 2011, we believed the most recent data represented the best source available, by virtue of being the closest to the FY 2011 timeframe. We also stated that as actual data for RUG—IV utilization became available, we intended to assess the effectiveness of the parity adjustment in maintaining budget neutrality and, if necessary, to recalibrate the adjustment in future years (see 74 FR 40339).

Since the FY 2011 SNF PPS update notice was published, actual first quarter RUG—IV claims data became available. Our continued monitoring of recent claims data indicates that actual RUG—IV utilization patterns differ significantly from those we had projected using the FY 2009 claims data. In particular, the proportion of patients grouped in the highest-paying RUG therapy categories, such as Ultra High Rehabilitation, greatly exceeded our expectations. This is likely due to the significant reduction in the use of concurrent therapy, which first quarter 2011 RUG—IV claims data suggest has been reduced to less than 5 percent of all therapy utilization. These first quarter 2011 RUG—IV claims also suggest a significant increase in the utilization of individual and group therapy, which, given current MDS coding instructions, may also account for the high proportion of SNF residents classified in the Ultra High Rehabilitation RUG categories.

Based on this initial RUG—IV claims data, it would appear that rather than simply achieving parity, the FY 2011 parity adjustment may have inadvertently triggered a significant increase in overall payment levels. We

believe that if this preliminary assessment is confirmed as further FY 2011 RUG-IV claims data become available, a recalibration of the parity adjustment may become warranted in the FY 2012 final rule, in order to ensure that the adjustment continues to serve as intended to make the transition from RUG-53 to RUG-IV in a budget-neutral manner. As discussed in the FY 2010 SNF PPS final rule (74 FR 40296), we believe that ensuring parity (that is, ensuring that the RUG-IV classification system is implemented as intended on a budget-neutral basis) is integral to the process of providing "for an appropriate adjustment to account for case mix" that is based upon appropriate data in accordance with section 1888(e)(4)(G)(i) of the Act. Accordingly, in this proposed rule, we include the following analysis based on first quarter RUG-IV data in order to provide the public with information on the potential scope and impact of the recalibration we are considering for FY 2012.

To determine a specific parity adjustment factor that, under the initial RUG-IV claims data currently available, would be needed to reestablish budget neutrality, we used approximately 920,000 first quarter 2011 claims (the most current data available at the time) to compare the distribution of payment days by RUG category under the original RUG-53 model with the distribution of payment days observed in the first quarter of 2011 under the RUG-IV model. Using a file which linked these 920,000 claims to the corresponding MDS assessments, we determined the appropriate RUG group for the patients covered by the aforementioned set of claims under RUG-53. This permitted a more precise comparison of the same patients under both systems, to control for potential variations in case-mix or patient volume. Given the RUG assignments for this set of SNF residents under both RUG-53 and RUG-IV, we were able to determine a distribution of RUG assignments.

To determine the appropriate parity adjustment, consistent with the methodology described in the FY 2010 SNF PPS final rule (74 FR 40296) and detailed in the FY 2006 SNF PPS proposed rule (70 FR 29077 through 29079), we determined the total number of first quarter FY 2011 RUG-IV payment days, as well as the number of first quarter FY 2011 payment days of each RUG-IV category based on the first quarter FY 2011 SNF PPS claims. By linking these FY 2011 claims with the corresponding MDS 3.0 data, we were able to determine the appropriate RUG-53 category for each FY 2011 SNF resident represented in the sample of FY

2011 claims. We multiplied the percentage of SNF residents in each RUG-IV and RUG-53 category by the total number of first quarter FY 2011 payment days of service in order to determine a distribution of RUG-IV and RUG-53 payment days, given the first quarter FY 2011 claims and linked MDS 3.0 data. We then multiplied the projected RUG-IV and RUG-53 days of service by the FY 2012 unadjusted Federal per diem payment rate components, multiplied by the unadjusted case mix indexes to establish expenditures under the RUG-53 and RUG-IV systems. The parity adjustment used to ensure that the transition between the two systems is budget-neutral and does not create, in and of itself, an increase in the amount of SNF expenditures, was determined as the percent increase necessary for the nursing CMIs to generate estimated expenditure levels under the RUG-IV system that were equal to those estimated under the RUG-53 system. Based on the first quarter FY 2011 RUG-IV claims data, we determined that the adjustment, which had originally produced an increase of 61 percent to the nursing CMIs as discussed in the FY 2011 SNF PPS update notice, would need to be decreased to 22.55 percent to achieve budget neutrality, if we were to apply the parity adjustment equally to all nursing CMIs as we have done in the past. However, given that the most notable differences between expected and actual utilization patterns occurred within the therapy RUG categories, we believe that rather than applying the new parity adjustment percentage to all the nursing CMIs, it would be more appropriate to achieve budget neutrality between the RUG-53 and RUG-IV systems by maintaining the 61 percent parity adjustment to the nursing CMIs for the RUG-IV non-therapy groups, and reducing the 61 percent parity adjustment as it applied to the nursing CMIs for the RUG-IV therapy groups. Using this recalibration methodology described above, we found that the adjustment to the nursing CMIs of the RUG-IV therapy groups necessary to achieve parity, while maintaining the 61 percent parity adjustment for RUG-IV non-therapy groups, would be an updated adjustment of 19.81 percent. An analysis of recent utilization patterns is provided in Table 4. In this proposed rule, we are including Tables 5A and 6A, which illustrate the payment rates that would be derived from nursing CMIs reflecting this recalibration methodology.

TABLE 4—FY 2011 PROJECTED VERSUS ACTUAL RUG-IV UTILIZATION DISTRIBUTION AS PERCENT OF TOTAL DAYS OF SERVICE

| RUG-IV group | Projected (percent) | Actual (percent) |
|--------------|---------------------|------------------|
| RUX | 0.18 | 0.60 |
| RUL | 0.05 | 0.75 |
| RVX | 0.36 | 0.41 |
| RVL | 0.53 | 0.56 |
| RHX | 0.43 | 0.17 |
| RHL | 0.72 | 0.19 |
| RMX | 0.76 | 0.33 |
| RML | 0.79 | 0.28 |
| RLX | 0.00 | 0.01 |
| RUC | 3.56 | 12.68 |
| RUB | 3.26 | 16.19 |
| RUA | 2.12 | 12.80 |
| RVC | 5.49 | 7.82 |
| RVB | 7.17 | 9.67 |
| RVA | 8.61 | 9.13 |
| RHC | 6.34 | 3.77 |
| RHB | 7.09 | 3.54 |
| RHA | 11.41 | 3.54 |
| RMC | 4.95 | 3.06 |
| RMB | 6.84 | 2.42 |
| RMA | 8.74 | 2.41 |
| RLB | 0.21 | 0.07 |
| RLA | 0.23 | 0.06 |
| ES3 | 0.52 | 0.14 |
| ES2 | 0.17 | 0.14 |
| ES1 | 0.35 | 0.29 |
| HE2 | 0.04 | 0.10 |
| HE1 | 1.40 | 0.32 |
| HD2 | 0.32 | 0.09 |
| HD1 | 1.30 | 0.42 |
| HC2 | 0.78 | 0.06 |
| HC1 | 1.33 | 0.33 |
| HB2 | 0.78 | 0.07 |
| HB1 | 0.61 | 0.31 |
| LE2 | 0.05 | 0.12 |
| LE1 | 0.70 | 0.65 |
| LD2 | 0.28 | 0.12 |
| LD1 | 1.31 | 0.78 |
| LC2 | 0.26 | 0.07 |
| LC1 | 0.60 | 0.57 |
| LB2 | 0.02 | 0.04 |
| LB1 | 0.34 | 0.23 |
| CE2 | 0.15 | 0.04 |
| CE1 | 0.21 | 0.21 |
| CD2 | 0.58 | 0.07 |
| CD1 | 0.70 | 0.46 |
| CC2 | 0.36 | 0.07 |
| CC1 | 0.67 | 0.53 |
| CB2 | 0.65 | 0.05 |
| CB1 | 0.53 | 0.44 |
| CA2 | 0.32 | 0.07 |
| CA1 | 1.41 | 0.66 |
| BB2 | 0.07 | 0.02 |
| BB1 | 0.27 | 0.22 |
| BA2 | 0.01 | 0.01 |
| BA1 | 0.26 | 0.17 |
| PE2 | 0.03 | 0.02 |
| PE1 | 0.07 | 0.17 |
| PD2 | 0.00 | 0.03 |
| PD1 | 0.38 | 0.38 |
| PC2 | 0.01 | 0.05 |
| PC1 | 1.26 | 0.51 |
| PB2 | 0.02 | 0.01 |
| PB1 | 0.59 | 0.25 |
| PA2 | 0.05 | 0.01 |

TABLE 4—FY 2011 PROJECTED VERSUS ACTUAL RUG–IV UTILIZATION DISTRIBUTION AS PERCENT OF TOTAL DAYS OF SERVICE—Continued

| RUG–IV group | Projected (percent) | Actual (percent) |
|--------------|---------------------|------------------|
| PA1 | 0.40 | 0.24 |

Note: Projected utilization data based on STRIVE study results. Actual utilization data based on first quarter 2011 claims data.

We want to emphasize that any such recalibration would be implemented on a prospective basis only, which we believe would be the most equitable approach with regard to its potential impact on providers. For FY 2012, the aggregate impact of the recalibration described in this proposed rule would be the difference between the increase of 61 percent for all nursing CMI (as set forth in the FY 2011 update notice), and the recalibrated increase of 19.81 percent for the nursing CMIs for the RUG–IV therapy groups (maintaining the 61 percent parity adjustment to the nursing CMIs for the RUG–IV non-therapy groups), or a negative \$4.47 billion. We note that the negative \$4.47 billion would be partly offset by the FY 2012 market basket adjustment factor of 1.5 percent, or \$530 million, with a net result of a negative \$3.94 billion update for FY 2012 (an aggregate negative impact of 11.3 percent).

We note that as an alternative to the preceding recalibration methodology, we initially considered applying a recalibration to all nursing CMIs, irrespective of RUG category. However, we found that such a recalibration most drastically affected non-therapy RUG groups, such as the Extensive Services RUG–IV group, which seemed incongruent with the perceived reasons for differences between expected and actual utilization patterns, as noted in Table 4. In addition, we considered using an analytical approach that would reflect implementing partial adjustments to the case-mix indexes over multiple years until parity is achieved. However, we believe that such an approach would continue to reimburse in amounts that significantly exceed our intended policy. Moreover, as we move forward with programs designed to enhance and restructure our post-acute care payment systems, we believe that payments under the SNF PPS should be established at their intended and most appropriate levels. We believe that stabilizing the baseline is a necessary first step toward properly implementing and maintaining the integrity of the RUG–IV classification

methodology and the SNF PPS as a whole.

As explained above, in determining the parity adjustment in the FY 2011 update notice, we used CY 2009 data as representing the most recent final claims data available at that time. However, we believe that it is appropriate to standardize the new model for the time period in which it is used, and we believe that using actual claims data under RUG–IV would allow us to calibrate the RUG–IV model more precisely. While, in the past, we have waited for a full year of claims data before recalibrating the CMIs, under the recalibration methodology discussed above, we are considering using partial FY 2011 claims data (that is, FY 2011 RUG–IV claims data available at the time of the final rule) to recalibrate the CMIs for FY 2012 if our analysis of such data prior to the final rule confirms our initial assessment (based on first quarter FY 2011 claims data) that the parity adjustment implemented in the FY 2011 update notice has inadvertently triggered an increase in overall payments as discussed above. We believe it would be reasonable and appropriate to use actual RUG–IV claims data from FY 2011 to estimate utilization under RUG–IV, as we believe that it provides the most recent, clear evidence of utilization patterns and evolving provider behaviors under RUG–IV. Additionally, using FY 2010 claims data, we analyzed the quality of representation of the first quarter of FY 2010, in terms of both the volume of claims received and RUG distribution, for FY 2010 as a whole and found there to be no examples of seasonality which would affect predictions of SNF volume or utilization patterns. Given this analysis, we believe that using the partial FY 2011 claims data would provide a representative and reasonable sample from which to project FY 2011 utilization patterns and expenditures. We invite comments on the recalibration methodology considered above, as well as on potential alternative methodologies for recalibrating the parity adjustment in an accurate and equitable manner.

We also note that any measures taken to achieve parity for RUG–IV may happen to coincide with the introduction of various revisions under the RUG–IV system (for example, the original RUG–IV parity adjustment took effect on October 1, 2010, along with the allocation of concurrent therapy time). As noted in our discussion of the proposed allocation of group therapy time that appears later in this proposed rule in section V.C, preliminary data indicate a recent significant increase in

the provision of individual and group therapy services, which have not, to date, been subject to the allocation requirement, and a corresponding decrease in the provision of concurrent therapy, which has been subject to the allocation requirement. We anticipate that imposing a similar allocation requirement for group therapy time (as discussed further in section V.C of this proposed rule) would eliminate an existing incentive to substitute such therapy for either concurrent or individual therapy.

However, even if the distribution of therapy minutes between individual, concurrent, and group therapy changes, this does not mean that a reduction in the parity adjustment for the RUG–IV therapy groups would be inappropriate. As explained previously, the purpose of the parity adjustment is simply to ensure that the transition from the RUG–53 model to the RUG–IV model does not trigger, in and of itself, an increase or decrease in overall payment levels. Because the FY 2011 first quarter RUG–IV utilization trends indicated that the most notable differences between expected and actual RUG–IV utilization patterns occurred within the therapy RUG categories, we believe that focusing any recalibration on these groups would provide for budget neutrality in an equitable manner given the RUG–IV utilization.

Moreover, even under the previous RUG–53 model, it is clear that the predominant mode of therapy that the payment rates were designed to address was individual therapy rather than concurrent or group therapy. As far back as the SNF PPS final rule for FY 2000, we specified that the minutes of group therapy received by the beneficiary may account for no more than 25 percent of the therapy (per discipline) received in a 7-day period (64 FR 41662, July 30, 1999). In addition, the SNF PPS rulemaking has on numerous occasions included discussions of concurrent therapy: In the FY 2002 proposed rule (66 FR 23991–23992, May 10, 2001) and final rule (66 FR 39567–68, July 31, 2001); in the FY 2006 proposed rule (70 FR 29082–29083, May 19, 2005) and final rule (70 FR 45036–45037, August 4, 2005); and, most recently, in the FY 2010 proposed rule (74 FR 22222–23, May 12, 2009) and final rule (74 FR 40315–19, August 11, 2009). These discussions clearly establish that we have always considered concurrent therapy as an infrequent exception rather than the norm. However, as discussed previously, the significant increase in individual and group therapy services and the reduction in concurrent therapy utilization reflected

in the first quarter RUG–IV data indicate that actual RUG–IV utilization patterns differ significantly from those we had projected using FY 2009 claims data in calculating the parity adjustment. The resulting unintended and significant increase in overall payment levels has prompted the need to reexamine the parity adjustment.

Thus, under the Medicare program, the standard of practice in the SNF setting has always been individual therapy, which is generally necessary to ensure that the services being delivered provide the high degree of individualized treatment and complex skill level required for Medicare coverage. We recognize that some SNFs may have actually used a less intensive combination of therapy modalities in the past year for some patients in response to the way in which therapy minutes were counted. However, the SNF PPS payment rates themselves have always reflected a standard of practice in which individual therapy is the predominant treatment modality. Further, because the overall payment rates under the previous RUG–III model were constructed to be sufficient to accommodate this level of resource intensity, we believe that the adequacy of those payment rates in this context would carry over to the payment rates under the current RUG–IV model, even if modified by an updated parity adjustment.

Given the apparent magnitude of the recalibration that would be needed to restore parity based on the initial RUG–IV claims data currently available (as discussed in the preceding analysis), we have provided in Tables 5A and 6A the case-mix adjusted RUG–IV payment rates which reflect the parity adjustment recalibration considered above based on our preliminary analysis using first quarter FY 2011 claims data. As further FY 2011 RUG–IV data become available, before we publish the final rule, we would review such additional data to confirm our preliminary assessment of the recalibration that would be

necessary to achieve parity between the RUG–53 and RUG–IV models and would revise the parity adjustment in the final rule as necessary based on this additional data. We believe that the very magnitude of the potential recalibration, based on first quarter FY 2011 data, would make it inappropriate for us merely to consider payment rates for FY 2012 that solely reflect the standard update methodology without regard to the need for maintaining parity, as such an approach ultimately could result in continuing to make overall payments that significantly exceed their intended levels for an indefinite period.

b. Option for Application of Standard Update for FY 2012 Without Recalibration

Although our preliminary analysis of the RUG–IV data currently available suggests that recalibration of the parity adjustment would be needed to restore parity between the RUG–53 and RUG–IV models, in the circumstances discussed below, we are also considering not recalibrating the CMIs for FY 2012 and applying the standard update to the FY 2011 payment rates. As we observed in the preceding discussion of the recalibration option, it would appear from the currently available FY 2011 claims data that overall payments under the parity adjustment are significantly exceeding their intended levels. However, it is also possible that the apparent magnitude of the overpayments may itself represent a temporary aberrance resulting from the limited FY 2011 data that are available at this point in time. Moreover, we note that as with any significant programmatic change, the transition from the previous case-mix classification system to RUG–IV has been accompanied by a learning curve for providers, as they work to familiarize themselves with the requirements of the new system. As a consequence, it is possible that as additional FY 2011 claims data become available, they may indicate utilization

patterns that are more consistent with our projections, and expenditures that are more in parity with those under the previous RUG–53 model. For this reason, we reserve the option to not implement in the final rule the type of recalibration discussed above, and instead to apply the standard update of the payment rates for FY 2012 if we find that the additional RUG–IV claims data collected prior to publication of the final rule are consistent with parity in expenditures between the current RUG–IV and previous RUG–53 models.

Accordingly, in this proposed rule, we are considering two separate options regarding the FY 2012 payment rates: One that incorporates the kind of recalibration discussed above which, based on the initial RUG–IV claims data currently available, may be necessary to restore overall payments under the parity adjustment to their intended levels (which recalibration may be adjusted based on further FY 2011 RUG–IV claims data that become available prior to publication of the final rule), and another that simply reflects the standard update to the FY 2011 payment rates without a recalibration of the FY 2011 parity adjustment. We solicit comments on these options as described above.

We list the case-mix adjusted RUG–IV payment rates which would exist if we choose to move forward with the recalibration of the parity adjustment described throughout this section, provided separately for urban and rural SNFs in Tables 5A and 6A, with the corresponding case-mix values which reflect the parity adjustment recalibration discussed above. Similarly, the case-mix adjusted RUG–IV rates, which would occur in the absence of such a recalibration of the parity adjustment, are listed in Tables 5B and 6B. These tables do not reflect the AIDS add-on enacted by section 511 of the MMA, which we apply only after making all other adjustments (wage and case-mix).

TABLE 5A—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES (INCLUDING PARITY ADJUSTMENT RECALIBRATION)
[Urban]

| RUG–IV category | Nursing index | Therapy index | Nursing component | Therapy component | Non-case mix therapy comp | Non-case mix component | Total rate |
|-----------------|---------------|---------------|-------------------|-------------------|---------------------------|------------------------|------------|
| RUX | 2.67 | 1.87 | \$427.73 | \$225.67 | | \$81.76 | \$735.16 |
| RUL | 2.57 | 1.87 | 411.71 | 225.67 | | 81.76 | 719.14 |
| RVX | 2.61 | 1.28 | 418.12 | 154.47 | | 81.76 | 654.35 |
| RVL | 2.19 | 1.28 | 350.84 | 154.47 | | 81.76 | 587.07 |
| RHX | 2.55 | 0.85 | 408.51 | 102.58 | | 81.76 | 592.85 |
| RHL | 2.15 | 0.85 | 344.43 | 102.58 | | 81.76 | 528.77 |
| RMX | 2.47 | 0.55 | 395.69 | 66.37 | | 81.76 | 543.82 |
| RML | 2.19 | 0.55 | 350.84 | 66.37 | | 81.76 | 498.97 |
| RLX | 2.26 | 0.28 | 362.05 | 33.79 | | 81.76 | 477.60 |

TABLE 5A—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES (INCLUDING PARITY ADJUSTMENT RECALIBRATION)—Continued
[Urban]

| RUG–IV category | Nursing index | Therapy index | Nursing component | Therapy component | Non-case mix therapy comp | Non-case mix component | Total rate |
|-----------------|---------------|---------------|-------------------|-------------------|---------------------------|------------------------|------------|
| RUC | 1.56 | 1.87 | 249.91 | 225.67 | | 81.76 | 557.34 |
| RUB | 1.56 | 1.87 | 249.91 | 225.67 | | 81.76 | 557.34 |
| RUA | 0.99 | 1.87 | 158.60 | 225.67 | | 81.76 | 466.03 |
| RVC | 1.51 | 1.28 | 241.90 | 154.47 | | 81.76 | 478.13 |
| RVB | 1.11 | 1.28 | 177.82 | 154.47 | | 81.76 | 414.05 |
| RVA | 1.10 | 1.28 | 176.22 | 154.47 | | 81.76 | 412.45 |
| RHC | 1.45 | 0.85 | 232.29 | 102.58 | | 81.76 | 416.63 |
| RHB | 1.19 | 0.85 | 190.64 | 102.58 | | 81.76 | 374.98 |
| RHA | 0.91 | 0.85 | 145.78 | 102.58 | | 81.76 | 330.12 |
| RMC | 1.36 | 0.55 | 217.87 | 66.37 | | 81.76 | 366.00 |
| RMB | 1.22 | 0.55 | 195.44 | 66.37 | | 81.76 | 343.57 |
| RMA | 0.84 | 0.55 | 134.57 | 66.37 | | 81.76 | 282.70 |
| RLB | 1.50 | 0.28 | 240.30 | 33.79 | | 81.76 | 355.85 |
| RLA | 0.71 | 0.28 | 113.74 | 33.79 | | 81.76 | 229.29 |
| ES3 | 3.58 | | 573.52 | | 15.90 | 81.76 | 671.18 |
| ES2 | 2.67 | | 427.73 | | 15.90 | 81.76 | 525.39 |
| ES1 | 2.32 | | 371.66 | | 15.90 | 81.76 | 469.32 |
| HE2 | 2.22 | | 355.64 | | 15.90 | 81.76 | 453.30 |
| HE1 | 1.74 | | 278.75 | | 15.90 | 81.76 | 376.41 |
| HD2 | 2.04 | | 326.81 | | 15.90 | 81.76 | 424.47 |
| HD1 | 1.60 | | 256.32 | | 15.90 | 81.76 | 353.98 |
| HC2 | 1.89 | | 302.78 | | 15.90 | 81.76 | 400.44 |
| HC1 | 1.48 | | 237.10 | | 15.90 | 81.76 | 334.76 |
| HB2 | 1.86 | | 297.97 | | 15.90 | 81.76 | 395.63 |
| HB1 | 1.46 | | 233.89 | | 15.90 | 81.76 | 331.55 |
| LE2 | 1.96 | | 313.99 | | 15.90 | 81.76 | 411.65 |
| LE1 | 1.54 | | 246.71 | | 15.90 | 81.76 | 344.37 |
| LD2 | 1.86 | | 297.97 | | 15.90 | 81.76 | 395.63 |
| LD1 | 1.46 | | 233.89 | | 15.90 | 81.76 | 331.55 |
| LC2 | 1.56 | | 249.91 | | 15.90 | 81.76 | 347.57 |
| LC1 | 1.22 | | 195.44 | | 15.90 | 81.76 | 293.10 |
| LB2 | 1.46 | | 233.89 | | 15.90 | 81.76 | 331.55 |
| LB1 | 1.14 | | 182.63 | | 15.90 | 81.76 | 280.29 |
| CE2 | 1.68 | | 269.14 | | 15.90 | 81.76 | 366.80 |
| CE1 | 1.50 | | 240.30 | | 15.90 | 81.76 | 337.96 |
| CD2 | 1.56 | | 249.91 | | 15.90 | 81.76 | 347.57 |
| CD1 | 1.38 | | 221.08 | | 15.90 | 81.76 | 318.74 |
| CC2 | 1.29 | | 206.66 | | 15.90 | 81.76 | 304.32 |
| CC1 | 1.15 | | 184.23 | | 15.90 | 81.76 | 281.89 |
| CB2 | 1.15 | | 184.23 | | 15.90 | 81.76 | 281.89 |
| CB1 | 1.02 | | 163.40 | | 15.90 | 81.76 | 261.06 |
| CA2 | 0.88 | | 140.98 | | 15.90 | 81.76 | 238.64 |
| CA1 | 0.78 | | 124.96 | | 15.90 | 81.76 | 222.62 |
| BB2 | 0.97 | | 155.39 | | 15.90 | 81.76 | 253.05 |
| BB1 | 0.90 | | 144.18 | | 15.90 | 81.76 | 241.84 |
| BA2 | 0.70 | | 112.14 | | 15.90 | 81.76 | 209.80 |
| BA1 | 0.64 | | 102.53 | | 15.90 | 81.76 | 200.19 |
| PE2 | 1.50 | | 240.30 | | 15.90 | 81.76 | 337.96 |
| PE1 | 1.40 | | 224.28 | | 15.90 | 81.76 | 321.94 |
| PD2 | 1.38 | | 221.08 | | 15.90 | 81.76 | 318.74 |
| PD1 | 1.28 | | 205.06 | | 15.90 | 81.76 | 302.72 |
| PC2 | 1.10 | | 176.22 | | 15.90 | 81.76 | 273.88 |
| PC1 | 1.02 | | 163.40 | | 15.90 | 81.76 | 261.06 |
| PB2 | 0.84 | | 134.57 | | 15.90 | 81.76 | 232.23 |
| PB1 | 0.78 | | 124.96 | | 15.90 | 81.76 | 222.62 |
| PA2 | 0.59 | | 94.52 | | 15.90 | 81.76 | 192.18 |
| PA1 | 0.54 | | 86.51 | | 15.90 | 81.76 | 184.17 |

TABLE 5B—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES (WITHOUT PARITY ADJUSTMENT RECALIBRATION)
[Urban]

| RUG–IV category | Nursing index | Therapy index | Nursing component | Therapy component | Non-case mix therapy comp | Non-case mix component | Total rate |
|-----------------|---------------|---------------|-------------------|-------------------|---------------------------|------------------------|------------|
| RUX | 3.59 | 1.87 | \$575.12 | \$225.67 | | \$81.76 | \$882.55 |
| RUL | 3.45 | 1.87 | 552.69 | 225.67 | | 81.76 | 860.12 |

TABLE 5B—RUG—IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES (WITHOUT PARITY ADJUSTMENT RECALIBRATION)—Continued
[Urban]

| RUG—IV category | Nursing index | Therapy index | Nursing component | Therapy component | Non-case mix therapy comp | Non-case mix component | Total rate |
|-----------------|---------------|---------------|-------------------|-------------------|---------------------------|------------------------|------------|
| RVX | 3.51 | 1.28 | 562.30 | 154.47 | | 81.76 | 798.53 |
| RVL | 2.95 | 1.28 | 472.59 | 154.47 | | 81.76 | 708.82 |
| RHX | 3.43 | 0.85 | 549.49 | 102.58 | | 81.76 | 733.83 |
| RHL | 2.89 | 0.85 | 462.98 | 102.58 | | 81.76 | 647.32 |
| RMX | 3.31 | 0.55 | 530.26 | 66.37 | | 81.76 | 678.39 |
| RML | 2.95 | 0.55 | 472.59 | 66.37 | | 81.76 | 620.72 |
| RLX | 3.04 | 0.28 | 487.01 | 33.79 | | 81.76 | 602.56 |
| RUC | 2.10 | 1.87 | 336.42 | 225.67 | | 81.76 | 643.85 |
| RUB | 2.10 | 1.87 | 336.42 | 225.67 | | 81.76 | 643.85 |
| RUA | 1.33 | 1.87 | 213.07 | 225.67 | | 81.76 | 520.50 |
| RVC | 2.02 | 1.28 | 323.60 | 154.47 | | 81.76 | 559.83 |
| RVB | 1.49 | 1.28 | 238.70 | 154.47 | | 81.76 | 474.93 |
| RVA | 1.48 | 1.28 | 237.10 | 154.47 | | 81.76 | 473.33 |
| RHC | 1.94 | 0.85 | 310.79 | 102.58 | | 81.76 | 495.13 |
| RHB | 1.60 | 0.85 | 256.32 | 102.58 | | 81.76 | 440.66 |
| RHA | 1.23 | 0.85 | 197.05 | 102.58 | | 81.76 | 381.39 |
| RMC | 1.83 | 0.55 | 293.17 | 66.37 | | 81.76 | 441.30 |
| RMB | 1.63 | 0.55 | 261.13 | 66.37 | | 81.76 | 409.26 |
| RMA | 1.13 | 0.55 | 181.03 | 66.37 | | 81.76 | 329.16 |
| RLB | 2.01 | 0.28 | 322.00 | 33.79 | | 81.76 | 437.55 |
| RLA | 0.95 | 0.28 | 152.19 | 33.79 | | 81.76 | 267.74 |
| ES3 | 3.58 | | 573.52 | | 15.90 | 81.76 | 671.18 |
| ES2 | 2.67 | | 427.73 | | 15.90 | 81.76 | 525.39 |
| ES1 | 2.32 | | 371.66 | | 15.90 | 81.76 | 469.32 |
| HE2 | 2.22 | | 355.64 | | 15.90 | 81.76 | 453.30 |
| HE1 | 1.74 | | 278.75 | | 15.90 | 81.76 | 376.41 |
| HD2 | 2.04 | | 326.81 | | 15.90 | 81.76 | 424.47 |
| HD1 | 1.60 | | 256.32 | | 15.90 | 81.76 | 353.98 |
| HC2 | 1.89 | | 302.78 | | 15.90 | 81.76 | 400.44 |
| HC1 | 1.48 | | 237.10 | | 15.90 | 81.76 | 334.76 |
| HB2 | 1.86 | | 297.97 | | 15.90 | 81.76 | 395.63 |
| HB1 | 1.46 | | 233.89 | | 15.90 | 81.76 | 331.55 |
| LE2 | 1.96 | | 313.99 | | 15.90 | 81.76 | 411.65 |
| LE1 | 1.54 | | 246.71 | | 15.90 | 81.76 | 344.37 |
| LD2 | 1.86 | | 297.97 | | 15.90 | 81.76 | 395.63 |
| LD1 | 1.46 | | 233.89 | | 15.90 | 81.76 | 331.55 |
| LC2 | 1.56 | | 249.91 | | 15.90 | 81.76 | 347.57 |
| LC1 | 1.22 | | 195.44 | | 15.90 | 81.76 | 293.10 |
| LB2 | 1.46 | | 233.89 | | 15.90 | 81.76 | 331.55 |
| LB1 | 1.14 | | 182.63 | | 15.90 | 81.76 | 280.29 |
| CE2 | 1.68 | | 269.14 | | 15.90 | 81.76 | 366.80 |
| CE1 | 1.50 | | 240.30 | | 15.90 | 81.76 | 337.96 |
| CD2 | 1.56 | | 249.91 | | 15.90 | 81.76 | 347.57 |
| CD1 | 1.38 | | 221.08 | | 15.90 | 81.76 | 318.74 |
| CC2 | 1.29 | | 206.66 | | 15.90 | 81.76 | 304.32 |
| CC1 | 1.15 | | 184.23 | | 15.90 | 81.76 | 281.89 |
| CB2 | 1.15 | | 184.23 | | 15.90 | 81.76 | 281.89 |
| CB1 | 1.02 | | 163.40 | | 15.90 | 81.76 | 261.06 |
| CA2 | 0.88 | | 140.98 | | 15.90 | 81.76 | 238.64 |
| CA1 | 0.78 | | 124.96 | | 15.90 | 81.76 | 222.62 |
| BB2 | 0.97 | | 155.39 | | 15.90 | 81.76 | 253.05 |
| BB1 | 0.90 | | 144.18 | | 15.90 | 81.76 | 241.84 |
| BA2 | 0.70 | | 112.14 | | 15.90 | 81.76 | 209.80 |
| BA1 | 0.64 | | 102.53 | | 15.90 | 81.76 | 200.19 |
| PE2 | 1.50 | | 240.30 | | 15.90 | 81.76 | 337.96 |
| PE1 | 1.40 | | 224.28 | | 15.90 | 81.76 | 321.94 |
| PD2 | 1.38 | | 221.08 | | 15.90 | 81.76 | 318.74 |
| PD1 | 1.28 | | 205.06 | | 15.90 | 81.76 | 302.72 |
| PC2 | 1.10 | | 176.22 | | 15.90 | 81.76 | 273.88 |
| PC1 | 1.02 | | 163.40 | | 15.90 | 81.76 | 261.06 |
| PB2 | 0.84 | | 134.57 | | 15.90 | 81.76 | 232.23 |
| PB1 | 0.78 | | 124.96 | | 15.90 | 81.76 | 222.62 |
| PA2 | 0.59 | | 94.52 | | 15.90 | 81.76 | 192.18 |
| PA1 | 0.54 | | 86.51 | | 15.90 | 81.76 | 184.17 |

TABLE 6A—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES (INCLUDING PARITY ADJUSTMENT RECALIBRATION)
[Rural]

| RUG–IV category | Nursing index | Therapy index | Nursing component | Therapy component | Non-case mix therapy comp | Non-case mix component | Total rate |
|-----------------|---------------|---------------|-------------------|-------------------|---------------------------|------------------------|------------|
| RUX | 2.67 | 1.87 | \$408.70 | \$260.21 | | \$83.28 | \$752.19 |
| RUL | 2.57 | 1.87 | 393.39 | 260.21 | | 83.28 | 736.88 |
| RVX | 2.61 | 1.28 | 399.51 | 178.11 | | 83.28 | 660.90 |
| RVL | 2.19 | 1.28 | 335.22 | 178.11 | | 83.28 | 596.61 |
| RHX | 2.55 | 0.85 | 390.33 | 118.28 | | 83.28 | 591.89 |
| RHL | 2.15 | 0.85 | 329.10 | 118.28 | | 83.28 | 530.66 |
| RMX | 2.47 | 0.55 | 378.08 | 76.53 | | 83.28 | 537.89 |
| RML | 2.19 | 0.55 | 335.22 | 76.53 | | 83.28 | 495.03 |
| RLX | 2.26 | 0.28 | 345.94 | 38.96 | | 83.28 | 468.18 |
| RUC | 1.56 | 1.87 | 238.79 | 260.21 | | 83.28 | 582.28 |
| RUB | 1.56 | 1.87 | 238.79 | 260.21 | | 83.28 | 582.28 |
| RUA | 0.99 | 1.87 | 151.54 | 260.21 | | 83.28 | 495.03 |
| RVC | 1.51 | 1.28 | 231.14 | 178.11 | | 83.28 | 492.53 |
| RVB | 1.11 | 1.28 | 169.91 | 178.11 | | 83.28 | 431.30 |
| RVA | 1.10 | 1.28 | 168.38 | 178.11 | | 83.28 | 429.77 |
| RHC | 1.45 | 0.85 | 221.95 | 118.28 | | 83.28 | 423.51 |
| RHB | 1.19 | 0.85 | 182.15 | 118.28 | | 83.28 | 383.71 |
| RHA | 0.91 | 0.85 | 139.29 | 118.28 | | 83.28 | 340.85 |
| RMC | 1.36 | 0.55 | 208.18 | 76.53 | | 83.28 | 367.99 |
| RMB | 1.22 | 0.55 | 186.75 | 76.53 | | 83.28 | 346.56 |
| RMA | 0.84 | 0.55 | 128.58 | 76.53 | | 83.28 | 288.39 |
| RLB | 1.50 | 0.28 | 229.61 | 38.96 | | 83.28 | 351.85 |
| RLA | 0.71 | 0.28 | 108.68 | 38.96 | | 83.28 | 230.92 |
| ES3 | 3.58 | | 547.99 | | 16.97 | 83.28 | 648.24 |
| ES2 | 2.67 | | 408.70 | | 16.97 | 83.28 | 508.95 |
| ES1 | 2.32 | | 355.12 | | 16.97 | 83.28 | 455.37 |
| HE2 | 2.22 | | 339.82 | | 16.97 | 83.28 | 440.07 |
| HE1 | 1.74 | | 266.34 | | 16.97 | 83.28 | 366.59 |
| HD2 | 2.04 | | 312.26 | | 16.97 | 83.28 | 412.51 |
| HD1 | 1.60 | | 244.91 | | 16.97 | 83.28 | 345.16 |
| HC2 | 1.89 | | 289.30 | | 16.97 | 83.28 | 389.55 |
| HC1 | 1.48 | | 226.54 | | 16.97 | 83.28 | 326.79 |
| HB2 | 1.86 | | 284.71 | | 16.97 | 83.28 | 384.96 |
| HB1 | 1.46 | | 223.48 | | 16.97 | 83.28 | 323.73 |
| LE2 | 1.96 | | 300.02 | | 16.97 | 83.28 | 400.27 |
| LE1 | 1.54 | | 235.73 | | 16.97 | 83.28 | 335.98 |
| LD2 | 1.86 | | 284.71 | | 16.97 | 83.28 | 384.96 |
| LD1 | 1.46 | | 223.48 | | 16.97 | 83.28 | 323.73 |
| LC2 | 1.56 | | 238.79 | | 16.97 | 83.28 | 339.04 |
| LC1 | 1.22 | | 186.75 | | 16.97 | 83.28 | 287.00 |
| LB2 | 1.46 | | 223.48 | | 16.97 | 83.28 | 323.73 |
| LB1 | 1.14 | | 174.50 | | 16.97 | 83.28 | 274.75 |
| CE2 | 1.68 | | 257.16 | | 16.97 | 83.28 | 357.41 |
| CE1 | 1.50 | | 229.61 | | 16.97 | 83.28 | 329.86 |
| CD2 | 1.56 | | 238.79 | | 16.97 | 83.28 | 339.04 |
| CD1 | 1.38 | | 211.24 | | 16.97 | 83.28 | 311.49 |
| CC2 | 1.29 | | 197.46 | | 16.97 | 83.28 | 297.71 |
| CC1 | 1.15 | | 176.03 | | 16.97 | 83.28 | 276.28 |
| CB2 | 1.15 | | 176.03 | | 16.97 | 83.28 | 276.28 |
| CB1 | 1.02 | | 156.13 | | 16.97 | 83.28 | 256.38 |
| CA2 | 0.88 | | 134.70 | | 16.97 | 83.28 | 234.95 |
| CA1 | 0.78 | | 119.39 | | 16.97 | 83.28 | 219.64 |
| BB2 | 0.97 | | 148.48 | | 16.97 | 83.28 | 248.73 |
| BB1 | 0.90 | | 137.76 | | 16.97 | 83.28 | 238.01 |
| BA2 | 0.70 | | 107.15 | | 16.97 | 83.28 | 207.40 |
| BA1 | 0.64 | | 97.96 | | 16.97 | 83.28 | 198.21 |
| PE2 | 1.50 | | 229.61 | | 16.97 | 83.28 | 329.86 |
| PE1 | 1.40 | | 214.30 | | 16.97 | 83.28 | 314.55 |
| PD2 | 1.38 | | 211.24 | | 16.97 | 83.28 | 311.49 |
| PD1 | 1.28 | | 195.93 | | 16.97 | 83.28 | 296.18 |
| PC2 | 1.10 | | 168.38 | | 16.97 | 83.28 | 268.63 |
| PC1 | 1.02 | | 156.13 | | 16.97 | 83.28 | 256.38 |
| PB2 | 0.84 | | 128.58 | | 16.97 | 83.28 | 228.83 |
| PB1 | 0.78 | | 119.39 | | 16.97 | 83.28 | 219.64 |
| PA2 | 0.59 | | 90.31 | | 16.97 | 83.28 | 190.56 |
| PA1 | 0.54 | | 82.66 | | 16.97 | 83.28 | 182.91 |

TABLE 6B—RUG—IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES: WITHOUT PARITY ADJUSTMENT
 (RECALIBRATION)
 [Rural]

| RUG—IV category | Nursing index | Therapy index | Nursing component | Therapy component | Non-case mix therapy comp | Non-case mix component | Total rate |
|-----------------|---------------|---------------|-------------------|-------------------|---------------------------|------------------------|------------|
| RUX | 3.59 | 1.87 | \$549.52 | \$260.21 | | \$83.28 | \$893.01 |
| RUL | 3.45 | 1.87 | 528.09 | 260.21 | | 83.28 | 871.58 |
| RVX | 3.51 | 1.28 | 537.28 | 178.11 | | 83.28 | 798.67 |
| RVL | 2.95 | 1.28 | 451.56 | 178.11 | | 83.28 | 712.95 |
| RHX | 3.43 | 0.85 | 525.03 | 118.28 | | 83.28 | 726.59 |
| RHL | 2.89 | 0.85 | 442.37 | 118.28 | | 83.28 | 643.93 |
| RMX | 3.31 | 0.55 | 506.66 | 76.53 | | 83.28 | 666.47 |
| RML | 2.95 | 0.55 | 451.56 | 76.53 | | 83.28 | 611.37 |
| RLX | 3.04 | 0.28 | 465.33 | 38.96 | | 83.28 | 587.57 |
| RUC | 2.10 | 1.87 | 321.45 | 260.21 | | 83.28 | 664.94 |
| RUB | 2.10 | 1.87 | 321.45 | 260.21 | | 83.28 | 664.94 |
| RUA | 1.33 | 1.87 | 203.58 | 260.21 | | 83.28 | 547.07 |
| RVC | 2.02 | 1.28 | 309.20 | 178.11 | | 83.28 | 570.59 |
| RVB | 1.49 | 1.28 | 228.07 | 178.11 | | 83.28 | 489.46 |
| RVA | 1.48 | 1.28 | 226.54 | 178.11 | | 83.28 | 487.93 |
| RHC | 1.94 | 0.85 | 296.96 | 118.28 | | 83.28 | 498.52 |
| RHB | 1.60 | 0.85 | 244.91 | 118.28 | | 83.28 | 446.47 |
| RHA | 1.23 | 0.85 | 188.28 | 118.28 | | 83.28 | 389.84 |
| RMC | 1.83 | 0.55 | 280.12 | 76.53 | | 83.28 | 439.93 |
| RMB | 1.63 | 0.55 | 249.50 | 76.53 | | 83.28 | 409.31 |
| RMA | 1.13 | 0.55 | 172.97 | 76.53 | | 83.28 | 332.78 |
| RLB | 2.01 | 0.28 | 307.67 | 38.96 | | 83.28 | 429.91 |
| RLA | 0.95 | 0.28 | 145.42 | 38.96 | | 83.28 | 267.66 |
| ES3 | 3.58 | | 547.99 | | \$16.97 | 83.28 | 648.24 |
| ES2 | 2.67 | | 408.70 | | 16.97 | 83.28 | 508.95 |
| ES1 | 2.32 | | 355.12 | | 16.97 | 83.28 | 455.37 |
| HE2 | 2.22 | | 339.82 | | 16.97 | 83.28 | 440.07 |
| HE1 | 1.74 | | 266.34 | | 16.97 | 83.28 | 366.59 |
| HD2 | 2.04 | | 312.26 | | 16.97 | 83.28 | 412.51 |
| HD1 | 1.60 | | 244.91 | | 16.97 | 83.28 | 345.16 |
| HC2 | 1.89 | | 289.30 | | 16.97 | 83.28 | 389.55 |
| HC1 | 1.48 | | 226.54 | | 16.97 | 83.28 | 326.79 |
| HB2 | 1.86 | | 284.71 | | 16.97 | 83.28 | 384.96 |
| HB1 | 1.46 | | 223.48 | | 16.97 | 83.28 | 323.73 |
| LE2 | 1.96 | | 300.02 | | 16.97 | 83.28 | 400.27 |
| LE1 | 1.54 | | 235.73 | | 16.97 | 83.28 | 335.98 |
| LD2 | 1.86 | | 284.71 | | 16.97 | 83.28 | 384.96 |
| LD1 | 1.46 | | 223.48 | | 16.97 | 83.28 | 323.73 |
| LC2 | 1.56 | | 238.79 | | 16.97 | 83.28 | 339.04 |
| LC1 | 1.22 | | 186.75 | | 16.97 | 83.28 | 287.00 |
| LB2 | 1.46 | | 223.48 | | 16.97 | 83.28 | 323.73 |
| LB1 | 1.14 | | 174.50 | | 16.97 | 83.28 | 274.75 |
| CE2 | 1.68 | | 257.16 | | 16.97 | 83.28 | 357.41 |
| CE1 | 1.50 | | 229.61 | | 16.97 | 83.28 | 329.86 |
| CD2 | 1.56 | | 238.79 | | 16.97 | 83.28 | 339.04 |
| CD1 | 1.38 | | 211.24 | | 16.97 | 83.28 | 311.49 |
| CC2 | 1.29 | | 197.46 | | 16.97 | 83.28 | 297.71 |
| CC1 | 1.15 | | 176.03 | | 16.97 | 83.28 | 276.28 |
| CB2 | 1.15 | | 176.03 | | 16.97 | 83.28 | 276.28 |
| CB1 | 1.02 | | 156.13 | | 16.97 | 83.28 | 256.38 |
| CA2 | 0.88 | | 134.70 | | 16.97 | 83.28 | 234.95 |
| CA1 | 0.78 | | 119.39 | | 16.97 | 83.28 | 219.64 |
| BB2 | 0.97 | | 148.48 | | 16.97 | 83.28 | 248.73 |
| BB1 | 0.90 | | 137.76 | | 16.97 | 83.28 | 238.01 |
| BA2 | 0.70 | | 107.15 | | 16.97 | 83.28 | 207.40 |
| BA1 | 0.64 | | 97.96 | | 16.97 | 83.28 | 198.21 |
| PE2 | 1.50 | | 229.61 | | 16.97 | 83.28 | 329.86 |
| PE1 | 1.40 | | 214.30 | | 16.97 | 83.28 | 314.55 |
| PD2 | 1.38 | | 211.24 | | 16.97 | 83.28 | 311.49 |
| PD1 | 1.28 | | 195.93 | | 16.97 | 83.28 | 296.18 |
| PC2 | 1.10 | | 168.38 | | 16.97 | 83.28 | 268.63 |
| PC1 | 1.02 | | 156.13 | | 16.97 | 83.28 | 256.38 |
| PB2 | 0.84 | | 128.58 | | 16.97 | 83.28 | 228.83 |
| PB1 | 0.78 | | 119.39 | | 16.97 | 83.28 | 219.64 |
| PA2 | 0.59 | | 90.31 | | 16.97 | 83.28 | 190.56 |
| PA1 | 0.54 | | 82.66 | | 16.97 | 83.28 | 182.91 |

C. Wage Index Adjustment to Federal Rates

Section 1888(e)(4)(G)(ii) of the Act requires that we adjust the Federal rates to account for differences in area wage levels, using a wage index that we find appropriate. Since the inception of a PPS for SNFs, we have used hospital wage data in developing a wage index to be applied to SNFs. We are maintaining that practice for FY 2012, as we continue to believe that in the absence of SNF-specific wage data, using the hospital inpatient wage index is appropriate and reasonable for the SNF PPS. As explained in the update notice for FY 2005 (69 FR 45786, July 30, 2004), the SNF PPS does not use the hospital area wage index's occupational mix adjustment, as this adjustment serves specifically to define the occupational categories more clearly in a hospital setting; moreover, the collection of the occupational wage data also excludes any wage data related to SNFs. Therefore, we believe that using the updated wage data exclusive of the occupational mix adjustment continues to be appropriate for SNF payments.

Finally, we continue to use the same methodology discussed in the SNF PPS final rule for FY 2008 (72 FR 43423) to address those geographic areas in which there are no hospitals and, thus, no hospital wage index data on which to base the calculation of the FY 2012 SNF PPS wage index. For rural geographic areas that do not have hospitals and, therefore, lack hospital wage data on which to base an area wage adjustment, we use the average wage index from all contiguous Core-Based Statistical Areas (CBSAs) as a reasonable proxy. This methodology was used to construct the wage index for rural Massachusetts for FY 2011. However, there is now a rural hospital with wage data upon which to base an area wage index for rural Massachusetts. Therefore, it is not necessary to apply this methodology to rural Massachusetts for FY 2012. For rural Puerto Rico, we do not apply this methodology due to the distinct economic circumstances that exist there, but instead continue using the most recent wage index previously available for that area. For urban areas without specific hospital wage index data, we use the average wage indexes of all of the urban areas within the State to serve as a reasonable proxy for the wage index of that urban CBSA. For FY 2012, there is an additional urban area without hospital wage index data. Therefore, for FY 2012, the two urban areas without wage index data available are CBSA 25980, Hinesville-Fort Stewart, GA, and CBSA 49700, Yuba City, CA.

To calculate the SNF PPS wage index adjustment, we apply the wage index adjustment to the labor-related portion of the Federal rate, which is 68.805 percent of the total rate. This percentage reflects the labor-related relative importance for FY 2012, using the revised and rebased FY 2004-based market basket. The labor-related relative importance for FY 2011 was 69.311, as shown in Table 11. We calculate the labor-related relative importance from the SNF market basket, and it approximates the labor-related portion of the total costs after taking into account historical and projected price changes between the base year and FY 2012. The price proxies that move the different cost categories in the market basket do not necessarily change at the same rate, and the relative importance captures these changes. Accordingly, the relative importance figure more closely reflects the cost share weights for FY 2012 than the base year weights from the SNF market basket.

We calculate the labor-related relative importance for FY 2012 in four steps. First, we compute the FY 2012 price index level for the total market basket and each cost category of the market basket. Second, we calculate a ratio for each cost category by dividing the FY 2012 price index level for that cost category by the total market basket price index level. Third, we determine the FY 2012 relative importance for each cost category by multiplying this ratio by the base year (FY 2004) weight. Finally, we add the FY 2012 relative importance for each of the labor-related cost categories (wages and salaries, employee benefits, non-medical professional fees, labor-intensive services, and a portion of capital-related expenses) to produce the FY 2012 labor-related relative importance. Tables 7A and 8A show the case-mix adjusted RUG-IV Federal rates by labor-related and non-labor-related components that would exist if we choose to move forward with the parity adjustment recalibration described in section II.B.2. Similarly, Tables 7B and 8B show the case-mix adjusted RUG-IV Federal rates by labor-related and non-labor related components in the absence of such a parity adjustment recalibration.

TABLE 7A—RUG-IV CASE-MIX ADJUSTED FEDERAL RATES FOR URBAN SNFs BY LABOR AND NON-LABOR COMPONENT

[Including parity adjustment recalibration]

| RUG-IV category | Total rate | Labor portion | Non-labor portion |
|-----------------|------------|---------------|-------------------|
| RUX | \$735.16 | \$505.83 | \$229.33 |
| RUL | 719.14 | 494.80 | 224.34 |
| RVX | 654.35 | 450.23 | 204.12 |
| RVL | 587.07 | 403.93 | 183.14 |
| RHX | 592.85 | 407.91 | 184.94 |
| RHL | 528.77 | 363.82 | 164.95 |
| RMX | 543.82 | 374.18 | 169.64 |
| RML | 498.97 | 343.32 | 155.65 |
| RLX | 477.60 | 328.61 | 148.99 |
| RUC | 557.34 | 383.48 | 173.86 |
| RUB | 557.34 | 383.48 | 173.86 |
| RUA | 466.03 | 320.65 | 145.38 |
| RVC | 478.13 | 328.98 | 149.15 |
| RVB | 414.05 | 284.89 | 129.16 |
| RVA | 412.45 | 283.79 | 128.66 |
| RHC | 416.63 | 286.66 | 129.97 |
| RHB | 374.98 | 258.00 | 116.98 |
| RHA | 330.12 | 227.14 | 102.98 |
| RMC | 366.00 | 251.83 | 114.17 |
| RMB | 343.57 | 236.39 | 107.18 |
| RMA | 282.70 | 194.51 | 88.19 |
| RLB | 355.85 | 244.84 | 111.01 |
| RLA | 229.29 | 157.76 | 71.53 |
| ES3 | 671.18 | 461.81 | 209.37 |
| ES2 | 525.39 | 361.49 | 163.90 |
| ES1 | 469.32 | 322.92 | 146.40 |
| HE2 | 453.30 | 311.89 | 141.41 |
| HE1 | 376.41 | 258.99 | 117.42 |
| HD2 | 424.47 | 292.06 | 132.41 |
| HD1 | 353.98 | 243.56 | 110.42 |
| HC2 | 400.44 | 275.52 | 124.92 |
| HC1 | 334.76 | 230.33 | 104.43 |
| HB2 | 395.63 | 272.21 | 123.42 |
| HB1 | 331.55 | 228.12 | 103.43 |
| LE2 | 411.65 | 283.24 | 128.41 |
| LE1 | 344.37 | 236.94 | 107.43 |
| LD2 | 395.63 | 272.21 | 123.42 |
| LD1 | 331.55 | 228.12 | 103.43 |
| LC2 | 347.57 | 239.15 | 108.42 |
| LC1 | 293.10 | 201.67 | 91.43 |
| LB2 | 331.55 | 228.12 | 103.43 |
| LB1 | 280.29 | 192.85 | 87.44 |
| CE2 | 366.80 | 252.38 | 114.42 |
| CE1 | 337.96 | 232.53 | 105.43 |
| CD2 | 347.57 | 239.15 | 108.42 |
| CD1 | 318.74 | 219.31 | 99.43 |
| CC2 | 304.32 | 209.39 | 94.93 |
| CC1 | 281.89 | 193.95 | 87.94 |
| CB2 | 281.89 | 193.95 | 87.94 |
| CB1 | 261.06 | 179.62 | 81.44 |
| CA2 | 238.64 | 164.20 | 74.44 |
| CA1 | 222.62 | 153.17 | 69.45 |
| BB2 | 253.05 | 174.11 | 78.94 |
| BB1 | 241.84 | 166.40 | 75.44 |
| BA2 | 209.80 | 144.35 | 65.45 |
| BA1 | 200.19 | 137.74 | 62.45 |
| PE2 | 337.96 | 232.53 | 105.43 |
| PE1 | 321.94 | 221.51 | 100.43 |
| PD2 | 318.74 | 219.31 | 99.43 |
| PD1 | 302.72 | 208.29 | 94.43 |
| PC2 | 273.88 | 188.44 | 85.44 |
| PC1 | 261.06 | 179.62 | 81.44 |
| PB2 | 232.23 | 159.79 | 72.44 |
| PB1 | 222.62 | 153.17 | 69.45 |
| PA2 | 192.18 | 132.23 | 59.95 |
| PA1 | 184.17 | 126.72 | 57.45 |

TABLE 7B—RUG—IV CASE-MIX ADJUSTED FEDERAL RATES FOR URBAN SNFS BY LABOR AND NON-LABOR COMPONENT

[Without parity adjustment recalibration]

| RUG—IV category | Total rate | Labor portion | Non-labor portion |
|-----------------|------------|---------------|-------------------|
| RUX | \$882.55 | \$607.24 | \$275.31 |
| RUL | 860.12 | 591.81 | 268.31 |
| RVX | 798.53 | 549.43 | 249.10 |
| RVL | 708.82 | 487.70 | 221.12 |
| RHX | 733.83 | 504.91 | 228.92 |
| RHL | 647.32 | 445.39 | 201.93 |
| RMX | 678.39 | 466.77 | 211.62 |
| RML | 620.72 | 427.09 | 193.63 |
| RLX | 602.56 | 414.59 | 187.97 |
| RUC | 643.85 | 443.00 | 200.85 |
| RUB | 643.85 | 443.00 | 200.85 |
| RUA | 520.50 | 358.13 | 162.37 |
| RVC | 559.83 | 385.19 | 174.64 |
| RVB | 474.93 | 326.78 | 148.15 |
| RVA | 473.33 | 325.67 | 147.66 |
| RHC | 495.13 | 340.67 | 154.46 |
| RHB | 440.66 | 303.20 | 137.46 |
| RHA | 381.39 | 262.42 | 118.97 |
| RMC | 441.30 | 303.64 | 137.66 |
| RMB | 409.26 | 281.59 | 127.67 |
| RMA | 329.16 | 226.48 | 102.68 |
| RLB | 437.55 | 301.06 | 136.49 |
| RLA | 267.74 | 184.22 | 83.52 |
| ES3 | 671.18 | 461.81 | 209.37 |
| ES2 | 525.39 | 361.49 | 163.90 |
| ES1 | 469.32 | 322.92 | 146.40 |
| HE2 | 453.30 | 311.89 | 141.41 |
| HE1 | 376.41 | 258.99 | 117.42 |
| HD2 | 424.47 | 292.06 | 132.41 |
| HD1 | 353.98 | 243.56 | 110.42 |
| HC2 | 400.44 | 275.52 | 124.92 |
| HC1 | 334.76 | 230.33 | 104.43 |
| HB2 | 395.63 | 272.21 | 123.42 |
| HB1 | 331.55 | 228.12 | 103.43 |
| LE2 | 411.65 | 283.24 | 128.41 |
| LE1 | 344.37 | 236.94 | 107.43 |
| LD2 | 395.63 | 272.21 | 123.42 |
| LD1 | 331.55 | 228.12 | 103.43 |
| LC2 | 347.57 | 239.15 | 108.42 |
| LC1 | 293.10 | 201.67 | 91.43 |
| LB2 | 331.55 | 228.12 | 103.43 |
| LB1 | 280.29 | 192.85 | 87.44 |
| CE2 | 366.80 | 252.38 | 114.42 |
| CE1 | 337.96 | 232.53 | 105.43 |
| CD2 | 347.57 | 239.15 | 108.42 |
| CD1 | 318.74 | 219.31 | 99.43 |
| CC2 | 304.32 | 209.39 | 94.93 |
| CC1 | 281.89 | 193.95 | 87.94 |
| CB2 | 281.89 | 193.95 | 87.94 |
| CB1 | 261.06 | 179.62 | 81.44 |
| CA2 | 238.64 | 164.20 | 74.44 |
| CA1 | 222.62 | 153.17 | 69.45 |
| BB2 | 253.05 | 174.11 | 78.94 |
| BB1 | 241.84 | 166.40 | 75.44 |
| BA2 | 209.80 | 144.35 | 65.45 |
| BA1 | 200.19 | 137.74 | 62.45 |
| PE2 | 337.96 | 232.53 | 105.43 |
| PE1 | 321.94 | 221.51 | 100.43 |
| PD2 | 318.74 | 219.31 | 99.43 |
| PD1 | 302.72 | 208.29 | 94.43 |
| PC2 | 273.88 | 188.44 | 85.44 |
| PC1 | 261.06 | 179.62 | 81.44 |
| PB2 | 232.23 | 159.79 | 72.44 |
| PB1 | 222.62 | 153.17 | 69.45 |
| PA2 | 192.18 | 132.23 | 59.95 |
| PA1 | 184.17 | 126.72 | 57.45 |

TABLE 8A—RUG—IV CASE-MIX ADJUSTED FEDERAL RATES FOR RURAL SNFS BY LABOR AND NON-LABOR COMPONENT

[Including parity adjustment recalibration]

| RUG—IV category | Total rate | Labor portion | Non-labor portion |
|-----------------|------------|---------------|-------------------|
| RUX | \$752.19 | \$517.54 | \$234.65 |
| RUL | 736.88 | 507.01 | 229.87 |
| RVX | 660.90 | 454.73 | 206.17 |
| RVL | 596.61 | 410.50 | 186.11 |
| RHX | 591.89 | 407.25 | 184.64 |
| RHL | 530.66 | 365.12 | 165.54 |
| RMX | 537.89 | 370.10 | 167.79 |
| RML | 495.03 | 340.61 | 154.42 |
| RLX | 468.18 | 322.13 | 146.05 |
| RUC | 582.28 | 400.64 | 181.64 |
| RUB | 582.28 | 400.64 | 181.64 |
| RUA | 495.03 | 340.61 | 154.42 |
| RVC | 492.53 | 338.89 | 153.64 |
| RVB | 431.30 | 296.76 | 134.54 |
| RVA | 429.77 | 295.70 | 134.07 |
| RHC | 423.51 | 291.40 | 132.11 |
| RHB | 383.71 | 264.01 | 119.70 |
| RHA | 340.85 | 234.52 | 106.33 |
| RMC | 367.99 | 253.20 | 114.79 |
| RMB | 346.56 | 238.45 | 108.11 |
| RMA | 288.39 | 198.43 | 89.96 |
| RLB | 351.85 | 242.09 | 109.76 |
| RLA | 230.92 | 158.88 | 72.04 |
| ES3 | 648.24 | 446.02 | 202.22 |
| ES2 | 508.95 | 350.18 | 158.77 |
| ES1 | 455.37 | 313.32 | 142.05 |
| HE2 | 440.07 | 302.79 | 137.28 |
| HE1 | 366.59 | 252.23 | 114.36 |
| HD2 | 412.51 | 283.83 | 128.68 |
| HD1 | 345.16 | 237.49 | 107.67 |
| HC2 | 389.55 | 268.03 | 121.52 |
| HC1 | 326.79 | 224.85 | 101.94 |
| HB2 | 384.96 | 264.87 | 120.09 |
| HB1 | 323.73 | 222.74 | 100.99 |
| LE2 | 400.27 | 275.41 | 124.86 |
| LE1 | 335.98 | 231.17 | 104.81 |
| LD2 | 384.96 | 264.87 | 120.09 |
| LD1 | 323.73 | 222.74 | 100.99 |
| LC2 | 339.04 | 233.28 | 105.76 |
| LC1 | 287.00 | 197.47 | 89.53 |
| LB2 | 323.73 | 222.74 | 100.99 |
| LB1 | 274.75 | 189.04 | 85.71 |
| CE2 | 357.41 | 245.92 | 111.49 |
| CE1 | 329.86 | 226.96 | 102.90 |
| CD2 | 339.04 | 233.28 | 105.76 |
| CD1 | 311.49 | 214.32 | 97.17 |
| CC2 | 297.71 | 204.84 | 92.87 |
| CC1 | 276.28 | 190.09 | 86.19 |
| CB2 | 276.28 | 190.09 | 86.19 |
| CB1 | 256.38 | 176.40 | 79.98 |
| CA2 | 234.95 | 161.66 | 73.29 |
| CA1 | 219.64 | 151.12 | 68.52 |
| BB2 | 248.73 | 171.14 | 77.59 |
| BB1 | 238.01 | 163.76 | 74.25 |
| BA2 | 207.40 | 142.70 | 64.70 |
| BA1 | 198.21 | 136.38 | 61.83 |
| PE2 | 329.86 | 226.96 | 102.90 |
| PE1 | 314.55 | 216.43 | 98.12 |
| PD2 | 311.49 | 214.32 | 97.17 |
| PD1 | 296.18 | 203.79 | 92.39 |
| PC2 | 268.63 | 184.83 | 83.80 |
| PC1 | 256.38 | 176.40 | 79.98 |
| PB2 | 228.83 | 157.45 | 71.38 |
| PB1 | 219.64 | 151.12 | 68.52 |
| PA2 | 190.56 | 131.11 | 59.45 |
| PA1 | 182.91 | 125.85 | 57.06 |

TABLE 8B—RUG—IV CASE-MIX ADJUSTED FEDERAL RATES FOR RURAL SNFS BY LABOR AND NON-LABOR COMPONENT

[Without parity adjustment recalibration]

| RUG—IV category | Total rate | Labor portion | Non-Labor portion |
|-----------------|------------|---------------|-------------------|
| RUX | 893.01 | \$614.44 | \$278.57 |
| RUL | 871.58 | 599.69 | 271.89 |
| RVX | 798.67 | 549.52 | 249.15 |
| RVL | 712.95 | 490.55 | 222.40 |
| RHX | 726.59 | 499.93 | 226.66 |
| RHL | 643.93 | 443.06 | 200.87 |
| RMX | 666.47 | 458.56 | 207.91 |
| RML | 611.37 | 420.65 | 190.72 |
| RLX | 587.57 | 404.28 | 183.29 |
| RUC | 664.94 | 457.51 | 207.43 |
| RUB | 664.94 | 457.51 | 207.43 |
| RUA | 547.07 | 376.41 | 170.66 |
| RVC | 570.59 | 392.59 | 178.00 |
| RVB | 489.46 | 336.77 | 152.69 |
| RVA | 487.93 | 335.72 | 152.21 |
| RHC | 498.52 | 343.01 | 155.51 |
| RHB | 446.47 | 307.19 | 139.28 |
| RHA | 389.84 | 268.23 | 121.61 |
| RMC | 439.93 | 302.69 | 137.24 |
| RMB | 409.31 | 281.63 | 127.68 |
| RMA | 332.78 | 228.97 | 103.81 |
| RLB | 429.91 | 295.80 | 134.11 |
| RLA | 267.66 | 184.16 | 83.50 |
| ES3 | 648.24 | 446.02 | 202.22 |
| ES2 | 508.95 | 350.18 | 158.77 |
| ES1 | 455.37 | 313.32 | 142.05 |
| HE2 | 440.07 | 302.79 | 137.28 |
| HE1 | 366.59 | 252.23 | 114.36 |
| HD2 | 412.51 | 283.83 | 128.68 |
| HD1 | 345.16 | 237.49 | 107.67 |
| HC2 | 389.55 | 268.03 | 121.52 |
| HC1 | 326.79 | 224.85 | 101.94 |
| HB2 | 384.96 | 264.87 | 120.09 |
| HB1 | 323.73 | 222.74 | 100.99 |
| LE2 | 400.27 | 275.41 | 124.86 |
| LE1 | 335.98 | 231.17 | 104.81 |
| LD2 | 384.96 | 264.87 | 120.09 |
| LD1 | 323.73 | 222.74 | 100.99 |
| LC2 | 339.04 | 233.28 | 105.76 |
| LC1 | 287.00 | 197.47 | 89.53 |
| LB2 | 323.73 | 222.74 | 100.99 |
| LB1 | 274.75 | 189.04 | 85.71 |
| CE2 | 357.41 | 245.92 | 111.49 |
| CE1 | 329.86 | 226.96 | 102.90 |
| CD2 | 339.04 | 233.28 | 105.76 |
| CD1 | 311.49 | 214.32 | 97.17 |
| CC2 | 297.71 | 204.84 | 92.87 |
| CC1 | 276.28 | 190.09 | 86.19 |
| CB2 | 276.28 | 190.09 | 86.19 |
| CB1 | 256.38 | 176.40 | 79.98 |
| CA2 | 234.95 | 161.66 | 73.29 |
| CA1 | 219.64 | 151.12 | 68.52 |
| BB2 | 248.73 | 171.14 | 77.59 |
| BB1 | 238.01 | 163.76 | 74.25 |
| BA2 | 207.40 | 142.70 | 64.70 |
| BA1 | 198.21 | 136.38 | 61.83 |
| PE2 | 329.86 | 226.96 | 102.90 |
| PE1 | 314.55 | 216.43 | 98.12 |
| PD2 | 311.49 | 214.32 | 97.17 |
| PD1 | 296.18 | 203.79 | 92.39 |
| PC2 | 268.63 | 184.83 | 83.80 |
| PC1 | 256.38 | 176.40 | 79.98 |
| PB2 | 228.83 | 157.45 | 71.38 |
| PB1 | 219.64 | 151.12 | 68.52 |
| PA2 | 190.56 | 131.11 | 59.45 |
| PA1 | 182.91 | 125.85 | 57.06 |

Section 1888(e)(4)(G)(ii) of the Act also requires that we apply this wage index in a manner that does not result in aggregate payments that are greater or less than would otherwise be made in the absence of the wage adjustment. For FY 2012 (Federal rates effective October 1, 2011), we apply an adjustment to fulfill the budget neutrality requirement. We meet this requirement by multiplying each of the components of the unadjusted Federal rates by a budget neutrality factor equal to the ratio of the weighted average wage adjustment factor for FY 2011 to the weighted average wage adjustment factor for FY 2012. For this calculation, we use the same 2010 claims utilization data for both the numerator and denominator of this ratio. We define the wage adjustment factor used in this calculation as the labor share of the rate component multiplied by the wage index plus the non-labor share of the rate component. The budget neutrality factor for this year is 1.0001. The wage index applicable to FY 2012 is set forth in Tables A and B, which appear in the Addendum of this proposed rule.

In the SNF PPS final rule for FY 2006 (70 FR 45026, August 4, 2005), we adopted the changes discussed in the Office of Management and Budget (OMB) Bulletin No. 03-04 (June 6, 2003), available online at <http://www.whitehouse.gov/omb/bulletins/b03-04.html>, which announced revised definitions for Metropolitan Statistical Areas (MSAs), and the creation of Micropolitan Statistical Areas and Combined Statistical Areas. In addition, OMB published subsequent bulletins regarding CBSA changes, including changes in CBSA numbers and titles. As indicated in the FY 2008 SNF PPS final rule (72 FR 43423, August 3, 2007), this and all subsequent SNF PPS rules and notices are considered to incorporate the CBSA changes published in the most recent OMB bulletin that applies to the hospital wage data used to determine the current SNF PPS wage index. The OMB bulletins are available online at <http://www.whitehouse.gov/omb/bulletins/index.html>.

In adopting the OMB CBSA geographic designations, we provided for a 1-year transition with a blended wage index for all providers. For FY 2006, the wage index for each provider consisted of a blend of 50 percent of the FY 2006 MSA-based wage index and 50 percent of the FY 2006 CBSA-based wage index (both using FY 2002 hospital data). We referred to the blended wage index as the FY 2006 SNF PPS transition wage index. As discussed in the SNF PPS final rule for FY 2006 (70 FR 45041), subsequent to the

expiration of this 1-year transition on September 30, 2006, we used the full CBSA-based wage index values, as now presented in Tables A and B in the Addendum of this proposed rule.

D. Updates to the Federal Rates

In accordance with section 1888(e)(4)(E) of the Act as amended by section 311 of the BIPA, and section 1888(e)(5)(B) of the Act as amended by section 3401(b) of the Affordable Care Act, the payment rates in this proposed rule reflect an update equal to the full SNF market basket, estimated at 2.7 percentage points, reduced by the MFP adjustment. As discussed in sections I.G.2 and VI.C of this proposed rule, the annual update includes a 1.2 percentage point reduction to account for the MFP adjustment described in the latter section, for a net update of 1.5 percent for FY 2012. We continue to disseminate the rates, wage index, and case-mix classification methodology through the **Federal Register** before the August 1 that precedes the start of each succeeding FY.

E. Relationship of Case-Mix Classification System to Existing Skilled Nursing Facility Level-of-Care Criteria

As discussed in § 413.345, we include in each update of the Federal payment rates in the **Federal Register** the designation of those specific RUGs under the classification system that represent the required SNF level of care, as provided in § 409.30. As set forth in the FY 2011 SNF PPS update notice (75 FR 42910, July 22, 2010), this designation reflects an administrative presumption under the 66-group RUG-IV system that beneficiaries who are correctly assigned to one of the upper 52 RUG-IV groups on the initial 5-day, Medicare-required assessment are automatically classified as meeting the SNF level of care definition up to and including the assessment reference date on the 5-day Medicare-required assessment.

A beneficiary assigned to any of the lower 14 RUG-IV groups is not automatically classified as either meeting or not meeting the definition, but instead receives an individual level of care determination using the existing administrative criteria. This presumption recognizes the strong likelihood that beneficiaries assigned to one of the upper 52 RUG-IV groups during the immediate post-hospital period require a covered level of care, which would be less likely for those beneficiaries assigned to one of the lower 14 RUG-IV groups.

In this proposed rule, we once again propose to designate the upper 52 RUG-

IV groups for purposes of this administrative presumption, consisting of all groups encompassed by the following RUG-IV categories:

- Rehabilitation plus Extensive Services;
- Ultra High Rehabilitation;
- Very High Rehabilitation;
- High Rehabilitation;
- Medium Rehabilitation;
- Low Rehabilitation;
- Extensive Services;
- Special Care High;
- Special Care Low; and,
- Clinically Complex.

However, we note that this administrative presumption policy does not supersede the SNF's responsibility to ensure that its decisions relating to level of care are appropriate and timely, including a review to confirm that the services prompting the beneficiary's assignment to one of the upper 52 RUG-IV groups (which, in turn, serves to trigger the administrative presumption) are themselves medically necessary. As we explained in the FY 2000 SNF PPS final rule (64 FR 41667, July 30, 1999), the administrative presumption

* * * is itself rebuttable in those individual cases in which the services actually received by the resident do not meet the basic statutory criterion of being reasonable and necessary to diagnose or treat a beneficiary's condition (according to section 1862(a)(1) of the Act). Accordingly, the presumption would not apply, for example, in those situations in which a resident's assignment to one of the upper * * * groups is itself based on the receipt of services that are subsequently determined to be not reasonable and necessary.

Moreover, we want to stress the importance of careful monitoring for changes in each patient's condition to determine the continuing need for Part A SNF benefits after the assessment reference date of the 5-day assessment.

F. Example of Computation of Adjusted PPS Rates and SNF Payment

Using the hypothetical SNF XYZ described below, Tables 9A and 9B show the adjustments made to the Federal per diem rates to compute the provider's actual per diem PPS payment under each of the described scenarios (that is, with a parity adjustment recalibration and without a parity adjustment recalibration). SNF XYZ's 12-month cost reporting period begins October 1, 2011. As illustrated in Table 9A, SNF XYZ's total PPS payment would equal \$40,021.02 with the application of a parity adjustment recalibration (calculated using first quarter FY 2011 data), as described in section II.B.2 above. SNF XYZ's total PPS payment would equal \$42,636.62

without the application of the parity adjustment recalibration considered in section II.B.2, as illustrated in Table 9B.

We derive the Labor and Non-labor columns from Tables 7A and 7B.

TABLE 9A—RUG—IV—INCLUDING PARITY ADJUSTMENT RECALIBRATION SNF XYZ: LOCATED IN CEDAR RAPIDS, IA
[(Urban CBSA 16300) Wage Index: 0.8857]

| RUG—IV group | Labor | Wage index | Adjusted labor | Non-labor | Adjusted rate | Percent adjustment | Medicare days | Payment |
|--------------|----------|------------|----------------|-----------|---------------|--------------------|---------------|------------|
| RVX | \$450.23 | 0.8857 | \$398.77 | \$204.12 | \$602.89 | \$602.89 | 14 | \$8,440.46 |
| ES2 | 361.49 | 0.8857 | 320.17 | 163.90 | 484.07 | 484.07 | 30 | 14,522.10 |
| RHA | 227.14 | 0.8857 | 201.18 | 102.98 | 304.16 | 304.16 | 16 | 4,866.56 |
| CC2* | 209.39 | 0.8857 | 185.46 | 94.93 | 280.39 | 639.29 | 10 | 6,392.90 |
| BA2 | 144.35 | 0.8857 | 127.85 | 65.45 | 193.30 | 193.30 | 30 | 5,799.00 |
| | | | | | | | 100 | 40,021.02 |

* Reflects a 128 percent adjustment from section 511 of the MMA.

TABLE 9B—RUG—IV—WITHOUT PARITY ADJUSTMENT RECALIBRATION SNF XYZ: LOCATED IN CEDAR RAPIDS, IA
[(Urban CBSA 16300) Wage Index: 0.8857]

| RUG—IV group | Labor | Wage index | Adjusted labor | Non-labor | Adjusted rate | Percent adjustment | Medicare days | Payment |
|--------------|----------|------------|----------------|-----------|---------------|--------------------|---------------|-------------|
| RVX | \$549.43 | 0.8857 | \$486.63 | \$249.10 | \$735.73 | \$735.73 | 14 | \$10,300.22 |
| ES2 | 361.49 | 0.8857 | 320.17 | 163.90 | 484.07 | 484.07 | 30 | 14,522.10 |
| RHA | 262.42 | 0.8857 | 232.43 | 118.97 | 351.40 | 351.40 | 16 | 5,622.40 |
| CC2* | 209.39 | 0.8857 | 185.46 | 94.93 | 280.39 | 639.29 | 10 | 6,392.90 |
| BA2 | 144.35 | 0.8857 | 127.85 | 65.45 | 193.30 | 193.30 | 30 | 5,799.00 |
| | | | | | | | 100 | 42,636.62 |

* Reflects a 128 percent adjustment from section 511 of the MMA.

III. Resource Utilization Groups, Version 4 (RUG—IV)

A. Prospective Payment for SNF Non-therapy Ancillary Costs

1. Previous Research

We have conducted several studies since 1999 to refine the reimbursement methodology for non-therapy ancillary (NTA) services covered by the SNF PPS. At the inception of the SNF PPS, payment for NTA services was included in the 44-group RUG system of case-mix groups. Analysis showed that there was only a weak correlation between NTA services costs and the RUG—III classification group. As the current RUG—IV system, similar to the RUG—III system, has maintained NTA costs coverage as part of the nursing CMI, we believe that the present methodology for case-mix adjusting the NTA payment amount may not be the most accurate predictor of NTA costs. We are particularly concerned that the present system could underestimate NTA costs for the patients with the highest NTA needs, which could lead to restricted access to care for those patients.

As a result of research conducted in the late 1990s, one proposal included in the FY 2001 proposed rule was to modify the RUG system by adding 14 additional RUG groups (65 FR 19193–

19194, 19203, April 10, 2000). These additional groups were designed to recognize that patients qualifying for both a Rehabilitation RUG and an Extensive Services RUG incurred NTA costs estimated to be as much as three times higher than those of patients who qualify solely for a Rehabilitation RUG.

As noted in the 2006 Report to Congress on case-mix refinements (available online at http://www.cms.gov/SNFPPS/Downloads/RC_2006_PC-PPSSNF.pdf), additional research conducted by Abt Associates in the late 1990s experimented with several mathematical models of NTA costs. Results from this work could have practical application as an ancillary “add-on” index based on the beneficiary’s predicted, per diem NTA costs. As discussed in the FY 2001 SNF PPS proposed rule (65 FR 19195, April 10, 2000), NTA index models (both weighted and unweighted) were tested after exploring MDS variables that appeared to be predictive of NTA costs. In the unweighted model, cost predictions were based on counts of qualifying patient characteristics (characteristics such as respiratory infection or skin wounds). In the weighted models, a small set of payment groups were defined from “index models” that weighted the predictors where the weights were proportional to

the marginal impact of a patient characteristic on estimated NTA costs. The array of predicted costs generated by the equation could be subdivided into ranges of costs, or intervals, in order to define a small number of payment groups. As discussed in the Technical Appendix to the FY 2001 proposed rule (65 FR 19240, 19248, April 10, 2000), variations were created by applying the index models to alternative sets of RUG groups. As further discussed in the FY 2001 proposed rule (65 FR 19196), we proposed a separate unweighted NTA index to be applied to certain RUG categories based on clinical variables on the MDS. In addition, to facilitate the incorporation of this proposed refinement into the case-mix classification system, we proposed to create a new component of the payment rates for NTA services (65 FR 19192).

As explained in the FY 2001 SNF PPS final rule (65 FR 46773, July 31, 2000), while the expanded RUG groups approach and the NTA index approach initially appeared to improve payment accuracy in comparison to the existing case-mix system, attempts to validate the results on a later national PPS data set did not confirm the initial findings. As a result, we did not finalize the proposals made in April 2000.

We sponsored subsequent research by the Urban Institute using claims samples from 2001. This work led to the FY 2006 final rule (70 FR 45026, 45030–34, August 4, 2005), which essentially implemented a variation of the 58-group RUG proposal developed by Abt Associates discussed above. In that rule, we finalized a system composed of 53 groups, by augmenting the original 44-group system with nine additional groups identifying patients simultaneously qualifying for the Extensive Services and Rehabilitation groups. This incremental change to the grouping system was accompanied by an across-the-board increase in the case-mix weights for the payment component that includes NTA costs. Both of these modifications were intended to enable the original RUG–III payment model to account more accurately for variation in NTA costs.

Using the 2001 data set, the Urban Institute also experimented with prediction models that were extensions of the original Abt Associates NTA index approaches. A small number of additional variables (for example, age) and improvements to the methodology used to measure independent variables in the data base led to potential improvements over the earlier model. The Urban Institute also explored substantially more complex models that incorporated variables derived from qualifying hospital stay claims; these models were estimated separately for patients after subdividing them into one of three groups: Acute, chronic, or rehabilitation.

In 2008, the Medicare Payment Advisory Commission (MedPAC) sponsored analyses by researchers from the Urban Institute extending some of the Institute's earlier work. This led to a MedPAC proposal that was based on the most promising results of the Institute's earlier work. The study used 2003 Medicare data. It resulted in a prediction equation for NTA services that used a large number of variables derived from the MDS assessments and hospital claims (for example, diagnosis), a measure of length of stay, as well as patient age (Bowen Garrett and Douglas A. Wissoker, "Modeling Alternative Designs for a Revised PPS for Skilled Nursing Facilities: A study conducted by staff from the Urban Institute for the Medicare Payment Advisory Commission," June, 2008; available online at http://www.medpac.gov/documents/jun08_SNF_PPS_CONTRACTOR_CC.pdf). MedPAC did not propose a system of NTA case-mix groups based on the prediction equation. However, the basic equation could be used to generate an array of

predictions in the population and to group the predictions into cost intervals for defining a smaller number of payment groups. This is the same approach that Abt Associates took with its index model.

In a June 2010 memo to MedPAC (available online at http://www.medpac.gov/documents/Oct10_SNF_NonTherapyAncillary_CONTRACTOR_CC.pdf), the Urban Institute described a series of refinements to MedPAC's 2008 proposed model. Most importantly, with their 2010 model, the Urban Institute sought to reduce the number of indicators from nearly 70 and ensure that all indicators are derived from information based on available administrative data. Additionally, when the Urban Institute used 2007 SNF data files (as compared to the 2003 data files used to support the previous model), they found that the predictive ability of the model was reduced slightly from 23 percent to 21 percent.

After completing a revised statistical analysis and eliminating indicators for conditions that were either relatively rare or had little impact on NTA costs, the Urban Institute advanced a 20-variable "streamlined" model that maintained almost equivalent predictive accuracy to MedPAC's 2008 proposed model described above. The streamlined model included many of the "high-impact" variables contained in the 69-variable model, such as IV medication use and respiratory services. Additionally, the streamlined model included variables suggested by CMS, such as the nursing case-mix index and the MDS diabetes diagnosis, which were also found to be strong indicators of anticipated NTA costs.

2. Conceptual Analysis

Based on our initial research, we continue to believe that an administratively feasible and equitable approach to prospective payments for NTA costs would incorporate the following criteria:

- Uses information from available administrative data (data available on claims or on the MDS assessment);
- Uses predictor variables that represent meaningful correlates of NTA services that are highly predictive, clinically sensible, sensitive to patient NTA variation, and do not promote undesirable incentives for providers;
- Is developed by using the best and most recently available data sources, in order to assure that it reflects current care practices and resource utilization;
- Results in a separate NTA component and index that uses a minimal number of payment groups, or

tiers, to limit the complexity of the SNF PPS as a whole; and

- Uses payment groups and predictor variables that are readily understandable and clinically intuitive.

These criteria and our initial research intent were discussed in the FY 2010 SNF PPS proposed rule (74 FR 22238 through 22241, May 12, 2009), and responses to comments on this initial research proposal were part of the FY 2010 SNF PPS final rule (74 FR 40341 through 40342, August 11, 2009). These comments helped to guide our initial research to develop the conceptual model discussed in this proposed rule.

In addition to the criteria specified above, our research is also guided by the results of multiple recent studies, such as those conducted by the Urban Institute, regarding the relationship between NTA utilization and resident condition. Most relevant to our work in this area, these studies suggest that the highest-cost ancillary services (such as respiratory services, enteral and parenteral feeding, and treatment of chronic conditions, such as AIDS) are used by a small subset of the SNF population, and that the high and varied cost of individual services or drugs by these populations—rather than the volume of NTA utilization—can at least partially explain the wide variance in NTA costs.

To continue our analytic work for developing a payment methodology for NTA costs, we have utilized a large analytic data file that combines Medicare SNF claims, cost reports, and MDS assessments from FY 2007. The file has been used to study relationships between reported claims charges for NTA-related revenue centers and predictor variables defined from items on the MDS. We augmented the analytic file with diagnosis information from the patient's qualifying hospital stay as a way of compensating for potentially incomplete diagnosis reporting on MDS and on SNF claims. (As noted earlier, it is not our intention to use hospital-assigned diagnoses directly in any tiered system we may propose.) Because three-quarters of the NTA costs are pharmacy-related, we have summarized the patient's recent diagnoses using the diagnosis classification system CMS developed for Medicare Part D risk adjustment. This is known as the RxHCC system. The RxHCC system was developed from the Hierarchical Condition Categories (HCCs) used for risk-adjustment in Medicare Part C. We also continue to examine the performance of the diagnosis flags from Section I of the MDS.

Now that more recent data are available, we are developing a similar

file using FY 2009 data, which may be used to test our initial model formulas and monitor any recent changes to NTA utilization patterns. We solicit comment on the criteria specified above and the conceptual model discussed in the following sections.

3. Analytic Sample

To develop the analytic sample, we linked FY 2007 SNF cost reports with SNF Medicare Part A claims covering services delivered during the SNF's cost reporting period. The actual cost of the NTA services is determined by adjusting claims charges for NTA services in accordance with cost-to-charge ratios (CCRs) from the cost report. The NTA costs are then used as the dependent variable in all subsequent analyses, while MDS items and claims diagnoses act as the independent variables. We collected all claims, and used only those claims submitted within the reporting period for the cost reports available. Requiring a matched cost report eliminated some SNFs represented in the 2007 National Claims History. The SNFs that do not meet this threshold tend to be smaller SNFs, though this requirement does not adversely affect the representativeness of the analytic sample.

We have studied the same three general categories of NTAs as previous research has suggested: Respiratory-related costs (for example, ventilator services), drug-related costs, and other non-therapy ancillary (ONTA) costs (for example, wound dressings). We derive category-specific CCRs for each facility's cost report remaining in the sample. An additional requirement for an SNF to be in the sample is that it reports some drug and ONTA charges on the claims; otherwise, the facility's data may not be accurate enough to be used in the sample. Positive respiratory charges are not necessary, as these types of charges are not always reported. One reason is that some respiratory charges, such as oxygen-related supplies, are reported as ONTAs, based on certain reporting standards.

We trimmed the sample to eliminate facilities with extreme values for CCRs, as outlying CCRs could skew the results of our analysis. Finally, we compared the drug and ONTA charges on the claims to the SNF's cost report drug and ONTA charges, since wide differences could be the result of incomplete or inaccurate reporting. Facilities that were found to exhibit such wide differences were dropped from the sample. For our analysis, accurate charge reporting is critical for the measurement of our dependent-variable, CCR-adjusted NTA charges.

4. Approach to Analysis

The dependent variable in our analysis is the NTA charges, adjusted by CCRs. The independent variables are diagnosis groupings and variables selected from the matched MDS assessments. With the recent implementation of the MDS 3.0, we will monitor any changes in our selected set of variables and, based on research conducted as part of the Post Acute Care Payment Reform Demonstration (PAC-PRD), we may explore changes to the MDS assessment which would allow us to collect more detailed information on NTA costs and utilization. However, as our current analytic database is based on FY 2007 and FY 2009 data, our analysis still utilizes the MDS 2.0. The following sections of the MDS 2.0 contribute variables to be tested for their predictive value:

E: Mood and Behavior Problems
G: Physical Functioning and Structural Problems
H: Continence in Last 14 Days
I: Disease Diagnoses
J: Health Conditions
K: Oral/Nutritional Status
L: Oral/Dental Status
M: Skin Condition
O: Medications
P: Special Treatments and Procedures

Our study of the ability of particular MDS items and diagnosis groupings to predict NTA costs builds on previous research discussed above and adheres to the criteria outlined earlier in this section. Now that we have completed the initial phase of this research, we are in a better position to understand the relationship between NTA costs and certain classes of illness. Understanding these relationships has led us to explore potential groupings of conditions, distinct from the RUG classification or qualifying hospital condition, which could suggest a feasible system for NTA payment tiers.

5. Payment Methodology

The payments associated with a new NTA component of the SNF PPS would be financed by reallocating that portion of the current nursing component which has been previously considered to account for NTA costs. Our intent in adding a separate NTA component, distinct from the nursing component, would be to provide greater predictive ability, promote more equitable NTA reimbursement, and achieve a more cost-effective payment structure for SNFs.

The NTA payment would be broken into two parts: A routine NTA bundled payment (RNP) and a tiered non-routine NTA payment (TNP).

a. Routine Non-Therapy Ancillary Payment

The RNP would constitute a base payment for every patient day, distinct from the tiered NTA payment described below and separate from the nursing component, to cover the cost of routine NTA services (drugs, laboratory services, *etc.*) that are commonly given to a wide range of SNF patients. CMS is currently analyzing SNF claims data linked to specially collected data from Medicare research projects, such as the STRIVE study and the PAC-PRD project, to help determine the specific drugs and services that would be included in the RNP and an appropriate per diem amount to cover their purchase and administration. Examples of such routine NTAs could include high blood pressure medication, common analgesics, anti-infective agents, sleep aids, laxatives, and standard blood tests, among others. The RNP would help capture the daily cost of administering these types of routine NTAs, thereby allowing for a more clearly defined and appropriate tiered NTA bundled payment to cover non-routine NTA services, as well as a more transparent payment for such routine costs incurred by providers. We also believe that, in conjunction with a possible NTA outlier policy (discussed below), having an RNP component would limit the administrative burdens associated with reporting that might be required to administer outlier payments.

As with the other components of the SNF PPS, the RNP piece of the NTA component would be updated annually to account for changes in the market basket and other relevant adjustments. It would operate in much the same way as the non-therapy non-case mix adjusted component of the current SNF PPS, in that it would constitute a flat amount added to the payment for all applicable SNF claims.

b. Tiered Non-Routine NTA Bundled Payment

The TNP would operate as a variation of the model previously discussed in the FY 2001 SNF PPS proposed rule (65 FR 19188, April 10, 2000). Specifically, we are in the process of developing a tiered NTA bundled payment, where payment tiers track relative variations in NTA costs and utilization. The June 2008 Urban Institute report referenced above (Garrett and Wissoker, June 2008) suggested that average wage-adjusted per diem NTA costs were approximately \$68, with a standard deviation of \$94, which would support the use of multiple case-mix-adjusted tiers.

The TNP is designed to capture the average cost of the drugs and services, given the patient's clinical characteristics, excluding the drugs and services covered by the RNP or those already excluded from the SNF PPS altogether under the consolidated billing requirements. Such a cost schedule and tier structure is currently under development, using recent Medicare Part A claims data and data from the PAC-PRD.

We have focused on developing an index model in which predictions are arrayed and then subdivided into fixed ranges of cost values to form distinct payment groups, or tiers, as we believe this type of approach is better equipped to handle the number of explanatory variables needed to predict NTA costs reasonably well. The tiers which constitute the TNP will be based on average NTA costs as measured from available administrative data. Generally, based on the resident's case mix and the variables selected for predicting NTA costs, if the resident's expected NTA costs exceed a particular threshold, then the facility would be paid a prospective amount, which would be added to the base RNP amount.

c. Non-Routine NTA Outlier Payment

Though we currently lack explicit statutory authority to establish an SNF outlier policy, we are continuing to explore how such a policy could be implemented in the event that we receive statutory authority. Results of the STRIVE study suggest that it is the cost of individual high-cost pharmaceuticals and other NTAs, rather than a particular patient's use of a high volume of NTA services, which creates high NTA costs. Given the effect of specific high-cost items like prescription drugs or respiratory services, it is clear that any type of averaging system (such as the conceptual NTA model discussed here) will not in all cases account for the cost of such items. It will be insufficiently sensitive to high NTA costs deriving from variations among costs of individual medications and ONTAs.

Accordingly, we are currently reviewing the available data to determine how an outlier approach could be designed to address patient-specific expenditures that exceed the routine and non-routine NTA payments that we would make, while allowing for an outlier threshold. While we have not yet fully simulated a potential SNF outlier payment policy, we believe it is appropriate to conduct analysis at the stay level, because NTA utilization can fluctuate significantly during a given SNF stay. Using a stay-level analysis of

potential NTA cost outliers would help us to predict NTA costs more accurately over the course of a given SNF stay. Any further developments in this area will be discussed in future rulemaking.

6. Temporary AIDS Add-On Payment Under Section 511 of the MMA

As discussed in section I.E of this proposed rule, section 511 of the MMA amended section 1888(e)(12) of the Act to provide for a temporary increase of 128 percent in the PPS per diem payment for any SNF residents with Acquired Immune Deficiency Syndrome (AIDS), effective for services furnished on or after October 1, 2004. This special AIDS add-on was to remain in effect until “* * * the Secretary certifies that there is an appropriate adjustment in the case mix * * * to compensate for the increased costs associated with [such] residents. * * *” We know, as a result of the STRIVE study and a review of SNF cost data, that SNF residents with AIDS require much greater and more costly care than those without AIDS and that much of this additional cost is the result of NTAs, specifically high-cost medications.

Accordingly, as we have not yet completed work on the NTA component or an SNF outlier policy, we cannot yet determine whether such policy changes would be sufficient to compensate facilities for the costs associated with the treatment of residents with AIDS, in accordance with section 511 of the MMA. We will continue to study the relationship between NTA costs and resource use as they pertain to this population in order to develop an “appropriate adjustment” to account for such costs, as envisioned in the MMA.

IV. Ongoing Initiatives Under the Affordable Care Act

The Affordable Care Act contains a number of provisions that involve ongoing initiatives relating to SNFs. Here, we highlight several of these initiatives.

A. Value-Based Purchasing (Section 3006)

Section 3006(a) of the Affordable Care Act directs the Secretary to develop a plan to implement a value-based purchasing program for SNFs, with a report to Congress due by October 1, 2011. As we discussed previously in the SNF PPS proposed rule (73 FR 25932, May 7, 2008) and final rule (73 FR 46431–32, August 8, 2008) for FY 2009, value-based purchasing programs are intended to tie payment to performance in such a way as to reduce inappropriate or poorly provided care and identify

and reward those who provide effective and efficient patient care.

We are in the process of developing the SNF value-based purchasing implementation plan and report. In accordance with section 3006(a) of the Affordable Care Act, we will be consulting with stakeholders in developing the implementation plan, as well as considering the outcomes of any recent demonstration projects related to value-based purchasing which we believe might be relevant to the SNF setting. We anticipate being able to provide further information on the progress of our efforts in future rulemaking.

B. Payment Adjustment for Hospital-Acquired Conditions (Section 3008)

As we discussed previously in the SNF PPS proposed rule for FY 2009 (73 FR 25932, May 7, 2008), “The preventable hospital-acquired conditions (HAC) payment provision for IPPS hospitals is another of CMS’ value-based purchasing initiatives. The principal behind the HAC payment provision (Medicare not paying more for healthcare-associated conditions) could be applied to the Medicare payment systems for other settings of care.” Section 3008 of the Affordable Care Act amends section 1886 of the Act by adding a new subsection (p) to establish a payment adjustment beginning in FY 2015 for subsection (d) hospitals that fall in the top quartile of national, risk-adjusted HAC rates. For such hospitals, the payment amount under section 1886, section 1814(b)(3), or section 1814(l)(4) of the Act for all discharges would be reduced by 1 percent. Section 3008(b) of the Affordable Care Act goes on to direct the Secretary to conduct a study on expanding the already-existing HAC policy found in section 1886(d)(4)(D) of the Act to payments made in various post-acute settings, including SNFs. In developing this study, the Secretary is directed to include the impact of expanding the HAC policy on patient care, safety, and overall payments.

In accordance with section 3008 of the Affordable Care Act, we are in the process of developing such a study, the outcomes of which are to be reported to Congress no later than January 1, 2012. As with the value-based purchasing program described above, we plan to consult with stakeholders in developing this study, and anticipate being able to provide information on our progress in future rulemaking.

C. Nursing Home Transparency and Improvement (Section 6104)

This provision of the Affordable Care Act requires SNFs to report expenditures separately for direct care staff wages and benefits on the Medicare cost report, for cost reporting periods beginning on or after 2 years after its enactment. Not later than 1 year after enactment of this section of the Affordable Care Act, the Secretary must redesign the cost report after consultation with private sector accountants experienced with Medicare and Medicaid nursing facility home cost reports. Within 30 months of its enactment, the provision requires the Secretary, in consultation with the Medicare Payment Advisory Commission (MedPAC), the Medicaid and CHIP Payment and Access Commission, the Inspector General of the United States Department of Health and Human Services, and other expert parties the Secretary determines appropriate, to categorize expenditures for each SNF into specific functional accounts on an annual basis. The provision also requires the Secretary to establish procedures to make information on the expenditures available to interested parties upon request, subject to the requirements the Secretary may specify under such procedures. A discussion of the information collection requirements currently being proposed in connection with this provision appears in a notice that was published in the March 11, 2011 **Federal Register** (76 FR 13415 through 13418).

V. Other Issues

A. Required Disclosure of Ownership and Additional Disclosable Parties Information (Section 6101)

Section 6101 of the Affordable Care Act was enacted in March 2010 to improve transparency of information in all Medicare SNFs and Medicaid nursing facilities. Specifically, it requires these facilities to make available on request by the Secretary and others certain information on ownership, including a description of the governing body and organizational structure of the relevant Medicare SNF or Medicaid nursing facility, and information regarding additional disclosable parties. Thus, we are proposing additional information that must be disclosed by Medicare SNFs and Medicaid nursing facilities in order for them to maintain their enrollment in Medicare and/or Medicaid.

According to nursing home quality data collected by CMS in 2008, about 1.5 million Americans reside in the

Nation's 16,000 nursing homes on any given day. More than 3 million Americans rely on services provided by a nursing home at some point during the year. Those individuals, and an even larger number of their family members, friends, and relatives, must be able to count on nursing homes to provide reliable care of consistently high quality.

In 2007, the *New York Times* analyzed trends at nursing homes purchased by private investment groups. It subsequently reported that upon ownership by these private investment firms, the facilities' managers quickly cut costs by significantly decreasing the number of registered nurses, budgets for nursing supplies, resident activities, and other services. CMS's data revealed that of those homes bought by large private investment groups from 2000 to 2006, in 60 percent of those acquisitions, managers cut the number of clinical registered nurses far below levels required by the Medicare long-term care facility participation requirements under 42 CFR 483.30. Nursing homes owned by large private investment firms provided one clinical registered nurse for every 20 residents, which was 35 percent below the national average.

In its 2010 report to Congress entitled "Nursing Homes: Complexity of Private Investment Purchases Demonstrates Need for CMS to Improve the Usability and Completeness of Ownership Data" (GAO-10-710, available online at <http://www.gao.gov/new.items/d10710.pdf>), the GAO reported similar findings. The GAO found that, although certain information on ownership was available to the public upon request, that information was not transparent because it did not establish the relationship of each owner to the nursing home and to one another. Also, it was found that the information was not being utilized by the State agencies for review purposes.

Hearings were conducted in November and December of 2007 by the House Committee on Ways and Means, the United States Senate Special Committee on Aging, and the United States Senate Committee on Finance, seeking information on investor-owned nursing homes. Congress found through several hearings that legal schemes were being used by investment firms to shield themselves from liability and, in effect, to deny residents and their families legal remedy against the nursing home. Congress believed that these complex legal structures can also result in a lack of transparency regarding who is responsible for resident care and the

operation of investor-owned nursing homes.

We currently collect ownership information on nursing homes using the Medicare Provider Enrollment, Chain, and Ownership System (PECOS). In addition, we currently capture ownership information on Medicaid nursing facilities using the Online Survey Certification and Reporting System (OSCAR). Nursing home providers, along with any other provider or supplier, must report information about any individual or entity with a 5 percent ownership interest. As discussed in section IX. of this proposed rule, we are hereby proposing to revise the reporting requirements that Medicare SNFs and Medicaid nursing facilities must disclose at the time of enrollment and when any change in ownership occurs, in order to implement section 6101 of the Affordable Care Act.

B. Therapy Student Supervision

In this proposed rule, we are proposing to revise a policy that originally appeared in the SNF PPS final rule for FY 2000 (64 FR 41644, July 30, 1999). The preamble in that final rule had indicated (at 64 FR 41661) that a therapy student in the SNF setting must " * * * be under the 'line-of-sight' level of supervision of the professional therapist." We note that the corresponding standards for the other inpatient settings under Part A (such as acute care hospitals and inpatient rehabilitation facilities) are silent on the issue of therapy student supervision and currently do not impose this type of restriction, so that each provider is free to determine for itself the most appropriate manner of supervision in this context, consistent with applicable State and local laws and practice standards. Because we consider it inequitable for SNFs to be subject to a more restrictive set of standards in this regard than the other inpatient settings, we believe that line-of-sight supervision should no longer be required in the SNF setting. Instead, as with other inpatient settings, each SNF would determine for itself the appropriate manner of supervision of therapy students, consistent with applicable State and local laws and practice standards. Accordingly, we are proposing to revise our current policy regarding supervision of therapy students, such that a therapy student working in an SNF would no longer be required to be in the supervising therapist's line of sight. We invite comments on our proposed revision to the supervision requirements for therapy students working in SNFs, and note that we plan to continue

monitoring the provision of therapy services in the SNF setting. We also note that we may revisit this issue in the future; however, consistent with the aim of promoting greater uniformity across inpatient settings on this point, we believe that such an analysis would most appropriately take place in the broader context of therapy standards that pertain to inpatient settings generally.

C. Group Therapy and Therapy Documentation

When the original RUG—III model was developed, most therapy services were furnished on a one-to-one basis, and the minutes reported on the MDS served as a proxy for the staff resource time needed to provide the therapy care. However, the results of our multi-year STRIVE project showed that provider practice patterns had changed and that a significant amount of therapy was provided on a concurrent basis, which at that time was defined as simultaneous treatment of multiple patients who were receiving different types of therapy services. In the FY 2010 final rule (74 FR 40315), we stated that as Medicare and Medicaid patients are among the frailest and most vulnerable populations in nursing homes, we believed the most appropriate mode of providing therapy would usually be individual therapy, not concurrent therapy. Further, we expressed concern that the method for reporting concurrent therapy on the MDS under RUG—III created an inappropriate payment incentive to perform concurrent therapy in place of individual therapy, because the method of reporting under RUG—III permitted concurrent therapy time to be counted in the same manner as individual therapy time. As we stated in the SNF PPS final rule for FY 2010 (74 FR 40315), the SNF PPS is based on resource allocation and costs. When a therapist treats two patients concurrently for an hour, it does not cost the SNF twice the amount (or 2 hours of the therapist's salary) to provide those services. As a result, with the introduction of RUG—IV, we modified the way providers report and are reimbursed for concurrent therapy services such that allocated concurrent therapy minutes are used to assign patients to RUG—IV groups. Providers can no longer be reimbursed for one hour's therapy time for each of the two Medicare beneficiaries treated concurrently for one hour. Effective October 1, 2010, providers are required to report on the MDS 3.0 for each patient the total unallocated minutes of concurrent therapy and specify the mode as concurrent. We then divide the

total concurrent therapy time (60 minutes in this case) between the two patients in determining each patient's RUG—IV payment level (74 FR 40315–19). As we stated in the FY 2010 final rule (74 FR 40318), allocating concurrent therapy time reflects resource utilization more accurately for this type of therapy, and allows for more accurate RUG classification as well as the application of more appropriate CMLs. We note that in the FY 2010 final rule (74 FR 40317), we limited the number of concurrent therapy participants to two.

In comparison, we also considered the treatment of group therapy in the FY 2010 final rule (74 FR 40318); that is, simultaneous treatment of no more than four individuals (regardless of payer source) doing similar activities directed by a single therapist. Our STRIVE data showed that group therapy was used sparingly, and that utilization had not changed significantly since the inception of the SNF PPS in 1998. Further, in the FY 2010 proposed rule (74 FR 22223), we noted the difference between group and concurrent therapy. In group therapy, patients are performing similar activities, and by interacting with one another, group therapy patients observe and learn from each other and apply this new information to their own therapy program to progress and benefit from the group therapy setting. By contrast, in concurrent therapy, patients are not performing similar activities and often do not interact with each other. Because we had not proposed in the FY 2010 proposed rule to change the method in which group therapy minutes are used in RUG—IV classification, and the amount of group therapy being provided was low, in the FY 2010 final rule (74 FR 40318), we retained the original SNF PPS policy for payment of group therapy services, that is, group therapy minutes were not allocated but were limited to no more than 25 percent of the total weekly minutes per discipline for a particular patient. However, in the FY 2010 final rule (74 FR 40318), we discussed our intent “* * * to monitor therapy provided in the group setting, analyze data associated with group therapy, and, if needed, address any issues at a later time” in order to update these reporting requirements as necessary to maintain the accuracy and integrity of the RUG—IV payment system.

Using our STRIVE data as a baseline, we have identified two very significant changes in provider behavior related to the provision of therapy services to Medicare beneficiaries in SNFs under RUG—IV. First, we saw a major decrease

in the amount of concurrent therapy performed in SNFs. At the same time, we found a significant increase in the amount of group therapy services which are not subject to the allocation requirement. Given this increase in group therapy services, we are concerned that the current method for reporting group therapy on the MDS creates an inappropriate payment incentive to perform the less intensive group therapy in place of individual therapy, because the current method of reporting group therapy time does not require allocation among patients. In addition, the allocation of concurrent therapy minutes effective FY 2011 may have created an incentive to perform group therapy in place of concurrent therapy in situations where concurrent therapy may have otherwise been appropriate. After further reviewing data associated with group therapy, we are proposing to change our policies relating to group therapy as further discussed below.

As noted above, we believe there are unique benefits to group therapy. In group therapy, patients are performing similar activities. Thus, in contrast to concurrent therapy, group therapy gives patients the opportunity to benefit from each other's therapy regimen by observing and interacting with one another, and applying the lessons learned from others to one's own therapy program in order to progress. Large groups, such as those of five or more participants, can make it difficult for the participants to engage with one another over the course of the session. In addition, we have long believed that therapists could not adequately supervise large groups, and, since the inception of the SNF PPS in July 1998, we have capped the number of residents at four.

Furthermore, we believe that groups of fewer than four participants do not maximize the group therapy benefit for the participants. As discussed above, and in the FY 2010 proposed rule (74 FR 22223), the unique benefit of group therapy comes from the interaction between multiple patients, which permits them to observe and learn from one another and apply the new information to their own program to progress and benefit from the group therapy setting. We believe that in groups of 2 or 3 participants, the opportunities for patients in the group to interact and learn from each other are significantly diminished given the small size of the group. Thus, we believe that groups of two or three participants, given their small size, significantly limit the ability of patients to derive the unique benefits associated with group

therapy. In such small groups, these limitations become even more accentuated whenever one or two patients are absent from the therapy session (in fact, with groups of two participants, if one patient is absent from the session, there are no longer any patients with whom the remaining participant can interact, thereby eliminating any benefit that could be derived from participation in a group). Thus, for the reasons discussed above, we believe that the most appropriate group therapy size for the SNF setting is four, which we believe is the size that permits the therapy participants to derive the maximum benefit from the group therapy setting.

As discussed in the FY 2010 final rule, we are responsible for determining Medicare coverage and payment policy, that is, “the scope of services that will be paid for by the Medicare program under the SNF PPS and the manner in which those services will be reported and paid” (74 FR 40316). Thus, for purposes of payment under the Medicare SNF PPS, for the reasons discussed above, we are proposing to establish a standard that defines group therapy as therapy provided simultaneously to four patients who are performing similar therapy activities.

Furthermore, as we have stated previously, the SNF PPS is based on resource utilization and costs. We believe that when a therapist treats four patients in a group for an hour, it does not cost the SNF four times the amount (or four hours of a therapist’s salary) to provide those services. The therapist would appropriately receive one hour’s salary for the hour of therapy provided. Accordingly, we believe that allocating group therapy minutes among the four group therapy participants best captures the resource utilization associated with providing a maximally beneficial group therapy intervention. For therapists treating patients in a group setting, the full time spent by the therapist with these patients would be divided by 4 (the number of patients that comprise a group). For example, if a therapist spends 1 hour with four residents in a group therapy session, regardless of payer source, then the time used to determine the appropriate RUG–IV classification for each Medicare beneficiary receiving SNF care benefits as part of a qualified Part A stay will be 15 minutes, or 60 minutes of total therapist time divided by four. These 15 minutes, which may be referred to as the therapist’s “reimbursable therapy minutes” (RTM), are those minutes used to classify a patient for therapy purposes. For each of the RUG–IV categories, it is the number of

reimbursable therapy minutes that is used to classify a given patient into a therapy RUG–IV group. For example, if a therapist provides 400 minutes of individual therapy, 200 minutes of concurrent therapy, and 120 minutes of group therapy (given the proposed policy change to group therapy discussed here), then the therapist’s total RTM would be 530, or 400 RTM for individual therapy, 100 RTM for concurrent therapy, and 30 RTM for group therapy. The total of 530 RTM is what would be used to determine the patient’s appropriate RUG–IV classification. We hope that defining this concept of a reimbursable therapy minute will help clarify the number of minutes necessary to reach certain RUG–IV categories, given the allocation policies discussed here and in the FY 2010 proposed and final rules.

As is currently the procedure, the SNF would report the total unallocated group therapy minutes on the MDS 3.0 (60 minutes in the scenario above) for each patient. In terms of RUG–IV classification, this total time would be allocated (that is, divided) among the four group therapy participants to determine the appropriate number of RTM and, therefore, the appropriate RUG–IV therapy group and payment level, for each participant. The 25 percent cap on group therapy minutes, as defined in the July 30, 1999 final rule (64 FR 41662) will remain in effect, as we continue to believe that group therapy should serve only as an adjunct to individual therapy. The 25 percent cap would be applied to the patient’s reimbursable group therapy minutes. In addition, consistent with our current policy (64 FR 41662), the supervising therapist may not be supervising any individuals other than the four individuals who are in the group at the time of the therapy session. We invite comments on our proposals to revise our group therapy policies as discussed above, including the proposal to establish a standard that defines group therapy as a service provided to four patients, and the proposal to allocate group therapy minutes.

While we believe that group therapy can play an important role in SNF patient care, we note that group therapy is not appropriate for either all patients or for all conditions, and is primarily effective as a supplement to individual therapy, which we maintain should be considered the primary therapy mode and standard of care in therapy services provided to SNF residents. As evidenced by the application of a cap on the amount of group therapy services that may be provided to SNF residents, we do not believe that a SNF providing

the preponderance of therapy in the form of group therapy would be demonstrating the intensity of therapy appropriate to this most frail and vulnerable nursing home population. Accordingly, we believe it is important to clarify our expectations regarding the clinical documentation needed to support each patient’s plan of care, including the patient’s prescribed group therapy interventions, as further discussed below. Additionally, we specifically solicit comments on the types of patients for which group therapy may be appropriate, and the specific amounts of group therapy that may be beneficial for these types of patients. We anticipate using this information to assess the appropriate use of group therapy in SNFs and may revise standards of group therapy care in SNFs accordingly.

SNFs are currently required to prescribe the type, amount, frequency, and duration of physical therapy, occupational therapy, and speech-language pathology services in a patient’s plan of care. Under § 409.23(c), Medicare pays for therapy services if they are furnished, among other things, in accordance with a plan that meets the requirements of § 409.17(b) through (d). Section 409.17(c)(1) states that the plan must prescribe “the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual.” As evidenced by the discussion of care planning and the qualifications for skilled therapy services in Chapter 3, Section O of the RAI manual in relation to item O0400, SNFs are expected to include supporting documentation in each patient’s medical record on an ongoing basis. We further believe that such medical record documentation is needed so that SNFs can verify that the plan of care is being followed. In addition, we believe that such clinical documentation has always been necessary so that SNFs can identify when significant changes in a patient’s medical condition occur requiring an unscheduled assessment, such as a Significant Change in Status assessment. In fact, even when the clinical change is unrelated to the therapy program, these unscheduled assessments require completion of Section O, which reports therapy minutes by individual, concurrent, and group modes. Finally, we believe that such documentation has always been required so that contractors can verify medical necessity when they review SNF claims.

Additionally, under § 409.17(c)(2), SNFs must indicate “the diagnosis and anticipated goals” associated with the

therapy services prescribed in accordance with § 409.17(c)(1), as described above. It is incumbent upon providers to ensure that skilled therapy services provided to a given SNF resident are appropriate to the goals of the patient's individualized plan of care. Thus, it should be clear, based on the patient's medical record, therapy notes, and/or other related documentation, how the prescribed skilled therapy services contribute to the patient's anticipated progression toward the prescribed goals. Because group therapy is not appropriate for either all patients or all conditions, and in order to verify that group therapy is medically necessary and appropriate to the needs of each beneficiary, SNFs should include in the patient's plan of care an explicit justification for the use of group, rather than individual or concurrent, therapy. This description should include, but need not be limited to, the specific benefits to that particular patient of including the documented type and amount of group therapy; that is, how the prescribed type and amount of group therapy will meet the patient's needs and assist the patient in reaching the documented goals. In addition, we believe that the above documentation is necessary to demonstrate that the SNF is providing services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident in accordance with section 1819(b)(2) of the Act.

Should the actual utilization of therapy services deviate significantly from the patient's plan of care, we expect the facility to update the plan of care to prescribe the new type, amount, frequency, and duration of physical therapy, occupational therapy, and speech-language pathology services. Furthermore, we believe that such changes to the mode and/or intensity of therapy must be justified by changes in the beneficiary's underlying health condition; thus, in order to demonstrate that such changes are medically necessary, the provider should clearly describe in the plan of care the reasons for deviating from the original care plan. Consistent with § 409.17(c), the revised care plan must outline the updated goals and the revised type (that is, mode), amount, frequency, and duration of physical therapy, occupational therapy, and speech-language pathology services to be furnished to the patient.

In addition, with approximately 90 percent of the beneficiaries in Medicare stays receiving therapy, changes in the mode, amount, frequency, and/or duration of therapy services can have significant payment implications when

such changes also result in a reclassification of the beneficiary's case-mix group. Under § 413.343(b), SNFs are required to perform assessments on the 5th, 14th, 30th, 60th, and 90th days of posthospital SNF care, "and such other assessments that are necessary to account for changes in patient care needs." The unscheduled assessments exist to capture changes in a resident's skilled nursing or therapy needs outside the observation window used for the scheduled PPS assessments. We expect that the data reported in these required assessments, both scheduled and unscheduled, provide an accurate representation of the skilled therapy and nursing needs of the patient. Thus, if providers find changes in clinical and therapy status which would affect the accuracy of a resident's most recent assessment, then we would expect (as discussed above) that these changes would be recorded in the patient's plan of care and medical record, as well as through the use of unscheduled assessments, to determine if a subsequent change in payment is necessary. However, based on the available data, we believe that changes in resident status outside the observation window do not always generate an unscheduled assessment, as the changes, while significant for payment, do not always rise to the level of a significant change in clinical status. Additionally, in some cases, changes in therapy utilization levels may even be unrelated to the patient's clinical condition but may be caused by staffing constraints or facility practices. For these reasons, we are proposing alternative solutions which would help capture perceived changes in resident status, as discussed in section V.D below.

D. Proposed Changes to the MDS 3.0 Assessment Schedule and Other Medicare-Required Assessments

Under section 1888(e)(6) of the Act, SNFs are required to provide the Secretary, in a manner and within the timeframes prescribed by the Secretary, the resident assessment data necessary to develop and implement the payment rates. In order to receive proper payment for services provided during Part A Medicare SNF stays, SNFs must perform patient assessments in accordance with the assessment schedule outlined in the May 12, 1998 interim final rule (63 FR 26265–26268) and, under the discussion in that interim final rule, in accordance with the guidelines found in the RAI Manual, version 3.0. As discussed previously, the RAI Manual also includes the clarifications to the RAI Manual posted

on the MDS Web site at http://www.cms.gov/NursingHomeQualityInits/25_NHQIMDS30.asp. Following this schedule, SNFs must currently "perform patient assessments by the 5th day (although there is a grace period that allows performance by the 8th day) of the SNF stay, again by the 14th day, by the 30th day, and every 30 days thereafter as long as the patient is in a Medicare Part A stay" (63 FR 26265) (though there is a 5-day grace period for each of the 14-, 30-, 60-, and 90-day assessments as reflected in sections 2.8 and 2.9 of the RAI Manual, version 3.0). The current assessment schedule is also described at § 413.343(b). As set forth in sections 2.8 and 2.9 of the RAI Manual, version 3.0, these Medicare-required assessments must be performed based on an Assessment Reference Date (ARD) within the specified window, which is the end-point of the observation period for the relevant MDS assessment.

After further review of the MDS 3.0 assessment schedule, we believe that the combination of the current grace period allowance and observation period could cause MDS assessments to be performed in such a way that some of the information coded on a subsequent assessment is duplicative of the previous assessment. For example, if a 5-day assessment is completed with an ARD of day 8 of the Part A stay, and the ARD for the 14-day assessment is set for day 11, then the patient's status for four days of the stay will be coded twice for some items, that is, on the 5-day Medicare-required assessment and the 14-day Medicare-required assessment (because, given the 7-day lookback period for some items, days 5 through 8 would overlap between the two assessments). The intended purpose of the Medicare assessment schedule was to capture the changes in the patient's status, especially during the first few weeks of the Medicare stay. However, because the observation periods overlap so closely, changes in the patient's status are not reflected as originally intended. In addition, the ARD of the 30-day Medicare-required assessment may be set as early as day 21 of the Medicare Part A stay, in which case, for some items the first day of the observation period may be as early as day 15 (for items with a 7-day look back). For example, the patient may have the Brief Interview for Mental Status (BIMS) conducted on day 15 and thus coded on the 30-day Medicare-required assessment, which determines the RUG-IV group for payment days 31–60. Thus, the payment based on the assessment would not reflect the

patient's cognitive status near the 30th day of the stay, but instead would actually reflect that status at the 15th day of the stay.

Given the implications of these scenarios for both care quality and payment accuracy, we propose to modify the current Medicare-required assessment schedule (Table 10A) to

incorporate new assessment windows and grace days, as indicated in Table 10B, with appropriate changes to be made in the RAI Manual.

TABLE 10A—CURRENT MDS 3.0 ASSESSMENT SCHEDULE

| Medicare MDS assessment type | Reason for assessment (A0310B code) | Assessment reference date window | Assessment reference date grace days | Applicable medicare payment days |
|------------------------------|-------------------------------------|----------------------------------|--------------------------------------|----------------------------------|
| 5 day | 01 | Days 1–5 | 6–8 | 1 through 14. |
| 14 day | 02 | Days 11–14 | 15–19 | 15 through 30. |
| 30 day | 03 | Days 21–29 | 30–34 | 31 through 60. |
| 60 day | 04 | Days 50–59 | 60–64 | 61 through 90. |
| 90 day | 05 | Days 80–89 | 90–94 | 91 through 100. |

TABLE 10B—PROPOSED MDS 3.0 ASSESSMENT SCHEDULE

| Medicare MDS assessment type | Reason for assessment (A0310B code) | Assessment reference date window | Assessment reference date grace days | Applicable medicare payment days |
|------------------------------|-------------------------------------|----------------------------------|--------------------------------------|----------------------------------|
| 5 day * | 01 | Days 1–5 | 6–8 | 1 through 14. |
| 14 day | 02 | Days 13–14 | 15–18 | 15 through 30. |
| 30 day | 03 | Days 27–29 | 30–33 | 31 through 60. |
| 60 day | 04 | Days 57–59 | 60–63 | 61 through 90. |
| 90 day | 05 | Days 87–89 | 90–93 | 91 through 100. |

* Changes would also apply to Readmission/Return Assessment (A0310B code = 06).

We believe that these proposed changes to the Medicare-required assessment schedule will result in less duplication of information coded on subsequent assessments, and will better capture the patient's change in status, as well as the change in services/treatments, over the course of the stay without creating undue burden on providers. We also believe that ensuring the passage of a greater amount of time between assessments would improve patient and provider satisfaction and care quality, as it would not be necessary to repeat interview questions and assessment items required on the MDS assessments within such a short period of time. We solicit comments regarding these proposed changes to the current MDS 3.0 assessment schedule.

In addition, with regard to the completion of unscheduled PPS assessments, we wish to clarify a policy which first appeared in the FY 2010 final rule (74 FR 40347 through 40348). In the FY 2010 final rule (74 FR 40347 through 40348), we finalized the policy that the ARD for an End-of-Therapy (EOT) OMRA must be set 1 to 3 days after the discontinuation of all therapies (speech-language pathology services and occupational and physical therapies). Based on this policy, the EOT OMRA must be completed, at the latest, when a patient has not received therapy for three consecutive days (although we note that, as finalized in the FY 2010 final rule (74 FR 40348), in determining

the ARD, days currently are counted differently for facilities that provide therapy services 5 days per week as compared to facilities that provide therapy services 7 days per week, as further discussed below). Further, in the FY 2010 final rule (74 FR 40348), we cite the “daily basis” criteria at § 409.34(b) in order to clarify that a break in therapy of 1 or 2 days (such as may result from a brief illness or extreme fatigue), would not necessarily result in a provider having to complete an EOT OMRA. Thus, we are clarifying that, consistent with this policy and our policy regarding setting the ARD for the completion of an EOT OMRA, an EOT OMRA must be completed once such therapy services cease for three consecutive days, regardless of the reason.

We note that some SNFs have expressed concern over the use of the phrase “discontinuation of therapy services.” Therefore, we wish to clarify what is meant by the phrase “discontinuation of therapy services” as it applies to our policies governing completion of PPS assessments. We recognize that there may be two types of “discontinuation of therapy services.” A discontinuation in therapy services may be temporary; for example, in cases of illness, patient refusal, or visits to a doctor's office. Such breaks in therapy generally cannot be predicted in the plan of care and they may be characterized as an “unplanned”

discontinuation of therapy services. These types of discontinuations usually reflect an expectation that therapy will resume at some point. Alternatively, a discontinuation of therapy services may be characterized as a “planned” discontinuation, that is, the discontinuation is consistent with the patient's plan of care such as when the patient has reached the prescribed therapy goals. In the FY 2010 final rule, in finalizing our policy related to setting the ARD for an EOT OMRA at 1 to 3 days after discontinuation of therapy services, we did not distinguish between planned and temporary unplanned discontinuation of therapy. Thus, the ARD for the EOT OMRA must be set for Day 1 to 3 after the discontinuation, planned or unplanned, of all therapy services. Accordingly, we are clarifying that providers must complete an EOT OMRA for a patient classified in a RUG–IV therapy group if that patient goes three consecutive days without being furnished any therapy services, regardless of the reason for the discontinuation of therapy. We believe this clarification of the policy related to setting the ARD for the EOT OMRA, is consistent with the intent of this policy as expressed in the FY 2010 proposed and final rules (that is, to allow for more accurate classification of patients based on services needed and provided to the patient) (74 FR 22246, 74 FR 40347–48), the discussion of this policy found in section 2.9.07 of the MDS 3.0 RAI

Manual and MDS 3.0 training materials, which may be found at http://www.cms.gov/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp, as well as with the criteria set forth in 42 CFR 409.34(b), as discussed above.

Accordingly, providers are required to complete an EOT OMRA in cases where a resident who is currently assigned to a therapy RUG-IV group has not received any therapy services for three consecutive days. By completing the EOT OMRA, SNFs will be paid at the appropriate non-therapy RUG-IV rate (starting the day following the last day that therapy services were furnished to the patient), depending on other relevant characteristics of the patient's condition. If therapy resumes, the SNF may complete the optional Start-of-Therapy (SOT) OMRA, which can be used to reclassify the patient into a therapy RUG-IV group at any point during a resident's Part A SNF stay until completion of the next regularly scheduled PPS assessment.

Following publication of the FY 2010 final rule, some SNFs have expressed concern regarding the difficulty in determining if a given facility should be considered a 5-day or 7-day facility, for the purposes of setting the ARD for the EOT OMRA (that is, whether a facility should be considered as providing therapy services 5 days per week or 7 days per week). In the FY 2010 final rule, we discussed the days to be counted toward the establishment of the ARD for the EOT OMRA. In that rule (74 FR 40348), we stated "when a facility only provides therapy 5 days a week * * * the weekend days would not be counted toward the establishment of the ARD for the end-of-therapy OMRA." This policy has since caused significant confusion for providers who might use weekends to make up for therapy that was not provided during the week or who might only provide therapy on weekend days when a holiday falls on a weekday, as it is unclear to such providers whether they would be considered a 5-day facility or a 7-day facility. As such, to alleviate this confusion and add greater clarity and consistency to our policy regarding setting the ARD for the EOT OMRA as discussed above, we propose to eliminate the distinction between 5-day and 7-day facilities for purposes of setting the ARD for the EOT OMRA. Accordingly, we propose that, effective October 1, 2011, an EOT OMRA for a patient classified in a RUG-IV therapy group would be required if that patient goes three consecutive calendar days without being furnished any therapy services, regardless of whether the

facility is a 5-day or 7-day facility or the reason for the discontinuation in therapy services. However, while the ARD for the EOT OMRA would be required to be set by the third consecutive calendar day after discontinuation of therapy services, as we discuss above and in the FY 2010 final rule, the SNF also has the option of setting the ARD for the EOT OMRA on day 1 or day 2 after therapy services have been discontinued. Thus, if a facility (regardless of whether it is a 5-day or 7-day facility) discontinues therapy on a Friday, the ARD for the EOT OMRA would be required to be set for the immediately following Saturday, Sunday, or Monday, if the patient has not been provided therapy services in the interim. We believe that this proposed policy of requiring all SNFs to set the ARD for the EOT OMRA by the third consecutive calendar day after a patient's therapy services have been discontinued, appropriately reflects that the frail and vulnerable populations within SNFs require consistent therapy without significant breaks in services. In addition, this policy is consistent with our discussion of 42 CFR 409.34(b) in the FY 2010 final rule, in which a break of 1 or 2 days would not necessarily result in a provider having to complete an EOT OMRA. We invite comments on this proposed change to our policy related to setting the assessment ARD for the EOT OMRA.

In addition, some providers have suggested that the completion of an EOT OMRA and subsequent SOT OMRA may not be necessary for all patients, particularly in cases where therapy services resume at the same mode and intensity as the patient was receiving before the discontinuation of therapy service. We have considered this issue and we believe that, in some cases where an EOT OMRA has been completed and therapy resumes shortly thereafter, an SOT OMRA may not be necessary to establish the patient's clinical condition, specifically where the RUG-IV classification level has not changed (as further discussed below).

For the reasons discussed below, we propose that, effective for services provided on or after October 1, 2011, when an EOT OMRA has been completed and therapy subsequently resumes, SNFs may complete an End-of-Therapy Resumption (EOT-R) OMRA, rather than an SOT OMRA, in cases where therapy services have ceased for a period of no more than 5 consecutive calendar days, and have resumed at the same RUG-IV classification level that had been in effect prior to the EOT OMRA. In the situation where therapy services have resumed within such a

short period of time at the same RUG-IV classification level, we do not believe that a new therapy evaluation and SOT OMRA would be necessary to reclassify the patient back into a RUG-IV therapy group because, given that the therapy resumed at the same RUG-IV classification level, it is likely that the patient's clinical condition has not changed. Instead, the EOT-R OMRA may be used if the resumption date is no more than 5 consecutive calendar days after the date of the last therapy service furnished prior to the temporary discontinuation of therapy service reported on the EOT OMRA. To allow resumption of therapy reporting, two new items, O0450A and O0450B (Resumption of Therapy), would be added to the EOT OMRA item set so that it may be used as an EOT-R OMRA to report a resumption of therapy. These two new items would only be completed on an EOT OMRA (A0310C = 2 or 3) when therapy has resumed in the circumstances discussed above, for purposes of reporting the resumption of therapy services. As discussed above, we propose that the resumption of therapy must occur no more than 5 calendar days after the date that all therapy ends in order for completion of an EOT-R OMRA to be appropriate. For example, if therapy services are discontinued on Day 35 of a stay, then therapy services must resume for that patient (at the same level as the patient's RUG-IV classification prior to the discontinuation) by Day 39 of the stay in order for SNFs to have the option to complete an EOT-R OMRA for that patient. If therapy does not resume until Day 40 or later, then the SNF may not choose to complete an EOT-R OMRA under these circumstances. The resumption of therapy date is reported on the EOT OMRA if that EOT OMRA has not been submitted and accepted in the Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) system. If the EOT OMRA has already been accepted in the ASAP system without a resumption of therapy date, then the prior EOT OMRA record should be modified to add the resumption of therapy date. No other changes should be made with this modification.

In cases where therapy resumes more than five consecutive calendar days from the discontinuation of therapy service, we believe it is likely that the patient's clinical condition needs to be evaluated to identify changes in clinical and/or therapy needs. Thus, in this case, the SNF could either perform an optional SOT OMRA to classify the

patient into a RUG–IV therapy group, or wait until the completion of the next regularly scheduled PPS assessment to classify the patient into a RUG–IV therapy group, if such a classification is clinically appropriate. In these situations, the therapist would be required to conduct a therapy evaluation and establish a new therapy care plan for the patient.

As discussed above, SNFs would set the ARD for the EOT OMRA 1 to 3 calendar days after the discontinuation of all therapies (speech-language pathology services and occupational and physical therapies). The EOT–R OMRA would include the same items as the EOT OMRA with the addition of O0450A and O0450B as described above. We note that the EOT–R OMRA would be an optional assessment. If therapy resumes after completion of an EOT OMRA and the criteria are met for performance of an EOT–R OMRA (as discussed above), the SNF would have the option of performing the EOT–R OMRA, an SOT OMRA, or waiting until the next regularly scheduled PPS assessment to assess the patient's clinical condition. We solicit comments on our proposal to allow providers the option to complete an EOT–R OMRA in the circumstances described above.

In accordance with section 2.9.07 of the RAI Manual, Version 3.0 (available online at https://www.cms.gov/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp), completion of an EOT OMRA is required “* * * when the resident was classified in a RUG–IV Rehabilitation Plus Extensive Services or Rehabilitation group and continues to need Part A SNF-level services after the discontinuation of all rehabilitation therapies” (emphasis added).

Accordingly, we note that a SNF's completion of an EOT OMRA does not automatically result in the immediate termination of Part A coverage. Typically, a resident in this situation will have ongoing medical conditions that are clearly of sufficient intensity to justify continued coverage under one of the non-therapy RUGs, based on the need for daily skilled nursing services. Even when it may not be readily apparent that this is, in fact, the case (for example, when a resident is assigned to one of the less intensive RUGs, such as one that would result in receiving an individual level of care determination under the administrative presumption described in section II.E of this proposed rule), there may still be a need for continued skilled services, as when skilled observation is indicated for a resident whose overall medical

condition is precluding the resident from undergoing further therapy.

Moreover, even in situations where skilled rehabilitation is the sole reason for the SNF stay, the temporary discontinuation of therapy may not in itself necessarily have the effect of terminating coverage, if it is followed shortly thereafter by a resumption of therapy. For example, in discussing the effect of a brief absence from the facility on a resident's continued ability to meet the SNF level of care criterion of “daily” skilled rehabilitation, we noted in the FY 2000 final rule (64 FR 41670, July 30, 1999) that “* * * the requirement for daily skilled services should not be applied so strictly that it would not be met merely because there is a brief, isolated absence from the facility in a situation where discharge from the facility would not be practical.” Similarly, a resident who does not leave the facility at all may nonetheless experience a temporary inability to undergo therapy for such a brief period that discharge from the facility would not be practical, as described in 42 CFR 409.34(b). However, as discussed above, an EOT OMRA would need to be completed if the patient goes three consecutive calendar days without therapy services, regardless of the reason for the discontinuation of therapy services.

A related point on which we have recently received inquiries is the manner in which these policies relate to the requirements for providing an Advance Beneficiary Notice of Noncoverage (ABN). As explained in § 50.2.1 of the Medicare Claims Processing Manual, chapter 30 (available online at <http://www.cms.gov/manuals/downloads/clm104c30.pdf>), an ABN serves to notify a beneficiary of the provider's belief “* * * that an otherwise covered item or service may be denied either as not reasonable and necessary under § 1862(a)(1) of the Act or because the item or service constitutes custodial care under § 1862(a)(9) of the Act.” Section 70.2.3.1 describes the triggering events for issuance of an SNF ABN.

In this context, it has been suggested by some providers that when a facility furnishes therapy only on weekdays, it should routinely issue an ABN every Friday afternoon in order to anticipate the possibility that a given resident might be unable or unwilling to undergo therapy on the following Monday, thereby triggering an EOT OMRA and potentially causing the patient to drop below a covered level of care in the SNF.

We would note at the outset that under the current policy set forth in the

FY 2010 final rule (74 FR 40348), a facility that provides therapy services 5 days per week would not count the weekend days in determining the ARD for the EOT OMRA and, thus, an EOT OMRA would not necessarily be triggered if the patient were to be unwilling or unable to undergo therapy on the following Monday. Nevertheless, we note that, as discussed above, we are proposing in this rule to eliminate the distinction between 5 and 7-day facilities for purposes of setting the ARD for the EOT OMRA. Even so, it is still important to bear in mind that, in this situation, the decision to issue an ABN is an individualized action, and should not be applied across the board to all patients. The ABN should not be provided merely because of the possibility that the patient might be unwilling or unable to participate in therapy the next day. There must be an actual discontinuation of therapy before the SNF can anticipate that the patient may enter into custodial care. In addition, it may not be the case for every patient that the continued SNF stay would become noncovered custodial care as a result of the cessation of therapy. Thus, it is not until that point has actually been reached that the issuance of an ABN would become appropriate. The ABN should inform the beneficiary of the provider's belief that Medicare will no longer pay for the SNF stay because the patient is unwilling or unable to continue therapy and that therapy was the only reason the SNF stay was covered by Medicare. This information will help the patient make an informed decision about the potential consequences of failing to undergo the therapy session.

However, we expect that these unplanned discontinuations in service will be relatively rare. If such unplanned discontinuations in service occur on a repeated basis, the provider should carefully evaluate whether or not the patient continues to meet Medicare coverage criteria.

Finally, as noted in section V.C above, we have found some cases where therapy services recorded on a given PPS assessment did not provide an accurate account of the therapy provided to a given resident outside the observation window used for the most recent assessment. We believe that when service levels change, whether inside or outside the observation period, such changes should be based on medical evidence. However, we have found that the current range of PPS assessments may not permit SNFs adequate flexibility to report such changes in therapy services outside the observation window. As discussed

above, based on the available data, we believe that changes in resident status outside the observation window do not always generate an unscheduled assessment, because the changes, while significant for payment, do not always rise to the level of a significant change in clinical status under § 483.20(b)(2)(ii). Additionally, in some cases, changes in therapy utilization levels may even be unrelated to the patient's clinical condition but may be caused by staffing constraints or facility practices.

Accordingly, we propose that, effective for services provided on or after October 1, 2011, SNFs would be required to complete a Change of Therapy (COT) OMRA, for patients classified into a RUG-IV therapy group, whenever the intensity of therapy (that is, the total RTM delivered) changes to such a degree that it would no longer reflect the RUG-IV classification and payment assigned for a given SNF resident based on the most recent assessment used for Medicare payment. The COT OMRA would be a new type of required PPS assessment, which would use the same item set as the current EOT OMRA. The ARD for the COT OMRA would be set for Day 7 of a COT observation period, which is a rolling 7-day window beginning on the day following the ARD set for the most recent scheduled or unscheduled PPS assessment (or beginning the day therapy resumes in cases where an EOT-R OMRA is completed, as further discussed below), and ending every 7 calendar days thereafter. For example, if a facility sets the ARD for its 14-day assessment to Day 14, then Day 1 for the purposes of the COT observation period would be Day 15 of the SNF stay, and the facility would be required to review its therapy minutes for the week consisting of Days 15 through 21. The ARD for the COT OMRA would then be set for Day 21, if the facility were to determine that the total RTM has changed such that the RUG classification found on the 14-day assessment (assuming no intervening assessments) is no longer accurate. If the SNF were to determine that the total RTM has not changed to such an extent that the RUG classification on the 14-day assessment is no longer accurate (assuming no intervening assessments), then the COT OMRA would not be completed and the next evaluation of the patient's total RTM, for the purposes of completing a COT OMRA, would occur on Day 28. We want to stress that SNFs would be required to complete a COT OMRA only if a patient's total RTM changes to such an extent that the

patient's RUG classification, based on their last PPS assessment, is no longer an accurate representation of their current clinical condition. However, an evaluation of the necessity for a COT OMRA (that is, an evaluation of the patient's total RTM) must be completed every seven calendar days starting from the day following the ARD set for the most recent scheduled or unscheduled PPS assessment (or in the case of an EOT-R OMRA, starting the day that therapy resumes, as discussed below).

In cases when an unscheduled assessment must be completed within a COT observation period, then Day 1, for the purposes of setting the ARD for the COT OMRA would be the day after the ARD set for the intervening assessment or, in a case where the intervening assessment is an EOT-R OMRA, Day 1 would be the day that therapy resumed. For example, consider a patient for whom the ARD of the 30-day PPS assessment is set to Day 30 and is classified into a RUG-IV therapy group. The patient receives therapy on Days 31 through 35, does not receive therapy on Days 36 through 39, but is expected to resume therapy on Day 40. In this case, the SNF would have evaluated the patient's total RTM on Day 37. Assuming that the patient's total RTM is consistent with the patient's RUG classification on the 30-day assessment (most recent scheduled or unscheduled PPS assessment), then the next assessment that the SNF must complete, given the above scenario, would be an EOT OMRA with an ARD set for Day 36, Day 37, or Day 38 (given that therapy is expected to resume on Day 40, we would advise the SNF to hold off on submitting the EOT OMRA until after therapy has resumed, so that the EOT OMRA may be modified into an EOT-R OMRA with an accurate resumption date). Assuming therapy resumes on Day 40 at the same RUG classification level and an EOT-R OMRA is completed, the COT observation period for this patient would then begin on Day 40, and the next evaluation of the patient's total RTM would be necessary on Day 46. In terms of payment for this patient, the SNF would be paid beginning Day 31 at the rate for the RUG-IV therapy group determined on the basis of the patient's clinical condition reported on the 30-day assessment, paid for Days 36 through 39 at the corresponding non-therapy rate, based on the patient's clinical condition reported on the 30-day assessment (because therapy services were discontinued on Day 36 and an EOT OMRA was completed) and, beginning Day 40, would resume payment at the

previous therapy rate (because therapy services resumed at the same RUG classification level and an EOT-R OMRA was completed). Given this scenario, the next evaluation of the patient's total RTM should occur on Day 46.

It should be noted that this proposed policy regarding the COT observation period and setting the ARD for completion of the COT OMRA would be independent of the policy for setting the ARD for the EOT OMRA as described previously. That is, if a patient classified in a RUG-IV therapy group does not receive any therapy services for three consecutive calendar days, then the provider would be required to complete an EOT OMRA with an ARD not later than the third calendar day (in accordance with the proposed policy discussed previously for setting the ARD for an EOT OMRA), even if the provider completed a COT OMRA during the temporary discontinuation of therapy service. For example, in contrast to the previous scenario, if the evaluation of the patient's total RTM on Day 37 reveals that the intensity of therapy provided to the patient has changed to such a degree that it no longer reflects the patient's RUG-IV classification as reported on the 30-day assessment, then the SNF would be required to complete a COT OMRA, with an ARD set for Day 37, which is the last day of that patient's COT observation period. Assuming the patient is still classified into a RUG-IV therapy group after completion of the COT OMRA, and all other conditions of the above scenario remain the same, then the SNF would be paid at the revised therapy RUG-IV rate beginning Day 31, the corresponding non-therapy rate for Days 36 through 39, and would resume payment at the revised RUG-IV therapy group rate beginning Day 40 (assuming therapy resumes at the same RUG classification level as determined on the COT OMRA). As in the above scenario, the next evaluation of the patient's total RTM would occur on Day 46. Thus, the new RUG-IV group resulting from the COT OMRA would be billed starting the first day of the COT observation period for which the COT OMRA was completed, and would remain at this level until a new assessment is completed which changes the patient's RUG-IV classification.

We believe that the COT OMRA would allow us to track changes in the patient's condition and in the provision of therapy services more accurately, resulting in improving the accuracy of reimbursement for therapy services and enhancing the SNF's ability to provide quality care to SNF residents. We invite

comments on this proposal to require a COT OMRA when the total RTM changes to such a degree as to affect RUG–IV classification and payment.

E. Discussion of Possible Future Initiatives

We are considering a number of possible future initiatives that may help to ensure the long-term stability of the SNF PPS and further improve the accuracy of the rate-setting process. Along with our broad, ongoing objectives of ensuring stability and promoting accuracy of the SNF PPS, this analysis has been prompted in particular by our recent experience of needing to recalibrate the CMLs in 2 of the last 3 years. Accordingly, we have begun to consider a number of possible future modifications to certain aspects of the SNF PPS. We note that we are not proposing new Medicare policy in this discussion of possible future modifications, as we recognize that depending on how such modifications are ultimately formulated, their actual implementation may require new statutory authority.

We note that previous research by the Urban Institute, as cited in Chapter 8 of MedPAC's June 2007 Report to Congress entitled "Promoting Greater Efficiency in Medicare" (available online at http://www.medpac.gov/documents/jun07_entirereport.pdf), has recommended an approach to therapy reimbursement based on actual patient need. This approach would consider patient diagnosis and service needs to predict and reimburse prospectively for an appropriate level of therapy. While this methodology would eliminate

reliance on the actual minutes of therapy provided, we are evaluating ways to verify utilization to prevent underutilization or overutilization of therapy services.

We are also more closely examining certain methodologies that could make at least partial payment prospectively for therapy services based on anticipated patient need, rather than solely on actual service utilization. This could resemble the methodology already in use under the home health PPS, in which the projected number of therapy visits on the assessment completed at the start of the episode serves as the initial basis for payment, but that projection is subsequently verified against the actual visit information submitted in line-item detail on the claim (please refer to § 10.1.19.1 in Chapter 10 of the Medicare Claims Processing Manual, which is available online at <http://www.cms.gov/manuals/downloads/clm104c10.pdf>). The advantage of this type of approach is that it could target therapy payments and the intensity of therapy provided to patients with those diagnoses and conditions that are most likely to require such services.

A third possible approach would be to consider recalibrating the CMLs every year in order to account for significant fluctuations and changes in provider practices. Such a practice would be consistent with findings in a December 2010 OIG report entitled "Questionable Billing by Skilled Nursing Facilities" (report no. OEI–02–09–00202, available online at <http://oig.hhs.gov/oei/reports/oei-02-09-00202.pdf>), in which OIG noted a recent increase in questionable

billings for higher-paying RUGs. In addition, we note that MedPAC recently cited plans to examine changes in SNF care costs and practice patterns as a possible prelude to considering the desirability of totally rebasing the system (please refer to page 10 of "Assessing Payment Adequacy: Skilled Nursing Facilities," January 13, 2011, available online at <http://www.medpac.gov/transcripts/SNF%20Jan%202011%20public.pdf>). Such an approach, while not a change in the payment methodology per se, would reestablish baseline expenditure levels using more recent data than the 1995 cost reports.

VI. The Skilled Nursing Facility Market Basket Index

Section 1888(e)(5)(A) of the Act requires us to establish a SNF market basket index (input price index), that reflects changes over time in the prices of an appropriate mix of goods and services included in the SNF PPS. This proposed rule incorporates the latest available projections of the SNF market basket index. We will incorporate updated projections based on the latest available data when we publish the SNF final rule. Accordingly, we have developed a SNF market basket index that encompasses the most commonly used cost categories for SNF routine services, ancillary services, and capital-related expenses.

Each year, we calculate a revised labor-related share based on the relative importance of labor-related cost categories in the input price index. Table 11 summarizes the updated labor-related share for FY 2012.

TABLE 11—LABOR-RELATED RELATIVE IMPORTANCE, FY 2011 AND FY 2012

| | Relative importance, labor-related, FY 2011 10:2 forecast* | Relative importance, labor-related, FY 2012 11:1 forecast** |
|------------------------------------|--|---|
| Wages and salaries | 50.654 | 50.231 |
| Employee benefits | 11.511 | 11.514 |
| Nonmedical professional fees | 1.320 | 1.308 |
| Labor-intensive services | 3.427 | 3.390 |
| Capital-related (.391) | 2.399 | 2.362 |
| Total | 69.311 | 68.805 |

* Published in **Federal Register**; based on second quarter 2010 IHS Global Insight Inc. forecast.

** Based on the first quarter 2011 IHS Global Insight forecast, with historical data through the fourth quarter 2010.

A. Use of the Skilled Nursing Facility Market Basket Percentage

Section 1888(e)(5)(B) of the Act defines the SNF market basket percentage as the percentage change in the SNF market basket index from the

average of the previous FY to the average of the current FY. For the Federal rates established in this proposed rule, we use the percentage increase in the SNF market basket index to compute the update factor for FY

2012. This is based on the IGI (formerly DRI–WEFA) first quarter 2011 forecast (with historical data through the fourth quarter 2010) of the FY 2012 percentage increase in the FY 2004-based SNF market basket index for routine,

ancillary, and capital-related expenses, which is used to compute the update factor in this proposed rule. As discussed in section VI.C of this proposed rule, this market basket percentage change is reduced by the MFP adjustment as required by section 1888(e)(5)(B)(ii) of the Act. Finally, as discussed in section I.A of this proposed rule, we no longer compute update factors to adjust a facility-specific portion of the SNF PPS rates, because the initial 3-phase transition period from facility-specific to full Federal rates that started with cost reporting periods beginning in July 1998 has expired.

B. Market Basket Forecast Error Adjustment

As discussed in the June 10, 2003, supplemental proposed rule (68 FR 34768) and finalized in the August 4, 2003, final rule (68 FR 46057 through 46059), the regulations at § 413.337(d)(2) provide for an adjustment to account for market basket forecast error. The initial adjustment applied to the update of the FY 2003 rate for FY 2004, and took into account the cumulative forecast error for the period from FY 2000 through FY 2002, resulting in an increase of 3.26 percent. Subsequent adjustments in succeeding FYs take into account the forecast error from the most recently available FY for which there is final data, and apply whenever the difference between the forecasted and actual change in the market basket exceeds a specified threshold. We originally used a 0.25 percentage point threshold for this

purpose; however, for the reasons specified in the FY 2008 SNF PPS final rule (72 FR 43425, August 3, 2007), we adopted a 0.5 percentage point threshold effective with FY 2008. As discussed previously in section I.G.2 of this proposed rule, as the difference between the estimated and actual amounts of increase in the market basket index for FY 2010 (the most recently available FY for which there is final data) does not exceed the 0.5 percentage point threshold, the payment rates for FY 2012 do not include a forecast error adjustment.

C. Multifactor Productivity Adjustment

Section 3401(b) of the Affordable Care Act requires that, in FY 2012 (and in subsequent FYs), the market basket percentage under the SNF payment system as described in section 1888(e)(5)(B)(i) is to be reduced annually by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. As explained in the Senate Finance Committee report that accompanied S.1796 (“America’s Healthy Future Act of 2009,” the Senate’s initial version of the health reform legislation), the purpose of this type of productivity adjustment is to help ensure that the market basket update, in accounting for changes in the costs of goods and services used to provide patient care, also reflects “* * * increases in provider productivity that could reduce the actual cost of providing services (such as through new technology, fewer inputs, *etc.*)” (S. Rep. No. 111–89 at 261). Specifically, section 3401(a) of the Affordable Care Act

amends section 1886(b)(3)(B) of the Act to add clause (xi)(II), which sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the “MFP adjustment”). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. Please see <http://www.bls.gov/mfp> to obtain the BLS historical published MFP data.

The projection of MFP is currently produced by IGI, an economic forecasting firm. In order to generate a forecast of MFP, IGI replicated the MFP measure calculated by the BLS, using a series of proxy variables derived from IGI’s U.S. macroeconomic models. These models take into account a very broad range of factors that influence the total U.S. economy. IGI forecasts the underlying proxy components, such as Gross Domestic Product (GDP), capital, and labor inputs required to estimate MFP, and then combines those projections according to the BLS methodology. In Table 12, we identify each of the major MFP component series employed by the BLS to measure MFP. We also provide the corresponding concepts forecasted by IGI and determined to be the best available proxies for the BLS series.

TABLE 12—MULTIFACTOR PRODUCTIVITY COMPONENT SERIES EMPLOYED BY THE BUREAU OF LABOR STATISTICS AND IHS GLOBAL INSIGHT

| BLS series | IGI series |
|---|--|
| Real value-added output, constant 2005 dollars | Non-housing non-government non-farm real GDP, Billions of chained 2005 dollars—annual rate. |
| Private non-farm business sector labor input; 2005 = 100.00 | Hours of all persons in private nonfarm establishments, 2005 = 100.00, adjusted for labor composition effects. |
| Aggregate capital inputs; 2005 = 100.00 | Real effective capital stock used for full employment GDP, Billions of chained 2005 dollars. |

IGI found that the historical growth rates of the BLS components used to calculate MFP and the IGI components identified are consistent across all series and, therefore, suitable proxies for calculating MFP. We have included below a more detailed description of the methodology used by IGI to construct a forecast of MFP, which is aligned closely with the methodology employed by the BLS. For more information regarding the BLS method for estimating productivity, please see the following

link: <http://www.bls.gov/mfp/mprtech.pdf>.
At the time of this proposed rule, the BLS has published a historical time series of private nonfarm business MFP for 1987 through 2009, with 2009 being a preliminary value. Using this historical MFP series and the IGI forecasted series, IGI has developed a forecast of MFP for 2010 through 2021, as described below.
To create a forecast of BLS’ MFP index, the forecasted annual growth

rates of the “non-housing, nongovernment, non-farm, real GDP,” “hours of all persons in private nonfarm establishments adjusted for labor composition,” and “real effective capital stock” series (ranging from 2010 to 2021) are used to “grow” the levels of the “real value-added output,” “private non-farm business sector labor input,” and “aggregate capital input” series published by the BLS. Projections of the “hours of all persons” measure are calculated using the difference between

the projected growth rates of real output per hour and real GDP. This difference is then adjusted to account for changes in labor composition in the forecast interval. Using these three key concepts, MFP is derived by subtracting the contribution of labor and capital inputs from output growth. However, in order to estimate MFP, we need to understand the relative contributions of labor and capital to total output growth.

Therefore, two additional measures are needed to operationalize the estimation of the IGI MFP projection: Labor compensation and capital income. The sum of labor compensation and capital income represents total income. The BLS calculates labor compensation and capital income (in current dollar terms) to derive the nominal values of labor and capital inputs. IGI uses the “nongovernment total compensation” and “flow of capital services from the total private non-residential capital stock” series as proxies for the BLS’s income measures. These two proxy measures for income are divided by total income to obtain the shares of labor compensation and capital income to total income. In order to estimate labor’s contribution and capital’s contribution to the growth in total output, the growth rates of the proxy variables for labor and capital inputs are multiplied by their respective shares of total income. These contributions of labor and capital to output growth are subtracted from total output growth to calculate the “change in the growth rates of multifactor productivity” using the following formula:

$$\text{MFP} = \text{Total output growth} - ((\text{labor input growth} * \text{labor compensation share}) + (\text{capital input growth} * \text{capital income share}))$$

The change in the growth rates (also referred to as the compound growth rates) of the IGI MFP are multiplied by 100 in order to calculate the percent change in growth rates (the percent change in growth rates is published by the BLS for its historical MFP measure). Finally, the growth rates of the IGI MFP are converted to index levels based to 2005 to be consistent with the BLS’ methodology. For benchmarking purposes, the historical growth rates of IGI’s proxy variables were used to estimate a historical measure of MFP, which was compared to the historical MFP estimate published by the BLS. The comparison revealed that the growth rates of the components were consistent across all series and, therefore, validated the use of the proxy variables in generating the IGI MFP projections. The resulting MFP index was then interpolated to a quarterly

frequency using the Bassie method for temporal disaggregation. The Bassie technique utilizes an indicator (pattern) series for its calculations. IGI uses the index of output per hour (published by the BLS) as an indicator when interpolating the MFP index.

1. Incorporating the Multifactor Productivity Adjustment Into the Market Basket Update

According to section 1888(e)(5)(A) of the Act, the Secretary “shall establish a skilled nursing facility market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered skilled nursing facility services.” As described in section I.G.2 of this proposed rule, we are proposing to estimate the SNF PPS market basket percentage for FY 2012 under section 1888(e)(5)(B)(i) of the Act based on the FY 2004-based SNF market basket. Section 3401(b) of the Affordable Care Act amends section 1888(e)(5)(B) of the Act, in part, by adding a new clause (ii), which requires that for FY 2012 and each subsequent FY, after determining the market basket percentage described in section 1888(e)(5)(B)(i) of the Act, “the Secretary shall reduce such percentage by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II)” (which we refer to as the MFP adjustment). Section 1888(e)(5)(B)(ii) of the Act further states that the reduction of the market basket percentage by the MFP adjustment may result in the market basket percentage being less than zero for a FY, and may result in payment rates under section 1888(e) of the Act for a FY being less than such payment rates for the preceding FY. Thus, if the application of the MFP adjustment to the market basket percentage calculated under section 1888(e)(5)(B)(i) results in an MFP-adjusted market basket percentage that is less than zero, then the annual update to the unadjusted Federal per diem rates under section 1888(e)(4)(E)(ii) would be negative, and such rates would decrease relative to the prior FY.

To calculate the MFP-adjusted update for the SNF PPS, we propose that the MFP percentage adjustment will be subtracted from the FY 2012 market basket percentage calculated using the FY 2004-based SNF market basket. We propose that the end of the 10-year moving average of changes in the MFP should coincide with the end of the appropriate FY update period. Since the market basket percentage is reduced by the MFP adjustment to determine the annual update for the SNF PPS, we believe it is appropriate for the numbers

associated with both components of the calculation (the market basket percentage and the productivity adjustment) to be projected as of the same end date so that changes in market conditions are aligned. Therefore, for the FY 2012 update, the MFP adjustment would be calculated as the 10-year moving average of changes in MFP for the period ending September 30, 2012. We propose to round the final annual adjustment to the one-tenth of one percentage point level up or down as applicable according to conventional rounding rules (that is, if the number we are rounding is followed by 5, 6, 7, 8, or 9, we will round the number up; if the number we are rounding is followed by 0, 1, 2, 3, or 4, we will round the number down).

In accordance with section 1888(e)(5)(B)(i) of the Act, the market basket percentage for FY 2012 for the SNF PPS is based on the 1st quarter 2011 forecast of the FY 2004-based SNF market basket update, which is estimated to be 2.7 percent. In accordance with section 1888(e)(5)(B)(ii) of the Act (as added by section 3401(b) of the Affordable Care Act), this market basket percentage would then be reduced by the MFP adjustment (the 10-year moving average of changes in MFP for the period ending September 30, 2012) of 1.2 percent, which is calculated as described above and based on IGI’s 1st quarter 2011 forecast. The resulting MFP-adjusted market basket update would be equal to 1.5 percent, or 2.7 percent less 1.2 percentage points.

Furthermore, in fiscal years where a forecast error adjustment is applicable, we would first apply the forecast error adjustment to the market basket percentage, before applying the MFP adjustment. As discussed previously, in determining whether a forecast error adjustment should be applied, CMS compares the forecasted market basket percentage computed under section 1888(e)(5)(B)(i) of the Act for the most recently available fiscal year for which there is final data to the actual market basket percentage for that fiscal year. Because the forecast error adjustment is intended to address errors in the forecast of the market basket percentage, we believe that this adjustment is part of the establishment of the appropriate market basket percentage under section 1888(e)(5)(B)(i) of the Act. Section 1888(e)(5)(B)(ii) of the Act (as added by section 3401(b) of the Affordable Care Act) requires the MFP adjustment to be applied “after determining the percentage described in clause (i).” Thus, we would apply the forecast error adjustment (when applicable) to the market basket percentage prior to

applying the MFP adjustment, to determine the update to the unadjusted Federal per diem rates for a fiscal year.

Accordingly, we propose to revise § 413.337 by adding a new paragraph (d)(3) to require, for FY 2012 and each subsequent FY, that the market basket index percentage change (as modified by any applicable forecast error adjustment) be reduced by the MFP adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act in determining the annual update of the unadjusted Federal per diem rates. Consistent with section 1888(e)(5)(B)(ii) of the Act (as added by section 3401(b) of the Affordable Care Act), § 413.337(d)(3) would also state that the reduction of the market basket percentage change by the MFP adjustment may result in the market basket percentage change being less than zero for a fiscal year, and may result in the unadjusted Federal payment rates for a fiscal year being less than such payment rates for the preceding fiscal year.

In addition, we propose to revise existing paragraphs (d)(1) and (d)(2) of § 413.337, as discussed below. First, we are proposing to revise § 413.337(d)(1) so that the text more accurately tracks the corresponding statutory requirements at section 1888(e)(4)(E) of the Act. Currently, § 413.337(d)(1) does not reflect the amendments made to section 1888(e)(4)(E)(ii) by section 311 of the BIPA (see section I.D of this proposed rule). While we have always updated the unadjusted Federal per diem rates in accordance with the requirements set forth in section 1888(e)(4)(E)(ii) of the Act as amended by section 311 of the BIPA, we have inadvertently failed to update the regulation text to conform with the BIPA requirements. Therefore, we now propose to revise § 413.337(d)(1) to conform with the current statutory language in section 1888(e)(4)(E) as amended by section 311 of the BIPA. Second, we propose to revise § 413.337(d)(2) to specify the existing thresholds we employ in determining whether a forecast error adjustment is applicable.

D. Federal Rate Update Factor

Section 1888(e)(4)(E)(ii)(IV) of the Act requires that the update factor used to establish the FY 2011 unadjusted Federal rates be at a level equal to the market basket percentage change. Accordingly, to establish the update factor, we determined the total growth from the average market basket level for the period of October 1, 2010 through September 30, 2011 to the average market basket level for the period of

October 1, 2011 through September 30, 2012. Using this process, the market basket update factor for FY 2012 SNF PPS unadjusted Federal rates would be 2.7 percent. As required by section 1888(e)(5)(B) of the Act, this market basket percentage is then reduced by the MFP adjustment (the 10-year moving average of changes in MFP for the period ending September 30, 2012) of 1.2 percent as described in section VI.C. The resulting MFP-adjusted market basket update would be equal to 1.5 percent, or 2.7 percent less 1.2 percentage points. We used this MFP-adjusted market basket update factor to compute the SNF PPS rate shown in Tables 2 and 3.

VII. Consolidated Billing

Section 4432(b) of the BBA established a consolidated billing requirement that places the Medicare billing responsibility for virtually all of the services that the SNF's residents receive with the SNF, except for a small number of services that the statute specifically identifies as being excluded from this provision. As noted previously in section I. of this proposed rule, subsequent legislation enacted a number of modifications in the consolidated billing provision.

Specifically, section 103 of the BBRA amended this provision by further excluding a number of individual "high-cost, low-probability" services, identified by the Healthcare Common Procedure Coding System (HCPCS) codes, within several broader categories (chemotherapy and its administration, radioisotope services, and customized prosthetic devices) that otherwise remained subject to the provision. We discuss this BBRA amendment in greater detail in the proposed and final rules for FY 2001 (65 FR 19231 through 19232, April 10, 2000, and 65 FR 46790 through 46795, July 31, 2000), as well as in Program Memorandum AB-00-18 (Change Request #1070), issued March 2000, which is available online at <http://www.cms.gov/transmittals/downloads/ab001860.pdf>.

Section 313 of the BIPA further amended this provision by repealing its Part B aspect; that is, its applicability to services furnished to a resident during a SNF stay that Medicare Part A does not cover. (However, physical therapy, occupational therapy, and speech-language pathology services remain subject to consolidated billing, regardless of whether the resident who receives these services is in a covered Part A stay.) We discuss this BIPA amendment in greater detail in the proposed and final rules for FY 2002 (66 FR 24020 through 24021, May 10, 2001,

and 66 FR 39587 through 39588, July 31, 2001).

In addition, section 410 of the MMA amended this provision by excluding certain practitioner and other services furnished to SNF residents by RHCs and FQHCs. We discuss this MMA amendment in greater detail in the update notice for FY 2005 (69 FR 45818 through 45819, July 30, 2004), as well as in Medicare Learning Network (MLN) Matters article #MM3575, which is available online at <http://www.cms.gov/MLN/MattersArticles/downloads/MM3575.pdf>.

Further, while not substantively revising the consolidated billing requirement itself, a related provision was enacted in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, Pub. L. 110-275). Specifically, section 149 of MIPPA amended section 1834(m)(4)(C)(ii) of the Act to add subclause (VII), which adds SNFs (as defined in section 1819(a) of the Act) to the list of entities that can serve as a telehealth "originating site" (that is, the location at which an eligible individual can receive, through a telecommunications system, services of a physician or other practitioner who is located elsewhere at a "distant site").

As explained in the Medicare Physician Fee Schedule (PFS) final rule for calendar year (CY) 2009 (73 FR 69726, 69879, November 19, 2008), a telehealth originating site receives a facility fee which is always separately payable under Part B outside of any other payment methodology. Section 149(b) of MIPPA amended section 1888(e)(2)(A)(ii) of the Act to exclude telehealth services furnished under section 1834(m)(4)(C)(ii)(VII) of the Act from the definition of "covered skilled nursing facility services" that are paid under the SNF PPS. Thus, a SNF " * * * can receive separate payment for a telehealth originating site facility fee even in those instances where it also receives a bundled per diem payment under the SNF PPS for a resident's covered Part A stay" (73 FR 69881). By contrast, under section 1834(m)(2)(A) of the Act, a telehealth distant site service is payable under Part B to an eligible physician or practitioner only to the same extent that it would have been so payable if furnished without the use of a telecommunications system. Thus, as explained in the CY 2009 Physician Fee Schedule final rule (73 FR 69726), eligible distant site physicians or practitioners can receive payment for a telehealth service that they furnish

* * * only if the service is separately payable under the PFS when furnished in a

face-to-face encounter at that location. For example, we pay distant site physicians or practitioners for furnishing services via telehealth only if such services are not included in a bundled payment to the facility that serves as the originating site (73 FR 69880).

This means that in those situations where a SNF serves as the telehealth originating site, the distant site professional services would be separately payable under Part B only to the extent that they are not already included in the SNF PPS bundled per diem payment and subject to consolidated billing. Thus, for a type of practitioner whose services are not otherwise excluded from consolidated billing when furnished during a face-to-face encounter, the use of a telehealth distant site would not serve to unbundle those services. In fact, consolidated billing does exclude the professional services of physicians, along with those of most of the other types of telehealth practitioners that the law specifies at section 1842(b)(18)(C) of the Act; that is, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse midwives, and clinical psychologists (see section 1888(e)(2)(A)(ii) of the Act and 42 CFR 411.15(p)(2)). However, the services of clinical social workers, registered dietitians and nutrition professionals remain subject to consolidated billing when furnished to a SNF's Part A resident and, thus, cannot qualify for separate Part B payment as telehealth distant site services in this situation. Additional information on this provision appears in MLN Matters article #MM6215, which is available online at <http://www.cms.gov/MLN MattersArticles/downloads/MLN6215.pdf>.

To date, the Congress has enacted no further legislation affecting the consolidated billing provision. However, as noted above and explained in the proposed rule for FY 2001 (65 FR 19232, April 10, 2000), the amendments enacted in section 103 of the BBRA not only identified for exclusion from this provision a number of particular service codes within four specified categories (that is, chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices), but also gave the Secretary “* * * the authority to designate additional, individual services for exclusion within each of the specified service categories.” In the proposed rule for FY 2001, we also noted that the BBRA Conference report (H.R. Rep. No. 106–479 at 854 (1999) (Conf. Rep.)) characterizes the

individual services that this legislation targets for exclusion as “* * * high-cost, low probability events that could have devastating financial impacts because their costs far exceed the payment [SNFs] receive under the prospective payment system * * *.” According to the conferees, section 103(a) “is an attempt to exclude from the PPS certain services and costly items that are provided infrequently in SNFs * * *.” By contrast, we noted that the Congress declined to designate for exclusion any of the remaining services within those four categories (thus leaving all of those services subject to SNF consolidated billing), because they are relatively inexpensive and are furnished routinely in SNFs.

As we further explained in the final rule for FY 2001 (65 FR 46790, July 31, 2000), and as our longstanding policy, any additional service codes that we might designate for exclusion under our discretionary authority must meet the same statutory criteria used in identifying the original codes excluded from consolidated billing under section 103(a) of the BBRA: They must fall within one of the four service categories specified in the BBRA, and they also must meet the same standards of high cost and low probability in the SNF setting, as discussed in the BBRA Conference report. Accordingly, we characterized this statutory authority to identify additional service codes for exclusion “* * * as essentially affording the flexibility to revise the list of excluded codes in response to changes of major significance that may occur over time (for example, the development of new medical technologies or other advances in the state of medical practice)” (65 FR 46791). In this proposed rule, we specifically invite public comments identifying codes in any of these four service categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) representing recent medical advances that might meet our criteria for exclusion from SNF consolidated billing. We may consider excluding a particular service if it meets our criteria for exclusion as specified above. Commenters should identify in their comments the specific HCPCS code that is associated with the service in question, as well as their rationale for requesting that the identified HCPCS code(s) be excluded.

We note that the original BBRA legislation (as well as the implementing regulations) identified a set of excluded services by means of specifying HCPCS codes that were in effect as of a particular date (in that case, as of July

1, 1999). Identifying the excluded services in this manner made it possible for us to utilize program issuances as the vehicle for accomplishing routine updates of the excluded codes, in order to reflect any minor revisions that might subsequently occur in the coding system itself (for example, the assignment of a different code number to the same service). Accordingly, in the event that we identify through the current rulemaking cycle any new services that would actually represent a substantive change in the scope of the exclusions from SNF consolidated billing, we would identify these additional excluded services by means of the HCPCS codes that are in effect as of a specific date (in this case, as of October 1, 2011). By making any new exclusions in this manner, we could similarly accomplish routine future updates of these additional codes through the issuance of program instructions.

VIII. Application of the SNF PPS to SNF Services Furnished by Swing-Bed Hospitals

In accordance with section 1888(e)(7) of the Act, as amended by section 203 of the BIPA, Part A pays critical access hospitals (CAHs) on a reasonable cost basis for SNF services furnished under a swing-bed agreement. However, effective with cost reporting periods beginning on or after July 1, 2002, the swing-bed services of non-CAH rural hospitals are paid under the SNF PPS. As explained in the final rule for FY 2002 (66 FR 39562, July 31, 2001), we selected this effective date consistent with the statutory provision to integrate swing-bed rural hospitals into the SNF PPS by the end of the SNF transition period, June 30, 2002.

Accordingly, all non-CAH swing-bed rural hospitals have come under the SNF PPS as of June 30, 2003. Therefore, all rates and wage indexes outlined in earlier sections of this proposed rule for the SNF PPS also apply to all non-CAH swing-bed rural hospitals. A complete discussion of assessment schedules, the MDS and the transmission software (RAVEN–SB for Swing Beds) appears in the final rule for FY 2002 (66 FR 39562, July 31, 2001) and in the final rule for FY 2010 (74 FR 40288, August 11, 2009). As finalized in the FY 2010 SNF PPS final rule (74 FR 40356–57), effective October 1, 2010, non-CAH swing-bed rural hospitals are required to complete an MDS 3.0 swing-bed assessment which is limited to the required demographic, payment, and quality items. The latest changes in the MDS for swing-bed rural hospitals appear on the SNF PPS Web site, <http://www.cms.gov/snfpps>.

IX. Provisions of the Proposed Rule

In this proposed rule, in addition to accomplishing the required annual update of the SNF PPS payment rates, we also propose making the following revisions to the regulation text:

As discussed previously in section VI.C of this proposed rule, we are proposing to implement section 3401(b) of the Affordable Care Act by revising § 413.337. We would add a new paragraph (d)(3) to that section to require that, for FY 2012 and each subsequent FY, the market basket percentage change (as modified by any applicable forecast error adjustment) be reduced by the MFP adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act in determining the annual update of the unadjusted Federal per diem rates. In addition, consistent with section 1888(e)(5)(B)(ii) of the Act (as added by section 3401(b) of the Affordable Care Act), § 413.337(d)(3) would also state that the reduction of the market basket percentage change by the MFP adjustment may result in the market basket percentage change being less than zero for a fiscal year, and may result in the unadjusted Federal payment rates for a fiscal year being less than such payment rates for the preceding fiscal year.

Further, as discussed in section VI.C., we propose to revise existing paragraphs (d)(1) and (d)(2) of § 413.337 so that the text more accurately tracks the corresponding statutory requirements at section 1888(e)(4)(E) of the Act (§ 413.337(d)(1)), and to specify the existing thresholds we apply in determining whether a forecast error adjustment is appropriate (§ 413.337(d)(2)).

In addition, to implement section 6101 of the Affordable Care Act as discussed previously in section V.A. of this proposed rule, we are proposing to revise the reporting requirements that Medicare SNFs and Medicaid nursing facilities must disclose at the time of enrollment and when any change in ownership occurs. These reporting requirements will occur in PECOS for Medicare SNFs, which will be revised to capture the additional requirements. We are proposing to add a definition for “additional disclosable party” and “organizational structure.” We also plan to require that these additional reporting requirements be included among the changes that must be reported in accordance with § 424.516(e) and § 455.104. Consistent with the requirements set forth in section 6101 of the Affordable Care Act, we propose to define an “additional disclosable party” to mean, with respect to a Medicare SNF

or Medicaid nursing facility, any person or entity (such as a contractor, full- and part-time employee or consultant) that exercises financial, operational, or managerial control over the facility (or a part thereof); provides policies or procedures for any of the operations of the facility, including policies or procedures that establish clinical decision making capabilities directly related to resident care; provides financial or cash management services to the facility; leases or subleases real property to the facility or owns a whole or part interest equal to or exceeding 5 percent of the total value of such real property; or provides management or administrative services, management or clinical consulting services, or accounting or financial services to the facility. Broadly defined, this proposed definition mirrors the statutory definition of “additional disclosable party,” which is set forth at section 1124(c)(5)(A) of the Act. Given the potentially broad nature of the term “additional disclosable parties,” we understand that it may be difficult for SNFs and Medicaid nursing facilities, under certain circumstances, to reasonably know without explicit guidance which parties and individuals associated with their facility are subject to the disclosure requirements discussed in this section. Therefore, we specifically solicit comment on how best to narrow the scope of the definition of this term to ensure that the additional reporting requirements described in this section apply only to those parties and individuals that are capable of exercising actual operational, financial, or managerial control over the given facility or performing any of the other functions specified in section 6101 of the Affordable Care Act.

In addition, our proposed definition for “organizational structure” mirrors the statutory definition for that term, which is set forth at section 1124(c)(5)(D) of the Act. With respect to the additional reporting requirements at § 424.516(e) addressed by this proposed rule, for a Medicare SNF defined at section 1819(a) of the Act, we propose to define a “managing employee” to include consultants and any individual who directly or indirectly manages, advises or supervises any element of the practices, finances, or operations of the facility.

In § 424.516, we are proposing to add new paragraphs (e)(4) and (e)(5). Paragraph (e)(4) includes the requirement that a Medicare SNF or Medicaid nursing facility must report the name, title, and period of service for each disclosable party. It observes that each Medicare SNF or Medicaid nursing

facility must also report the organizational structure of each additional disclosable party of the facility and a description of each additional disclosable party's relationship to the facility and to one another. Proposed paragraph (e)(5) states that Medicare SNFs (as defined in section 1819(a) of the Act) must certify as a condition of participation and payment under the program under Title XVIII of the Act that the information reported by the facility in accordance with these regulations is, to the best of the facility's knowledge, accurate and correct.

While we propose (as discussed in the preceding paragraph) to collect the required information consistent with the requirements set forth in § 424.516, we also seek comment on a potential alternative approach in which we would collect this information only upon revalidation consistent with the requirements set forth in § 424.515. In accordance with § 424.515, Medicare SNFs generally would be subject to revalidation requirements every 5 years. Paragraph (d) of § 424.515, however, provides for off-cycle revalidations. We believe that an approach that requires a Medicare SNF to report the additional requirements covered by this rule at the same time CMS requires the Medicare SNF to revalidate with the Medicare program may not only allow us to satisfy the legislative intent of collecting the required additional information, but also may generally represent a decreased burden on Medicare SNFs. Thus, we seek comment on this approach.

We also propose to amend the definition of “managing employee” at § 455.101, with respect to a Medicaid nursing facility as defined by section 1919(a) of the Act, to include a consultant who directly or indirectly manages, advises or supervises any element of the practices, finances, or operations of the facility. In addition, we propose to include at § 455.101 definitions of “additional disclosable party” and “organizational structure.” Finally, we propose to add a requirement to § 455.104 regarding these new disclosure requirements by Medicaid nursing facilities, which includes a certification as a condition of participation and payment under the program under Title XIX of the Act that the information reported by the facility in accordance with these regulations is, to the best of the facility's knowledge, accurate and correct.

X. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide a 60-day notice in the **Federal Register** and solicit public comments before a collection of information requirement is submitted to OMB for review and approval. In order to evaluate fairly whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comments on the following issues:

- Need for the information collection and its usefulness in carrying out the proper functions of our agency.
- Accuracy of our estimate of the information collection burden.
- Quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The information collection requirements referenced in this proposed rule with regard to resident assessment information used to determine facility payments are currently approved under OMB #0938–0739, which relates to the Medicare PPS Assessment Form (MPAF) information collection, and OMB #0938–0872, which relates to the Minimum Data Set for Swing-Bed Hospitals. We note that this proposed rule will not affect the burden associated with either of those collections.

With regard to the disclosure of information requirements included in section V.A of this rule, we currently require nursing home providers, including Medicare SNFs and Medicaid nursing facilities, to report information about any individual or entity with a 5 percent or greater ownership interest. As discussed in section IX. of this proposed rule, we are proposing to revise existing regulations to require that Medicare SNFs and Medicaid nursing facilities report the following at the time of enrollment and when any change in ownership occurs:

- Each member of the governing body of the facility, including the name, title, and period of service of each such member;
- Each person or entity who is an officer, director, member, partner, trustee, or managing employee of the facility, including the name, title, and period of service of each such person or entity; and
- Each person or entity who is an additional disclosable party of the facility.

We are also requiring information on the organizational structure of each

additional disclosable party of the facility and a description of the relationship of each such additional disclosable party to the facility and to one another.

In connection with the proposed implementation of the disclosure of ownership provisions set forth in section 6101 of the Affordable Care Act, we note that if a provider wants to enroll in Medicare or maintain its Medicare enrollment status, then the provider must complete the application for enrollment (Form CMS–855A) and submit it to the appropriate Medicare Administrative Contractor or Fiscal Intermediary. Form CMS–855A will be revised so that it collects the additional information required by this proposed rule from Medicare providers. (We are seeking OMB approval for the revisions under notice and comment periods separate from those associated with this proposed rule.) The burden associated with this requirement is the time and effort necessary to complete and submit the Form CMS–855A. While this requirement is subject to the PRA, the associated burden has been approved under OMB control number 0938–0685 with an expiration date of 1/31/2012.

Section V.D. of this proposed rule also contains a discussion of information collections related to a new required resident assessment, the COT OMRA. The following is a discussion of this new required PPS assessment.

As discussed previously in section V.D of this proposed rule, we are proposing to make certain modifications in the existing requirements for completing OMRA's. We propose to introduce a new COT OMRA, to be completed whenever the intensity of therapy (that is, the total RTM) changes to such an extent that it would no longer reflect the RUG–IV classification and payment assigned for a given SNF resident, based on the resident's most recent assessment used for Medicare payment. This will help to ensure that the SNF's payments accurately reflect the amount of therapy actually being provided. We have submitted a copy of this proposed rule to OMB for its review and approval of the information collection requirements discussed herein.

SNFs would be required to complete a COT OMRA only when the intensity of therapy actually being furnished changes to such a degree that it would no longer reflect the RUG–IV classification and payment assigned for a given SNF resident based on the most recent assessment used for Medicare payment. The burden associated with this requirement is the time and effort necessary to complete the COT OMRA,

coding the appropriate responses, and data reporting timeframes. Because providers currently are not required to report RTM that occur outside the observation window of a given PPS assessment, we do not have the relevant data to predict with certainty the number of COT OMRA's that may be required per year. However, we have attempted to use the administrative data currently available as a reasonable proxy to determine estimates of provider burden. We estimate that, based on average burden associated with the EOT OMRA, which uses the same basic item set as the proposed COT OMRA, it will take 50 minutes (0.83 hours) to collect the information necessary for coding a COT OMRA, 10 minutes (0.17 hours) to code the responses, and 2 minutes (0.03 hours) to transmit the results, or a total of 62 minutes (1.03 hours) to complete a single COT OMRA. The estimated cost per COT OMRA is \$33.84, as discussed below.

Based on information from the Bureau of Labor Statistics of May, 2009 and a 30 percent benefits rate, we estimated hourly wage rates for a Registered Nurse (RN), and for a data operator. MDS preparation costs were estimated using RN hourly wage rates based on \$56,060 per year, which amounts to \$0.45 per minute without consideration of employee benefits, and \$0.58 per minute after increasing the rate by 30 percent to account for employee benefit compensation. For coding functions, we used a blended rate of \$41,090; this was the average for RNs (\$56,060/year) and data operators (\$26,120/year). The blended rate calculates to \$0.33 per minute without consideration of employee benefits, and \$0.43 per minute after increasing the rate by 30 percent to account for employee benefit compensation. The blended rate of RN and data operator wages reflects that SNF providers historically have used both RN and support staff for the data entry function. For transmission personnel, we used data operator wages of \$26,120 per year, or \$0.21 per minute without consideration of employee benefits, and \$0.27 per minute after increasing the rate by 30 percent to account for employee benefit compensation. The total amount of time for a single COT OMRA is 62 minutes (1.03 hours), consisting of 50 minutes (0.8333 hours) of RN time for preparation, 10 minutes (0.1667 hours) of blended RN/data operator time for coding, and 2 minutes (0.0333 hours) for data operator time for transmission. This results in an average estimated cost per COT OMRA of \$33.84.

The number of stays for 2009 was approximately 2.26 million. Based on a 30-day average length of stay for RUG-IV, we believe the average number of times that a COT OMRA would need to be completed due to a decrease in therapy is once per stay. Based on our review of FY 2011 first quarter data, we found that approximately 40 percent of the claims resulted in assignment to a higher-than-projected Rehabilitation RUG. A possible reason for the difference between projected and actual FY 2011 RUG-IV case-mix utilization could involve instances where the intensity of therapy actually being furnished changed (that is, decreased) within the payment period to such a degree that it no longer reflected the RUG-IV classification and payment assigned for a given SNF resident based on the most recent assessment used for Medicare payment. As discussed previously, if such changes or decreases in therapy utilization occur outside the observation window of a given PPS assessment, such changes currently are not captured on a resident assessment, and the provider would continue to be reimbursed under a higher-paying Rehabilitation RUG until the next PPS assessment.

For FY 2012, providers would be required to complete a COT OMRA in these situations. Although we believe that only some of the 40 percent difference is likely attributable to these instances, the 40 percent would provide a quantifiable maximum burden estimate for these cases. At this time, we are unable to determine other quantifiable estimates for decreases in therapy utilization necessitating a COT OMRA. Using the percentage of claims resulting in a higher-than-projected Rehabilitation RUG as a way to estimate the maximum number of times that a therapy decrease could result in the need for a COT OMRA, 40 percent or 813,074 stays could be affected. The total number of estimated COT OMRA per SNF for FY 2011 would be 57.

In addition, the COT OMRA can be used when providers increase the amount of therapy provided. The Start-of-Therapy (SOT) OMRA represents situations where therapy has increased to a level significant enough to change the RUG to a therapy RUG. The estimate for the possible number of times that a COT OMRA would be required due to an increase in therapy uses the number of SOT OMRA as a proxy. Using the number of SOT OMRA completed in the first quarter of FY 2011 projected for the entire year, we estimate that the total COT OMRA required due to an increase in therapy would be 142,660, or 10 times per facility per year.

Therefore, the estimated total number of COT OMRA per facility per year is 67. The total annual hour burden for completing COT OMRA is estimated to be 796,414 hours for reporting, 159,320 hours for coding, and 31,826 hours for transmission for a total burden of 987,560 hours for all 14,266 SNFs. Based on an average estimated cost per COT OMRA of \$33.84, we estimate that the additional annual cost across all SNFs would be approximately \$32.34 million, or \$2,267.02 per facility. Further, we note that the completion of an EOT-R OMRA, as proposed in section V.D, would be entirely voluntary on the part of the facility and, thus, would not represent the imposition of a mandatory burden.

If you comment on these information collection and recordkeeping requirements, please do either of the following: Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or Mail copies to the address specified in the **ADDRESSES** section of this proposed rule and to the Office of Information and Regulatory Affairs, Room 10235, New Executive Office Building, Washington, DC 20503.

ATTN: CMS Desk Officer (CMS-1351-P).

Fax: (202) 395-6974.

XI. 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.

XII. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, 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. This 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 (RIA) as further discussed below. Also, the rule has been reviewed by the Office of Management and Budget.

2. Statement of Need

This proposed rule would update the SNF prospective payment rates for fiscal year 2012 as required under section 1888(e)(4)(E) of the Act. It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to “provide for publication in the **Federal Register**” before the August 1 that precedes the start of each fiscal year, the unadjusted Federal per diem rates, the case-mix classification system, and the wage index values used in computing the prospective payment rates for that fiscal year. As these statutory provisions prescribe a detailed methodology for calculating and disseminating payment rates under the SNF PPS, we do not have the discretion to adopt an alternative approach.

3. Overall Impacts

If we implement the recalibration option in FY 2012, as described above in section II.B.2, we estimate the aggregate impact would be a net decrease of \$3.94 billion in payments to SNFs, resulting from a \$530 million increase from the update to the payment rates and a \$4.47 billion reduction from the recalibration of the case-mix adjustment. However, if we implement the option of applying the standard update without a recalibration for FY 2012, as described above in section II.B.2, we estimate the aggregate impact would be a net increase of \$530 million in payments to SNFs, resulting from the update to the payment rates. Accordingly, we have prepared a RIA that, to the best of our ability, presents the costs and benefits of the rulemaking, with respect to the two options presented in section II.B.2. of this proposed rule.

The update set forth in this proposed rule applies to payments in FY 2012. Accordingly, the analysis that follows

only describes the impact of this single year. In accordance with the requirements of the Act, we will publish a notice for each subsequent FY that will provide for an update to the payment rates and include an associated impact analysis.

The two options being considered regarding the recalibration of the case-mix indexes are presented in section II.B.2. A detailed economic impact analysis of these two options appears below.

4. Detailed Economic Analysis

This proposed rule sets forth updates of the SNF PPS rates contained in the update notice for FY 2011 (75 FR 42886, July 22, 2010) and the associated correction notice (75 FR 55801, September 14, 2010). Based on the above, if we implement the recalibration option for FY 2012, we estimate that the aggregate impact would be a net decrease of \$3.94 billion in payments to SNFs, resulting from a \$530 million increase from the update to the payment rates and a \$4.47 billion reduction from the recalibration of the case-mix adjustment. If we do not recalibrate the CMIs for FY 2012, as discussed in section II.B.2, we estimate that the aggregate impact would be a net increase of \$530 million in payments to SNFs, resulting primarily from the update to the payment rates. The impact analysis of this proposed rule represents the projected effects of the changes in the SNF PPS from FY 2011 to FY 2012 for each of these two possible options. We assess the effects by estimating payments under each of the two options while holding all other payment-related variables constant. Although the best data available are utilized, there is no attempt to predict behavioral responses to these changes, or to make adjustments for future changes in such variables as days or case-mix.

Certain events may occur to limit the scope or accuracy of our impact analysis, as this analysis is future-oriented and, thus, very susceptible to forecasting errors due to certain events that may occur within the assessed impact time period. Some examples of possible events may include newly legislated general Medicare program funding changes by the Congress, or changes specifically related to SNFs. In addition, changes to the Medicare program may continue to be made as a result of previously enacted legislation, or new statutory provisions. Although these changes may not be specific to the SNF PPS, the nature of the Medicare

program is that the changes may interact and, thus, the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon SNFs.

In accordance with section 1888(e)(4)(E) and (e)(5) of the Act, we update the payment rates for FY 2011 by a factor equal to the market basket index percentage increase adjusted by the FY 2010 forecast error adjustment (if applicable) and the MFP adjustment to determine the payment rates for FY 2012. As discussed previously, for FY 2012 and each subsequent FY, as required by section 1888(e)(5)(B) of the Act as amended by section 3401(b) of the Affordable Care Act, the market basket percentage is reduced by the MFP adjustment. The special AIDS add-on established by section 511 of the MMA remains in effect until “* * * such date as the Secretary certifies that there is an appropriate adjustment in the case mix * * *.” We have not provided a separate impact analysis for the MMA provision. Our latest estimates indicate that there are less than 3,500 beneficiaries who qualify for the AIDS add-on payment. The impact to Medicare is included in the “total” column of Tables 13A and 13B. In updating the rates for FY 2012, we made a number of standard annual revisions and clarifications mentioned elsewhere in this proposed rule (for example, the update to the wage and market basket indexes used for adjusting the Federal rates).

We estimate that if we were to implement the recalibration option for FY 2012, the aggregate impact would be a net decrease of \$3.94 billion in payments to SNFs, resulting from a \$530 million increase from the update to the payment rates and a \$4.47 billion reduction from the recalibration of the case-mix adjustment. If we do not implement the recalibration option for FY 2012, we estimate that the aggregate impact would be a net increase of \$530 million in payments to SNFs, resulting from the update to the payment rates. The FY 2012 impacts that would result from implementing the recalibration option in FY 2012 are presented in Table 13A. The FY 2012 impacts that would result from not implementing the recalibration of the case-mix indexes in FY 2012 are presented in Table 13B.

a. Impacts of Implementing the Recalibration Option for FY 2012

The breakdown of the various categories of data in Table 13A is as follows.

The first column shows the breakdown of all SNFs by urban or rural status, hospital-based or freestanding status, and census region.

The “total” row shows the estimated effects of the various changes on all facilities. The next six rows show the effects on facilities split by hospital-based, freestanding, urban, and rural categories. The urban and rural designations are based on the location of the facility under the CBSA designation. The next 19 rows show the effects on urban versus rural status by census region. The last 3 rows show the effects on ownership by government, profit and non-profit status.

The second column in Table 13A shows the number of facilities in the impact database.

The third column in Table 13A shows the effects of recalibrating the nursing CMIs of the RUG–IV therapy groups. As explained previously in section II.B.2 of this proposed rule, we are considering this recalibration so that the CMIs more accurately reflect parity in expenditures under the RUG–IV system introduced in FY 2011 relative to payments under the previous RUG–53 system, based on our review of initial FY 2011 claims data. The total impact of this change is a decrease of 12.6 percent. We note that some individual providers may experience larger decreases in payment than others due to case-mix utilization.

The fourth column of Table 13A shows the effect of the annual update to the wage index. This represents the effect of using the most recent wage data available. The total impact of this change is zero percent; however, there are distributional effects of the change.

The fifth column of Table 13A shows the effect of all of the changes on the FY 2012 payments. The update of 1.5 percent, consisting of the market basket increase of 2.7 percentage points, reduced by the 1.2 percentage point MFP adjustment is constant for all providers and, though not shown individually, is included in the total column. It is projected that aggregate payments will decrease by 11.3 percent, assuming that facilities do not change their care delivery and billing practices in response.

As shown in Table 13A, the combined effects of all of the changes vary by specific types of providers and by location.

TABLE 13A—RUG—IV PROJECTED IMPACT TO THE SNF PPS FOR FY 2012

[Includes recalibration of the case-mix indexes]

| | Number of facilities FY 2012 | Revised CMIs (percent) | Update wage data (percent) | Total FY 2012 change (percent) |
|----------------------------|---------------------------------|---------------------------|----------------------------------|--------------------------------------|
| Group: | | | | |
| Total | 14,266 | -12.6 | 0.0 | -11.3 |
| Urban | 10,049 | -12.8 | 0.0 | -11.5 |
| Rural | 4,217 | -11.9 | 0.1 | -10.5 |
| Hospital based urban | 421 | -12.4 | 0.1 | -11.1 |
| Freestanding urban | 9,628 | -12.8 | 0.0 | -11.5 |
| Hospital based rural | 310 | -11.4 | 0.0 | -10.2 |
| Freestanding rural | 3,907 | -11.9 | 0.1 | -10.5 |
| Urban by region: | | | | |
| New England | 792 | -12.6 | 0.0 | -11.3 |
| Middle Atlantic | 1,391 | -12.9 | 0.2 | -11.5 |
| South Atlantic | 1,682 | -12.8 | -0.3 | -11.7 |
| East North Central | 1,962 | -12.9 | -0.4 | -11.9 |
| East South Central | 482 | -12.7 | -0.4 | -11.8 |
| West North Central | 819 | -12.8 | 0.3 | -11.2 |
| West South Central | 1,134 | -12.7 | 0.5 | -10.9 |
| Mountain | 459 | -12.8 | 0.2 | -11.3 |
| Pacific | 1,325 | -12.8 | 0.2 | -11.3 |
| Outlying | 3 | -3.7 | 1.1 | -1.1 |
| Rural by region: | | | | |
| New England | 137 | -11.7 | 1.1 | -9.4 |
| Middle Atlantic | 233 | -12.4 | -0.1 | -11.1 |
| South Atlantic | 546 | -11.8 | -0.1 | -10.6 |
| East North Central | 867 | -12.1 | -0.1 | -10.9 |
| East South Central | 455 | -11.8 | -0.5 | -10.9 |
| West North Central | 984 | -12.1 | 0.4 | -10.4 |
| West South Central | 679 | -11.7 | 0.9 | -9.6 |
| Mountain | 204 | -11.8 | 0.4 | -10.2 |
| Pacific | 112 | -11.8 | -0.5 | -11.0 |
| Ownership: | | | | |
| Government | 710 | -12.5 | -0.1 | -11.3 |
| Profit | 9,959 | -12.6 | 0.0 | -11.3 |
| Non-profit | 3,597 | -12.7 | 0.0 | -11.4 |

Note: The Total column includes the 2.7 percent market basket increase, reduced by the 1.2 percentage point MFP adjustment. Additionally, we found no SNFs in rural outlying areas.

b. Impacts of Not Implementing the Recalibration Option for FY 2012

The first column of Table 13B shows the breakdown of all SNFs by urban or rural status, hospital-based or freestanding status, and census region.

The "total" row of Table 13B describes the estimated effects of the various changes on all facilities. The next six rows show the effects on facilities split by hospital-based, freestanding, urban, and rural categories. The urban and rural designations are based on the location of the facility under the CBSA designation. The next 19 rows show the effects on urban versus rural status by

census region. The last 3 rows show the effects on ownership by government, profit and non-profit status.

The second column in Table 13B shows the number of facilities in the impact database.

The third column in Table 13B shows the effect of the annual update to the wage index. This represents the effect of using the most recent wage data available. The total impact of this change is zero percent; however, there are distributional effects of the change.

The fourth column of Table 13B shows the effect of all of the changes on the FY 2012 payments. The update of

1.5 percent, consisting of the market basket increase of 2.7 percentage points, reduced by the 1.2 percentage point MFP adjustment is constant for all providers and, though not shown individually, is included in the total column. It is projected that aggregate payments will increase by 1.5 percent, assuming that facilities do not change their care delivery and billing practices in response.

As shown in Table 13B, the combined effects of all of the changes vary by specific types of providers and by location.

TABLE 13B—RUG—IV PROJECTED IMPACT TO THE SNF PPS FOR FY 2012

[Does not include recalibration of the case-mix indexes]

| | Number of facilities | Wage index (percent) | Total impact (percent) |
|----------------------------|----------------------|-------------------------|---------------------------|
| Group: | | | |
| Total | 14,266 | 0.0 | 1.5 |
| Urban | 10,049 | 0.0 | 1.5 |
| Rural | 4,217 | 0.1 | 1.6 |
| Hospital based urban | 421 | 0.1 | 1.6 |
| Freestanding urban | 9,628 | 0.0 | 1.5 |
| Hospital based rural | 310 | 0.0 | 1.5 |

TABLE 13B—RUG—IV PROJECTED IMPACT TO THE SNF PPS FOR FY 2012—Continued

[Does not include recalibration of the case-mix indexes]

| | Number of facilities | Wage index (percent) | Total impact (percent) |
|--------------------------|----------------------|----------------------|------------------------|
| Freestanding rural | 3,907 | 0.1 | 1.6 |
| Urban by region: | | | |
| New England | 792 | 0.0 | 1.5 |
| Middle Atlantic | 1,391 | 0.2 | 1.7 |
| South Atlantic | 1,682 | −0.3 | 1.2 |
| East North Central | 1,962 | −0.4 | 1.1 |
| East South Central | 482 | −0.4 | 1.1 |
| West North Central | 819 | 0.3 | 1.8 |
| West South Central | 1,134 | 0.5 | 2.1 |
| Mountain | 459 | 0.2 | 1.7 |
| Pacific | 1,325 | 0.2 | 1.7 |
| Outlying | 3 | 1.1 | 2.7 |
| Rural by region: | | | |
| New England | 137 | 1.1 | 2.6 |
| Middle Atlantic | 233 | −0.1 | 1.4 |
| South Atlantic | 546 | −0.1 | 1.4 |
| East North Central | 867 | −0.1 | 1.4 |
| East South Central | 455 | −0.5 | 1.0 |
| West North Central | 984 | 0.4 | 1.9 |
| West South Central | 679 | 0.9 | 2.4 |
| Mountain | 204 | 0.4 | 1.9 |
| Pacific | 112 | −0.5 | 1.0 |
| Ownership: | | | |
| Government | 710 | −0.1 | 1.4 |
| Profit | 9,959 | 0.0 | 1.5 |
| Non-profit | 3,597 | 0.0 | 1.5 |

The proposed implementation of the disclosure of ownership requirements set forth in section 6101 of the Affordable Care Act (as discussed previously in section V.A. of this proposed rule) will affect all Medicaid nursing facilities and Medicare SNFs providing care to a Medicare and/or Medicaid beneficiary. Currently, these facilities are required to disclose information and maintain up-to-date information in PECOS and/or OSCAR. Thus, these new requirements are an extension of requirements to which the facility should already be accustomed to maintain compliance. Also, the proposed new disclosure requirements do not appear to impose any labor- or system-intensive burden on the facilities.

We solicit comment on the economic impact analysis of the two options presented in section II.B.2 (that is, recalibration and no recalibration for FY 2012).

5. Alternatives Considered

As described above, if we implement the recalibration option for FY 2012, the aggregate impact would be a net decrease of \$3.94 billion in payments to SNFs, resulting from a \$530 million increase from the update to the payment rates and a \$4.47 billion reduction from the recalibration of the case-mix adjustment. If we move forward with the option of applying the standard

update without a recalibration for FY 2012, we estimate that the aggregate impact would be a net increase of \$530 million in payments to SNFs, resulting from the update to the payment rates. In view of the potential economic impact, we considered the alternatives described below.

Section 1888(e) of the Act establishes the SNF PPS for the payment of Medicare SNF services for cost reporting periods beginning on or after July 1, 1998. This section of the statute prescribes a detailed formula for calculating payment rates under the SNF PPS, and does not provide for the use of any alternative methodology. It specifies that the base year cost data to be used for computing the SNF PPS payment rates must be from FY 1995 (October 1, 1994, through September 30, 1995). In accordance with the statute, we also incorporated a number of elements into the SNF PPS (for example, case-mix classification methodology, the MDS assessment schedule, a market basket index, a wage index, and the urban and rural distinction used in the development or adjustment of the Federal rates). Further, section 1888(e)(4)(H) of the Act specifically requires us to disseminate the payment rates for each new FY through the **Federal Register**, and to do so before the August 1 that precedes the start of the new FY. Accordingly, we are not pursuing alternatives with respect to the

payment methodology as discussed above.

Using our authority to establish an appropriate adjustment for case mix under section 1888(e)(4)(G)(i) of the Act, this proposed rule considers a recalibration of the adjustment to the nursing case-mix indexes based on actual FY 2011 data. In the FY 2010 SNF PPS final rule (74 FR 40339), we committed to monitoring the accuracy and effectiveness of the parity adjustment to maintain budget neutrality. We believe that using actual FY 2011 claims data to perform the recalibration analysis may result in case-mix weights that better reflect the resources used, produce more accurate payment, and represent an appropriate case-mix adjustment. Using FY 2011 data would be consistent with our intent to make the change from the RUG-53 model to the RUG-IV model in a budget neutral manner, as described in the SNF PPS final rule for FY 2010 (74 FR 40339).

In reviewing our initial projections, we found that the disparity which formed the basis for our considering a recalibration of the nursing case-mix indexes was at least partially the result of a shift in the mode of therapy provided to beneficiaries in a Part A stay under RUG-IV. The amount of concurrent therapy decreased significantly from historical levels, with a portion of the SNFs reporting 0

minutes of concurrent therapy for all MDS 3.0s submitted during the FY 2011 sampling period. Many of these facilities reported large increases in the amount of group therapy provided during the same time period. During the period before we publish the final rule for FY 2012, we plan to continue to collect and analyze MDS 3.0 and SNF PPS claims data to confirm our preliminary assessment of the parity adjustment considered in this rule. Then, in the final rule, we would use the expanded FY 2011 MDS 3.0 data and SNF PPS claims data to decide whether or not to pursue the considered FY 2012 recalibration of the SNF PPS rates.

We considered various alternatives for implementing a recalibrated case-mix adjustment. Most notably, as described previously in section II.B.2 of this proposed rule, we considered applying a recalibration to all nursing CMI, irrespective of RUG category. However, we found that such a recalibration most drastically affected non-therapy RUG groups, which seemed incongruent with the perceived reasons for differences between expected and actual utilization patterns, as noted in Table 4. We will continue to monitor utilization trends in case such a methodology might become more viable in the future.

In addition, we considered implementing partial adjustments to the case-mix indexes over multiple years until parity was achieved. However, we believe that this alternative would continue to reimburse in amounts that significantly exceed our intended policy. Moreover, as we move forward with programs designed to enhance and restructure our post-acute care payment systems, we believe that payments under the SNF PPS should be established at their intended and most appropriate levels. Stabilizing the baseline is a necessary first step toward properly implementing and maintaining the integrity of the RUG-IV classification methodology and the SNF PPS as a whole. Therefore, for FY 2012, we are considering only the two options described in section II.B.2 above. We solicit comment on the alternatives considered in this analysis.

6. Accounting Statement

As required by OMB Circular A-4 (available online at http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf), in Table 14, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule, based on whether or not we implement the recalibration of the

case-mix indexes. Tables 14A and 14B provide our best estimate of the possible changes in Medicare payments under the SNF PPS as a result of the policies in this proposed rule, based on the data for 14,266 SNFs in our database. All expenditures are classified as transfers to Medicare providers (that is, SNFs).

TABLE 14A—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2011 SNF PPS FISCAL YEAR TO THE 2012 SNF PPS FISCAL YEAR

[Including recalibration of case-mix indexes]

| Category | Transfers |
|---|---|
| Annualized Monetized Transfers. From Whom To Whom? | – \$3.94 billion.* Federal Government to SNF Medicare Providers. |

* The net decrease of \$3.94 billion in transfer payments is a result of the decrease of \$4.47 billion due to the proposed recalibration of the case mix adjustment, together with the proposed market basket increase of \$530 million.

TABLE 14B—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2011 SNF PPS FISCAL YEAR TO THE 2012 SNF PPS FISCAL YEAR

[Without recalibration of case-mix indexes]

| Category | Transfers |
|---|--|
| Annualized Monetized Transfers. From Whom To Whom? | \$530 million.* Federal Government to SNF Medicare Providers. |

* The net increase of \$530 million in transfer payments is a result of the proposed market basket increase of 1.5 percent.

7. Conclusion

If we implement the recalibration of the case-mix indexes, the overall estimated payments for SNFs in FY 2012 are projected to decrease by \$3.94 billion, or 11.3 percent, compared with those in FY 2011. With this option, we estimate that under RUG-IV, SNFs in urban and rural areas would experience, on average, an 11.5 and 10.5 percent decrease, respectively, in estimated payments compared with FY 2011. Providers in the urban East North Central region would experience the largest estimated decrease in payments of approximately 11.9 percent. If we do not implement the recalibration of the case-mix indexes for FY 2012, the overall estimated payments for SNFs in FY 2012 are projected to increase by \$530 million, or 1.5 percent, compared

with FY 2011. We estimate that under this option, SNFs in urban and rural areas would experience, on average, a 1.5 and 1.6 percent increase, respectively, in estimated RUG-IV payments compared with FY 2011. Outlying urban providers and providers in the rural New England region would experience the largest estimated increase in payments of 2.7 and 2.6 percent, respectively.

The disclosure of ownership requirements in section 6101 of the Affordable Care Act that we now propose to implement involve necessary information that would provide the public with a greater assurance that there is transparency and, thus, improved oversight. We believe it was the intent of Congress to complement that information which is already being supplied by the facility. With that in mind, we propose specific disclosure information that would identify the unique business and operating structures of Medicare SNFs and Medicaid nursing facilities. By providing PECOS and OSCAR with this more detailed facility ownership information, this proposed revision would help ensure that program expenditures are made in the most efficient and appropriate manner.

B. Regulatory Flexibility Act Analysis

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, non-profit organizations, and small governmental jurisdictions. Most SNFs and most other providers and suppliers are small entities, either by their non-profit status or by having revenues of \$13.5 million or less in any 1 year. For purposes of the RFA, approximately 91 percent of SNFs are considered small businesses according to the Small Business Administration's latest size standards, with total revenues of \$13.5 million or less in any 1 year. (For details, see the Small Business Administration's Web site at <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2465b064ba6965cc1fbd2eae60854b11&rgn=div8&view=text&node=13:1.0.1.1.16.1.266.9&idno=13>). Individuals and States are not included in the definition of a small entity. In addition, approximately 21 percent of SNFs classified as small entities are non-profit organizations. Finally, the estimated number of small business entities does not distinguish provider establishments that are within a single firm and, therefore, the number of SNFs classified as small entities may

be higher than the estimate above. We expect that the disclosure requirements discussed in section V.A of this proposed rule will aid us in determining which providers may be appropriately classified as small entities.

This proposed rule updates the SNF PPS rates published in the update notice for FY 2011 (75 FR 42886, July 22, 2010) and the associated correction notice (75 FR 55801, September 14, 2010). We estimate that implementing the recalibration option considered under section II.B.2 above would result in a net decrease of \$3.94 billion in payments to SNFs for FY 2012. This would reflect a \$530 million increase from the update to the payment rates and a \$4.47 billion reduction from the recalibration of the case-mix adjustment. As indicated in Table 13A, the estimated effect of this recalibration option on facilities for FY 2012 would be an aggregate negative impact of 11.3 percent. While it is projected in Table 13A that all providers would experience a net decrease in payments, we note that some individual providers may experience larger decreases in payments than others due to the distributional impact of the FY 2012 wage indexes and the degree of Medicare utilization.

Alternatively, we estimate that not implementing the recalibration option considered under section II.B.2 above would result in a net increase of \$530 million in payments to SNFs for FY 2012, reflecting the standard update to the payment rates. As indicated in Table 13B, the estimated effect of this option on facilities for FY 2012 would be an aggregate positive impact of 1.5 percent. While it is projected in Table 13B that all providers would experience a net increase in payments, we note that some individual providers may experience larger increases in payments than others due to the distributional impact of the FY 2012 wage indexes and the degree of Medicare utilization.

Guidance issued by the Department of Health and Human Services on the proper assessment of the impact on small entities in rulemakings, utilizes a cost or revenue impact of 3 to 5 percent as a significance threshold under the RFA. According to MedPAC, Medicare covers approximately 12 percent of total patient days in freestanding facilities and 23 percent of facility revenue (March 2011). However, it is worth noting that the distribution of days and payments is highly variable. That is, the majority of SNFs have significantly lower Medicare utilization. As a result, for most facilities, when all payers are included in the revenue stream, the overall impact effect to total revenues should be substantially less than those

presented in Table 13A, which reflects the impacts of implementing the recalibration of the case-mix indexes. However, not implementing the recalibration of the case-mix indexes, as presented in Table 13B, yields an aggregate positive net impact of 1.5 percent on all SNF providers, with outlying urban providers and providers in the rural New England region experiencing the largest estimated increase in payments of 2.7 and 2.6 percent, respectively. Therefore, the Secretary has determined that this proposed rule may have a significant impact on a substantial number of small entities, depending on the option considered (that is, recalibration of the parity adjustment for FY 2012 or application of the standard update without recalibration for FY 2012).

We offer an analysis of the alternatives considered in section XII.A.5 of this proposed rule. The analysis above, together with the remainder of this preamble, constitutes the initial regulatory flexibility analysis. We solicit comment on the RFA analysis.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. The proposed rule would affect small rural hospitals that (a) furnish SNF services under a swing-bed agreement or (b) have a hospital-based SNF. We anticipate that the impact on small rural hospitals would be similar to the impact on SNF providers overall. Therefore, the Secretary has determined that this proposed rule may have a significant impact on the operations of a substantial number of small rural hospitals, depending on the option considered, as discussed above (that is, recalibration of the parity adjustment for FY 2012 or application of the standard update without recalibration for FY 2012).

C. Unfunded Mandates Reform Act Analysis

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 of \$100 million in 1995 dollars, updated annually for inflation. In 2011, that

threshold is approximately \$136 million. This proposed rule would not impose spending costs on State, local, or Tribal governments in the aggregate, or by the private sector, of \$136 million.

D. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that impose substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This proposed rule would have no substantial direct effect on State and local governments, preempt State law, or otherwise have Federalism implications.

List of Subjects

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 455

Fraud, Grant programs—health, Health facilities, Health professions, Investigations, Medicaid, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

1. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106–133 (113 Stat. 1501A–332).

Subpart J—Prospective Payment for Skilled Nursing Facilities

2. Section 413.337 is amended by—
A. Revising paragraphs (d)(1) and (d)(2).
B. Adding paragraph (d)(3).

The revisions and addition read as follows:

§ 413.337 Methodology for calculating the prospective payment rates.

* * * *

(d) * * *

(1) *Update formula.* The unadjusted Federal payment rate shall be updated as follows:

(i) For the initial period beginning on July 1, 1998, and ending on September 30, 1999, the unadjusted Federal payment rate is equal to the rate computed under paragraph (b)(5)(iii) of this section increased by a factor equal to the SNF market basket index percentage change for such period minus 1 percentage point.

(ii) For fiscal year 2000, the unadjusted Federal payment rate is equal to the rate computed for the initial period described in paragraph (d)(1)(i) of this section increased by a factor equal to the SNF market basket index percentage change for that period minus 1 percentage point.

(iii) For fiscal year 2001, the unadjusted Federal payment rate is equal to the rate computed for the previous fiscal year increased by a factor equal to the SNF market basket index percentage change for the fiscal year.

(iv) For fiscal years 2002 and 2003, the unadjusted Federal payment rate is equal to the rate computed for the previous fiscal year increased by a factor equal to the SNF market basket index percentage change for the fiscal year involved minus 0.5 percentage points.

(v) For each subsequent fiscal year, the unadjusted Federal payment rate is equal to the rate computed for the previous fiscal year increased by a factor equal to the SNF market basket index percentage change for the fiscal year involved.

(2) *Forecast error adjustment.* Beginning with fiscal year 2004, an adjustment to the annual update of the previous fiscal year's rate will be computed to account for forecast error. The initial adjustment (in fiscal year 2004) to the update of the previous fiscal year's rate will take into account the cumulative forecast error between fiscal years 2000 and 2002. Subsequent adjustments in succeeding fiscal years will take into account the forecast error from the most recently available fiscal year for which there is final data. The forecast error adjustment applies whenever the difference between the forecasted and actual percentage change in the SNF market basket index exceeds the following threshold:

(i) 0.25 percentage points for fiscal years 2004 through 2007; and

(ii) 0.5 percentage points for fiscal year 2008 and subsequent fiscal years.

(3) *Multifactor productivity (MFP) adjustment.* For fiscal year 2012 and each subsequent fiscal year, the SNF market basket index percentage change for the fiscal year (as modified by any applicable forecast error adjustment under paragraph (d)(2) of this section) shall be reduced by the MFP adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The reduction of the market basket percentage change by the MFP adjustment may result in the market basket percentage change being less than zero for a fiscal year, and may result in the unadjusted Federal payment rates for a fiscal year being less than such payment rates for the preceding fiscal year.

* * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

3. 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).

Subpart P—Requirements for Establishing and Maintaining Medicare Billing Privileges

4. Section 424.502 is amended by—

A. Adding the definitions of “Additional disclosable party” and “Organizational structure” in alphabetical order.

B. Revising the definition of “Managing employee”.

The revision and additions read as follows:

§ 424.502 Definitions.

* * * *

Additional disclosable party means, with respect to a skilled nursing facility defined at section 1819(a) of the Act, any person or entity who—

(1) Exercises operational, financial, or managerial control over the facility or a part thereof, or provides policies or procedures for any of the operations of the facility, or provides financial or cash management services to the facility;

(2) Leases or subleases real property to the facility, or owns a whole or part interest equal to or exceeding 5 percent of the total value of such real property; or

(3) Provides management or administrative services, management or clinical consulting services, or accounting or financial services to the facility.

* * * *

Managing employee means a general manager, business manager,

administrator, director, or other individual that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the provider or supplier, either under contract or through some other arrangement, whether or not the individual is a W–2 employee of the provider or supplier. With respect to the additional requirements at § 424.516(e) of this chapter for a skilled nursing facility defined at section 1819(a) of the Act, a “managing employee” means an individual, including a general manager, business manager, administrator, director, or consultant, who directly or indirectly manages, advises, or supervises any element of the practices, finances, or operations of the facility.

* * * *

Organizational structure means, with respect to a skilled nursing facility defined at section 1819(a) of the Act, in the case of—

(1) A corporation, the officers, directors, and shareholders of the corporation who have an ownership interest in the corporation which is equal to or exceeds 5 percent;

(2) A limited liability company, the members and managers of the limited liability company including, as applicable, what percentage each member and manager has of the ownership interest in the limited liability company;

(3) A general partnership, the partners of the general partnership;

(4) A limited partnership, the general partners and any limited partners of the limited partnership who have an ownership interest in the limited partnership which is equal to or exceeds 10 percent;

(5) A trust, the trustees of the trust; and

(6) An individual, contact information for the individual.

* * * *

6. Section 424.516 is amended by adding paragraphs (e)(4) and (e)(5) to read as follows:

§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

* * * *

(e) * * *

(4) In addition, a skilled nursing facility (as defined by section 1819(a) of the Act) must report upon enrollment and within 30 days of any change to the following information:

(i) The identity of and information on all of the following:

(A) Each member of the governing body of the facility, including the name,

title, and period of service for each member.

(B) Each person or entity who is an officer, director, member, partner, trustee, or managing employee (as defined in § 424.502) of the facility, including the name, title, and period of service of each such person or entity.

(C) Each person or entity who is an additional disclosable party of the facility, as defined in § 424.502.

(ii) The organizational structure (as defined in § 424.502 of this chapter) of each additional disclosable party of the facility and a description of the relationship of each such additional disclosable party to the facility and to one another.

(5) A skilled nursing facility (as defined by section 1819(a) of the Act) must certify as a condition of participation and payment under the program under Title XVIII of the Act that the information reported by the facility in accordance with these regulations is, to the best of the facility's knowledge, accurate and current.

* * * * *

PART 455—PROGRAM INTEGRITY: MEDICAID

7. The authority citation for part 455 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart B—Disclosure of Information by Providers and Fiscal Agents

8. Section 455.101 is amended by—

A. Adding the definitions of “Additional disclosable party” and “Organizational structure” in alphabetical order.

B. Revising the definition of “Managing employee”.

The revision and additions read as follows:

§ 455.101 Definitions.

Additional disclosable party means any person or entity who—

(1) Exercises operational, financial, or managerial control over the facility or a part thereof, or provides policies or procedures for any of the operations of the facility, or provides financial or cash management services to the facility;

(2) Leases or subleases real property to the facility, or owns a whole or part interest equal to or exceeding 5 percent of the total value of such real property; or

(3) Provides management or administrative services, management or clinical consulting services, or

accounting or financial services to the facility.

* * * * *

Managing employee means a general manager, business manager, administrator, director, or other individual who exercises operational or managerial control over, or who directly or indirectly controls the day-to-day operation of an institution, organization, or agency. With respect to nursing facilities defined by section 1919(a) of the Act, a “managing employee” means an individual, including a general manager, business manager, administrator, director, or consultant who directly or indirectly manages, advises, or supervises any element of the practices, finances, or operations of the facility.

Organizational structure means, in the case of—

(1) A corporation, the officers, directors, and shareholders of the corporation who have an ownership interest in the corporation which is equal to or exceeds 5 percent;

(2) A limited liability company, the members and managers of the limited liability company including, as applicable, what percentage each member and manager has of the ownership interest in the limited liability company;

(3) A general partnership, the partners of the general partnership;

(4) A limited partnership, the general partners and any limited partners of the limited partnership who have an ownership interest in the limited partnership which is equal to or exceeds 10 percent;

(5) A trust, the trustees of the trust; and

(6) An individual, contact information for the individual.

* * * * *

9. Section 455.104 is amended by—

A. Redesignating paragraph (e) as paragraph (f).

B. Adding a new paragraph (e).

The addition reads as follows:

§ 455.104 Disclosure by Medicaid providers and fiscal agents: Information on ownership and control.

* * * * *

(e) *Disclosures from Medicaid nursing facilities.* (1) *What disclosures must be provided.* Medicaid nursing facilities must provide all disclosures required for disclosing entities, above. In addition, Medicaid nursing facilities (as defined by section 1919(a) of the Act) must provide disclosures regarding additional disclosable parties, organizational structure, and managing employees of the Medicaid nursing

facility, as defined in § 455.101 of this part.

(i) These disclosures must include the identity of and information on all of the following:

(A) Each member of the governing body of the facility, including the name, title, and period of service for each member.

(B) Each person or entity who is an officer, director, member, partner, trustee, or managing employee (as defined in § 455.101) of the facility, including the name, title, and period of service of each such person or entity.

(C) Each person or entity who is an additional disclosable party (as defined in § 455.101) of the facility.

(ii) The organizational structure (as defined in § 455.101) of each additional disclosable party of the facility and a description of the relationship of each such additional disclosable party to the facility and to one another.

(2) *When the disclosures must be provided.* Medicaid nursing facilities must provide all the disclosures to the State Medicaid agency upon enrollment; on an annual basis to be determined by the State Medicaid agency; and within 30 days after any change to any of the above disclosures.

(3) *Medicaid nursing facility's certification.* Nursing facilities (as defined by section 1919(a) of the Act) must certify as a condition of participation and payment under the program under Title XIX of the Act that the information reported by the facility in accordance with these regulations is, to the best of the facility's knowledge, accurate and current.

* * * * *

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

Dated: March 24, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: April 26, 2011.

Kathleen Sebelius,

Secretary.

[Note: The following Addendum will not appear in the Code of Federal Regulations]

Addendum—FY 2012 CBSA Wage Index Tables

In this addendum, we provide the wage index tables referred to in the preamble to this proposed rule. Tables A and B display the CBSA-based wage index values for urban and rural providers.

BILLING CODE 4120-01-P

TABLE A: FY 2012 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|---|------------|
| 10180 | Abilene, TX Callahan County, TX Jones County, TX Taylor County, TX | 0.8470 |
| 10380 | Aguadilla-Isabela-San Sebastián, PR Aguada Municipio, PR Aguadilla Municipio, PR Añasco Municipio, PR Isabela Municipio, PR Lares Municipio, PR Moca Municipio, PR Rincón Municipio, PR San Sebastián Municipio, PR | 0.3622 |
| 10420 | Akron, OH Portage County, OH Summit County, OH | 0.8840 |

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| 10500 | Albany, GA Baker County, GA Dougherty County, GA Lee County, GA Terrell County, GA Worth County, GA | 0.8643 |
| 10580 | Albany-Schenectady-Troy, NY Albany County, NY Rensselaer County, NY Saratoga County, NY Schenectady County, NY Schoharie County, NY | 0.8706 |
| 10740 | Albuquerque, NM Bernalillo County, NM Sandoval County, NM Torrance County, NM Valencia County, NM | 0.9579 |
| 10780 | Alexandria, LA Grant Parish, LA Rapides Parish, LA | 0.8051 |
| 10900 | Allentown-Bethlehem-Easton, PA-NJ Warren County, NJ Carbon County, PA Lehigh County, PA Northampton County, PA | 0.9285 |
| 11020 | Altoona, PA Blair County, PA | 0.8943 |
| 11100 | Amarillo, TX Armstrong County, TX Carson County, TX Potter County, TX Randall County, TX | 0.8741 |
| 11180 | Ames, IA Story County, IA | 1.0039 |
| 11260 | Anchorage, AK Anchorage Municipality, AK Matanuska-Susitna Borough, AK | 1.2170 |
| 11300 | Anderson, IN Madison County, IN | 0.9280 |
| 11340 | Anderson, SC Anderson County, SC | 0.8513 |

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|-------|---|--------|
| 11460 | Ann Arbor, MI Washtenaw County, MI | 1.0158 |
| 11500 | Anniston-Oxford, AL Calhoun County, AL | 0.7987 |
| 11540 | Appleton, WI Calumet County, WI Outagamie County, WI | 0.9253 |
| 11700 | Asheville, NC Buncombe County, NC Haywood County, NC Henderson County, NC Madison County, NC | 0.8926 |
| 12020 | Athens-Clarke County, GA Clarke County, GA Madison County, GA Oconee County, GA Oglethorpe County, GA | 0.9671 |

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| 12060 | Atlanta-Sandy Springs-Marietta, GA Barrow County, GA Bartow County, GA Butts County, GA Carroll County, GA Cherokee County, GA Clayton County, GA Cobb County, GA Coweta County, GA Dawson County, GA DeKalb County, GA Douglas County, GA Fayette County, GA Forsyth County, GA Fulton County, GA Gwinnett County, GA Haralson County, GA Heard County, GA Henry County, GA Jasper County, GA Lamar County, GA Meriwether County, GA Newton County, GA Paulding County, GA Pickens County, GA Pike County, GA Rockdale County, GA Spalding County, GA Walton County, GA | 0.8992 |
| 12100 | Atlantic City-Hammonton, NJ Atlantic County, NJ | 1.1067 |
| 12220 | Auburn-Opelika, AL Lee County, AL | 0.8061 |
| 12260 | Augusta-Richmond County, GA-SC Burke County, GA Columbia County, GA McDuffie County, GA Richmond County, GA Aiken County, SC Edgefield County, SC | 0.9556 |

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|-------|---|--------|
| 13460 | Bend, OR Deschutes County, OR | 1.1429 |
| 13644 | Bethesda-Frederick-Gaithersburg, MD Frederick County, MD Montgomery County, MD | 1.0335 |
| 13740 | Billings, MT Carbon County, MT Yellowstone County, MT | 0.8602 |
| 13780 | Binghamton, NY Broome County, NY Tioga County, NY | 0.8757 |
| 13820 | Birmingham-Hoover, AL Bibb County, AL Blount County, AL Chilton County, AL Jefferson County, AL St. Clair County, AL Shelby County, AL Walker County, AL | 0.8453 |
| 13900 | Bismarck, ND Burleigh County, ND Morton County, ND | 0.7254 |
| 13980 | Blacksburg-Christiansburg-Radford, VA Giles County, VA Montgomery County, VA Pulaski County, VA Radford City, VA | 0.8290 |
| 14020 | Bloomington, IN Greene County, IN Monroe County, IN Owen County, IN | 0.8751 |
| 14060 | Bloomington-Normal, IL McLean County, IL | 0.9506 |
| 14260 | Boise City-Nampa, ID Ada County, ID Boise County, ID Canyon County, ID Gem County, ID Owyhee County, ID | 0.9298 |
| 14484 | Boston-Quincy, MA Norfolk County, MA Plymouth County, MA Suffolk County, MA | 1.2313 |

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| 12420 | Austin-Round Rock, TX Bastrop County, TX Caldwell County, TX Hays County, TX Travis County, TX Williamson County, TX | 0.9557 |
| 12540 | Bakersfield, CA Kern County, CA | 1.1786 |
| 12580 | Baltimore-Towson, MD Anne Arundel County, MD Baltimore County, MD Carroll County, MD Harford County, MD Howard County, MD Queen Anne's County, MD Baltimore City, MD | 1.0182 |
| 12620 | Bangor, ME Penobscot County, ME | 1.0009 |
| 12700 | Barnstable Town, MA Barnstable County, MA | 1.2876 |
| 12940 | Baton Rouge, LA Ascension Parish, LA East Baton Rouge Parish, LA East Feliciana Parish, LA Iberville Parish, LA Livingston Parish, LA Pointe Coupee Parish, LA St. Helena Parish, LA West Baton Rouge Parish, LA West Feliciana Parish, LA | 0.8549 |
| 12980 | Battle Creek, MI Calhoun County, MI | 0.9891 |
| 13020 | Bay City, MI Bay County, MI | 0.8954 |
| 13140 | Beaumont-Port Arthur, TX Hardin County, TX Jefferson County, TX Orange County, TX | 0.8749 |
| 13380 | Bellingham, WA Whatcom County, WA | 1.1784 |

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| 16180 | Carson City, NV Carson City, NV | 1.0628 |
| 16220 | Casper, WY Natrona County, WY | 1.0147 |
| 16300 | Cedar Rapids, IA Benton County, IA Jones County, IA Linn County, IA | 0.8857 |
| 16580 | Champaign-Urbana, IL Champaign County, IL Ford County, IL Piatt County, IL | 0.9911 |
| 16620 | Charleston, WV Boone County, WV Clay County, WV Kanawha County, WV Lincoln County, WV Putnam County, WV | 0.8195 |
| 16700 | Charleston-North Charleston-Summerville, SC Berkeley County, SC Charleston County, SC Dorchester County, SC | 0.9090 |
| 16740 | Charlotte-Gastonia-Concord, NC-SC Anson County, NC Cabarrus County, NC Gaston County, NC Mecklenburg County, NC Union County, NC York County, SC | 0.9311 |
| 16820 | Charlottesville, VA Albemarle County, VA Fluvanna County, VA Greene County, VA Nelson County, VA Charlottesville City, VA | 0.9215 |
| 16860 | Chattanooga, TN-GA Catoosa County, GA Dade County, GA Walker County, GA Hamilton County, TN Marion County, TN Sequatchie County, TN | 0.8763 |

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| 14500 | Boulder, CO Boulder County, CO | 1.0116 |
| 14540 | Bowling Green, KY Edmonson County, KY Warren County, KY | 0.8625 |
| 14740 | Bremerton-Silverdale, WA Kitsap County, WA | 1.1321 |
| 14860 | Bridgeport-Stamford-Norwalk, CT Fairfield County, CT | 1.2920 |
| 15180 | Brownsville-Harlingen, TX Cameron County, TX | 0.9211 |
| 15260 | Brunswick, GA Brantley County, GA Glynn County, GA McIntosh County, GA | 0.8484 |
| 15380 | Buffalo-Niagara Falls, NY Erie County, NY Niagara County, NY | 0.9617 |
| 15500 | Burlington, NC Alamance County, NC | 0.8691 |
| 15540 | Burlington-South Burlington, VT Chittenden County, VT Franklin County, VT Grand Isle County, VT | 1.0051 |
| 15764 | Cambridge-Newton-Framingham, MA Middlesex County, MA | 1.1208 |
| 15804 | Camden, NJ Burlington County, NJ Camden County, NJ Gloucester County, NJ | 1.0215 |
| 15940 | Canton-Massillon, OH Carroll County, OH Stark County, OH | 0.8966 |
| 15980 | Cape Coral-Fort Myers, FL Lee County, FL | 0.9369 |
| 16020 | Cape Girardeau-Jackson, MO-IL Alexander County, IL Bollinger County, MO Cape Girardeau County, MO | 0.8698 |

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| 17660 | Coeur d'Alene, ID Kootenai County, ID | 0.9395 |
| 17780 | College Station-Bryan, TX Brazos County, TX Burleson County, TX Robertson County, TX | 0.9719 |
| 17820 | Colorado Springs, CO El Paso County, CO Teller County, CO | 0.9877 |
| 17860 | Columbia, MO Boone County, MO Howard County, MO | 0.8130 |
| 17900 | Columbia, SC Calhoun County, SC Fairfield County, SC Kershaw County, SC Lexington County, SC Richland County, SC Saluda County, SC | 0.8760 |
| 17980 | Columbus, GA-AL Russell County, AL Chattahoochee County, GA Harris County, GA Marion County, GA Muscogee County, GA | 0.8989 |
| 18020 | Columbus, IN Bartholomew County, IN | 0.9752 |
| 18140 | Columbus, OH Delaware County, OH Fairfield County, OH Franklin County, OH Licking County, OH Madison County, OH Morrow County, OH Pickaway County, OH Union County, OH | 1.0024 |
| 18580 | Corpus Christi, TX Aransas County, TX Nueces County, TX San Patricio County, TX | 0.8703 |
| 18700 | Corvallis, OR Benton County, OR | 1.0930 |

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| 16940 | Cheyenne, WY Laramie County, WY | 0.9873 |
| 16974 | Chicago-Naperville-Joliet, IL Cook County, IL DeKalb County, IL DuPage County, IL Grundy County, IL Kane County, IL Kendall County, IL McHenry County, IL Will County, IL | 1.0632 |
| 17020 | Chico, CA Butte County, CA | 1.1345 |
| 17140 | Cincinnati-Middletown, OH-KY-IN Dearborn County, IN Franklin County, IN Ohio County, IN Boone County, KY Bracken County, KY Campbell County, KY Gallatin County, KY Grant County, KY Kenton County, KY Pendleton County, KY Brown County, OH Butler County, OH Clermont County, OH Hamilton County, OH Warren County, OH | 0.9453 |
| 17300 | Clarksville, TN-KY Christian County, KY Trigg County, KY Montgomery County, TN Stewart County, TN | 0.8216 |
| 17420 | Cleveland, TN Bradley County, TN Polk County, TN | 0.7697 |
| 17460 | Cleveland-Elyria-Mentor, OH Cuyahoga County, OH Geauga County, OH Lake County, OH Lorain County, OH Medina County, OH | 0.8967 |

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| 19740 | Denver-Aurora-Broomfield, CO Adams County, CO Arapahoe County, CO Broomfield County, CO Clear Creek County, CO Denver County, CO Douglas County, CO Elbert County, CO Gilpin County, CO Jefferson County, CO Park County, CO | 1.0679 |
| 19780 | Des Moines-West Des Moines, IA Dallas County, IA Guthrie County, IA Madison County, IA Polk County, IA Warren County, IA | 0.9812 |
| 19804 | Detroit-Livonia-Dearborn, MI Wayne County, MI | 0.9561 |
| 20020 | Dothan, AL Geneva County, AL Henry County, AL Houston County, AL | 0.6944 |
| 20100 | Dover, DE Kent County, DE | 0.9939 |
| 20220 | Dubuque, IA Dubuque County, IA | 0.8724 |
| 20260 | Duluth, MN-WI Carlton County, MN St. Louis County, MN Douglas County, WI | 1.0366 |
| 20500 | Durham-Chapel Hill, NC Chatham County, NC Durham County, NC Orange County, NC Person County, NC | 0.9663 |
| 20740 | Eau Claire, WI Chippewa County, WI Eau Claire County, WI | 0.9626 |

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| 18880 | Crestview-Fort Walton Beach-Destin, FL Okaloosa County, FL | 0.8988 |
| 19060 | Cumberland, MD-WV Allegany County, MD Mineral County, WV | 0.7849 |
| 19124 | Dallas-Plano-Irving, TX Collin County, TX Dallas County, TX Delta County, TX Denton County, TX Ellis County, TX Hunt County, TX Kaufman County, TX Rockwall County, TX | 0.9874 |
| 19140 | Dalton, GA Murray County, GA Whitfield County, GA | 0.8399 |
| 19180 | Danville, IL Vermilion County, IL | 0.9862 |
| 19260 | Danville, VA Pittsylvania County, VA Danville City, VA | 0.7919 |
| 19340 | Davenport-Moline-Rock Island, IA-IL Henry County, IL Mercer County, IL Rock Island County, IL Scott County, IA | 0.9084 |
| 19380 | Dayton, OH Greene County, OH Miami County, OH Montgomery County, OH Preble County, OH | 0.9309 |
| 19460 | Decatur, AL Lawrence County, AL Morgan County, AL | 0.7356 |
| 19500 | Decatur, IL Macon County, IL | 0.8032 |
| 19660 | Deltona-Daytona Beach-Ormond Beach, FL Volusia County, FL | 0.8892 |

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| 20764 | Edison-New Brunswick, NJ Middlesex County, NJ Monmouth County, NJ Ocean County, NJ Somerset County, NJ | 1.0892 |
| 20940 | El Centro, CA Imperial County, CA | 0.9630 |
| 21060 | Elizabethtown, KY Hardin County, KY Larue County, KY | 0.8745 |
| 21140 | Elkhart-Goshen, IN Elkhart County, IN | 0.9433 |
| 21300 | Elmira, NY Chemung County, NY | 0.8547 |
| 21340 | El Paso, TX El Paso County, TX | 0.8541 |
| 21500 | Erie, PA Erie County, PA | 0.8171 |
| 21660 | Eugene-Springfield, OR Lane County, OR | 1.1621 |
| 21780 | Evansville, IN-KY Gibson County, IN Posey County, IN Vanderburgh County, IN Warrick County, IN Henderson County, KY Webster County, KY | 0.8697 |
| 21820 | Fairbanks, AK Fairbanks North Star Borough, AK | 1.1356 |
| 21940 | Fajardo, PR Ceiba Municipio, PR Fajardo Municipio, PR Luquillo Municipio, PR | 0.3834 |
| 22020 | Fargo, ND-MN Cass County, ND Clay County, MN | 0.8161 |
| 22140 | Farmington, NM San Juan County, NM | 0.9825 |
| 22180 | Fayetteville, NC Cumberland County, NC Hoke County, NC | 0.9464 |
| 22220 | Fayetteville-Springdale-Rogers, AR-MO Benton County, AR Madison County, AR Washington County, AR McDonald County, MO | 0.9291 |
| 22380 | Flagstaff, AZ Coconino County, AZ | 1.2464 |
| 22420 | Flint, MI Genesee County, MI | 1.1150 |
| 22500 | Florence, SC Darlington County, SC Florence County, SC | 0.8235 |
| 22520 | Florence-Muscle Shoals, AL Colbert County, AL Lauderdale County, AL | 0.7752 |
| 22540 | Fond du Lac, WI Fond du Lac County, WI | 0.9319 |
| 22660 | Fort Collins-Loveland, CO Larimer County, CO | 0.9906 |
| 22744 | Fort Lauderdale-Pompano Beach-Deerfield Beach, FL Broward County, FL | 1.0190 |
| 22900 | Fort Smith, AR-OK Crawford County, AR Franklin County, AR Sebastian County, AR Le Flore County, OK Sequoyah County, OK | 0.7084 |
| 23060 | Fort Wayne, IN Allen County, IN Wells County, IN Whitley County, IN | 0.9396 |
| 23104 | Fort Worth-Arlington, TX Johnson County, TX Parker County, TX Tarrant County, TX Wise County, TX | 0.9558 |

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| 24780 | Greenville, NC Greene County, NC Pitt County, NC | 0.9665 |
| 24860 | Greenville-Mauldin-Easley, SC Greenville County, SC Laurens County, SC Pickens County, SC | 0.9465 |
| 25020 | Guayama, PR Arroyo Municipio, PR Guayama Municipio, PR Patillas Municipio, PR | 0.3742 |
| 25060 | Gulport-Biloxi, MS Hancock County, MS Harrison County, MS Stone County, MS | 0.8531 |
| 25180 | Hagerstown-Martinsburg, MD-WV Washington County, MD Berkeley County, WV Morgan County, WV | 0.9196 |
| 25260 | Hanford-Corcoran, CA Kings County, CA | 1.0732 |
| 25420 | Harrisburg-Carlisle, PA Cumberland County, PA Dauphin County, PA Perry County, PA | 0.9428 |
| 25500 | Harrisonburg, VA Rockingham County, VA Harrisonburg City, VA | 0.8800 |
| 25540 | Hartford-West Hartford-East Hartford, CT Hartford County, CT Middlesex County, CT Tolland County, CT | 1.0716 |
| 25620 | Hattiesburg, MS Forrest County, MS Lamar County, MS Perry County, MS | 0.7956 |
| 25860 | Hickory-Lenoir-Morganton, NC Alexander County, NC Burke County, NC Caldwell County, NC Catawba County, NC | 0.8881 |

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| 23420 | Fresno, CA Fresno County, CA | 1.1128 |
| 23460 | Gadsden, AL Etowah County, AL | 0.8125 |
| 23540 | Gainesville, FL Alachua County, FL Gilchrist County, FL | 0.9403 |
| 23580 | Gainesville, GA Hall County, GA | 0.9029 |
| 23844 | Gary, IN Jasper County, IN Lake County, IN Newton County, IN Porter County, IN | 0.9220 |
| 24020 | Glens Falls, NY Warren County, NY Washington County, NY | 0.8530 |
| 24140 | Goldsboro, NC Wayne County, NC | 0.8713 |
| 24220 | Grand Forks, ND-MN Polk County, MN Grand Forks County, ND | 0.7595 |
| 24300 | Grand Junction, CO Mesa County, CO | 0.9422 |
| 24340 | Grand Rapids-Wyoming, MI Barry County, MI Ionia County, MI Kent County, MI Newaygo County, MI | 0.9172 |
| 24500 | Great Falls, MT Cascade County, MT | 0.8488 |
| 24540 | Greeley, CO Weld County, CO | 0.9582 |
| 24580 | Green Bay, WI Brown County, WI Kewaunee County, WI Oconto County, WI | 0.9694 |
| 24660 | Greensboro-High Point, NC Guilford County, NC Randolph County, NC Rockingham County, NC | 0.8784 |

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| 25980 | Hinesville-Fort Stewart, GA ¹ Liberty County, GA Long County, GA | 0.8817 |
| 26100 | Holland-Grand Haven, MI Ottawa County, MI | 0.8548 |
| 26180 | Honolulu, HI Honolulu County, HI | 1.1610 |
| 26300 | Hot Springs, AR Garland County, AR | 0.9103 |
| 26380 | Houma-Bayou Cane-Thibodaux, LA Lafourche Parish, LA Terrebonne Parish, LA | 0.7864 |
| 26420 | Houston-Sugar Land-Baytown, TX Austin County, TX Brazoria County, TX Chambers County, TX Fort Bend County, TX Galveston County, TX Harris County, TX Liberty County, TX Montgomery County, TX San Jacinto County, TX Waller County, TX | 0.9976 |
| 26580 | Huntington-Ashland, WV-KY-OH Boyd County, KY Greenup County, KY Lawrence County, OH Cabell County, WV Wayne County, WV | 0.8919 |
| 26620 | Huntsville, AL Limestone County, AL Madison County, AL | 0.9022 |
| 26820 | Idaho Falls, ID Bonneville County, ID Jefferson County, ID | 0.9364 |
| 26900 | Indianapolis-Carmel, IN Boone County, IN Brown County, IN Hamilton County, IN Hancock County, IN Hendricks County, IN Johnson County, IN Marion County, IN Morgan County, IN Putnam County, IN Shelby County, IN | 0.9689 |
| 26980 | Iowa City, IA Johnson County, IA Washington County, IA | 1.0100 |
| 27060 | Ithaca, NY Tompkins County, NY | 0.8845 |
| 27100 | Jackson, MI Jackson County, MI | 0.8965 |
| 27140 | Jackson, MS Copiah County, MS Hinds County, MS Madison County, MS Rankin County, MS Simpson County, MS | 0.8197 |
| 27180 | Jackson, TN Chester County, TN Madison County, TN | 0.7996 |
| 27260 | Jacksonville, FL Baker County, FL Clay County, FL Duval County, FL Nassau County, FL St. Johns County, FL | 0.8905 |
| 27340 | Jacksonville, NC Onslow County, NC | 0.8011 |
| 27500 | Janesville, WI Rock County, WI | 0.9262 |
| 27620 | Jefferson City, MO Callaway County, MO Cole County, MO Moniteau County, MO Osage County, MO | 0.8247 |

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| 28700 | Kingsport-Bristol-Bristol, TN-VA Hawkins County, TN Sullivan County, TN Bristol City, VA Scott County, VA Washington County, VA | 0.7421 |
| 28740 | Kingston, NY Ulster County, NY | 0.9198 |
| 28940 | Knoxville, TN Anderson County, TN Blount County, TN Knox County, TN Loudon County, TN Union County, TN | 0.7863 |
| 29020 | Kokomo, IN Howard County, IN Tipton County, IN | 0.9214 |
| 29100 | La Crosse, WI-MN Houston County, MN La Crosse County, WI | 0.9714 |
| 29140 | Lafayette, IN Benton County, IN Carroll County, IN Tippecanoe County, IN | 0.9536 |
| 29180 | Lafayette, LA Lafayette Parish, LA St. Martin Parish, LA | 0.8335 |
| 29340 | Lake Charles, LA Calcasieu Parish, LA Cameron Parish, LA | 0.8022 |
| 29404 | Lake County-Kenosha County, IL-WI Lake County, IL Kenosha County, WI | 1.0338 |
| 29420 | Lake Havasu City-Kingman, AZ Mohave County, AZ | 0.9997 |
| 29460 | Lakeland-Winter Haven, FL Polk County, FL | 0.8457 |
| 29540 | Lancaster, PA Lancaster County, PA | 0.9467 |

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| 27740 | Johnson City, TN Carter County, TN Unicoi County, TN Washington County, TN | 0.7839 |
| 27780 | Johnstown, PA Cambria County, PA | 0.8741 |
| 27860 | Jonesboro, AR Craighead County, AR Poinsett County, AR | 0.7680 |
| 27900 | Joplin, MO Jasper County, MO Newton County, MO | 0.8214 |
| 28020 | Kalamazoo-Portage, MI Kalamazoo County, MI Van Buren County, MI | 0.9939 |
| 28100 | Kankakee-Bradley, IL Kankakee County, IL | 0.9837 |
| 28140 | Kansas City, MO-KS Franklin County, KS Johnson County, KS Leavenworth County, KS Linn County, KS Miami County, KS Wyandotte County, KS Bates County, MO Caldwell County, MO Cass County, MO Clay County, MO Clinton County, MO Jackson County, MO Lafayette County, MO Platte County, MO Ray County, MO | 0.9663 |
| 28420 | Kennewick-Pasco-Richland, WA Benton County, WA Franklin County, WA | 0.9611 |
| 28660 | Killeen-Temple-Fort Hood, TX Bell County, TX Coryell County, TX Lampasas County, TX | 0.9529 |

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| 30860 | Logan, UT-ID Franklin County, ID Cache County, UT | 0.8617 |
| 30980 | Longview, TX Gregg County, TX Rusk County, TX Upshur County, TX | 0.8556 |
| 31020 | Longview, WA Cowlitz County, WA | 1.0019 |
| 31084 | Los Angeles-Long Beach-Glendale, CA Los Angeles County, CA | 1.2305 |
| 31140 | Louisville-Jefferson County, KY-IN Clark County, IN Floyd County, IN Harrison County, IN Washington County, IN Bullitt County, KY Henry County, KY Meade County, KY Nelson County, KY Oldham County, KY Shelby County, KY Spencer County, KY Trimble County, KY | 0.8927 |
| 31180 | Lubbock, TX Crosby County, TX Lubbock County, TX | 0.8820 |
| 31340 | Lynchburg, VA Annherst County, VA Appomattox County, VA Bedford County, VA Campbell County, VA Bedford City, VA Lynchburg City, VA | 0.8792 |
| 31420 | Macon, GA Bibb County, GA Crawford County, GA Jones County, GA Monroe County, GA Twiggs County, GA | 0.9082 |
| 31460 | Madera-Chowchilla, CA Madera County, CA | 0.8139 |

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| 29620 | Lansing-East Lansing, MI Clinton County, MI Eaton County, MI Ingham County, MI | 1.0497 |
| 29700 | Laredo, TX Webb County, TX | 0.7753 |
| 29740 | Las Cruces, NM Dona Ana County, NM | 0.9133 |
| 29820 | Las Vegas-Paradise, NV Clark County, NV | 1.2083 |
| 29940 | Lawrence, KS Douglas County, KS | 0.8879 |
| 30020 | Lawton, OK Comanche County, OK | 0.8571 |
| 30140 | Lebanon, PA Lebanon County, PA | 0.8066 |
| 30300 | Lewiston, ID-WA Nez Perce County, ID Asotin County, WA | 0.9088 |
| 30340 | Lewiston-Auburn, ME Androscoggin County, ME | 0.9065 |
| 30460 | Lexington-Fayette, KY Bourbon County, KY Clark County, KY Fayette County, KY Jessamine County, KY Scott County, KY Woodford County, KY | 0.8860 |
| 30620 | Lima, OH Allen County, OH | 0.9399 |
| 30700 | Lincoln, NE Lancaster County, NE Seward County, NE | 0.9638 |
| 30780 | Little Rock-North Little Rock-Conway, AR Faulkner County, AR Grant County, AR Lonoke County, AR Perry County, AR Pulaski County, AR Saline County, AR | 0.8571 |

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| 33340 | Milwaukee-Waukesha-West Allis, WI Milwaukee County, WI Ozaukee County, WI Washington County, WI Waukesha County, WI | 0.9954 |
| 33460 | Minneapolis-St. Paul-Bloomington, MN-WI Anoka County, MN Carver County, MN Chisago County, MN Dakota County, MN Hennepin County, MN Isanti County, MN Ramsey County, MN Scott County, MN Sherburne County, MN Washington County, MN Wright County, MN Pierce County, WI St. Croix County, WI | 1.1173 |
| 33540 | Missoula, MT Missoula County, MT | 0.9181 |
| 33660 | Mobile, AL Mobile County, AL | 0.7986 |
| 33700 | Modesto, CA Stanislaus County, CA | 1.2678 |
| 33740 | Monroe, LA Ouachita Parish, LA Union Parish, LA | 0.7939 |
| 33780 | Monroe, MI Monroe County, MI | 0.8754 |
| 33860 | Montgomery, AL Autauga County, AL Elmore County, AL Lowndes County, AL Montgomery County, AL Morgantown, WV Monongalia County, WV Preston County, WV | 0.8119 |
| 34060 | Morristown, TN Grainger County, TN Hamblen County, TN Jefferson County, TN | 0.8222 |
| 34100 | | 0.6977 |

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| 31540 | Madison, WI Columbia County, WI Dane County, WI Iowa County, WI | 1.1267 |
| 31700 | Manchester-Nashua, NH Hillsborough County, NH | 1.0050 |
| 31740 | Manhattan, KS Geary County, KS Pottawatomie County, KS Riley County, KS | 0.7936 |
| 31860 | Mankato-North Mankato, MN Blue Earth County, MN Nicollet County, MN | 0.9374 |
| 31900 | Mansfield, OH Richland County, OH | 0.9242 |
| 32420 | Mayaguez, PR Hormigueros Municipio, PR Mayaguez Municipio, PR | 0.3687 |
| 32580 | McAllen-Edinburg-Mission, TX Hidalgo County, TX | 0.8904 |
| 32780 | Medford, OR Jackson County, OR | 1.0349 |
| 32820 | Memphis, TN-MS-AR Crittenden County, AR DeSoto County, MS Marshall County, MS Tate County, MS Tunica County, MS Fayette County, TN Shelby County, TN Tipton County, TN | 0.9247 |
| 32900 | Merced, CA Merced County, CA | 1.2451 |
| 33124 | Miami-Miami Beach-Kendall, FL Miami-Dade County, FL | 1.0116 |
| 33140 | Michigan City-La Porte, IN LaPorte County, IN | 0.9386 |
| 33260 | Midland, TX Midland County, TX | 1.0546 |

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|-------|---|--------|
| 35380 | New Orleans-Metairie-Kenner, LA Jefferson Parish, LA Orleans Parish, LA Plaquemines Parish, LA St. Bernard Parish, LA St. Charles Parish, LA St. John the Baptist Parish, LA St. Tammany Parish, LA | 0.9053 |
| 35644 | New York-White Plains-Wayne, NY-NJ Bergen County, NJ Hudson County, NJ Passaic County, NJ Bronx County, NY Kings County, NY New York County, NY Putnam County, NY Queens County, NY Richmond County, NY Rockland County, NY Westchester County, NY | 1.3063 |
| 35660 | Niles-Benton Harbor, MI Berrien County, MI | 0.8654 |
| 35840 | North Port-Bradenton-Sarasota-Venice, FL Manatee County, FL Sarasota County, FL | 0.9464 |
| 35980 | Norwich-New London, CT New London County, CT | 1.1261 |
| 36084 | Oakland-Fremont-Hayward, CA Alameda County, CA Contra Costa County, CA | 1.6090 |
| 36100 | Ocala, FL Marion County, FL | 0.8475 |
| 36140 | Ocean City, NJ Cape May County, NJ | 1.0673 |
| 36220 | Odessa, TX Ector County, TX | 0.9839 |
| 36260 | Ogden-Clearfield, UT Davis County, UT Morgan County, UT Weber County, UT | 0.9248 |

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|-------|---|--------|
| 34580 | Mount Vernon-Anacortes, WA Skagit County, WA | 1.0266 |
| 34620 | Muncie, IN Delaware County, IN | 0.7841 |
| 34740 | Muskegon-Norton Shores, MI Muskegon County, MI | 0.9997 |
| 34820 | Myrtle Beach-North Myrtle Beach-Conway, SC Horry County, SC | 0.8669 |
| 34900 | Napa, CA Napa County, CA | 1.4739 |
| 34940 | Naples-Marco Island, FL Collier County, FL | 0.9769 |
| 34980 | Nashville-Davidson—Murfreesboro-Franklin, TN Cannon County, TN Cheatham County, TN Davidson County, TN Dickson County, TN Hickman County, TN Macon County, TN Robertson County, TN Rutherford County, TN Smith County, TN Sumner County, TN Trousdale County, TN Williamson County, TN Wilson County, TN | 0.9239 |
| 35004 | Nassau-Suffolk, NY Nassau County, NY Suffolk County, NY | 1.2450 |
| 35084 | Newark-Union, NJ-PA Essex County, NJ Hunterdon County, NJ Morris County, NJ Sussex County, NJ Union County, NJ Pike County, PA | 1.1346 |
| 35300 | New Haven-Milford, CT New Haven County, CT | 1.1591 |

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|-------|--|--------|
| 37620 | Parkersburg-Marietta-Vienna, WV-OH Washington County, OH Pleasants County, WV Wirt County, WV Wood County, WV | 0.7670 |
| 37700 | Pascagoula, MS George County, MS Jackson County, MS | 0.7909 |
| 37764 | Peabody, MA Essex County, MA | 1.0481 |
| 37860 | Pensacola-Ferry Pass-Brent, FL Escambia County, FL Santa Rosa County, FL | 0.8037 |
| 37900 | Peoria, IL Marshall County, IL Peoria County, IL Stark County, IL Tazewell County, IL Woodford County, IL | 0.8856 |
| 37964 | Philadelphia, PA Bucks County, PA Chester County, PA Delaware County, PA Montgomery County, PA Philadelphia County, PA | 1.0786 |
| 38060 | Phoenix-Mesa-Scottsdale, AZ Maricopa County, AZ Pinal County, AZ | 1.0595 |
| 38220 | Pine Bluff, AR Cleveland County, AR Jefferson County, AR Lincoln County, AR | 0.7723 |
| 38300 | Pittsburgh, PA Allegheny County, PA Armstrong County, PA Beaver County, PA Butler County, PA Fayette County, PA Washington County, PA Westmoreland County, PA | 0.8695 |
| 38340 | Pittsfield, MA Berkshire County, MA | 1.0648 |

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|-------|---|--------|
| 36420 | Oklahoma City, OK Canadian County, OK Cleveland County, OK Grady County, OK Lincoln County, OK Logan County, OK McClain County, OK Oklahoma County, OK | 0.8960 |
| 36500 | Olympia, WA Thurston County, WA | 1.1373 |
| 36540 | Omaha-Council Bluffs, NE-IA Harrison County, IA Mills County, IA Pottawattamie County, IA Cass County, NE Douglas County, NE Sully County, NE Saunders County, NE Washington County, NE | 0.9894 |
| 36740 | Orlando-Kissimmee, FL Lake County, FL Orange County, FL Osceola County, FL Seminole County, FL | 0.9155 |
| 36780 | Oshkosh-Neenah, WI Winnebago County, WI | 0.9342 |
| 36980 | Owensboro, KY Davies County, KY Hancock County, KY McLean County, KY | 0.8226 |
| 37100 | Oxnard-Thousand Oaks-Ventura, CA Ventura County, CA | 1.2841 |
| 37340 | Palm Bay-Melbourne-Titusville, FL Brevard County, FL | 0.9069 |
| 37380 | Palm Coast, FL Flagler County, FL | 0.9402 |
| 37460 | Panama City-Lynn Haven-Panama City Beach, FL Bay County, FL | 0.8413 |

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|-------|--|--------|-------|---|--------|
| 38540 | Pocatello, ID Bannock County, ID Power County, ID | 0.9455 | 39540 | Racine, WI Racine County, WI | 0.8651 |
| 38660 | Ponce, PR Juana Diaz Municipio, PR Ponce Municipio, PR Villalba Municipio, PR | 0.4188 | 39580 | Raleigh-Cary, NC Franklin County, NC Johnston County, NC Wake County, NC | 0.9626 |
| 38860 | Portland-South Portland-Biddeford, ME Cumberland County, ME Sagadahoc County, ME York County, ME | 0.9690 | 39660 | Rapid City, SD Meade County, SD Pennington County, SD | 1.0233 |
| 38900 | Portland-Vancouver-Beaverton, OR-WA Clackamas County, OR Columbia County, OR Multnomah County, OR Washington County, OR Yamhill County, OR Clark County, WA Skamania County, WA | 1.1489 | 39740 | Reading, PA Berks County, PA | 0.9240 |
| 38940 | Port St. Lucie, FL Martin County, FL St. Lucie County, FL | 0.9814 | 39820 | Redding, CA Shasta County, CA | 1.5023 |
| 39100 | Poughkeepsie-Newburgh-Middletown, NY Dutchess County, NY Orange County, NY | 1.1361 | 39900 | Reno-Sparks, NV Storey County, NV Washoe County, NV | 1.0623 |
| 39140 | Prescott, AZ Yavapai County, AZ | 1.2298 | 40060 | Richmond, VA Amelia County, VA Caroline County, VA Charles City County, VA Chesterfield County, VA Cumberland County, VA Dinwiddie County, VA Goochland County, VA Hanover County, VA Henrico County, VA King and Queen County, VA King William County, VA Louisa County, VA New Kent County, VA Powhatan County, VA Prince George County, VA Sussex County, VA Colonial Heights City, VA Hopewell City, VA Petersburg City, VA Richmond City, VA | 0.9824 |
| 39300 | Providence-New Bedford-Fall River, RI-MA Bristol County, MA Bristol County, RI Kent County, RI Newport County, RI Providence County, RI Washington County, RI | 1.0666 | 40140 | Riverside-San Bernardino-Ontario, CA Riverside County, CA San Bernardino County, CA | 1.1434 |
| 39340 | Provo-Orem, UT Juab County, UT Utah County, UT | 0.9432 | | | |
| 39380 | Pueblo, CO Pueblo County, CO | 0.8697 | | | |
| 39460 | Punta Gorda, FL Charlotte County, FL | 0.8827 | | | |

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|-------|--|--------|
| 41140 | St. Joseph, MO-KS Doniphan County, KS Andrew County, MO Buchanan County, MO DeKalb County, MO | 1.0286 |
| 41180 | St. Louis, MO-IL Bond County, IL Calhoun County, IL Clinton County, IL Jersey County, IL Macoupin County, IL Madison County, IL Monroe County, IL St. Clair County, IL Crawford County, MO Franklin County, MO Jefferson County, MO Lincoln County, MO St. Charles County, MO St. Louis County, MO Warren County, MO Washington County, MO St. Louis City, MO | 0.9172 |
| 41420 | Salem, OR Marion County, OR Polk County, OR | 1.1258 |
| 41500 | Salinas, CA Monterey County, CA | 1.5650 |
| 41540 | Salisbury, MD Somerset County, MD Wicomico County, MD | 0.9254 |
| 41620 | Salt Lake City, UT Salt Lake County, UT Summit County, UT Tooele County, UT | 0.9444 |
| 41660 | San Angelo, TX Irion County, TX Tom Green County, TX | 0.8293 |

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| 40220 | Roanoke, VA Botetourt County, VA Craig County, VA Franklin County, VA Roanoke County, VA Roanoke City, VA Salem City, VA | 0.9169 |
| 40340 | Rochester, MN Dodge County, MN Olmsted County, MN Wabasha County, MN | 1.0834 |
| 40380 | Rochester, NY Livingston County, NY Monroe County, NY Ontario County, NY Orleans County, NY Wayne County, NY | 0.8627 |
| 40420 | Rockford, IL Boone County, IL Winnebago County, IL | 0.9968 |
| 40484 | Rockingham County-Strafford County, NH Rockingham County, NH Strafford County, NH | 1.0216 |
| 40580 | Rocky Mount, NC Edgecombe County, NC Nash County, NC | 0.9125 |
| 40660 | Rome, GA Floyd County, GA | 0.8854 |
| 40900 | Sacramento-Arden-Arcade-Roseville, CA El Dorado County, CA Placer County, CA Sacramento County, CA Yolo County, CA | 1.3786 |
| 40980 | Saginaw-Saginaw Township North, MI Saginaw County, MI | 0.8519 |
| 41060 | St. Cloud, MN Benton County, MN Stearns County, MN | 1.0757 |
| 41100 | St. George, UT Washington County, UT | 0.9097 |

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| 41700 | San Antonio, TX Atascosa County, TX Bandera County, TX Bexar County, TX Comal County, TX Guadalupe County, TX Kendall County, TX Medina County, TX Wilson County, TX | 0.9028 |
| 41740 | San Diego-Carlsbad-San Marcos, CA San Diego County, CA | 1.1951 |
| 41780 | Sandusky, OH Erie County, OH | 0.8192 |
| 41884 | San Francisco-San Mateo-Redwood City, CA Marin County, CA San Francisco County, CA San Mateo County, CA | 1.5813 |
| 41900 | San Germán-Cabo Rojo, PR Cabo Rojo Municipio, PR Lajas Municipio, PR Sabana Grande Municipio, PR San Germán Municipio, PR | 0.4626 |
| 41940 | San Jose-Sunnyvale-Santa Clara, CA San Benito County, CA Santa Clara County, CA | 1.6826 |

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| 41980 | San Juan-Caguas-Guaynabo, PR Aguas Buenas Municipio, PR Aibonito Municipio, PR Arecibo Municipio, PR Barceloneta Municipio, PR Barranquitas Municipio, PR Bayamón Municipio, PR Caguas Municipio, PR Camuy Municipio, PR Canóvanas Municipio, PR Carolina Municipio, PR Cataño Municipio, PR Cayey Municipio, PR Ciales Municipio, PR Cidra Municipio, PR Comerio Municipio, PR Corozal Municipio, PR Dorado Municipio, PR Florida Municipio, PR Guaynabo Municipio, PR Gurabo Municipio, PR Hatillo Municipio, PR Humacao Municipio, PR Juncos Municipio, PR Las Piedras Municipio, PR Loíza Municipio, PR Manatí Municipio, PR Maunabo Municipio, PR Morovis Municipio, PR Naguabo Municipio, PR Naranjito Municipio, PR Orocovis Municipio, PR Quebradillas Municipio, PR Río Grande Municipio, PR San Juan Municipio, PR San Lorenzo Municipio, PR Toa Alta Municipio, PR Toa Baja Municipio, PR Trujillo Alto Municipio, PR Vega Alta Municipio, PR Vega Baja Municipio, PR Yabucoa Municipio, PR | 0.4353 |
| 42020 | San Luis Obispo-Paso Robles, CA San Luis Obispo County, CA | 1.3106 |

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| 43620 | Sioux Falls, SD Lincoln County, SD McCook County, SD Minnehaha County, SD Turner County, SD | 0.9181 |
| 43780 | South Bend-Mishawaka, IN-MI St. Joseph County, IN Cass County, MI | 0.9454 |
| 43900 | Spartanburg, SC Spartanburg County, SC | 0.9353 |
| 44060 | Spokane, WA Spokane County, WA | 1.0541 |
| 44100 | Springfield, IL Menard County, IL Sangamon County, IL | 0.8987 |
| 44140 | Springfield, MA Franklin County, MA Hampden County, MA Hampshire County, MA | 1.0270 |
| 44180 | Springfield, MO Christian County, MO Dallas County, MO Greene County, MO Polk County, MO Webster County, MO | 0.8706 |
| 44220 | Springfield, OH Clark County, OH | 0.9008 |
| 44300 | State College, PA Centre County, PA | 0.9279 |
| 44600 | Steubenville-Weirton, OH-WV Jefferson County, OH Brooke County, WV Hancock County, WV | 0.7075 |
| 44700 | Stockton, CA San Joaquin County, CA | 1.3087 |
| 44940 | Sumter, SC Sumter County, SC | 0.7573 |
| 45060 | Syracuse, NY Madison County, NY Onondaga County, NY Oswego County, NY | 0.9806 |

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| 42044 | Santa Ana-Anaheim-Irvine, CA Orange County, CA | 1.2034 |
| 42060 | Santa Barbara-Santa Maria-Goleta, CA Santa Barbara County, CA | 1.2279 |
| 42100 | Santa Cruz-Watsonville, CA Santa Cruz County, CA | 1.6910 |
| 42140 | Santa Fe, NM Santa Fe County, NM | 1.0692 |
| 42220 | Santa Rosa-Petaluma, CA Sonoma County, CA | 1.5837 |
| 42340 | Savannah, GA Bryan County, GA Chatham County, GA Effingham County, GA | 0.9007 |
| 42540 | Scranton--Wilkes-Barre, PA Lackawanna County, PA Luzerne County, PA Wyoming County, PA | 0.8353 |
| 42644 | Seattle-Bellevue-Everett, WA King County, WA Snohomish County, WA | 1.1575 |
| 42680 | Sebastian-Vero Beach, FL Indian River County, FL | 0.9059 |
| 43100 | Sheboygan, WI Sheboygan County, WI | 0.9222 |
| 43300 | Sherman-Denison, TX Grayson County, TX | 0.8035 |
| 43340 | Shreveport-Bossier City, LA Bossier Parish, LA Caddo Parish, LA De Soto Parish, LA | 0.8530 |
| 43580 | Sioux City, IA-NE-SD Woodbury County, IA Dakota County, NE Dixon County, NE Union County, SD | 0.9566 |

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| 46220 | Tuscaloosa, AL Greene County, AL Hale County, AL Tuscaloosa County, AL | 0.8691 |
| 46340 | Tyler, TX Smith County, TX | 0.8361 |
| 46540 | Utica-Rome, NY Herkimer County, NY Oneida County, NY | 0.8437 |
| 46660 | Valdosta, GA Brooks County, GA Echols County, GA Lanier County, GA Lowndes County, GA | 0.7846 |
| 46700 | Vallejo-Fairfield, CA Solano County, CA | 1.4680 |
| 47020 | Victoria, TX Calhoun County, TX Goliad County, TX Victoria County, TX | 0.8460 |
| 47220 | Vineland-Millville-Bridgeton, NJ Cumberland County, NJ | 1.0253 |
| 47260 | Virginia Beach-Norfolk-Newport News, VA-NC Currituck County, NC Gloucester County, VA Isle of Wight County, VA James City County, VA Mathews County, VA Surry County, VA York County, VA Chesapeake City, VA Hampton City, VA Newport News City, VA Norfolk City, VA Poquoson City, VA Portsmouth City, VA Suffolk City, VA Virginia Beach City, VA Williamsburg City, VA | 0.9028 |
| 47300 | Visalia-Porterville, CA Tulare County, CA | 1.0310 |

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| 45104 | Tacoma, WA Pierce County, WA | 1.1411 |
| 45220 | Tallahassee, FL Gadsden County, FL Jefferson County, FL Leon County, FL Wakulla County, FL | 0.8619 |
| 45300 | Tampa-St. Petersburg-Clearwater, FL Hernando County, FL Hillsborough County, FL Pasco County, FL Pinellas County, FL | 0.9099 |
| 45460 | Terre Haute, IN Clay County, IN Sullivan County, IN Vermillion County, IN Vigo County, IN | 0.9237 |
| 45500 | Texarkana, TX-Texarkana, AR Miller County, AR Bowie County, TX | 0.7961 |
| 45780 | Toledo, OH Fulton County, OH Lucas County, OH Ottawa County, OH Wood County, OH | 0.9175 |
| 45820 | Topeka, KS Jackson County, KS Jefferson County, KS Osage County, KS Shawnee County, KS Wabaunsee County, KS | 0.8844 |
| 45940 | Trenton-Ewing, NJ Mercer County, NJ | 1.0092 |
| 46060 | Tucson, AZ Pima County, AZ | 0.9346 |
| 46140 | Tulsa, OK Creek County, OK Okmulgee County, OK Osage County, OK Pawnee County, OK Rogers County, OK Tulsa County, OK Wagoner County, OK | 0.8387 |

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| 48540 | Wheeling, WV-OH Belmont County, OH Marshall County, WV Ohio County, WV | 0.6755 |
| 48620 | Wichita, KS Butler County, KS Harvey County, KS Sedgwick County, KS Sumner County, KS | 0.8673 |
| 48660 | Wichita Falls, TX Archer County, TX Clay County, TX Wichita County, TX | 1.0128 |
| 48700 | Williamsport, PA Lycoming County, PA | 0.8108 |
| 48864 | Wilmington, DE-MD-NJ New Castle County, DE Cecil County, MD Salem County, NJ | 1.0694 |
| 48900 | Wilmington, NC Brunswick County, NC New Hanover County, NC Pender County, NC | 0.9120 |
| 49020 | Winchester, VA-WV Frederick County, VA Winchester City, VA Hampshire County, WV | 0.9134 |
| 49180 | Winston-Salem, NC Davie County, NC Forsyth County, NC Stokes County, NC Yadkin County, NC | 0.8317 |
| 49340 | Worcester, MA Worcester County, MA | 1.1027 |
| 49420 | Yakima, WA Yakima County, WA | 1.0464 |
| 49500 | Yauco, PR Guánica Municipio, PR Guayanilla Municipio, PR Peñuelas Municipio, PR Yauco Municipio, PR | 0.3768 |

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| 47380 | Waco, TX McLennan County, TX | 0.8584 |
| 47580 | Warner Robins, GA Houston County, GA | 0.8129 |
| 47644 | Warren-Troy-Farmington Hills, MI Lapeer County, MI Livingston County, MI Macomb County, MI Oakland County, MI St. Clair County, MI | 0.9633 |
| 47894 | Washington-Arlington-Alexandria, DC-VA-MD-WV District of Columbia, DC Calvert County, MD Charles County, MD Prince George's County, MD Arlington County, VA Clarke County, VA Fairfax County, VA Fauquier County, VA Loudoun County, VA Prince William County, VA Spotsylvania County, VA Stafford County, VA Warren County, VA Alexandria City, VA Fairfax City, VA Falls Church City, VA Fredericksburg City, VA Manassas City, VA Manassas Park City, VA Jefferson County, WV | 1.0839 |
| 47940 | Waterloo-Cedar Falls, IA Black Hawk County, IA Bremer County, IA Grundy County, IA | 0.8391 |
| 48140 | Wausau, WI Marathon County, WI | 0.8989 |
| 48300 | Wenatchee-East Wenatchee, WA Chelan County, WA Douglas County, WA | 1.0199 |
| 48424 | West Palm Beach-Boca Raton-Boynton Beach, FL Palm Beach County, FL | 0.9853 |

TABLE B: FY 2012 WAGE INDEX BASED ON CBSA LABOR MARKET AREAS FOR RURAL AREAS

| State Code | Nonurban Area | Wage Index |
|------------|---------------|------------|
| 1 | Alabama | 0.7249 |
| 2 | Alaska | 1.2885 |
| 3 | Arizona | 0.8853 |
| 4 | Arkansas | 0.7215 |
| 5 | California | 1.1428 |
| 6 | Colorado | 1.0136 |
| 7 | Connecticut | 1.1317 |
| 8 | Delaware | 1.0038 |
| 10 | Florida | 0.8386 |
| 11 | Georgia | 0.7566 |
| 12 | Hawaii | 1.1003 |
| 13 | Idaho | 0.7553 |
| 14 | Illinois | 0.8450 |
| 15 | Indiana | 0.8570 |
| 16 | Iowa | 0.8644 |
| 17 | Kansas | 0.8079 |
| 18 | Kentucky | 0.7846 |
| 19 | Louisiana | 0.7787 |
| 20 | Maine | 0.8601 |

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| 49620 | York-Hanover, PA York County, PA | 0.9704 |
| 49660 | Youngstown-Warren-Boardman, OH-PA Mahoning County, OH Trumbull County, OH Mercer County, PA | 0.8360 |
| 49700 | Yuba City, CA ¹ Sutter County, CA Yuba County, CA | 1.2783 |
| 49740 | Yuma, AZ Yuma County, AZ | 0.9378 |

¹ At this time, there are no hospitals located in this urban area on which to base a wage index.

| State Code | Nonurban Area | Wage Index |
|------------|---------------------------|------------|
| 21 | Maryland | 0.9319 |
| 22 | Massachusetts | 1.4004 |
| 23 | Michigan | 0.8320 |
| 24 | Minnesota | 0.9037 |
| 25 | Mississippi | 0.7549 |
| 26 | Missouri | 0.7699 |
| 27 | Montana | 0.8641 |
| 28 | Nebraska | 0.8898 |
| 29 | Nevada | 0.9672 |
| 30 | New Hampshire | 1.0473 |
| 31 | New Jersey | ----- |
| 32 | New Mexico | 0.8905 |
| 33 | New York | 0.8176 |
| 34 | North Carolina | 0.8291 |
| 35 | North Dakota | 0.7317 |
| 36 | Ohio | 0.8480 |
| 37 | Oklahoma | 0.7869 |
| 38 | Oregon | 1.0308 |
| 39 | Pennsylvania | 0.8456 |
| 40 | Puerto Rico ¹ | 0.4047 |
| 41 | Rhode Island ¹ | ----- |
| 42 | South Carolina | 0.8313 |
| 43 | South Dakota | 0.8324 |
| 44 | Tennessee | 0.7744 |
| 45 | Texas | 0.7946 |
| 46 | Utah | 0.8745 |
| 47 | Vermont | 0.9738 |
| 48 | Virgin Islands | 0.7528 |
| 49 | Virginia | 0.7841 |
| 50 | Washington | 1.0234 |
| 51 | West Virginia | 0.7393 |
| 52 | Wisconsin | 0.8997 |
| 53 | Wyoming | 0.9422 |
| 65 | Guam | 0.9611 |

¹ All counties within the State are classified as urban, with the exception of Puerto Rico. Puerto Rico has areas designated as rural; however, no short-term, acute care hospitals are located in the area(s) for FY 2012. The Puerto Rico wage index is the same as FY 2011.



FEDERAL REGISTER

Vol. 76

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No. 88

May 6, 2011

Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 412

Medicare Program; Inpatient Psychiatric Facilities Prospective Payment System—Update for Rate Year Beginning July 1, 2011 (RY 2012); Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS-1346-F]

RIN 0938-AQ23

Medicare Program; Inpatient Psychiatric Facilities Prospective Payment System—Update for Rate Year Beginning July 1, 2011 (RY 2012)

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

ACTION: Final rule.

SUMMARY: This final rule updates the prospective payment rates for Medicare inpatient hospital services provided by inpatient psychiatric facilities (IPFs) for discharges occurring during the rate year (RY) beginning July 1, 2011 through September 30, 2012. The final rule also changes the IPF prospective payment system (PPS) payment rate update period to a RY that coincides with a fiscal year (FY). In addition, the rule implements policy changes affecting the IPF PPS teaching adjustment. It also rebases and revises the Rehabilitation, Psychiatric, and Long-Term Care (RPL) market basket, and makes some clarifications and corrections to terminology and regulations text.

DATES: These regulations are effective on July 1, 2011.

FOR FURTHER INFORMATION CONTACT:

Dorothy Myrick or Jana Lindquist, (410) 786-4533 (for general information).

Mary Carol Barron, (410) 786-7943, or Bridget Dickensheets, (410) 786-8670, (for information regarding the market basket and labor-related share).

Theresa Bean, (410) 786-2287 (for information regarding the regulatory impact analysis).

SUPPLEMENTARY INFORMATION:

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 - k. Medical Instruments
 - l. Photographic Supplies
 - m. Rubber and Plastics
 - n. Paper and Printing Products
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 - p. Machinery and Equipment
 - q. Miscellaneous Products
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Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

BBRA Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, (Pub. L. 106-113)

CBSA Core-Based Statistical Area

CCR Cost-to-charge ratio

CAH Critical access hospital

DSM-IV-TR Diagnostic and Statistical Manual of Mental Disorders Fourth Edition—Text Revision

DRGs Diagnosis-related groups

FY Federal fiscal year (October 1 through September 30)

ICD-9-CM International Classification of Diseases, 9th Revision, Clinical Modification

IPFs Inpatient psychiatric facilities

IRFs Inpatient rehabilitation facilities

LTCHs Long-term care hospitals

MedPAR Medicare provider analysis and review file

RPL Rehabilitation, Psychiatric, and Long-Term Care

RY Rate Year (July 1 through June 30)

TEFRA Tax Equity and Fiscal Responsibility Act of 1982, (Pub. L. 97-248)

I. Background

A. Annual Requirements for Updating the IPF PPS

In November 2004, we implemented the inpatient psychiatric facilities (IPF) prospective payment system (PPS) in a final rule that appeared in the November 15, 2004 **Federal Register** (69 FR 66922). In developing the IPF PPS, in order to ensure that the IPF PPS is able to account adequately for each IPF's case-mix, we performed an

extensive regression analysis of the relationship between the per diem costs and certain patient and facility characteristics to determine those characteristics associated with statistically significant cost differences on a per diem basis. For characteristics with statistically significant cost differences, we used the regression coefficients of those variables to determine the size of the corresponding payment adjustments.

In that final rule, we explained that we believe it is important to delay updating the adjustment factors derived from the regression analysis until we have IPF PPS data that includes as much information as possible regarding the patient-level characteristics of the population that each IPF serves. Therefore, we indicated that we did not intend to update the regression analysis and recalculate the Federal per diem base rate and the patient- and facility-level adjustments until we complete that analysis. Until that analysis is complete, we stated our intention to publish a notice in the **Federal Register** each spring to update the IPF PPS (71 FR 27041). However, in this final rule, we are changing the payment rate update period to a rate year (RY) that coincides with a fiscal year (FY) update. Therefore, future update notices will be published in the **Federal Register** in the summer. We discuss this change in more detail in section III of this final rule.

Updates to the IPF PPS as specified in 42 CFR § 412.428 include the following:

- A description of the methodology and data used to calculate the updated Federal per diem base payment amount.
- The rate of increase factor as described in § 412.424(a)(2)(iii), which is based on the Excluded Hospital With Capital market basket under the update methodology of section 1886(b)(3)(B)(ii) of the Social Security Act (the Act) for each year (effective from the implementation period until June 30, 2006).
- For discharges occurring on or after July 1, 2006, the rate of increase factor for the Federal portion of the IPF's payment, which is based on the Rehabilitation, Psychiatric, and Long-Term Care (RPL) market basket.
- The best available hospital wage index and information regarding whether an adjustment to the Federal per diem base rate is needed to maintain budget neutrality.
- Updates to the fixed dollar loss threshold amount in order to maintain the appropriate outlier percentage.
- Description of the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM)

coding and diagnosis-related groups (DRGs) classification changes discussed in the annual update to the hospital inpatient prospective payment system (IPPS) regulations.

- Update to the electroconvulsive therapy (ECT) payment by a factor specified by CMS.
- Update to the national urban and rural cost-to-charge ratio medians and ceilings.
- Update to the cost of living adjustment factors for IPFs located in Alaska and Hawaii, if appropriate.

Our most recent IPF PPS annual update occurred in the April 30, 2010 **Federal Register** notice (75 FR 23106) (hereinafter referred to as the April 2010 IPF PPS notice) that set forth updates to the IPF PPS payment rates for RY 2011. This notice updated the IPF PPS per diem payment rates that were published in the May 2009 IPF PPS notice in accordance with our established policies.

Since implementation of the IPF PPS, we have explained that we believe it is important to delay updating the adjustment factors derived from the regression analysis until we have IPF PPS data that include as much information as possible regarding the patient-level characteristics of the population that each IPF serves. Since we are now approximately 5 years into the system, we believe that we have enough data to begin that process. Therefore, we have begun the necessary analysis in order to make future refinements. While we did not propose to make refinements in this rulemaking, as explained in section V.D.3 below, we believe that in the next rulemaking, for FY 2013, we will be ready to propose potential refinements.

B. Overview of the Legislative Requirements of the IPF PPS

Section 124 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) required implementation of the IPF PPS. Specifically, section 124 of the BBRA mandated that the Secretary develop a per diem PPS for inpatient hospital services furnished in psychiatric hospitals and psychiatric units that includes an adequate patient classification system that reflects the differences in patient resource use and costs among psychiatric hospitals and psychiatric units.

Section 405(g)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) extended the IPF PPS to

distinct part psychiatric units of critical access hospitals (CAHs).

To implement these provisions, we published various proposed and final rules in the **Federal Register**. For more information regarding these rules, see the CMS Web site <http://www.cms.hhs.gov/InpatientPsychFacilPPS/>.

Section 3401(f) of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by section 10319(e) of that Act and by section 1105(d) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (hereafter referred to as “The Affordable Care Act”) added subsection (s) to section 1886 of the Act.

Section 1886(s)(1) is titled “Reference to Establishment and Implementation of System” and it refers to section 124 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, which relates to the establishment of the IPF PPS.

Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the RY beginning in 2012 and each subsequent RY. Section 1886(s)(2)(A)(ii) of the Act requires the application of an “other adjustment” that reduces any update to an IPF PPS base rate by percentages specified in section 1886(s)(3) of the Act for rate years beginning in 2010 through the RY beginning in 2019. For the RY beginning in 2011, the reduction is 0.25 percentage point. We are implementing that provision for RY 2012 in this RY 2012 IPF PPS final rule.

Section 1886(s)(4) of the Act requires the establishment of a quality data reporting program for the IPF PPS beginning in RY 2014.

C. General Overview of the IPF PPS

The November 2004 IPF PPS final rule (69 FR 66922) established the IPF PPS, as authorized under section 124 of the BBRA and codified at subpart N of part 412 of the Medicare regulations. The November 2004 IPF PPS final rule set forth the per diem Federal rates for the implementation year (the 18-month period from January 1, 2005 through June 30, 2006), and it provided payment for the inpatient operating and capital costs to IPFs for covered psychiatric services they furnish (that is, routine, ancillary, and capital costs, but not costs of approved educational activities, bad debts, and other services or items that are outside the scope of the IPF PPS). Covered psychiatric services include services for which benefits are provided under the fee-for-service Part A

(Hospital Insurance Program) Medicare program.

The IPF PPS established the Federal per diem base rate for each patient day in an IPF derived from the national average daily routine operating, ancillary, and capital costs in IPFs in FY 2002. The average per diem cost was updated to the midpoint of the first year under the IPF PPS, standardized to account for the overall positive effects of the IPF PPS payment adjustments, and adjusted for budget neutrality.

The Federal per diem payment under the IPF PPS is comprised of the Federal per diem base rate described above and certain patient- and facility-level payment adjustments that were found in the regression analysis to be associated with statistically significant per diem cost differences.

The patient-level adjustments include age, DRG assignment, comorbidities, and variable per diem adjustments to reflect higher per diem costs in the early days of an IPF stay. Facility-level adjustments include adjustments for the IPF's wage index, rural location, teaching status, a cost of living adjustment for IPFs located in Alaska and Hawaii, and presence of a qualifying emergency department (ED).

The IPF PPS provides additional payment policies for: Outlier cases; stop-loss protection (which was applicable only during the IPF PPS transition period); interrupted stays; and a per treatment adjustment for patients who undergo ECT.

A complete discussion of the regression analysis appears in the November 2004 IPF PPS final rule (69 FR 66933 through 66936).

Section 124 of BBRA does not specify an annual update rate strategy for the IPF PPS and is broadly written to give the Secretary discretion in establishing an update methodology. Therefore, in the November 2004 IPF PPS final rule, we implemented the IPF PPS using the following update strategy:

- Calculate the final Federal per diem base rate to be budget neutral for the 18-month period of January 1, 2005 through June 30, 2006.
- Use a July 1 through June 30 annual update cycle.
- Allow the IPF PPS first update to be effective for discharges on or after July 1, 2006 through June 30, 2007.

D. Transition Period for Implementation of the IPF PPS

In the November 2004 IPF PPS final rule, we provided for a 3-year transition period. During this 3-year transition period, an IPF's total payment under the PPS was based on an increasing percentage of the Federal rate with a

corresponding decreasing percentage of the IPF PPS payment that is based on reasonable cost concepts. However, effective for cost reporting periods beginning on or after January 1, 2008, IPF PPS payments are based on 100 percent of the Federal rate.

II. Provisions of the Proposed Rule and Responses to Public Comments

On January 27, 2011, we published a proposed rule that appeared in the **Federal Register** (76 FR 4998) entitled, "Inpatient Psychiatric Facilities Prospective Payment System—Update for Rate Year Beginning July 1, 2011 (RY 2012)." The January 2011 proposed rule (hereinafter referred to as the RY 2012 IPF PPS proposed rule) set forth the proposed annual update to the proposed PPS for IPFs for discharges occurring during the RY beginning July 1, 2011.

In addition to the annual rate update, we proposed to—

- Switch the annual update period for the IPF PPS from a RY that begins on July 1 and goes through June 30 to one that coincides with a FY, that is, that begins on October 1 and goes through September 30. For the update period that begins in 2012, that is, FY 2013, we would refer to the update period as a FY. In order to make this switch, we proposed that RY 2012 be a 15-month period, from July 1, 2011 through September 30, 2012.

- Rebase and revise the FY 2002-based RPL market basket to a FY 2008-based RPL market basket. Apply a 0.25 percentage point reduction to the market basket update as required by section 1886(s)(3) of the Act.

- Adopt IPF policies similar to such IPPS graduate medical education (GME) policies providing for temporary adjustments to an IPF's FTE cap to reflect residents added due to the closure of an IPF or an IPF's residency training program.

- Update the fixed dollar loss threshold amount in order to maintain the appropriate outlier percentage.

- Update the ECT adjustment by a factor specified by CMS.

- Update the national urban and rural cost-to-charge ratio medians and ceilings.

- Update the cost of living adjustment factors for IPFs located in Alaska and Hawaii, if appropriate.

- Describe the ICD-9-CM and MS-DRG classification changes discussed in the annual update to the hospital inpatient prospective payment system regulations.

- Use the best available hospital wage index and information regarding whether an adjustment to the Federal

per diem base rate is needed to maintain budget neutrality.

- Retain the 17 percent adjustment for IPFs located in rural areas, the 1.31 adjustment for IPFs with a qualifying ED, the 0.5150 teaching adjustment to the Federal per diem rate, and the MS-DRG adjustment factor currently being paid to IPFs for RY 2011.

- Update the MS-DRG listing and comorbidity categories to reflect the ICD-9-CM revisions effective October 1, 2010.

In addition, we proposed to make clarifying changes to the regulations text. We noted that these proposed changes would not impact policy.

We provided for a 60 day comment period on the RY 2012 IPF PPS proposed rule. We received 12 public comments from hospital associations and psychiatric hospitals and units. In general, many of the commenters strongly supported our proposed policy changes, including changes to the payment rate update cycle and the teaching policy. A few commenters expressed concern regarding the proposed decrease in the labor-related share. Several commenters recommended that we explore the creation of an inpatient rehabilitation and psychiatric facilities (RP) market basket. Summaries of the public comments received and our responses to those comments are provided in the appropriate sections in the preamble of this final rule.

III. Changing the IPF PPS Payment Rate Update Period From a Rate Year to a Fiscal Year

In the RY 2012 IPF PPS proposed rule, we proposed to change the current period for the annual updates of the IPF PPS Federal payment rates. Specifically, we proposed to revise the IPF PPS payment rate update period by switching from a RY that begins on July 1 and goes through June 30 to a period that coincides with a FY, that is, October 1 through September 30. We proposed to refer to the update period as a FY beginning with the update period that begins in 2012, that is, FY 2013. We specified that this change in the annual update period would allow us to consolidate Medicare publications by aligning the IPF PPS update with the annual update of the ICD-9-CM codes, which are effective on October 1 of each year. Currently, in addition to our annual proposed and final rulemaking documents, we publish a change request transmittal every August updating the ICD-9-CM codes related to the DRG and comorbidity adjustments. By proposing to align the IPF PPS with the same update period as the ICD-9-CM codes,

we aimed to eliminate the need to publish a transmittal off-cycle.

We maintain the same diagnostic coding and DRG classification for IPFs that are used under the IPPS for providing the psychiatric care. When the IPF PPS was implemented, we adopted the same diagnostic code set and DRG patient classification systems (that is, the CMS DRGs) that were utilized at the time under the hospital IPPS. Every year, changes to the ICD–9–CM coding system are addressed in the IPPS proposed and final rules. These changes are effective October 1 of each year and must be used by acute care hospitals as well as other providers to report diagnostic and procedure information. The IPF PPS has always incorporated ICD–9–CM coding changes made in the annual IPPS update. This proposed change to the annual payment rate update period would allow the annual update to the rates and the ICD–9–CM coding update to occur on the same schedule and appear in the same **Federal Register** document.

Our intent in making the change in the payment rate update schedule is to place the IPF PPS on the same update cycle as other PPSs, making it administratively efficient. In order to smoothly transition to a payment update period that runs from October 1 through September 30, we proposed that the RY 2012 period run from July 1, 2011 to September 30, 2012 such that RY 2012 would be 15 months. As proposed and for this final rule, after RY 2012, the rate update period for the IPF PPS payment rates and other policy changes will begin on October 1 and go through September 30. The next update to the IPF PPS rates after RY 2012 would be the FY 2013 update cycle, which will begin on October 1, 2012 and go through September 30, 2013. In addition, we proposed to make a change to the regulations at § 412.402 to add the term “IPF Prospective Payment System Rate Year” which would mean October 1 through September 30. We proposed that the RY would be referred to as a FY. For a discussion of the proposed 15-month market basket update for the proposed 2012 RY, we refer readers to the RY 2012 IPF PPS proposed rule (76 FR 4998).

Public comments and our responses on the switch from a RY to a FY are summarized below.

Comment: A few commenters supported moving the payment rate update period from a RY to a FY. They supported a 15-month update for RY 2012 in order to transition to a FY update period.

Response: We appreciate the commenters' support to move the IPF

PPS payment rate update period to a period that begins on October 1 and goes through the following September, with a 15-month update for RY 2012 in order to transition to a FY. We are adopting as final, without modification, the proposal to revise the IPF PPS payment period to a FY with a 15-month update for RY 2012 in order to transition to a FY update period.

Final Rule Action: In summary, for RY 2012, we are revising the IPF PPS payment rate update period by switching the RY period from July 1 through June 30 to a period that coincides with a FY. In order to transition to a FY update period, RY 2012 is a 15-month period. We are also making a change to § 412.402 to add the term “IPF Prospective Payment System Rate Year” which means October 1 through September 30 will be referred to as a Fiscal year.

IV. Rebasement and Revising of the Rehabilitation, Psychiatric, and Long-Term Care (RPL) Market Basket for Inpatient Psychiatric Facilities

A. Background

The input price index (that is, the market basket) that was used to develop the IPF PPS was the Excluded Hospital with Capital market basket. This market basket was based on 1997 Medicare cost report data and included data for Medicare participating IPFs, inpatient rehabilitation facilities (IRFs), long-term care hospitals (LTCHs), cancer hospitals, and children's hospitals. Although “market basket” technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term “market basket” as used in this document refers to a hospital input price index.

Beginning with the May 2006 IPF PPS final rule (71 FR 27046 through 27054), IPF PPS payments were updated using a FY 2002-based market basket reflecting the operating and capital cost structures for IRFs, IPFs, and LTCHs (hereafter referred to as the Rehabilitation, Psychiatric, and Long-Term Care (RPL) market basket).

We excluded cancer and children's hospitals from the RPL market basket because these hospitals are not reimbursed through a PPS; rather, their payments are based entirely on reasonable costs subject to rate-of-increase limits established under the authority of section 1886(b) of the Act, which are implemented in regulations at § 413.40. Moreover, the FY 2002 cost

structures for cancer and children's hospitals are noticeably different than the cost structures of the IRFs, IPFs, and LTCHs. A complete discussion of the FY 2002-based RPL market basket appears in the May 2006 IPF PPS final rule (71 FR 27046 through 27054).

In the May 1, 2009 IPF PPS notice (74 FR 20362), we expressed our interest in exploring the possibility of creating a stand-alone IPF market basket that reflects the cost structures of only IPF providers. We noted that, of the available options, one would be to join the Medicare cost report data from freestanding IPF providers (presently incorporated into the FY 2002-based RPL market basket) with data from hospital-based IPF providers. We indicated that an examination of the Medicare cost report data comparing freestanding and hospital-based IPFs revealed considerable differences between the two with respect to cost levels and cost structures. At that time, we were unable to fully understand the differences between these two types of IPF providers. As a result, we felt that further research was required and we solicited public comment for additional information that might help us to better understand the reasons for the variations in costs and cost structures, as indicated by the cost report data, between freestanding and hospital-based IPFs (74 FR 20376).

We summarized the public comments we received and our responses in the April 2010 IPF PPS notice (75 FR 23111 through 23113). Despite receiving comments from the public on this issue, we remain unable to sufficiently understand the observed differences in costs and cost structures between hospital-based and freestanding IPFs, and therefore we do not feel it is appropriate at this time to incorporate data from hospital-based IPFs with those of freestanding IPFs to create a stand-alone IPF market basket.

Although we do not feel it would be appropriate to propose a stand-alone IPF market basket, we are currently exploring the viability of creating two separate market baskets from the current RPL, one of which would include freestanding IPFs and freestanding IRFs and would be used to update payments under both the IPF and IRF payment systems. The other would be a stand-alone LTCH market basket. Depending on the outcome of our research, we anticipate the possibility of proposing a rehabilitation and psychiatric (RP) market basket in the next update cycle. In the RY 2012 IPF PPS proposed rule, we welcomed public comment on the possibility of using this type of market

basket to update IPF payments in the future.

For this update cycle, we proposed to rebase and revise the FY 2002-based RPL market basket by creating a proposed FY 2008-based RPL market basket. For this RY 2012 IPF PPS final rule, we are finalizing the FY 2008-based RPL market basket as proposed. In the following section, we provide an overview of the market basket and describe the methodologies we proposed to use, and are finalizing in this final rule, for purposes of determining the operating and capital portions of the FY 2008-based RPL market basket.

Public comments and our responses on the rebasing and revising of the RPL market basket for IPFs are summarized below.

Comment: One commenter, while generally supporting use of the RPL market basket at the time of implementation, stated that it has its limitations, and recommended that CMS explore the creation of an RP market basket. Several commenters supported CMS' efforts to determine if a separate market basket for inpatient psychiatric and rehabilitation facilities is appropriate.

Response: CMS will continue its efforts to investigate the viability of an alternative market basket to update IPF providers. Any possible changes to the market basket used to update IPF payments would appear in a future rulemaking and be subject to public comment.

Comment: Several commenters expressed concern regarding a recent trend in facility closures of hospital-based IPFs and stated that hospital-based IPF facilities are a vital component in preserving access to care for patients suffering from mental illness, particularly those who have coexisting physical conditions or experience a crisis and enter the emergency department for treatment. Therefore, the commenters recommended that CMS continue exploring reasons behind the differences in costs and cost structures between freestanding and hospital-based providers.

Response: We are continuing to analyze the Medicare cost report data in order to better understand the differences between freestanding and hospital-based IPF providers.

B. Overview of the FY 2008-Based RPL Market Basket

The FY 2008-based RPL market basket is a fixed weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time,

of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

The index itself is constructed in three steps. First, a base period is selected (in this final rule, the base period is FY 2008) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories with the proportion of total costs that each category represents being calculated. These proportions are called cost or expenditure weights. Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a price proxy. In nearly every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish hospital services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a hospital hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the hospital, but would not be factored into the price change measured by a fixed-weight hospital market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so the cost weights reflect recent changes in the mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care between base periods.

C. Rebasing and Revising of the RPL Market Basket

In the RY 2012 IPF PPS proposed rule, we proposed to rebase and revise

the market basket used to update the IPF PPS. We solicited public comments on our proposed methodological changes to the RPL market basket. We did not receive any specific comments on these proposed changes. Therefore, we are finalizing the methodology for calculating the rebased and revised FY 2008-based market basket as proposed. The methodology is described in more detail below.

The terms "rebasing" and "revising," while often used interchangeably, actually denote different activities. "Rebasing" means moving the base year for the structure of costs of an input price index (for example, in this final rule, we are shifting the base year cost structure for the RPL market basket from FY 2002 to FY 2008). "Revising" means changing data sources, price proxies, or methods, used to derive the input price index.

1. Development of Cost Categories and Weights

a. Medicare Cost Reports

As proposed, and in this final rule, the FY 2008-based RPL market basket consists of several major cost categories derived from the FY 2008 Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs, including wages and salaries, pharmaceuticals, professional liability insurance, capital, and a residual. These FY 2008 cost reports include providers whose cost reporting periods began on or after October 1, 2007 and before October 1, 2008. We choose to use FY 2008 as the base year because we believe that the Medicare cost reports for this year represent the most recent, complete set of Medicare cost report data available for IRFs, IPFs, and LTCHs. However, for the FY 2008 cost reports, IRFs, IPFs, and LTCHs were not required to complete the Medicare cost report worksheet for benefits and contract labor (Worksheet S-3, part II). As a result, less than 30 percent of providers reported data for these categories, and we do not expect these FY 2008 data to improve over time. Furthermore, the issue of incomplete Medicare cost report data for benefits and contract labor also existed when we finalized the FY 2002-based RPL market basket, since, at that time, IRFs, IPFs and LTCHs were not required to submit data for Worksheet S-3, part II in the FY 2002 cost reporting year. Due to the incomplete benefits and contract labor data for IRFs, IPFs, and LTCHs, for these cost weights, rather than using IRF/IPF/LTCH cost report data, we instead used FY 2008 IPPS hospital cost report data (similar to the method that was used for the FY 2002-

based RPL market basket). Additional detail is provided later in this section.

Since our goal is to measure cost shares that are reflective of case mix and practice patterns associated with providing services to Medicare beneficiaries, we limited our selection of Medicare cost reports to those from hospitals that have a Medicare average length of stay (LOS) that is within a comparable range of their total facility average LOS. We believe this provides a more accurate reflection of the structure of costs for Medicare covered days. We used the cost reports of IRFs and LTCHs with Medicare average LOS within 15 percent (that is, 15 percent higher or lower) of the total facility average LOS for the hospital. This is the same edit applied to derive the FY 2002-based RPL market basket and generally includes those LTCHs and IRFs with Medicare LOS within approximately 5 days of the facility average LOS of the hospital.

We used a less stringent measure of Medicare LOS for IPFs. For this provider-type, and in order to produce a robust sample size, we used those facilities' Medicare cost reports whose average LOS is within 30 or 50 percent (depending on the total facility average LOS) of the total facility average LOS. This is the same edit applied to derive the FY 2002-based RPL market basket.

We applied these LOS edits to first obtain a set of cost reports for facilities that have a Medicare LOS within a comparable range of their total facility LOS. Using this set of Medicare cost reports, we then calculated cost weights for four cost categories directly from the FY 2008 Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs (found in Table 1 below). These Medicare cost report cost weights were then supplemented with information obtained from other data sources (explained in more detail below) to derive the final FY 2008-based RPL market basket cost weights.

TABLE 1—MAJOR COST CATEGORIES AND THEIR RESPECTIVE COST WEIGHTS AS CALCULATED DIRECTLY FROM FY 2008 MEDICARE COST REPORTS

| Major cost categories | FY 2008-based RPL market basket (percent) |
|--|---|
| Wages and salaries | 47.371 |
| Professional Liability Insurance (Malpractice) | 0.764 |
| Pharmaceuticals | 6.514 |
| Capital | 8.392 |

TABLE 1—MAJOR COST CATEGORIES AND THEIR RESPECTIVE COST WEIGHTS AS CALCULATED DIRECTLY FROM FY 2008 MEDICARE COST REPORTS—Continued

| Major cost categories | FY 2008-based RPL market basket (percent) |
|-----------------------|---|
| All other | 36.959 |

b. Other Data Sources

In addition to the IRF, IPF and LTCH Medicare cost reports for freestanding IRFs and freestanding IPFs, and LTCHs, the other data sources we used to develop the FY 2008-based RPL market basket cost weights were the FY 2008 IPPS Medicare cost reports and the 2002 Benchmark Input-Output (I-O) Tables created by the Bureau of Economic Analysis (BEA), U.S. Department of Commerce. The FY 2008 Medicare cost reports include providers whose cost reporting periods began on or after October 1, 2007 and before October 1, 2008.

As noted above, the FY 2008-based RPL cost weights for benefits and contract labor were derived using FY 2008-based IPPS Medicare cost reports. We used these Medicare cost reports to calculate cost weights for Wages and Salaries, Benefits, and Contract Labor for IPPS hospitals for FY 2008. For the Benefits cost weight for the FY 2008-based RPL market basket, the ratio of the FY 2008 IPPS Benefits cost weight to the FY 2008 IPPS Wages and Salaries cost weight was applied to the RPL Wages and Salaries cost weight. Similarly, the ratio of the FY 2008 IPPS Contract Labor cost weight to the FY 2008 IPPS Wages and Salaries cost weight was applied to the RPL Wages and Salaries cost weight to derive a Contract Labor cost weight for the FY 2008-based RPL market basket.

The All Other cost category is divided into other hospital expenditure category shares using the 2002 BEA Benchmark I-O data following the removal of the portions of the All Other cost category provided in Table 1 that are attributable to Benefits and Contract Labor. The BEA Benchmark I-O data are scheduled for publication every 5 years. The most recent data available are for 2002. BEA also produces Annual I-O estimates; however, the 2002 Benchmark I-O data represent a much more comprehensive and complete set of data that are derived from the 2002 Economic Census. The Annual I-O is simply an update of the Benchmark I-O tables. For the FY 2002-

based RPL market basket, we used the 1997 Benchmark I-O data. Therefore, we used the 2002 Benchmark I-O data in the FY 2008-based RPL market basket, and instead of using the less detailed Annual I-O data, we aged the 2002 Benchmark I-O data forward to 2008. The methodology we used to age the data forward involves applying the annual price changes from the respective price proxies to the appropriate cost categories. We repeated this practice for each year.

The All Other cost category expenditure shares are determined as being equal to each category's proportion to total "all other" in the aged 2002 Benchmark I-O data. For instance, if the cost for telephone services represented 10 percent of the sum of the "all other" Benchmark I-O hospital expenditures, then telephone services would represent 10 percent of the RPL market basket's All Other cost category.

2. Final Cost Category Computation

As stated previously, for this rebasing we used the FY 2008 Medicare cost reports for IRFs, IPFs, and LTCHs to derive four major cost categories. The FY 2008-based RPL market basket includes two additional cost categories that were not broken out separately in the FY 2002-based RPL market basket: "Administrative and Business Support Services" and "Financial Services". The inclusion of these two additional cost categories, which are derived using the Benchmark I-O data, is consistent with the addition of these two cost categories to the FY 2006-based IPPS market basket (74 FR 43845). We chose to break out both categories so we can better match their respective expenses with more appropriate price proxies. Also, the FY 2008-based RPL market basket excludes one cost category: Photo Supplies. The 2002 Benchmark I-O weight for this category is considerably smaller than the 1997 Benchmark I-O weight, presently accounting for less than one-tenth of one percentage point of the RPL market basket. Therefore, we included the photo supplies costs in the Chemical cost category weight with other similar chemical products.

We did not change our definition of the labor-related share. However, we renamed our aggregate cost categories from "labor-intensive" and "nonlabor-intensive" services to "labor-related" and "nonlabor-related" services. This is consistent with the FY 2006-based IPPS market basket (74 FR 43845). As discussed in more detail below and similar to the FY 2002-based RPL market basket, we classify a cost category as labor-related and include it in the labor-related share if the cost

category is defined as being labor-intensive and its cost varies with the local labor market. In previous regulations, we grouped cost categories that met both of these criteria into labor-intensive services. We believe the new labels more accurately reflect the concepts that they are intended to convey. Therefore, we did not change our definition of the labor-related share because we continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market.

3. Selection of Price Proxies

After computing the FY 2008 cost weights for the rebased RPL market basket, it was necessary to select appropriate wage and price proxies to reflect the rate of price change for each expenditure category. With the exception of the proxy for Professional Liability Insurance, all of the proxies for the operating portion of the FY 2008-based RPL market basket are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

Producer Price Indexes—Producer Price Indexes (PPIs) measure price changes for goods sold in markets other than the retail market. PPIs are preferable price proxies for goods and services that hospitals purchase as inputs because these PPIs better reflect the actual price changes faced by hospitals. For example, we use a special PPI for prescription drugs, rather than the Consumer Price Index (CPI) for prescription drugs, because hospitals generally purchase drugs directly from a

wholesaler. The PPIs that we use measure price changes at the final stage of production.

Consumer Price Indexes—Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by the typical consumer. Because they may not represent the price faced by a producer, we used CPIs only if an appropriate PPI was not available, or if the expenditures were more similar to those faced by retail consumers in general rather than by purchasers of goods at the wholesale level. For example, the CPI for food purchased away from home is used as a proxy for contracted food services.

Employment Cost Indexes—Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. Appropriately, they are not affected by shifts in employment mix.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. Availability means that the proxy is publicly available. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs selected meet these criteria.

Table 2 sets forth the final FY 2008-based RPL market basket including cost categories, and their respective weights and price proxies. For comparison purposes, the corresponding FY 2002-based RPL market basket cost weights are listed, as well. For example, Wages and Salaries are 49.447 percent of total costs in the FY 2008-based RPL market basket compared to 52.895 percent for the FY 2002-based RPL market basket. Employee Benefits are 12.831 percent in the FY 2008-based RPL market basket compared to 12.982 percent for the FY 2002-based RPL market basket. As a result, compensation costs (Wages and Salaries plus Employee Benefits) for the FY 2008-based RPL market basket are 62.278 percent of total costs compared to 65.877 percent for the FY 2002-based RPL market basket.

Following Table 2 is a summary outlining the choice of the proxies used for the operating portion of the FY 2008-based RPL market basket. The price proxies used for the capital portion are described in more detail in the capital methodology section (see section IV.c.4 of this final rule).

We note that the proxies for the operating portion of the FY 2008-based RPL market basket are the same as those used for the FY 2006-based IPPS operating market basket. Because these proxies meet our criteria of reliability, timeliness, availability, and relevance, we believe they are the best measures of price changes for the cost categories. For further discussion on the FY 2006-based IPPS market basket, see the IPPS final rule published in the **Federal Register** on August 27, 2009 (74 FR 43843).

TABLE 2—FY 2008-BASED RPL MARKET BASKET COST CATEGORIES, WEIGHTS, AND PRICE PROXIES WITH FY 2002-BASED RPL MARKET BASKET COST WEIGHTS INCLUDED FOR COMPARISON

| Cost categories | FY 2002-based RPL market basket cost weights | FY 2008-based RPL market basket cost weights | FY 2008-based RPL market basket price proxies |
|---|--|--|---|
| 1. Compensation | 65.877 | 62.278 | |
| A. Wages and Salaries ¹ | 52.895 | 49.447 | ECI for Wages and Salaries, Civilian Hospital Workers. |
| B. Employee Benefits ¹ | 12.982 | 12.831 | ECI for Benefits, Civilian Hospital Workers. |
| 2. Utilities | 0.656 | 1.578 | |
| A. Electricity | 0.351 | 1.125 | PPI for Commercial Electric Power. |
| B. Fuel, Oil, and Gasoline | 0.108 | 0.371 | PPI for Petroleum Refineries. |
| C. Water and Sewage | 0.197 | 0.082 | CPI-U for Water & Sewerage Maintenance. |
| 3. Professional Liability Insurance | 1.161 | 0.764 | CMS Hospital Professional Liability Insurance Premium Index. |
| 4. All Other Products and Services | 22.158 | 26.988 | |
| A. All Other Products | 13.325 | 15.574 | |
| (1.) Pharmaceuticals | 5.103 | 6.514 | PPI for Pharmaceutical Preparations for Human Use(Prescriptions). |
| (2.) Food: Direct Purchases | 0.873 | 2.959 | PPI for Processed Foods & Feeds. |
| (3.) Food: Contract Services | 0.620 | 0.392 | CPI-U for Food Away From Home. |
| (4.) Chemicals ² | 1.100 | 1.100 | Blend of Chemical PPIs. |
| (5.) Medical Instruments | 1.014 | 1.795 | PPI for Medical, Surgical, and Personal Aid Devices. |
| (6.) Photographic Supplies | 0.096 | — | |

TABLE 2—FY 2008-BASED RPL MARKET BASKET COST CATEGORIES, WEIGHTS, AND PRICE PROXIES WITH FY 2002-BASED RPL MARKET BASKET COST WEIGHTS INCLUDED FOR COMPARISON—Continued

| Cost categories | FY 2002-based RPL market basket cost weights | FY 2008-based RPL market basket cost weights | FY 2008-based RPL market basket price proxies |
|---|--|--|--|
| (7.) Rubber and Plastics | 1.052 | 1.131 | PPI for Rubber & Plastic Products. |
| (8.) Paper and Printing Products | 1.000 | 1.021 | PPI for Converted Paper & Paperboard Products. |
| (9.) Apparel | 0.207 | 0.210 | PPI for Apparel. |
| (10.) Machinery and Equipment | 0.297 | 0.106 | PPI for Machinery & Equipment. |
| (11.) Miscellaneous Products | 1.963 | 0.346 | PPI for Finished Goods less Food and Energy. |
| B. All Other Services | 8.833 | 11.414 | |
| (1.) Labor-related Services | 5.111 | 4.681 | |
| (a.) Professional Fees: Labor-related. ³ | 2.892 | 2.114 | ECI for Compensation for Professional and Related Occupations. |
| (b.) Administrative and Business Support Services. ⁴ | n/a | 0.422 | ECI for Compensation for Office and Administrative Services. |
| (c.) All Other: Labor-Related Services ⁴ | 2.219 | 2.145 | ECI for Compensation for Private Service Occupations. |
| (2.) Nonlabor-Related Services | 3.722 | 6.733 | |
| (a.) Professional Fees: Nonlabor-Related ³ | n/a | 4.211 | ECI for Compensation for Professional and Related Occupations. |
| (b.) Financial Services ⁵ | n/a | 0.853 | ECI for Compensation for Financial Activities. |
| (c.) Telephone Services | 0.240 | 0.416 | CPI-U for Telephone Services. |
| (d.) Postage | 0.682 | 0.630 | CPI-U for Postage. |
| (e.) All Other: Nonlabor-Related Services ⁵ | 2.800 | 0.623 | CPI-U for All Items less Food and Energy. |
| 5. Capital-Related Costs | 10.149 | 8.392 | |
| A. Depreciation | 6.187 | 5.519 | |
| (1.) Fixed Assets | 4.250 | 3.286 | BEA chained price index for nonresidential construction for hospitals and special care facilities—vintage weighted (26 years). |
| (2.) Movable Equipment | 1.937 | 2.233 | PPI for Machinery and Equipment—vintage weighted (11 years). |
| B. Interest Costs | 2.775 | 1.954 | |
| (1.) Government/Nonprofit | 2.081 | 0.653 | Average yield on domestic municipal bonds (Bond Buyer 20 bonds)—vintage-weighted (26 years). |
| (2.) For Profit | 0.694 | 1.301 | Average yield on Moody's Aaa bonds—vintage-weighted (26 years). |
| C. Other Capital-Related Costs | 1.187 | 0.919 | CPI-U for Residential Rent. |
| Total | 100.000 | 100.000 | |

Note: Detail may not add to total due to rounding.

¹ Contract Labor is distributed to Wages and Salaries and Employee Benefits based on the share of total compensation that each category represents.

² To proxy the Chemicals cost category, we used a blended PPI composed of the PPI for Industrial Gases, the PPI for Other Basic Inorganic Chemical Manufacturing, the PPI for Other Basic Organic Chemical Manufacturing, and the PPI for Soap and Cleaning Compound Manufacturing. For more detail about this proxy, see section IV.C.3.j. of the preamble of this final rule.

³ The Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories were included in one cost category called Professional Fees in the FY 2002-based RPL market basket. For more detail about how these new categories were derived, we refer readers to sections IV.C.6. of the preamble of this final rule, on the labor-related share.

⁴ The Administrative and Business Support Services cost category was contained within All Other: Labor-intensive Services cost category in the FY 2002-based RPL market basket. The All Other: Labor-intensive Services cost category is renamed the All Other: Labor-related Services cost category for the FY 2008-based RPL market basket.

⁵ The Financial Services cost category was contained within the All Other: Non-labor Intensive Services cost category in the FY 2002-based RPL market basket. The All Other: Non-labor Intensive Services cost category is renamed the All Other: Nonlabor-related Services cost category for the FY 2008-based RPL market basket.

a. Wages and Salaries

We use the ECI for Wages and Salaries for Hospital Workers (All Civilian) (BLS series code CIU1026220000000I) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

b. Employee Benefits

We use the ECI for Employee Benefits for Hospital Workers (All Civilian) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

c. Electricity

We use the PPI for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

d. Fuel, Oil, and Gasoline

For the FY 2002-based RPL market basket, this category only included expenses classified under North American Industry Classification System (NAICS) 21 (Mining). We

proxied this category using the PPI for Commercial Natural Gas (BLS series code WPU0552). For the FY 2008-based market basket, we added costs to this category that had previously been grouped in other categories. The added costs include petroleum-related expenses under NAICS 324110 (previously captured in the miscellaneous category), as well as petrochemical manufacturing classified under NAICS 325110 (previously captured in the chemicals category). These added costs represent 80 percent

of the hospital industry's fuel, oil, and gasoline expenses (or 80 percent of this category). Because the majority of the industry's fuel, oil, and gasoline expenses originate from petroleum refineries (NAICS 324110), we use the PPI for Petroleum Refineries (BLS series code PCU324110324110) as the proxy for this cost category.

e. Water and Sewage

We use the CPI for Water and Sewerage Maintenance (All Urban Consumers) (BLS series code CUUR0000SEHG01) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

f. Professional Liability Insurance

We proxy price changes in hospital professional liability insurance premiums (PLI) using percentage changes as estimated by the CMS Hospital Professional Liability Index. To generate these estimates, we collect commercial insurance premiums for a fixed level of coverage while holding nonprice factors constant (such as a change in the level of coverage). This method is also used to proxy PLI price

changes in the Medicare Economic Index (75 FR 73268). This same proxy was used in the FY 2002-based RPL market basket.

g. Pharmaceuticals

We use the PPI for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. We note that we are not making a change to the PPI that is used to proxy this cost category. There was a recent change to the BLS naming convention for this series; however this is the same proxy that was used in the FY 2002-based RPL market basket.

h. Food: Direct Purchases

We use the PPI for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

i. Food: Contract Services

We use the CPI for Food Away From Home (All Urban Consumers) (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

j. Chemicals

We use a blended PPI composed of the PPI for Industrial Gas Manufacturing (NAICS 325120) (BLS series code PCU325120325120P), the PPI for Other Basic Inorganic Chemical Manufacturing (NAICS 325180) (BLS series code PCU32518–32518–), the PPI for Other Basic Organic Chemical Manufacturing (NAICS 325190) (BLS series code PCU32519–32519–), and the PPI for Soap and Cleaning Compound Manufacturing (NAICS 325610) (BLS series code PCU32561–32561–). Using the 2002 Benchmark I–O data, we found that these NAICS industries accounted for approximately 90 percent of the hospital industry's chemical expenses.

Therefore, we use this blended index because we believe its composition better reflects the composition of the purchasing patterns of hospitals than does the PPI for Industrial Chemicals (BLS series code WPU061), the proxy used in the FY 2002-based RPL market basket. Table 3 below shows the weights for each of the four PPIs used to create the blended PPI, which we determined using the 2002 Benchmark I–O data.

TABLE 3—BLENDED CHEMICAL PPI WEIGHTS

| Name | Weights (in percent) | NAICS |
|--|-------------------------|--------|
| PPI for Industrial Gas Manufacturing | 35 | 325120 |
| PPI for Other Basic Inorganic Chemical Manufacturing | 25 | 325180 |
| PPI for Other Basic Organic Chemical Manufacturing | 30 | 325190 |
| PPI for Soap and Cleaning Compound Manufacturing | 10 | 325610 |

k. Medical Instruments

We use the PPI for Medical, Surgical, and Personal Aid Devices (BLS series code WPU156) to measure the price growth of this cost category. In the 1997 Benchmark I–O data, approximately half of the expenses classified in this category were for surgical and medical instruments. Therefore, we used the PPI for Surgical and Medical Instruments and Equipment (BLS series code WPU1562) to proxy this category in the FY 2002-based RPL market basket. The 2002 Benchmark I–O data show that surgical and medical instruments now represent only 33 percent of these expenses and that the largest expense category is surgical appliance and supplies manufacturing (corresponding to BLS series code WPU1563). Due to this reallocation of costs over time, we use as the price proxy for this cost category the more aggregated PPI for Medical, Surgical, and Personal Aid Devices.

l. Photographic Supplies

We eliminated the cost category specific to photographic supplies for the FY 2008-based RPL market basket. These costs are now included in the Chemicals cost category because the costs are presently reported as all other chemical products. Notably, although we are eliminating the specific cost category, these costs are still accounted for within the RPL market basket.

m. Rubber and Plastics

We use the PPI for Rubber and Plastic Products (BLS series code WPU07) to measure price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

n. Paper and Printing Products

We use the PPI for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

o. Apparel

We use the PPI for Apparel (BLS series code WPU0381) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

p. Machinery and Equipment

We use the PPI for Machinery and Equipment (BLS series code WPU11) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

q. Miscellaneous Products

We use the PPI for Finished Goods Less Food and Energy (BLS series code WPUSOP3500) to measure the price growth of this cost category. Using this index removes the double-counting of food and energy prices, which are already captured elsewhere in the market basket. This same proxy was used in the FY 2002-based RPL market basket.

r. Professional Fees: Labor-Related

We use the ECI for Compensation for Professional and Related Occupations (Private Industry) (BLS series code CIS2020000120000I) to measure the price growth of this category. It includes occupations such as legal, accounting, and engineering services. This same proxy was used in the FY 2002-based RPL market basket.

s. Administrative and Business Support Services

We use the ECI for Compensation for Office and Administrative Support Services (Private Industry) (BLS series code CIU2010000220000I) to measure the price growth of this category. Previously these costs were included in the All Other: Labor-intensive category (now renamed the All Other: Labor-related Services category), and were proxied by the ECI for Compensation for Service Occupations. We believe that this compensation index better reflects the changing price of labor associated with the provision of administrative services and its incorporation represents a technical improvement to the market basket.

t. All Other: Labor-Related Services

We use the ECI for Compensation for Service Occupations (Private Industry) (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

u. Professional Fees: Nonlabor-Related

We use the ECI for Compensation for Professional and Related Occupations (Private Industry) (BLS series code CIS2020000120000I) to measure the price growth of this category. This is the same price proxy that we are using for the Professional Fees: Labor-related cost category.

v. Financial Services

We use the ECI for Compensation for Financial Activities (Private Industry) (BLS series code CIU201520A000000I) to measure the price growth of this cost category. Previously these costs were included in the All Other: Nonlabor-intensive category (now renamed the All Other: Nonlabor-related Services category), and were proxied by the CPI for All Items. We believe that this compensation index better reflects the changing price of labor associated with the provision of financial services and its incorporation represents a technical improvement to the market basket.

w. Telephone Services

We use the CPI for Telephone Services (BLS series code

CUUR0000SEED) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

x. Postage

We use the CPI for Postage (BLS series code CUUR0000SEEC01) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

y. All Other: Nonlabor-Related Services

We use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. Previously these costs were proxied by the CPI for All Items in the FY 2002-based RPL market basket. We believe that using the CPI for All Items Less Food and Energy removes the double counting of changes in food and energy prices, as they are already captured elsewhere in the market basket. Consequently, we believe that the incorporation of this proxy represents a technical improvement to the market basket.

4. Methodology for Capital Portion of the RPL Market Basket

In the FY 2002-based RPL market basket, we did not have IRF, IPF, and LTCH 2002 Medicare cost report data for the capital cost weights, due to a change in the 2002 reporting requirements. Therefore, we used these hospitals' 2001 expenditure data for the capital cost categories of depreciation, interest, and other capital expenses, and aged the data to a 2002 base year using relevant price proxies.

For the FY 2008-based RPL market basket, we calculated weights for the RPL market basket capital costs using the same set of FY 2008 Medicare cost reports used to develop the operating share for IRFs, IPFs, and LTCHs. To calculate the total capital cost weight, we first apply the same LOS edits as applied prior to calculating the operating cost weights as described above in section IV.C.3. The resulting capital weight for the FY 2008 base year is 8.392 percent.

Lease expenses are unique in that they are not broken out as a separate cost category in the RPL market basket, but rather are proportionally distributed amongst the cost categories of Depreciation, Interest, and Other, reflecting the assumption that the underlying cost structure of leases is similar to that of capital costs in general. As was done in the FY 2002-based RPL market basket, we first assumed 10 percent of lease expenses represents overhead and assigned those costs to the

Other Capital-Related Costs category accordingly. The remaining lease expenses were distributed across the three cost categories based on the respective weights of depreciation, interest, and other capital not including lease expenses.

Depreciation contains two subcategories: (1) Building & Fixed Equipment; and (2) Movable Equipment. The apportionment between building & fixed equipment and movable equipment was determined using the FY 2008 Medicare cost reports for freestanding IRFs, IPFs, and LTCHs. This methodology was also used to compute the apportionment used in the FY 2002-based RPL market basket (70 FR 47912).

The total Interest expense cost category is split between government/nonprofit interest and for-profit interest. The FY 2002-based RPL market basket allocated 75 percent of the total Interest cost weight to government/nonprofit interest and proxied that category by the average yield on domestic municipal bonds. The remaining 25 percent of the Interest cost weight was allocated to for-profit interest and was proxied by the average yield on Moody's Aaa bonds (70 FR 47912). This was based on the FY 2002-based IPPS capital input price index (70 FR 23406) due to insufficient Medicare cost report data for IPFs, IRFs, and LTCHs. For the FY 2008-based RPL market basket, we derived the split using the relative FY 2008 Medicare cost report data on interest expenses for government/nonprofit and for-profit IRFs, IPFs, and LTCHs. Based on these data, we calculated a 33/67 split between government/nonprofit and for-profit interest. We believe it is important that this split reflects the latest relative cost structure of interest expenses for RPL providers. As stated above, we first apply the LOS edits (as described in section IV.C.3.) prior to calculating this split. Therefore, we are using Medicare cost reports that are reflective of case mix and practice patterns associated with providing services to Medicare beneficiaries. Using data specific to government/nonprofit and for-profit IRFs, IPFs, and LTCHs as well as the application of these LOS edits are the primary reasons for the difference in this split relative to the FY 2002-based RPL market basket.

Because capital is acquired and paid for over time, capital expenses in any given year are determined by both past and present purchases of physical and financial capital. The vintage-weighted capital portion of the FY 2008-based RPL market basket is intended to capture the long-term consumption of capital, using vintage weights for

depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital purchases attributable to each year of the expected life of building & fixed equipment, movable equipment, and interest. We use the vintage weights to compute vintage-weighted price changes associated with depreciation and interest expense.

Vintage weights are an integral part of the FY 2008-based RPL market basket. Capital costs are inherently complicated and are determined by complex capital purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. The capital portion of the FY 2008-based RPL market basket would reflect the annual price changes associated with capital costs, and would be a useful simplification of the actual capital investment process. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual nonvintage price changes for capital are unstable due to the volatility of interest rate changes and, therefore, do not reflect the actual annual price changes for Medicare capital-related costs. The capital component of the FY 2008-based RPL market basket would reflect the underlying stability of the capital acquisition process and provides hospitals with the ability to plan for changes in capital payments.

To calculate the vintage weights for depreciation and interest expenses, we needed a time series of capital purchases for building & fixed equipment and movable equipment. We found no single source that provides a uniquely best time series of capital purchases by hospitals for all of the above components of capital purchases. The early Medicare cost reports did not have sufficient capital data to meet this need. Data we obtained from the American Hospital Association (AHA) do not include annual capital purchases. However, AHA does provide a consistent database back to 1963. We used data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We then used data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2008.

In order to estimate capital purchases using data on depreciation expenses, the expected life for each cost category

(building & fixed equipment, movable equipment, and interest) is needed to calculate vintage weights. For the FY 2002-based RPL market basket, due to insufficient Medicare cost report data for IRFs, IPFs, and LTCHs, we used 2001 Medicare Cost Reports for IPPS hospitals to determine the expected life of building & fixed equipment and movable equipment (70 FR 47913). The FY 2002-based RPL market basket was based on an expected life of building & fixed equipment of 23 years. It used 11 years as the expected life for movable equipment. We believed that this data source reflected the latest relative cost structure of depreciation expenses for hospitals at the time and was analogous to IRFs, IPFs, and LTCHs.

The expected life of any piece of equipment can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated useful life of an asset if depreciation were to continue at current year levels, assuming straight-line depreciation. Following a similar method to what was applied for the FY 2002-based RPL market basket, we use an expected life of building & fixed equipment equal to 26 years, and an expected life of movable equipment of 11 years for the FY 2008-based RPL market basket. These expected lives are calculated using FY 2008 Medicare cost reports for IPPS hospitals since we are currently unable to obtain robust measures of the expected lives for building & fixed equipment and movable equipment using the Medicare cost reports from IRFs, IPFs, and LTCHs.

We used the building & fixed equipment and movable equipment weights derived from FY 2008 Medicare cost reports for IRFs, IPFs, and LTCHs to separate the depreciation expenses into annual amounts of building & fixed equipment depreciation and movable equipment depreciation. Year-end asset costs for building & fixed equipment and movable equipment were determined by multiplying the annual depreciation amounts by the expected life calculations. We then calculated a time series, back to 1963, of annual capital purchases by subtracting the previous year asset costs from the current year asset costs. From this capital purchase time series, we were able to calculate the vintage weights for building & fixed equipment and for movable equipment. Each of these sets of vintage weights is explained in more detail below.

For the building & fixed equipment vintage weights, we used the real annual capital purchase amounts for building &

fixed equipment to capture the actual amount of the physical acquisition, net of the effect of price inflation. This real annual purchase amount for building & fixed equipment was produced by deflating the nominal annual purchase amount by the building & fixed equipment price proxy, BEA's chained price index for nonresidential construction for hospitals and special care facilities. Because building & fixed equipment have an expected life of 26 years, the vintage weights for building & fixed equipment are deemed to represent the average purchase pattern of building & fixed equipment over 26-year periods. With real building & fixed equipment purchase estimates available from 2008 back to 1963, we averaged twenty 26-year periods to determine the average vintage weights for building & fixed equipment that are representative of average building & fixed equipment purchase patterns over time. Vintage weights for each 26-year period are calculated by dividing the real building & fixed capital purchase amount in any given year by the total amount of purchases in the 26-year period. This calculation is done for each year in the 26-year period, and for each of the twenty 26-year periods. We used the average of each year across the twenty 26-year periods to determine the average building & fixed equipment vintage weights for the FY 2008-based RPL market basket.

For the movable equipment vintage weights, the real annual capital purchase amounts for movable equipment were used to capture the actual amount of the physical acquisition, net of price inflation. This real annual purchase amount for movable equipment was calculated by deflating the nominal annual purchase amounts by the movable equipment price proxy, the PPI for Machinery and Equipment. This is the same proxy used for the FY 2002-based RPL market basket. Based on our determination that movable equipment has an expected life of 11 years, the vintage weights for movable equipment represent the average expenditure for movable equipment over an 11-year period. With real movable equipment purchase estimates available from 2008 back to 1963, thirty-five 11-year periods were averaged to determine the average vintage weights for movable equipment that are representative of average movable equipment purchase patterns over time. Vintage weights for each 11-year period are calculated by dividing the real movable capital purchase amount for any given year by the total amount of purchases in the 11-

year period. This calculation was done for each year in the 11-year period and for each of the thirty-five 11-year periods. We used the average of each year across the thirty-five 11-year periods to determine the average movable equipment vintage weights for the FY 2008-based RPL market basket.

For the interest vintage weights, the nominal annual capital purchase amounts for total equipment (building & fixed, and movable) were used to capture the value of the debt instrument. Because we have

determined that hospital debt instruments have an expected life of 26 years, the vintage weights for interest are deemed to represent the average purchase pattern of total equipment over 26-year periods. With nominal total equipment purchase estimates available from 2008 back to 1963, twenty 26-year periods were averaged to determine the average vintage weights for interest that are representative of average capital purchase patterns over time. Vintage weights for each 26-year period are calculated by dividing the nominal total

capital purchase amount for any given year by the total amount of purchases in the 26-year period. This calculation is done for each year in the 26-year period and for each of the twenty 26-year periods. We used the average of each year across the twenty 26-year periods to determine the average interest vintage weights for the FY 2008-based RPL market basket. The vintage weights for the capital portion of the FY 2002-based RPL market basket and the FY 2008-based RPL market basket are presented in Table 4.

TABLE 4—FY 2002 AND FY 2008 VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES

| Year | Building & fixed equipment | | Movable equipment | | Interest | |
|-------------|----------------------------|---------------------|---------------------|---------------------|---------------------|---------------------|
| | FY 2002 23 years | FY 2008 26 years | FY 2002 11 years | FY 2008 11 years | FY 2002 23 years | FY 2008 26 years |
| 1 | 0.021 | 0.021 | 0.065 | 0.071 | 0.010 | 0.010 |
| 2 | 0.022 | 0.023 | 0.071 | 0.075 | 0.012 | 0.012 |
| 3 | 0.025 | 0.025 | 0.077 | 0.080 | 0.014 | 0.014 |
| 4 | 0.027 | 0.027 | 0.082 | 0.083 | 0.016 | 0.016 |
| 5 | 0.029 | 0.028 | 0.086 | 0.085 | 0.019 | 0.018 |
| 6 | 0.031 | 0.030 | 0.091 | 0.089 | 0.023 | 0.020 |
| 7 | 0.033 | 0.031 | 0.095 | 0.092 | 0.026 | 0.021 |
| 8 | 0.035 | 0.033 | 0.100 | 0.098 | 0.029 | 0.024 |
| 9 | 0.038 | 0.035 | 0.106 | 0.103 | 0.033 | 0.026 |
| 10 | 0.040 | 0.037 | 0.112 | 0.109 | 0.036 | 0.029 |
| 11 | 0.042 | 0.039 | 0.117 | 0.116 | 0.039 | 0.033 |
| 12 | 0.045 | 0.041 | | | 0.043 | 0.035 |
| 13 | 0.047 | 0.042 | | | 0.048 | 0.038 |
| 14 | 0.049 | 0.043 | | | 0.053 | 0.041 |
| 15 | 0.051 | 0.044 | | | 0.056 | 0.043 |
| 16 | 0.053 | 0.045 | | | 0.059 | 0.046 |
| 17 | 0.056 | 0.046 | | | 0.062 | 0.049 |
| 18 | 0.057 | 0.047 | | | 0.064 | 0.052 |
| 19 | 0.058 | 0.047 | | | 0.066 | 0.053 |
| 20 | 0.060 | 0.045 | | | 0.070 | 0.053 |
| 21 | 0.060 | 0.045 | | | 0.071 | 0.055 |
| 22 | 0.061 | 0.045 | | | 0.074 | 0.056 |
| 23 | 0.061 | 0.046 | | | 0.076 | 0.060 |
| 24 | | 0.046 | | | | 0.063 |
| 25 | | 0.045 | | | | 0.064 |
| 26 | | 0.046 | | | | 0.068 |
| Total | 1.000 | 1.000 | 1.000 | 1.000 | 1.000 | 1.000 |

Note: Numbers may not add to total due to rounding.

After the capital cost category weights were computed, it was necessary to select appropriate price proxies to reflect the rate-of-increase for each expenditure category. As proposed, and in this final rule, we use the same price proxies for the capital portion of the FY 2008-based RPL market basket that were used in the FY 2002-based RPL market basket, with the exception of the Boeckh Construction Index. We replaced the Boeckh Construction Index with BEA's chained price index for nonresidential construction for hospitals and special care facilities. The BEA index represents construction of facilities such as hospitals, nursing homes, hospices, and rehabilitation centers. Although these

price indices move similarly over time, we believe that it is more technically appropriate to use an index that is more specific to the hospital industry. We believe these are the most appropriate proxies for hospital capital costs that meet our selection criteria of relevance, timeliness, availability, and reliability.

The price proxies (prior to any vintage weighting) for each of the capital cost categories are the same as those used for the FY 2006-based Capital Input Price Index as described in the IPPS FY 2010 final rule (74 FR at 43857).

5. RY 2012 Market Basket Update

As proposed, and in this final rule, for RY 2012 (that is, beginning July 1, 2011

through September 30, 2012), we derived a 15-month estimate of the FY 2008-based RPL market basket based on the best available data. To determine a 15-month market basket update for RY 2012, we calculate the 5-quarter moving average index level for July 1, 2011 through September 30, 2012 and the 4-quarter moving average index level for July 1, 2010 through June 30, 2011. The percent change in these two values represents the 15-month market basket update.

Consistent with historical practice, we estimate the RPL market basket update for the IPF PPS based on IHS Global Insight's forecast using the most recent available data. IHS Global Insight, Inc.

is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets. In the RY 2012 IPF PPS proposed rule, we proposed a market basket update based on the 4th quarter 2010 forecast with history through the 3rd quarter of 2010. We also proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket) we would use such data, if appropriate, to determine the RY 2012 update in the final rule. Based on IHS Global Insight's 1st quarter 2011 forecast with history through the 4th quarter of 2010, the projected 15-month market basket update for the 15-month RY 2012 (July 1, 2011 through September 30, 2012) is 3.2 percent.

The most recent estimate of the FY 2008-based RPL market basket update

for July 1, 2011 through June 30, 2012, based on IHS Global Insight's 1st quarter 2011 forecast with history through the 4th quarter of 2010, is 2.8 percent. We determined this 12-month market basket update by calculating the 4-quarter moving average index level for July 1, 2011 through June 30, 2012 and the 4-quarter moving average index level for July 1, 2010 through June 30, 2011. The percent change in these two values represents the 12-month market basket update. Consistent with our historical practice of using market basket estimates based on the most recent available data, if we were not extending the 2012 IPF PPS RY by 3 months, the market basket update for a 12-month RY 2012 would be 2.8 percent, based on the most recent estimate of the 12-month RPL market basket update for July 1, 2011 through June 30, 2012.

Using the FY 2002-based RPL market basket and IHS Global Insight's 1st quarter 2011 forecast for the market basket components, the 15-month RY 2012 update would be 3.3 percent. The 12-month RY 2012 update would be 2.9 percent.

As proposed, for this RY 2012 IPF PPS final rule we have determined the RY 2012 update based on the most recent market basket estimate for the 15-month period. The current estimates of the FY 2002-based and FY 2008-based RPL market baskets are based on IHS Global Insight's first quarter 2011 forecast with historical data through fourth quarter 2010. Table 5 below compares the FY 2008-based RPL market basket and the FY 2002-based RPL market basket percent changes.

TABLE 5—FY 2002-BASED AND FY 2008-BASED RPL MARKET BASKET PERCENT CHANGES, RY 2006 THROUGH FY 2014

| Rate year (RY) or fiscal year (FY) | FY 2002-based RPL market basket index percent change | FY 2008-based RPL market basket index percent change |
|------------------------------------|---|---|
| Historical data: | | |
| RY 2006 ¹ | 3.8 | 3.7 |
| RY 2007 ¹ | 3.5 | 3.5 |
| RY 2008 ¹ | 3.5 | 3.6 |
| RY 2009 ¹ | 3.1 | 3.3 |
| RY 2010 ¹ | 2.2 | 2.1 |
| Average 2006–2010 | 3.2 | 3.2 |
| Forecast: | | |
| RY 2011 ¹ | 2.4 | 2.5 |
| RY 2012 ² | 3.3 | 3.2 |
| FY 2013 ³ | 2.9 | 2.9 |
| FY 2014 ³ | 3.0 | 3.0 |
| Average 2011–2014 | 2.9 | 2.9 |

¹ RY 2006 through RY 2011 represent 12-month updates, which include July 1 through June 30.

² RY 2012 represents a 15-month update, which includes July 1, 2011 through September 30, 2012.

³ FY 2013 through FY 2014 represent 12-month updates, which include October 1 through September 30.

Note that these market basket percent changes do not include any further adjustments as may be statutorily required.

Source: IHS Global Insight, Inc. 1st quarter 2011 forecast.

The 15-month RY 2012 market basket update using the FY 2008-based RPL market basket is 0.1 percentage point lower than the market basket update using the FY 2002-based RPL market basket. This is due to slightly offsetting factors. The lower total compensation weight in the FY 2008-based RPL market basket (62.278 percent) relative to the FY 2002-based RPL market basket (65.877 percent), absent other factors, would have resulted in a slightly lower market basket update using the FY 2008-based RPL market basket. This impact, however, is partially offset by the larger weight associated with the Professional Fees category. In both market baskets, these expenditures are

proxied by the ECI for Compensation for Professional and Related Services. The weight for Professional Fees in the FY 2002-based RPL market basket is 2.892 percent compared to 6.325 percent in the FY 2008-based RPL market basket.

We did not receive any public comments on the market basket updates in the RY 2012 IPF PPS proposed rule.

6. Labor-Related Share

As described in section VI.C.1. of this final rule, due to the variations in costs and geographic wage levels, we proposed that payment rates under the IPF PPS continue to be adjusted by a geographic wage index. This wage index would apply to the labor-related portion of the Federal per diem base rate,

hereafter referred to as the labor-related share.

The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. As proposed, and for this final rule, we continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market. Given this, based on our definition of the labor-related share, we proposed to include in the labor-related share the sum of the relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Business Support Services, All Other: Labor-

related Services (previously referred to in the FY 2002-based RPL market basket as labor-intensive), and a portion of the Capital-Related cost weight.

Consistent with previous rebasings, the All Other: Labor-related Services cost category is mostly comprised of building maintenance and security services (including, but not limited to, commercial and industrial machinery and equipment repair, nonresidential maintenance and repair, and investigation and security services). Because these services tend to be labor-intensive and are mostly performed at the hospital facility (and, therefore, unlikely to be purchased in the national market), we believe that they meet our definition of labor-related services.

As stated in the April 2010 IPF PPS notice (75 FR 23110), the labor-related share was defined as the sum of the relative importance of Wages and Salaries, Fringe Benefits, Professional Fees, Labor-intensive Services, and a portion of the capital share from an appropriate market basket. Therefore, to determine the labor-related share for the IPF PPS for RY 2011, we used the FY 2002-based RPL market basket cost weights relative importance to determine the labor-related share for the IPF PPS.

For the proposed FY 2008-based RPL market basket rebasing, the proposed inclusion of the Administrative and Business Support Services cost category into the labor-related share remained consistent with the current labor-related share because this cost category was previously included in the Labor-intensive cost category. As previously stated, we established a separate Administrative and Business Support Service cost category so that we can use the ECI for Compensation for Office and Administrative Support Services to more precisely proxy these specific expenses.

For the FY 2002-based RPL market basket, we assumed that all nonmedical professional services (including accounting and auditing services, engineering services, legal services, and management and consulting services) were purchased in the local labor market and, therefore, all of their associated fees varied with the local labor market. As a result, we previously included 100 percent of these costs in the labor-related share. In an effort to more accurately determine the share of professional fees that should be included in the labor-related share, we surveyed hospitals regarding the proportion of those fees that go to companies that are located beyond their own local labor market (the results are discussed below).

We continue to look for ways to refine our market basket approach to more accurately account for the proportion of costs influenced by the local labor market. To that end, we conducted a survey of hospitals to empirically determine the proportion of contracted professional services purchased by the industry that are attributable to local firms and the proportion that are purchased from national firms. We notified the public of our intent to conduct this survey on December 9, 2005 (70 FR 73250) and received no comments (71 FR 8588).

With approval from the Office of Management and Budget (OMB), we contacted a sample of IPF hospitals and received responses to our survey from 108 hospitals. We believe that these data serve as an appropriate proxy for the purchasing patterns of professional services for IPFs as they are also institutional providers of health care services. Using data on FTEs to allocate responding hospitals across strata (region of the country and urban/rural status), we calculated poststratification weights. Based on these weighted results, we determined that hospitals purchase, on average, the following portions of contracted professional services outside of their local labor market:

- 34 percent of accounting and auditing services.
- 30 percent of engineering services.
- 33 percent of legal services.
- 42 percent of management consulting services.

We applied each of these percentages to its respective Benchmark I-O cost category underlying the professional fees cost category. This is the methodology that we used to separate the FY 2008-based RPL market basket professional fees category into Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories. In addition to the professional services listed above, we also classified expenses under NAICS 55, Management of Companies and Enterprises, into the Professional Fees cost category as was done in previous rebasings. The NAICS 55 data are mostly comprised of corporate, subsidiary, and regional managing offices, or otherwise referred to as home offices. Formerly, all of the expenses within this category were considered to vary with, or be influenced by, the local labor market and were thus included in the labor-related share. Because many hospitals are not located in the same geographic area as their home office, we analyzed data from a variety of sources in order to determine what proportion

of these costs should be appropriately included in the labor-related share.

Using data primarily from the Medicare cost reports and a CMS database of Home Office Medicare Records (HOMER) (a database that provides city and state information (addresses) for home offices), we were able to determine that 19 percent of the total number of freestanding IRFs, freestanding IPFs, and LTCHs that had home offices had those home offices located in their respective local labor markets—defined as being in the same Metropolitan Statistical Area (MSA).

The Medicare cost report requires hospitals to report their home office provider numbers. Using the HOMER database to determine the home office location for each home office provider number, we compared the location of the provider with the location of the hospital's home office. We then placed providers into one of the following three groups:

- Group 1—Provider and home office are located in different States.
- Group 2—Provider and home office are located in the same State and same city.
- Group 3—Provider and home office are located in the same State and different city.

We found that 63 percent of the providers with home offices were classified into Group 1 (that is, different State) and, thus, these providers were determined to not be located in the same local labor market as their home office. Although there were a very limited number of exceptions (that is, providers located in different States but the same MSA as their home office), the 63 percent estimate was unchanged.

We found that 9 percent of all providers with home offices were classified into Group 2 (that is, same State and same city and, therefore, the same MSA). Consequently, these providers were determined to be located in the same local labor market as their home offices.

We found that 27 percent of all providers with home offices were classified into Group 3 (that is, same State and different city). Using data from the Census Bureau to determine the specific MSA for both the provider and its home office, we found that 10 percent of all providers with home offices were identified as being in the same State, a different city, but the same MSA.

Pooling these results, we were able to determine that approximately 19 percent of providers with home offices had home offices located within their local labor market (that is, 9 percent of providers with home offices had their

home offices in the same State and city (and, thus, the same MSA), and 10 percent of providers with home offices had their home offices in the same State, a different city, but the same MSA). We proposed to apportion the NAICS 55 expense data by this percentage. Thus, we proposed to classify 19 percent of these costs into the Professional Fees: Labor-related cost category and the remaining 81 percent into the Professional Fees: Nonlabor-related Services cost category.

We received several comments on our proposal to revise the labor-related share. These comments and our responses are provided below.

Comment: One commenter recommended that CMS move forward with this proposal, and stated a belief that the labor-related share has been overstated in the past, resulting in reduced payments to facilities in areas with low wage indices.

Response: We thank the commenter for this comment. We believe comments on prior years' labor-related shares would have been addressed in those rulemakings.

Comment: Several commenters objected to the proposed change in the treatment of professional fees in the calculation of the labor-related share,

and recommended maintaining the current methodology. One commenter questioned the sample size (108 hospitals) for estimating the allocation of professional fees. Several commenters believed that professional services, whether purchased within or outside the local labor market, are substitutes for hospital-employed staff and should be included as labor costs.

Response: We disagree with the request to reject the proposed change in the calculation of the labor-related share. A method that distributes professional fees based on empirical research and data represents a technical improvement to the construction of the market basket, where previously all professional fees were assumed to vary with the local labor market. In response to the concern about the sample of 108 hospitals, we provided more detail on that survey conducted below. We note that these same survey results were used in the IPPS market basket rebasing for the FY 2010 IPPS final rule (74 FR 43853).

The survey's methods unfolded in the following manner: Through an independent contractor, a small sample of 12 hospitals were initially pre-tested in order to ensure the understandability of the survey questions. The survey

prompted sample institutions to select from multiple choice answers the proportions of their professional fees that are purchased from firms located outside of their respective local labor market. The multiple choice answers for each type of professional service included the following options: 0 percent of fees; 1–20 percent of fees; 21–40 percent of fees; 41–60 percent of fees; 61–80 percent of fees; 81–99 percent of fees; and 100 percent of fees. All respondents were assured that the information they provided would be kept strictly confidential.

Understanding that larger, urban-based hospitals (and those located in areas with area wage indexes greater than 1.0) are most likely to be impacted by the survey's results, we used data on full-time equivalents (FTEs) to represent the sizes of hospitals and selected hospitals with probability proportional to their sizes across strata when drawing the full sample. Strata were formed by Census Region and Urban/Rural Status. The distributions of the hospital population, as well as weighted distributions for the responders, by Urban/Rural Status (including data on hospital size) and Census Region were as follows:

| | All hospitals percent distribution & average FTE size | Responding hospitals percent distribution & average FTE size |
|------------------------------|---|--|
| Total | 100%/994 | 100%/1,156 |
| Total Rurals | 30%/388 | 25%/449 |
| Total Urbans | 70%/1,255 | 75%/1,460 |
| Total Northeast Region | 15%/1,442 | 20%/1,078 |
| Total Mid-West Region | 23%/1,062 | 24%/1,656 |
| Total South Region | 42%/843 | 37%/944 |
| Total West Region | 20%/899 | 19%/1,081 |

Sample weights were calculated as the inverse of the selection probability and were subsequently adjusted for nonresponse bias by strata and post-stratified to derive final weights. This type of application represents a common survey approach and is based on valid and widely-accepted statistical techniques.

For the estimates of the nationwide proportion of nonmedical professional services fees purchased outside of the local labor market, we first examined the data on multiple levels. First, we found that fewer than 30 percent of the responding hospitals paid 100 percent of their professional fees to vendors located within their local labor market. Conversely, we found that roughly 20 percent of responding hospitals reported 81 percent or more of their professional

services fees are paid to vendors located outside of their local labor market.

In determining the specific and appropriate proportions of professional fees to consider labor-related and nonlabor-related, we generated weighted averages from the data in the following manner:

- For any multiple choice answer where the standard error associated with the weighted counts for that answer was less than 30 percent, we multiplied the weighted counts associated with that answer by the midpoint of the range within that answer. For example, for Accounting and Auditing services, if a weighted count of 500 hospitals responded that they pay "1 to 20 percent" of their professional fees for these services to firms located outside of their local labor market, we would multiply 500 times 10

percent. We repeat this for each possible multiple choice answer.

- For any multiple choice answer where the standard error associated with the weighted counts for that answer exceeded 30 percent, we multiplied the weighted hospital counts by the low point of the range. Using a similar example as above, if a weighted count of 300 hospitals responded that they pay "1 to 20 percent" of their professional fees for these services to firms located outside of their local labor market, and the standard error on that estimate was greater than 30 percent, we would multiply 300 times 1 percent.

- After applying one of these two techniques to each answer, dependent on its associated standard error, we took a weighted average of the results to determine the final proportion to be excluded from the labor-related share

for each of the four types of professional services surveyed.

Given the information provided above, we believe that the estimates based on this survey are valid. In response to the commenters' statement that professional services should be included as labor-related costs no matter where they are purchased, we again note that the purpose of the labor-related share is to determine the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We define the labor-related share as not

only those expenses that are labor-intensive but those that also vary with, or are influenced by, the local labor market. By application of this definition, it is relevant where these professional services are purchased. To the extent these services are not purchased in the local labor market, they are not included in the labor-related share.

After consideration of the public comments received, in this final rule we are finalizing our methodology for calculating the labor-related share for RY 2012. Using the same methodology

that was proposed in the RY 2012 IPF PPS proposed rule, we calculated a labor-related share for RY 2012 using the most recent data available at the time of this final rule. This estimate of the RY 2012 labor-related share is based on IHS Global Insight Inc.'s first quarter 2011 forecast, which is the same forecast used to derive the RY 2012 market basket update.

Table 6 below shows the RY 2012 relative importance labor-related share using the FY 2008-based RPL market basket and the FY 2002-based RPL market basket.

TABLE 6—COMPARISON OF THE RY 2011 (12-MONTH) RELATIVE IMPORTANCE LABOR-RELATED SHARE BASED ON THE FY 2002-BASED RPL MARKET BASKET AND THE RY 2012 (15-MONTH) RELATIVE IMPORTANCE LABOR-RELATED SHARE BASED ON THE FY 2008-BASED RPL MARKET BASKET

| | RY 2011 relative importance labor-related share ¹ | Final RY 2012 relative importance labor-related share ² |
|--|--|--|
| Wages and Salaries | 52.600 | 49.049 |
| Employee Benefits | 13.935 | 13.036 |
| Professional Fees: Labor-Related | 2.853 | 2.073 |
| Administrative and Business Support Services | | 0.416 |
| All Other: Labor-Related Services | 2.118 | 2.094 |
| Subtotal | 71.506 | 66.668 |
| Labor-Related Portion of Capital Costs (46%) | 3.894 | 3.649 |
| Total Labor-Related Share | 75.400 | 70.317 |

¹ Published in the RY 2011 IPF PPS notice (75FR 23110–23111) and based on the IHS Global Insight, Inc. first quarter 2010 forecast of the 2002-based RPL market basket.

² Based on IHS Global Insight, Inc. first quarter 2011 forecast of the 2008-based RPL market basket.

The labor-related share for RY 2012 is the sum of the RY 2012 relative importance of each labor-related cost category, and would reflect the different rates of price change for these cost categories between the base year (FY 2008) and RY 2012. The sum of the relative importance for RY 2012 for operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Business Support Services, and All Other: Labor-related Services) is 66.668 percent, as shown in Table 6 above. The portion of Capital that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the FY 2002-based RPL market basket. Since the relative importance for Capital-Related Costs is 7.932 percent of the FY 2008-based RPL market basket in RY 2012, we take 46 percent of 7.932 percent to determine the labor-related share of Capital for RY 2012. The result is 3.649 percent, which we add to 66.668 percent for the operating cost amount to determine the total labor-related share for RY 2012. Therefore, the labor-related share for the IPF PPS in RY 2012 is 70.317 percent.

This labor-related share is determined using the same methodology as employed in calculating all previous IPF labor-related shares (69 FR 66952). The wage index and the labor-related share are reflected in budget neutrality adjustments.

V. Updates to the IPF PPS for RY Beginning July 1, 2011

The IPF PPS is based on a standardized Federal per diem base rate calculated from IPF average per diem costs and adjusted for budget-neutrality in the implementation year. The Federal per diem base rate is used as the standard payment per day under the IPF PPS and is adjusted by the patient- and facility-level adjustments that are applicable to the IPF stay. A detailed explanation of how we calculated the average per diem cost appears in the November 2004 IPF PPS final rule (69 FR 66926).

A. Determining the Standardized Budget-Neutral Federal Per Diem Base Rate

Section 124(a)(1) of the BBRA requires that we implement the IPF PPS in a budget neutral manner. In other

words, the amount of total payments under the IPF PPS, including any payment adjustments, must be projected to be equal to the amount of total payments that would have been made if the IPF PPS were not implemented. Therefore, we calculated the budget-neutrality factor by setting the total estimated IPF PPS payments to be equal to the total estimated payments that would have been made under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) methodology had the IPF PPS not been implemented.

Under the IPF PPS methodology, we calculated the final Federal per diem base rate to be budget neutral during the IPF PPS implementation period (that is, the 18-month period from January 1, 2005 through June 30, 2006) using a July 1 update cycle. We updated the average cost per day to the midpoint of the IPF PPS implementation period (that is, October 1, 2005), and this amount was used in the payment model to establish the budget-neutrality adjustment.

A step-by-step description of the methodology used to estimate payments under the TEFRA payment system

appears in the November 2004 IPF PPS final rule (69 FR 66926).

1. Standardization of the Federal Per Diem Base Rate and Electroconvulsive Therapy (ECT) Rate

In the November 2004 IPF PPS final rule, we describe how we standardized the IPF PPS Federal per diem base rate in order to account for the overall positive effects of the IPF PPS payment adjustment factors. To standardize the IPF PPS payments, we compared the IPF PPS payment amounts calculated from the FY 2002 Medicare Provider Analysis and Review (MedPAR) file to the projected TEFRA payments from the FY 2002 cost report file updated to the midpoint of the IPF PPS implementation period (that is, October 2005). The standardization factor was calculated by dividing total estimated payments under the TEFRA payment system by estimated payments under the IPF PPS. The standardization factor was calculated to be 0.8367.

As described in detail in the May 2006 IPF PPS final rule (71 FR 27045), in reviewing the methodology used to simulate the IPF PPS payments used for the November 2004 IPF PPS final rule, we discovered that due to a computer code error, total IPF PPS payments were underestimated by about 1.36 percent. Since the IPF PPS payment total should have been larger than the estimated figure, the standardization factor should have been smaller (0.8254 vs. 0.8367). In turn, the Federal per diem base rate and the ECT rate should have been reduced by 0.8254 instead of 0.8367.

To resolve this issue, in RY 2007, we amended the Federal per diem base rate and the ECT payment rate prospectively. Using the standardization factor of 0.8254, the average cost per day was effectively reduced by 17.46 percent (100 percent minus 82.54 percent = 17.46 percent).

2. Calculation of the Budget Neutrality Adjustment

To compute the budget neutrality adjustment for the IPF PPS, we separately identified each component of the adjustment, that is, the outlier adjustment, stop-loss adjustment, and behavioral offset.

A complete discussion of how we calculate each component of the budget neutrality adjustment appears in the November 2004 IPF PPS final rule (69 FR 66932 through 66933) and in the May 2006 IPF PPS final rule (71 FR 27044 through 27046).

a. Outlier Adjustment

Since the IPF PPS payment amount for each IPF includes applicable outlier

amounts, we reduced the standardized Federal per diem base rate to account for aggregate IPF PPS payments estimated to be made as outlier payments. The outlier adjustment was calculated to be 2 percent. As a result, the standardized Federal per diem base rate was reduced by 2 percent to account for projected outlier payments.

b. Stop-Loss Provision Adjustment

As explained in the November 2004 IPF PPS final rule, we provided a stop-loss payment during the transition from cost-based reimbursement to the per diem payment system to ensure that an IPF's total PPS payments were no less than a minimum percentage of their TEFRA payment, had the IPF PPS not been implemented. We reduced the standardized Federal per diem base rate by the percentage of aggregate IPF PPS payments estimated to be made for stop-loss payments. As a result, the standardized Federal per diem base rate was reduced by 0.39 percent to account for stop-loss payments. Since the transition was completed in RY 2009, the stop-loss provision is no longer applicable, and for cost reporting periods beginning on or after January 1, 2008, IPFs were paid 100 percent PPS.

c. Behavioral Offset

As explained in the November 2004 IPF PPS final rule, implementation of the IPF PPS may result in certain changes in IPF practices, especially with respect to coding for comorbid medical conditions. As a result, Medicare may make higher payments than assumed in our calculations. Accounting for these effects through an adjustment is commonly known as a behavioral offset.

Based on accepted actuarial practices and consistent with the assumptions made in other PPSs, we assumed in determining the behavioral offset that IPFs would regain 15 percent of potential "losses" and augment payment increases by 5 percent. We applied this actuarial assumption, which is based on our historical experience with new payment systems, to the estimated "losses" and "gains" among the IPFs. The behavioral offset for the IPF PPS was calculated to be 2.66 percent. As a result, we reduced the standardized Federal per diem base rate by 2.66 percent to account for behavioral changes. As indicated in the November 2004 IPF PPS final rule, we do not plan to change adjustment factors or projections until we analyze IPF PPS data.

If we find that an adjustment is warranted, the percent difference may be applied prospectively to the established PPS rates to ensure the rates

accurately reflect the payment level intended by the statute. In conducting this analysis, we will be interested in the extent to which improved coding of patients' principal and other diagnoses, which may not reflect real increases in underlying resource demands, has occurred under the PPS.

B. Update of the Federal Per Diem Base Rate and Electroconvulsive Therapy Rate

As described in the November 2004 IPF PPS final rule (69 FR 66931), the average per diem cost was updated to the midpoint of the implementation year. This updated average per diem cost of \$724.43 was reduced by 17.46 percent to account for standardization to projected TEFRA payments for the implementation period, by 2 percent to account for outlier payments, by 0.39 percent to account for stop-loss payments, and by 2.66 percent to account for the behavioral offset. The Federal per diem base rate in the implementation year was \$575.95. The increase in the per diem base rate for RY 2009 included the 0.39 percent increase due to the removal of the stop-loss provision. We indicated in the November 2004 IPF PPS final rule (69 FR 66932) that we would remove this 0.39 percent reduction to the Federal per diem base rate after the transition. As discussed in section IV.D.2. of the May 2008 IPF PPS notice, we increased the Federal per diem base rate and the ECT base rate by 0.39 percent in RY 2009. Therefore for RY 2009 and beyond, the stop-loss provision has ended and is no longer a part of budget neutrality.

In accordance with section 1886(s)(2)(A)(ii) of the Act, which requires the application of an "other adjustment," described in section 1886(s)(3) of the Act (specifically, section 1886(s)(3)(A) for RYs 2011 and 2012) that reduces the update to the IPF PPS base rate for the RY beginning in Calendar Year (CY) 2011, we are adjusting the IPF PPS update by a 0.25 percentage point reduction for RY 2012. For this final rule, we are applying the 15-month 2008-based RPL market basket increase for RY 2012 of 3.2 percent, as adjusted by the "other adjustment" of -0.25 percentage point, and the wage index budget neutrality factor of 0.9995 to the RY 2011 Federal per diem base rate of \$665.71 yielding a Federal per diem base rate of \$685.01 for RY 2012. Similarly, we are applying the market basket increase, as adjusted by the "other adjustment", and the wage index budget neutrality factor to the RY 2011 ECT base rate, yielding an ECT base rate of \$294.91 for RY 2012.

Final Rule Action: In summary, for the RY 2012, we received no public comments concerning the “other adjustment”; therefore, we will apply the 15-month FY 2008-based RPL market basket increase of 3.2 percent with the “other adjustment” of –0.25 percent and the wage index budget neutrality factor to the RY 2011 ECT and Federal per diem base rates to yield the RY 2012 ECT base rate of \$294.91 and Federal per diem base rate of \$685.01.

VI. Update of the IPF PPS Adjustment Factors

A. Overview of the IPF PPS Adjustment Factors

The IPF PPS payment adjustments were derived from a regression analysis of 100 percent of the FY 2002 MedPAR data file, which contained 483,038 cases. For the proposed rule, we used the same results of the regression analysis used to implement the November 2004 IPF PPS final rule. For a more detailed description of the data file used for the regression analysis, see the November 2004 IPF PPS final rule (69 FR 66935 through 66936). While we have since used more recent claims data to set the fixed dollar loss threshold amount, we used the same results of this regression analysis to update the IPF PPS for RY 2011 and we proposed to use these same results for RY 2012. Now that we are approximately 5 years into the IPF PPS, we believe that we have enough data to begin looking at the process of refining the IPF PPS as appropriate. We believe that in the next rulemaking, for FY 2013, we will be ready to propose potential refinements to the system.

As we stated previously, we do not plan to update the regression analysis until we are able to analyze IPF PPS claims and cost report data. However, we continue to monitor claims and payment data independently from cost report data to assess issues, to determine whether changes in case-mix or payment shifts have occurred among freestanding governmental, non-profit and private psychiatric hospitals, and psychiatric units of general hospitals, and CAHs and other issues of importance to IPFs.

B. Patient-Level Adjustments

In the April 2010 IPF PPS notice (75 FR 23113 through 23117), we announced payment adjustments for the following patient-level characteristics: Medicare Severity diagnosis related groups (MS-DRGs) assignment of the patient's principal diagnosis, selected comorbidities, patient age, and the variable per diem adjustments.

1. Adjustment for MS-DRG Assignment

The IPF PPS includes payment adjustments for the psychiatric DRG assigned to the claim based on each patient's principal diagnosis. The IPF PPS recognizes the MS-DRGs. The DRG adjustment factors were expressed relative to the most frequently reported psychiatric DRG in FY 2002, that is, DRG 430 (psychoses). The coefficient values and adjustment factors were derived from the regression analysis.

In accordance with § 412.27(a), payment under the IPF PPS is conditioned on IPFs admitting “only patients whose admission to the unit is required for active treatment, of an intensity that can be provided appropriately only in an inpatient hospital setting, of a psychiatric principal diagnosis that is listed in Chapter Five (“Mental Disorders”) of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)” or in the Fourth Edition, Text Revision of the American Psychiatric Association's Diagnostic and Statistical Manual, (DSM-IV-TR). IPF claims with a principal diagnosis included in Chapter Five of the ICD-9-CM or the DSM-IV-TR are paid the Federal per diem base rate under the IPF PPS and all other applicable adjustments, including any applicable DRG adjustment. Psychiatric principal diagnoses that do not group to one of the designated DRGs still receive the Federal per diem base rate and all other applicable adjustments, but the payment would not include a DRG adjustment.

The Standards for Electronic Transaction final rule published in the **Federal Register** on August 17, 2000 (65 FR 50312), adopted the ICD-9-CM as the designated code set for reporting diseases, injuries, impairments, other health related problems, their manifestations, and causes of injury, disease, impairment, or other health related problems. Therefore, we use the ICD-9-CM as the designated code set for the IPF PPS.

We believe that it is important to maintain the same diagnostic coding and DRG classification for IPFs that are used under the IPPS for providing psychiatric care. Therefore, when the IPF PPS was implemented for cost reporting periods beginning on or after January 1, 2005, we adopted the same diagnostic code set and DRG patient classification system (that is, the CMS DRGs) that were utilized at the time under the hospital inpatient prospective payment system (IPPS). Since the inception of the IPF PPS, the DRGs used as the patient classification system under the IPF PPS have corresponded

exactly with the CMS DRGs applicable under the IPPS for acute care hospitals.

Every year, changes to the ICD-9-CM coding system are addressed in the IPPS proposed and final rules. The changes to the codes are effective October 1 of each year and must be used by acute care hospitals as well as other providers to report diagnostic and procedure information. The IPF PPS has always incorporated ICD-9-CM coding changes made in the annual IPPS update. We publish coding changes in a Transmittal/Change Request, similar to how coding changes are announced by the IPPS and LTCH PPS. Those ICD-9-CM coding changes are also published in the following IPF PPS RY update, in either the IPF PPS proposed and final rules, or in an IPF PPS update notice.

In the May 2008 IPF PPS notice (73 FR 25709), we discussed CMS' effort to better recognize resource use and the severity of illness among patients. CMS adopted the new MS-DRGs for the IPPS in the FY 2008 IPPS final rule with comment period (72 FR 47130). We believe by better accounting for patients' severity of illness in Medicare payment rates, the MS-DRGs encourage hospitals to improve their coding and documentation of patient diagnoses. The MS-DRGs, which are based on the CMS DRGs, represent a significant increase in the number of DRGs (from 538 to 745, an increase of 207). For a full description of the development and implementation of the MS-DRGs, see the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175).

In the May 2008 IPF PPS notice, the IPF PPS recognized the MS-DRGs. A crosswalk, to reflect changes that were made to the DRGs under the IPF PPS to the new MS-DRGs was provided (73 FR 25716). Since then, we have referred to the IPF PPS DRGs as MS-DRGs. In the RY 2012 IPF PPS proposed rule, we proposed that all references to the MS-DRGs used for the IPF PPS would be to MS-IPF-DRGs. This would only be a change in terminology. We proposed to revise § 412.402 to add the definition of MS-IPF-DRG.

Comment: One Commenter suggested for consistency sake, that the DRG name of MS-DRG should remain the same in this rule as it is in the IPPS rule. The commenter believes that the name change to MS-IPF-DRGs suggest that there are two separate and distinct DRG classification systems.

Response: We understand the commenter's concern that the name change from MS-DRG to MS-IPF-DRG could suggest that there are two separate DRG classification systems. Although we proposed to simply change the

terminology only and this change does not mean two separate and distinct DRG classification systems, we will retain the MS-DRG name for consistency sake and to avoid confusion. Therefore, we will not finalize the revision of § 412.402 to add the definition of MS-IPF-DRG. All references to the DRG name of MS-DRGs for the IPF PPS will remain the same.

All of the ICD-9-CM coding changes are reflected in the FY 2011 GROUPER, Version 28.0, effective for IPPS discharges occurring on or after October 1, 2010 through September 30, 2011. The GROUPER Version 28.0 software package assigns each case to an MS-DRG on the basis of the diagnosis and procedure codes and demographic information (that is, age, sex, and discharge status). The Medicare Code Editor (MCE) 27.0 uses the new ICD-9-CM codes to validate coding for IPPS discharges on or after October 1, 2010. For additional information on the GROUPER Version 28.0 and MCE 27.0, see Transmittal 2060 (Change Request 7134), dated October 1, 2010. The IPF PPS has always used the same GROUPER and Code Editor as the IPPS. Therefore, the ICD-9-CM changes, which were reflected in the GROUPER Version 28.0 and MCE 27.0 on October

1, 2010, also became effective for the IPF PPS for discharges occurring on or after October 1, 2010.

The impact of the new MS-DRGs on the IPF PPS was negligible. Mapping to the MS-DRGs resulted in the current 17 MS-DRGs, instead of the original 15, for which the IPF PPS provides an adjustment. Although the code set is updated, the same associated adjustment factors apply now that have been in place since implementation of the IPF PPS, with one exception that is unrelated to the update to the codes. When DRGs 521 and 522 were consolidated into MS-DRG 895, we carried over the adjustment factor of 1.02 from DRG 521 to the newly consolidated MS-DRG. This was done to reflect the higher claims volume under DRG 521, with more than eight times the number of claims than billed under DRG 522. The updates are reflected in Tables 7 and 8. For a detailed description of the mapping changes from the original DRG adjustment categories to the current MS-DRG adjustment categories we refer readers to the May 2008 IPF PPS notice (73 FR 25714).

The official version of the ICD-9-CM is available on CD-ROM from the U.S. Government Printing Office. The FY 2009 version can be ordered by

contacting the Superintendent of Documents, U.S. Government Printing Office, Department 50, Washington, DC 20402-9329, telephone number (202) 512-1800. Questions concerning the ICD-9-CM should be directed to Patricia E. Brooks, Co-Chairperson, ICD-9-CM Coordination and Maintenance Committee, CMS, Center for Medicare Management, Hospital and Ambulatory Policy Group, Division of Acute Care, Mailstop C4-08-06, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Further information concerning the official version of the ICD-9-CM can be found in the IPPS final rule with comment period, "Changes to Hospital Inpatient Prospective Payment System and Fiscal Year 2011 Rates" in the August 16, 2010 **Federal Register** (75 FR 50042) and at Tables 7 and 8 below list the FY 2011 new and revised ICD-9-CM diagnosis codes that group to one of the 17 MS-DRGs for which the IPF PPS provides an adjustment. These tables are only a listing of FY 2011 changes and do not reflect all of the currently valid and applicable ICD-9-CM codes classified in the MS-DRGs. When coded as a principal code or diagnosis, these codes receive the correlating MS-DRG adjustment.

TABLE 7—FY 2011 NEW DIAGNOSIS CODES

| Diagnosis code | MS-DRG descriptions | MS-DRG |
|----------------|--|--------|
| 799.51 | Attention or concentration deficit | 886 |
| 799.52 | Cognitive communication deficit | 884 |
| 799.54 | Psychomotor deficit | 884 |
| 799.55 | Frontal lobe and executive function deficit | 884 |
| 799.59 | Other signs and symptoms involving cognition | 884 |

TABLE 8—FY 2011 REVISED DIAGNOSIS CODE

| Diagnosis code | MS-DRG description | MS-DRG |
|----------------|------------------------------------|--------|
| 307.0 | Adult onset fluency disorder | 887 |

Because we do not plan to update the regression analysis until we are able to analyze IPF PPS data, we proposed that

the MS-IPF-DRG adjustment factors (as shown in Table 9) would continue to be

paid for discharges occurring in RY 2012.

TABLE 9—RY 2012 CURRENT MS-IPF-DRGs APPLICABLE FOR THE PRINCIPAL DIAGNOSIS ADJUSTMENT

| MS-DRG | MS-DRG descriptions | Adjustment factor |
|-----------|--|-------------------|
| 056 | Degenerative nervous system disorders w/MCC | 1.05 |
| 057 | Degenerative nervous system disorders w/o MCC | 1.05 |
| 080 | Nontraumatic stupor & coma w/MCC | 1.07 |
| 081 | Nontraumatic stupor & coma w/o MCC | 1.07 |
| 876 | O.R. procedure w/principal diagnoses of mental illness | 1.22 |
| 880 | Acute adjustment reaction & psychosocial dysfunction | 1.05 |
| 881 | Depressive neuroses | 0.99 |
| 882 | Neuroses except depressive | 1.02 |
| 883 | Disorders of personality & impulse control | 1.02 |

TABLE 9—RY 2012 CURRENT MS-IPF-DRGS APPLICABLE FOR THE PRINCIPAL DIAGNOSIS ADJUSTMENT—Continued

| MS-DRG | MS-DRG descriptions | Adjustment factor |
|-----------|---|-------------------|
| 884 | Organic disturbances & mental retardation | 1.03 |
| 885 | Psychoses | 1.00 |
| 886 | Behavioral & developmental disorders | 0.99 |
| 887 | Other mental disorder diagnoses | 0.92 |
| 894 | Alcohol/drug abuse or dependence, left AMA | 0.97 |
| 895 | Alcohol/drug abuse or dependence w/rehabilitation therapy | 1.02 |
| 896 | Alcohol/drug abuse or dependence w/o rehabilitation therapy w/MCC | 0.88 |
| 897 | Alcohol/drug abuse or dependence w/o rehabilitation therapy w/o MCC | 0.88 |

Final Rule Action: In summary, we received one public comment objecting to our proposed change to § 412.402 to change the terminology from MS-DRG to MS-IPF-DRG. Therefore, we will not revise § 412.402 to add the definition of MS-IPF-DRG. Instead, we will retain the MS-DRG name for consistency sake and in order to avoid confusion. All references to the DRG name of MS-DRG for the IPF PPS will remain the same. In addition, we are adopting the MS-DRG adjustments currently in effect and as shown in Table 9.

2. Payment for Comorbid Conditions

The intent of the comorbidity adjustments is to recognize the increased costs associated with comorbid conditions by providing additional payments for certain concurrent medical or psychiatric conditions that are expensive to treat. In the April 2010 IPF PPS notice (75 FR 23114), we explained that the IPF PPS includes 17 comorbidity categories and identified the new, revised, and deleted ICD-9-CM diagnosis codes that generate a comorbid condition payment adjustment under the IPF PPS for RY 2011 (75 FR 23115).

Comorbidities are specific patient conditions that are secondary to the

patient's principal diagnosis and that require treatment during the stay. Diagnoses that relate to an earlier episode of care and have no bearing on the current hospital stay are excluded and must not be reported on IPF claims. Comorbid conditions must exist at the time of admission or develop subsequently, and affect the treatment received, length of stay (LOS), or both treatment and LOS.

For each claim, an IPF may receive only one comorbidity adjustment per comorbidity category, but it may receive an adjustment for more than one comorbidity category. Billing instructions require that IPFs must enter the full ICD-9-CM codes for up to 8 additional diagnoses if they co-exist at the time of admission or develop subsequently and impact the treatment provided.

The comorbidity adjustments were determined based on the regression analysis using the diagnoses reported by IPFs in FY 2002. The principal diagnoses were used to establish the DRG adjustments and were not accounted for in establishing the comorbidity category adjustments, except where ICD-9-CM "code first" instructions apply. As we explained in

the April 2010 IPF PPS notice (75 FR 23115), the code first rule applies when a condition has both an underlying etiology and a manifestation due to the underlying etiology. For these conditions, the ICD-9-CM has a coding convention that requires the underlying conditions to be sequenced first followed by the manifestation. Whenever a combination exists, there is a "use additional code" note at the etiology code and a code first note at the manifestation code.

As discussed in the MS-DRG section, where we proposed that all references to MS-DRGs used for the IPF PPS be to MS-IPF-DRGs (as previously stated, we are not finalizing that proposal), it is our policy to maintain the same diagnostic coding set for IPFs that is used under the IPPS for providing the same psychiatric care. Although the ICD-9-CM code set has been updated, the same adjustment factors have been in place since the implementation of the IPF PPS.

Table 10 below lists the FY 2011 new ICD diagnosis codes that impact the comorbidity adjustments under the IPF PPS. Table 10 is not a list of all currently valid ICD codes applicable for the IPF PPS comorbidity adjustments.

TABLE 10—FY 2011 NEW ICD CODES APPLICABLE FOR THE COMORBIDITY ADJUSTMENT

| Diagnosis code | Description | Comorbidity category |
|----------------|-------------------------------|----------------------|
| 237.73 | Schwannomatosis | Oncology. |
| 237.79 | Other neurofibromatosis | Oncology. |

For RY 2012, we are applying the seventeen comorbidity categories for which we are providing an adjustment,

their respective codes, including the new FY 2011 ICD-9-CM codes, and

their respective adjustment factors in Table 11 below.

TABLE 11—RY 2012 DIAGNOSIS CODES AND ADJUSTMENT FACTORS FOR COMORBIDITY CATEGORIES

| Description of comorbidity | Diagnoses codes | Adjustment factor |
|-----------------------------------|--------------------------------------|-------------------|
| Developmental Disabilities | 317, 3180, 3181, 3182, and 319 | 1.04 |
| Coagulation Factor Deficits | 2860 through 2864. | 1.13 |
| Tracheostomy | 51900 through 51909 and V440 | 1.06 |

TABLE 11—RY 2012 DIAGNOSIS CODES AND ADJUSTMENT FACTORS FOR COMORBIDITY CATEGORIES—Continued

| Description of comorbidity | Diagnoses codes | Adjustment factor |
|---|---|-------------------|
| Renal Failure, Acute | 5845 through 5849, 63630, 63631, 63632, 63730, 63731, 63732, 6383, 6393, 66932, 66934, 9585. | 1.11 |
| Renal Failure, Chronic | 40301, 40311, 40391, 40402, 40412, 40413, 40492, 40493, 5853, 5854, 5855, 5856, 5859, 586, V451, V560, V561, and V562. | 1.11 |
| Oncology Treatment | 1400 through 2399 with a radiation therapy code 92.21–92.29 or chemotherapy code 99.25. | 1.07 |
| Uncontrolled Diabetes-Mellitus with or without complications. | 25002, 25003, 25012, 25013, 25022, 25023, 25032, 25033, 25042, 25043, 25052, 25053, 25062, 25063, 25072, 25073, 25082, 25083, 25092, and 25093. | 1.05 |
| Severe Protein Calorie Malnutrition | 260 through 262 | 1.13 |
| Eating and Conduct Disorders | 3071, 30750, 31203, 31233, and 31234 | 1.12 |
| Infectious Disease | 01000 through 04110, 042, 04500 through 05319, 05440 through 05449, 0550 through 0770, 0782 through 07889, and 07950 through 07959. | 1.07 |
| Drug and/or Alcohol Induced Mental Disorders. | 2910, 2920, 29212, 2922, 30300, and 30400 | 1.03 |
| Cardiac Conditions | 3910, 3911, 3912, 40201, 40403, 4160, 4210, 4211, and 4219 | 1.11 |
| Gangrene | 44024 and 7854. | 1.10 |
| Chronic Obstructive Pulmonary Disease. | 49121, 4941, 5100, 51883, 51884, V4611 and V4612, V4613 and V4614 | 1.12 |
| Artificial Openings—Digestive and Urinary. | 56960 through 56969, 9975, and V441 through V446 | 1.08 |
| Severe Musculoskeletal and Connective Tissue Diseases. | 6960, 7100, 73000 through 73009, 73010 through 73019, and 73020 through 73029 | 1.09 |
| Poisoning | 96500 through 96509, 9654, 9670 through 9699, 9770, 9800 through 9809, 9830 through 9839, 986, 9890 through 9897. | 1.11 |

Final Rule Action: In summary, we are adopting the comorbidity adjustments currently in effect and as shown in Table 11 above for RY 2012 beginning on July 1, 2011.

3. Patient Age Adjustments

As explained in the November 2004 IPF PPS final rule (69 FR 66922), we analyzed the impact of age on per diem cost by examining the age variable (that is, the range of ages) for payment adjustments.

In general, we found that the cost per day increases with age. The older age groups are more costly than the under 45 age group, the differences in per diem cost increase for each successive age group, and the differences are statistically significant.

We do not plan to update the regression analysis until we are able to analyze IPF PPS data. Therefore, for RY 2012, we proposed to continue to use the patient age adjustments currently in effect as shown in Table 12 below.

TABLE 12—AGE GROUPINGS AND ADJUSTMENT FACTORS

| Age | Adjustment factor |
|-----------------------|-------------------|
| Under 45 | 1.00 |
| 45 and under 50 | 1.01 |
| 50 and under 55 | 1.02 |
| 55 and under 60 | 1.04 |
| 60 and under 65 | 1.07 |
| 65 and under 70 | 1.10 |
| 70 and under 75 | 1.13 |
| 75 and under 80 | 1.15 |

TABLE 12—AGE GROUPINGS AND ADJUSTMENT FACTORS—Continued

| Age | Adjustment factor |
|-------------------|-------------------|
| 80 and over | 1.17 |

Final Rule Action: We received no comments on the RY 2012 IPF PPS proposed rule concerning the age adjustment. We are adopting the age adjustment currently in effect and as shown in Table 12 above for RY 2012.

4. Variable Per Diem Adjustments

We explained in the November 2004 IPF PPS final rule (69 FR 66946) that the regression analysis indicated that per diem cost declines as the LOS increases. The variable per diem adjustments to the Federal per diem base rate account for ancillary and administrative costs that occur disproportionately in the first days after admission to an IPF.

We used a regression analysis to estimate the average differences in per diem cost among stays of different lengths. As a result of this analysis, we established variable per diem adjustments that begin on day 1 and decline gradually until day 21 of a patient's stay. For day 22 and thereafter, the variable per diem adjustment remains the same each day for the remainder of the stay. However, the adjustment applied to day 1 depends upon whether the IPF has a qualifying ED. If an IPF has a qualifying ED, it receives a 1.31 adjustment factor for day

1 of each stay. If an IPF does not have a qualifying ED, it receives a 1.19 adjustment factor for day 1 of the stay. The ED adjustment is explained in more detail in section V.C.5 of this final rule.

For RY 2012, we proposed to continue to use the variable per diem adjustment factors currently in effect as shown in Table 13 below. A complete discussion of the variable per diem adjustments appears in the November 2004 IPF PPS final rule (69 FR 66946).

TABLE 13—VARIABLE PER DIEM ADJUSTMENTS

| Day-of-stay | Adjustment factor |
|---|-------------------|
| Day 1—IPF Without a Qualifying ED | 1.19 |
| Day 1—IPF With a Qualifying ED | 1.31 |
| Day 2 | 1.12 |
| Day 3 | 1.08 |
| Day 4 | 1.05 |
| Day 5 | 1.04 |
| Day 6 | 1.02 |
| Day 7 | 1.01 |
| Day 8 | 1.01 |
| Day 9 | 1.00 |
| Day 10 | 1.00 |
| Day 11 | 0.99 |
| Day 12 | 0.99 |
| Day 13 | 0.99 |
| Day 14 | 0.99 |
| Day 15 | 0.98 |
| Day 16 | 0.97 |
| Day 17 | 0.97 |
| Day 18 | 0.96 |
| Day 19 | 0.95 |
| Day 20 | 0.95 |
| Day 21 | 0.95 |

TABLE 13—VARIABLE PER DIEM ADJUSTMENTS—Continued

| Day-of-stay | Adjustment factor |
|--------------------|-------------------|
| After Day 21 | 0.92 |

Final Rule Action: In response to the RY 2012 IPF PPS proposed rule, we received no public comments concerning the variable per diem adjustment. We are adopting the variable per diem adjustment currently in effect and as shown in Table 13 above.

C. Facility-Level Adjustments

The IPF PPS includes facility-level adjustments for the wage index, IPFs located in rural areas, teaching IPFs, cost of living adjustments for IPFs located in Alaska and Hawaii, and IPFs with a qualifying ED.

1. Wage Index Adjustment

a. Background

As discussed in the May 2006 IPF PPS final rule and in the May 2008 and May 2009 IPF PPS notices, in providing an adjustment for geographic wage levels, the labor-related portion of an IPF's payment is adjusted using an appropriate wage index. Currently, an IPF's geographic wage index value is determined based on the actual location of the IPF in an urban or rural area as defined in § 412.64(b)(1)(ii)(A) through § 412.64(C).

b. Wage Index for RY 2012

Since the inception of the IPF PPS, we have used hospital wage data in developing a wage index to be applied to IPFs. We are continuing that practice for RY 2012. We apply the wage index adjustment to the labor-related portion of the Federal rate, which is 70.317 percent. This percentage reflects the labor-related relative importance of the FY 2008-based RPL market basket for RY 2012 (see section IV.C.6 of this final rule). The IPF PPS uses the pre-floor, pre-reclassified hospital wage index. Changes to the wage index are made in a budget neutral manner so that updates do not increase expenditures.

For RY 2012, we proposed to apply the most recent hospital wage index (that is, the FY 2011 pre-floor, pre-reclassified hospital wage index because this is the most appropriate index as it best reflects the variation in local labor costs of IPFs in the various geographic areas) using the most recent hospital wage data (that is, data from hospital cost reports for the cost reporting period beginning during FY 2007), and applying an adjustment in accordance

with our budget neutrality policy. This policy requires us to estimate the total amount of IPF PPS payments in RY 2011 using the applicable wage index value divided by the total estimated IPF PPS payments in RY 2012 using the most recent wage index. The estimated payments are based on FY 2009 IPF claims, inflated to the appropriate RY. This quotient is the wage index budget neutrality factor, and it is applied in the update of the Federal per diem base rate for RY 2012 in addition to the market basket described in section IV.C.5 of this final rule. The wage index budget neutrality factor for RY 2012 is 0.9995.

The wage index applicable for RY 2012 appears in Table 1 and Table 2 in Addendum B of this final rule. As explained in the May 2006 IPF PPS final rule for RY 2007 (71 FR 27061), the IPF PPS applies the hospital wage index without a hold-harmless policy, and without an out-commuting adjustment or out-migration adjustment because the statutory authority for these policies applies only to the IPPS.

Also in the May 2006 IPF PPS final rule for RY 2007 (71 FR 27061), we adopted the changes discussed in the Office of Management and Budget (OMB) Bulletin No. 03–04 (June 6, 2003), which announced revised definitions for Metropolitan Statistical Areas (MSAs), and the creation of Micropolitan Statistical Areas and Combined Statistical Areas. In adopting the OMB Core-Based Statistical Area (CBSA) geographic designations, since the IPF PPS was already in a transition period from TEFRA payments to PPS payments, we did not provide a separate transition for the CBSA-based wage index.

As was the case in RY 2011, for RY 2012 we proposed to continue to use the CBSA-based wage index values as presented in Tables 1 and 2 in Addendum B of this final rule. A complete discussion of the CBSA labor market definitions appears in the May 2006 IPF PPS final rule (71 FR 27061 through 27067).

In summary, for RY 2012 we proposed to use the FY 2011 wage index data (collected from cost reports submitted by hospitals for cost reporting periods beginning during FY 2007) to adjust IPF PPS payments beginning July 1, 2011.

c. OMB Bulletins

The Office of Management and Budget (OMB) publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. In the May 2008 IPF PPS notice, we incorporated the CBSA nomenclature changes published in the most recent OMB bulletin that applies to the hospital

wage data used to determine the current IPF PPS wage index (73 FR 25721). We will continue to do the same for all such OMB CBSA nomenclature changes in future IPF PPS rules and notices, as necessary. The OMB bulletins may be accessed online at <http://www.whitehouse.gov/omb/bulletins/index.html>.

Final Rule Action: We are finalizing our proposal to use FY 2011 wage index data to adjust IPF PPS payments beginning July 1, 2011.

2. Adjustment for Rural Location

In the November 2004 IPF PPS final rule, we provided a 17 percent payment adjustment for IPFs located in a rural area. This adjustment was based on the regression analysis, which indicated that the per diem cost of rural facilities was 17 percent higher than that of urban facilities after accounting for the influence of the other variables included in the regression. For RY 2012, we proposed to apply a 17 percent payment adjustment for IPFs located in a rural area as defined at § 412.64(b)(1)(ii)(C). As stated in the November 2004 IPF PPS final rule, we do not intend to update the adjustment factors derived from the regression analysis until we are able to analyze IPF PPS data. A complete discussion of the adjustment for rural locations appears in the November 2004 IPF PPS final rule (69 FR 66954).

Final Rule Action: In summary, we are adopting the 17 percent rural adjustment in effect for RY 2012.

3. Teaching Adjustment

In the November 2004 IPF PPS final rule, we implemented regulations at § 412.424(d)(1)(iii) to establish a facility-level adjustment for IPFs that are, or are part of, teaching hospitals. The teaching adjustment accounts for the higher indirect operating costs experienced by hospitals that participate in GME programs. The payment adjustments are made based on the number of full-time equivalent (FTE) interns and residents training in the IPF and the IPF's average daily census.

Medicare makes direct GME payments (for direct costs such as resident and teaching physician salaries, and other direct teaching costs) to all teaching hospitals including those paid under a PPS, and those paid under the TEFRA rate-of-increase limits. These direct GME payments are made separately from payments for hospital operating costs and are not part of the PPSs. The direct GME payments do not address the estimated higher indirect operating costs teaching hospitals may face.

For teaching hospitals paid under the TEFRA rate-of-increase limits,

Medicare does not make separate payments for indirect medical education costs because payments to these hospitals are based on the hospitals' reasonable costs which already include these higher indirect costs that may be associated with teaching programs.

The results of the regression analysis of FY 2002 IPF data established the basis for the payment adjustments included in the November 2004 IPF PPS final rule. The results showed that the indirect teaching cost variable is significant in explaining the higher costs of IPFs that have teaching programs. We calculated the teaching adjustment based on the IPF's "teaching variable," which is one plus the ratio of the number of FTE residents training in the IPF (subject to limitations described below) to the IPF's average daily census (ADC).

We established the teaching adjustment in a manner that limited the incentives for IPFs to add FTE residents for the purpose of increasing their teaching adjustment. We imposed a cap on the number of FTE residents that may be counted for purposes of calculating the teaching adjustment. The cap limits the number of FTE residents that teaching IPFs may count for the purpose of calculating the IPF PPS teaching adjustment, not the number of residents teaching institutions can hire or train. We calculated the number of FTE residents that trained in the IPF during a "base year" and used that FTE resident number as the cap. An IPF's FTE resident cap is ultimately determined based on the final settlement of the IPF's most recent cost report filed before November 15, 2004 (that is, the publication date of the IPF PPS final rule).

In the regression analysis, the logarithm of the teaching variable had a coefficient value of 0.5150. We converted this cost effect to a teaching payment adjustment by treating the regression coefficient as an exponent and raising the teaching variable to a power equal to the coefficient value. We note that the coefficient value of 0.5150 was based on the regression analysis holding all other components of the payment system constant.

As with other adjustment factors derived through the regression analysis, we do not plan to rerun the regression analysis until we analyze IPF PPS data. Therefore, in this final rule, for RY 2012, we are retaining the coefficient value of 0.5150 for the teaching adjustment to the Federal per diem base rate.

A complete discussion of how the teaching adjustment was calculated appears in the November 2004 IPF PPS

final rule (69 FR 66954 through 66957) and the May 2008 IPF PPS notice (73 FR 25721).

FTE Intern and Resident Cap Adjustment

CMS has been asked to reconsider the current IPF teaching policy and permit a temporary increase in the FTE resident cap when the IPF increases the number of FTE residents it trains due to the acceptance of displaced residents (residents that are training in an IPF or a program before the IPF or program closed) when another IPF closes or closes its medical residency training program.

To help us assess how many IPFs have been, or expect to be adversely affected by their inability to adjust their caps under § 412.424(d)(1) and under these situations, we specifically requested public comment from IPFs in the May 1, 2009 IPF PPS notice (74 FR 20376 through 20377). A summary of the comments and our response can be reviewed in the April 30, 2010 IPF PPS notice (75 FR 23106, 23117). All of the commenters recommended that CMS modify the IPF PPS teaching adjustment policy, supporting a policy change that would permit the IPF PPS residency cap to be temporarily adjusted when that IPF trains displaced residents due to closure of an IPF or closure of an IPF's medical residency training program(s). The commenters recommended a temporary resident cap adjustment policy similar to such policies applied in similar contexts for acute care hospitals.

We agree with the commenters that, when a hospital temporarily takes on residents because another hospital closes or discontinues its program, a temporary adjustment to the cap would be appropriate for rotation that occurs in an IPF setting (freestanding or units). In these situations, residents may have partially completed a medical residency training program at the hospital that has closed its training program and may be unable to complete their training at another hospital that is already training residents up to or in excess of its cap. We believe that it is appropriate to allow temporary adjustments to the FTE caps for an IPF that provides residency training to medical residents who have partially completed a residency training program at an IPF that closes or at an IPF that discontinues training residents in a residency training program(s) (also referred to as a "closed" program throughout this preamble). For this reason, we proposed to adopt the following temporary resident cap adjustment policies, similar to the temporary adjustments to the FTE cap

used for acute care hospitals. We proposed that the cap adjustment would be temporary because it is resident specific and would only apply to the displaced resident(s) until the resident(s) completes training in that specialty. We proposed that, as under the IPPS policy for displaced residents, the IPF PPS temporary cap adjustment would apply only to residents that were still training at the IPF at the time the IPF closed or at the time the IPF ceased training residents in the residency training program(s). Residents who leave the IPF, for whatever reason, before the closure of the IPF hospital or medical residency training program would not be considered displaced residents for purposes of the IPF temporary cap adjustment policy. Similarly, as under the IPPS policy, we proposed that medical students who match to a program at an IPF but the IPF or medical residency training program closes before the individual begins training at that IPF are also not considered displaced residents for purposes of the IPF temporary cap adjustments. For detailed information on these acute care hospital GME/IME payment policies, see 66 FR 39899 (August 1, 2001), 64 FR 41522 (July 30 1999), and 64 FR 24736 (May 7 1999). We note that although we proposed to adopt a policy under the IPF PPS that is consistent with the policy applicable under the IPPS, the actual caps under the two payment systems may not be commingled.

a. Temporary Adjustment to the FTE Cap To Reflect Residents Added Due to Hospital Closure

We proposed to allow an IPF to receive a temporary adjustment to the FTE cap to reflect residents added because of another IPF's closure. This adjustment is intended to account for medical residents who would have partially completed a medical residency training program at the hospital that has closed and may be unable to complete their training at another hospital because that hospital is already training residents up to or in excess of its cap. We proposed this change because IPFs have indicated a reluctance to accept additional residents from a closed IPF without a temporary adjustment to their caps. For purposes of this policy on IPF closure, we proposed to adopt the IPPS definition of "closure of a hospital" in 42 CFR 413.79(h) to mean the IPF terminates its Medicare provider agreement as specified in 42 CFR 489.52. Therefore, we proposed to add a new § 412.424(d)(1)(iii)(F)(1) to allow a temporary adjustment to an IPF's FTE cap to reflect residents added because of

an IPF's closure on or after July 1, 2011 to be effective for cost reporting periods beginning on or after July 1, 2011. We would allow an adjustment to an IPF's FTE cap if the IPF meets the following criteria: (a) The IPF is training displaced residents from an IPF that closed on or after July 1, 2011; and (b) the IPF that is training the displaced residents from the closed IPF submits a request for a temporary adjustment to its FTE cap to its Medicare contractor no later than 60 days after the hospital first begins training the displaced residents, and documents that the IPF is eligible for this temporary adjustment to its FTE cap by identifying the residents who have come from the closed IPF and have caused the IPF to exceed its cap, (or the IPF may already be over its cap), and specifies the length of time that the adjustment is needed. After the displaced residents leave the IPF's training program or complete their residency program, the IPF's cap would revert to its original level. This means that the temporary adjustment to the FTE cap would be available to the IPF only for the period of time necessary for the displaced residents to complete their training. Further, as under the IPPS policy, we also proposed that the total amount of temporary cap adjustment that can be distributed to all receiving hospitals cannot exceed the cap amount of the IPF that closed.

We also note that section 5506 of the Affordable Care Act, "Preservation of Resident Cap Positions from Closed Hospitals," does not apply to IPFs that closed. Section 5506 only amends sections 1886(d) and (h) of the Act with respect to direct GME and IPPS IME payments. Therefore, the IME FTE cap redistributions under section 5506 only apply to "subsection (d)" IPPS hospitals. Section 5506 has no applicability to the IME teaching adjustments under the IPF PPS (or the IRF PPS, for that matter).

b. Temporary Adjustment to FTE Cap To Reflect Residents Affected by Residency Program Closure

We proposed that if an IPF that ceases training residents in a residency training program(s) agrees to temporarily reduce its FTE cap, another IPF may receive a temporary adjustment to its FTE cap to reflect residents added because of the closure of another IPF's residency training program. For purposes of this policy on closed residency programs, we proposed to adopt the IPPS definition of "closure of a hospital residency training program" to mean that the hospital ceases to offer training for residents in a particular approved medical residency training program as specified in § 413.79(h). The

methodology for adjusting the caps for the "receiving IPF" and the "IPF that closed its program" is described below.

i. Receiving IPF

We proposed that an IPF(s) may receive a temporary adjustment to its FTE cap to reflect residents added because of the closure of another IPF's residency training program for cost reporting periods beginning on or after July 1, 2011 if—

- The IPF is training additional residents from the residency training program of an IPF that closed its program on or after July 1, 2011; and
- No later than 60 days after the IPF begins to train the residents, the IPF submits to its Medicare Contractor a request for a temporary adjustment to its FTE cap, documents that the IPF is eligible for this temporary adjustment by identifying the residents who have come from another IPF's closed program and have caused the IPF to exceed its cap, (or the IPF may already be in excess of its cap), specifies the length of time the adjustment is needed, and, as explained in more detail below, submits to its Medicare contractor a copy of the FTE cap reduction statement by the IPF closing the residency training program.

In general, the temporary adjustment criteria established for closed medical residency training programs at IPFs is similar to the criteria established for closed IPFs. More than one IPF may be eligible to apply for the temporary adjustment because residents from one closed program may migrate to different IPFs, or they may complete their training at more than one IPF. Also, only to the extent to which an IPF would exceed its FTE cap by training displaced residents would it be eligible for the temporary adjustment.

Finally, we proposed that IPFs that meet the proposed criteria would be eligible to receive temporary adjustments to their FTE caps for cost reporting periods beginning on or after July 1, 2011.

ii. IPF That Closed Its Program(s)

We proposed that an IPF that agrees to train residents who have been displaced by the closure of another IPF's resident teaching program may receive a temporary FTE cap adjustment only if the IPF with the closed program meets the following criteria—

- Temporarily reduces its FTE cap by the number of FTE residents in each program year, training in the program at the time of the program's closure. The yearly reduction would be determined by deducting the number of those residents who would have been training in the program during the year of the

closure, had the program not closed; and

- No later than 60 days after the residents who were in the closed program begin training at another IPF, submits to its Medicare contractor a statement signed and dated by its representative that specifies that it agrees to the temporary reduction in its FTE cap to allow the IPF training the displaced residents to obtain a temporary adjustment to its cap; identifies the residents who were training at the time of the program's closure; identifies the IPFs to which the residents are transferring once the program closes; and specifies the reduction for the applicable program years.

Unlike the proposed closed IPF policy at § 412.424(d)(1)(iii)(F)(1), we proposed under this closed program policy that in order for the receiving IPF(s) to qualify for a temporary adjustment to their FTE cap, the IPFs that are closing their programs would need to reduce their FTE cap for the duration of time the displaced residents would need to finish their training. We proposed this because the IPF that closes the program still retains the FTE slots in its cap, even if the IPF chooses not to fill the slots with residents. We believe it is inappropriate to allow an increase to the receiving IPF's cap without an attendant decrease to the cap of the IPF with the closed program, because the IPF that closed a program(s) could fill these slots with residents from other programs even if the increase and related decrease is only temporary.

We proposed that the cap reduction for the IPF with the closed program would be based on the number of FTE residents in each program year who were in the program at the IPF at the time of the program's closure, and who begin training at another IPF.

Comment: The majority of the commenters strongly supported the proposed policy to allow a temporary adjustment to the resident cap when an IPF closes or closes its residency teaching program. However, a few of the commenters urged CMS to modify the regulations to allow IPFs to receive the temporary cap adjustment if they are training displaced residents as of July 1, 2011. One commenter requested the amendment at § 412.424(d)(1)(iii)(F)(I)(i) be modified to state, "The IPF is training additional residents as of July 1, 2011 from an IPF that closed." The commenter also requested that we modify § 412.424(d)(1)(iii)(I)(ii) to state, "No later than 60 days after the IPF begins to train the resident or in the case where an IPF is training the residents as

of July 1, 2011, by August 31, 2011, the IPF submits. * * *

Response: We share the commenters' concern for those FTE residents who have been displaced before July 1, 2011 due to closure of an IPF. We carefully considered the commenters' request that CMS modify the IPF temporary cap adjustment policy to allow IPFs that volunteered to train displaced residents before July 1, 2011, to receive the temporary cap adjustment. We realize that at present, IPFs provide this important service to displaced residents without extra compensation. However, this is a new policy that was proposed rather than a correction to an existing policy, and as such the effective date of the IPF closure policy must be applied prospectively. Therefore, as proposed, we are finalizing the IPF PPS temporary cap adjustment to apply where an IPF is training additional residents from an IPF that closed or closed its residency program on or after July 1, 2011. The policy is effective for cost reporting periods beginning on or after July 1, 2011. We appreciate the support for the proposed policies to allow a temporary adjustment to the resident cap when an IPF closes or closes its residency teaching program. We are finalizing these policies as proposed.

Comment: Several commenters expressed concern about the caps on the number of FTE residents that can be used to calculate the teaching adjustment. These commenters believe that the current cap is based on a snapshot of activity freezing the status of residency education at a random point in time-2004. The commenters stated that they continue to advocate for a substantial increase in the total number of residency training positions supported by the Federal Government.

One commenter expressed concern about having caps in general since the current cap is based on 2004 data. Several commenters pointed out that the demand for health care services will continue with the growing needs of 78 million "baby boomers" that started retirement in 2010 and with the passage of Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equality Act of 2008. These commenters stated that the U.S. already faces a shortage of psychiatrist, and these factors could potentially elevate what is now a problem to what could be a crisis.

Response: We established the teaching adjustment in a manner that limited the incentives for IPFs to add FTE residents for the purpose of increasing their teaching adjustment. We imposed a cap on the number of FTE residents that may be counted for purposes of calculating the teaching

adjustment, similar to that established by sections 4621 (IME FTE cap for IPPS hospitals) and 4623 (direct GME FTE cap for all hospitals) of the BBA. The cap limits the number of residents that teaching IPFs may count for purposes of calculating the teaching adjustment, not the number of residents that teaching institutions can hire or train.

We acknowledge that the cap on the number of FTE residents that may be counted under the IPF PPS teaching adjustment is based on 2004 data and the cap freezes the number of residents that Medicare will recognize for payment under the IPF PPS teaching adjustment to that year. This policy is intended to exercise our statutory responsibility under the BBA to prevent any erosion of the resident caps established under the IPPS that could result from incentives created by the facility adjustment for teaching hospitals under the IPF PPS. In addition, we wanted to avoid creating incentives to artificially expand residency training in IPFs, and ensure that the resident base used to determine payments is related to the care needs in IPF institutions. We provided a detailed discussion in the November 15, 2004 **Federal Register** (69 FR 66954–66955) of the BBA cap. We are continually monitoring the impact of our policies to assess the appropriateness of the policies and will continue to monitor the impact of this policy closely and consider the appropriateness of our FTE cap for future refinements for the RY 2013.

Comment: One commenter recommended that CMS work with the Congress to provide a permanent distribution of the resident cap for IPFs that close, similar to the Affordable Care Act for acute care hospital closures.

Response: We believe the commenter is referring to section 5506 of the Affordable Care Act, "Preservation of Resident Cap Positions from Closed Hospitals," which does not apply to IPFs that closed. In the absence of such authority, we are finalizing the temporary adjustment to the FTE resident caps for when an IPF closes or closes its residency teaching program, as described above.

Final Rule Action: In summary, we are adding § 412.424(d)(1)(iii)(F)(1) and § 412.424(d)(1)(iii)(F)(2) to implement policies related to temporary adjustments to FTE caps to reflect residents added due to closure of an IPF or an IPFs medical residency training program respectfully.

4. Cost of Living Adjustment for IPFs Located in Alaska and Hawaii

The IPF PPS includes a payment adjustment for IPFs located in Alaska and Hawaii based upon the county in which the IPF is located. As we explained in the November 2004 IPF PPS final rule, the FY 2002 data demonstrated that IPFs in Alaska and Hawaii had per diem costs that were disproportionately higher than other IPFs. Other Medicare PPSs (for example, the IPPS and LTCH PPS) have adopted a cost of living adjustment (COLA) to account for the cost differential of care furnished in Alaska and Hawaii.

We analyzed the effect of applying a COLA to payments for IPFs located in Alaska and Hawaii. The results of our analysis demonstrated that a COLA for IPFs located in Alaska and Hawaii would improve payment equity for these facilities. As a result of this analysis, we provided a COLA in the November 2004 IPF PPS final rule.

A COLA adjustment for IPFs located in Alaska and Hawaii is made by multiplying the nonlabor-related portion of the Federal per diem base rate by the applicable COLA factor based on the COLA area in which the IPF is located.

The COLA factors are published on the OPM Web site at (<http://www.opm.gov/oca/cola/rates.asp>).

We note that the COLA areas for Alaska are not defined by county as are the COLA areas for Hawaii. In 5 CFR 591.207, the OPM established the following COLA areas:

- (a) City of Anchorage, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse;
- (b) City of Fairbanks, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse;
- (c) City of Juneau, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse;
- (d) Rest of the State of Alaska.

As previously stated in the November 2004 IPF PPS final rule, we update the COLA factors according to updates established by the U.S. Office of Personnel Management (OPM).

Sections 1911 through 1919 of the Nonforeign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense Authorization Act (NDAA) for Fiscal Year 2010 (Pub. L. 111–84, October 28, 2009), transitions the Alaska and Hawaii COLAs to locality pay. Under section 1914 of Public Law 111–84, locality pay is being phased in over a 3-year period beginning in January 2010, with COLA rates frozen as of the date of enactment, October 28, 2009, and then

proportionately reduced to reflect the phase-in of locality pay.

When we published the proposed COLA adjustment factors in the January 2011 proposed rule, we inadvertently selected the FY 2010 COLA rates. The FY 2010 COLA rates were reduced rates

to account for the phase-in of locality pay. We did not intend to propose reduced COLA rates, and we do not believe it is appropriate to finalize the reduced COLAs that we showed in our proposed rule. The 2009 COLA rates do not reflect the phase-in of locality pay.

Therefore, we are finalizing the FY 2009 COLA rates, which are the same rates that were in effect for both RY 2010 and RY 2011. We plan to address COLA in the future refinement process in FY 2013.

TABLE 14—COLA FACTORS FOR ALASKA AND HAWAII IPFs

| Area | Cost of living adjustment factor |
|---|----------------------------------|
| Alaska: | |
| City of Anchorage and 80-kilometer (50-mile) radius by road | 1.23 |
| City of Fairbanks and 80-kilometer (50-mile) radius by road | 1.23 |
| City of Juneau and 80-kilometer (50-mile) radius by road | 1.23 |
| Rest of Alaska | 1.25 |
| Hawaii: | |
| City and County of Honolulu | 1.25 |
| County of Hawaii | 1.18 |
| County of Kauai | 1.25 |
| County of Maui and County of Kalawao | 1.25 |

(The above factors are based on data obtained from the U.S. Office of Personnel Management Web site at: <http://www.opm.gov/oqa/cola/rates.asp>.)

Final Rule Action: In summary, although we did not propose the FY 2009 COLAs, in order to provide a full COLA, we are adopting the FY 2009 COLA rates obtained from the OPM Web site and as shown in Table 14 above.

5. Adjustment for IPFs With a Qualifying Emergency Department (ED)

Currently, the IPF PPS includes a facility-level adjustment for IPFs with qualifying EDs. We provide an adjustment to the Federal per diem base rate to account for the costs associated with maintaining a full-service ED. The adjustment is intended to account for ED costs incurred by a freestanding psychiatric hospital with a qualifying ED or a distinct part psychiatric unit of an acute hospital or a CAH for preadmission services otherwise payable under the Medicare Outpatient Prospective Payment System (OPPS) furnished to a beneficiary during the day immediately preceding the date of admission to the IPF (see § 413.40(c)(2)) and the overhead cost of maintaining the ED. This payment is a facility-level adjustment that applies to all IPF admissions (with one exception described below), regardless of whether a particular patient receives preadmission services in the hospital's ED.

The ED adjustment is incorporated into the variable per diem adjustment for the first day of each stay for IPFs with a qualifying ED. That is, IPFs with a qualifying ED receive an adjustment factor of 1.31 as the variable per diem adjustment for day 1 of each stay. If an IPF does not have a qualifying ED, it

receives an adjustment factor of 1.19 as the variable per diem adjustment for day 1 of each patient stay.

The ED adjustment is made on every qualifying claim except as described below. As specified in § 412.424(d)(1)(v)(B), the ED adjustment is not made where a patient is discharged from an acute care hospital or critical access hospital (CAH) and admitted to the same hospital's or CAH's psychiatric unit. An ED adjustment is not made in this case because the costs associated with ED services are reflected in the DRG payment to the acute care hospital or through the reasonable cost payment made to the CAH. If we provided the ED adjustment in these cases, the hospital would be paid twice for the overhead costs of the ED, as stated in the November 2004 IPF PPS final rule (69 FR 66960).

Therefore, when patients are discharged from an acute care hospital or CAH and admitted to the same hospital's or CAH's psychiatric unit, the IPF receives the 1.19 adjustment factor as the variable per diem adjustment for the first day of the patient's stay in the IPF.

For RY 2012, we proposed to retain the 1.31 adjustment factor for IPFs with qualifying EDs. A complete discussion of the steps involved in the calculation of the ED adjustment factor appears in the November 2004 IPF PPS final rule (69 FR 66959 through 66960) and the May 2006 IPF PPS final rule (71 FR 27070 through 27072).

Final Rule Action: We are retaining the 1.31 adjustment factor for IPFs with qualifying EDs for RY 2012.

D. Other Payment Adjustments and Policies

For RY 2012, the IPF PPS includes an outlier adjustment to promote access to IPF care for those patients who require expensive care and to limit the financial risk of IPFs treating unusually costly patients. In this section, we also explain the reason for ending the stop-loss provision that was applicable during the transition period.

1. Outlier Payments

In the November 2004 IPF PPS final rule, we implemented regulations at § 412.424(d)(3)(i) to provide a per-case payment for IPF stays that are extraordinarily costly. Providing additional payments to IPFs for extremely costly cases strongly improves the accuracy of the IPF PPS in determining resource costs at the patient and facility level. These additional payments reduce the financial losses that would otherwise be incurred in treating patients who require more costly care and, therefore, reduce the incentives for IPFs to under-serve these patients.

We make outlier payments for discharges in which an IPF's estimated total cost for a case exceeds a fixed dollar loss threshold amount (multiplied by the IPF's facility-level adjustments) plus the Federal per diem payment amount for the case.

In instances when the case qualifies for an outlier payment, we pay 80

percent of the difference between the estimated cost for the case and the adjusted threshold amount for days 1 through 9 of the stay (consistent with the median LOS for IPFs in FY 2002), and 60 percent of the difference for day 10 and thereafter. We established the 80 percent and 60 percent loss sharing ratios because we were concerned that a single ratio established at 80 percent (like other Medicare PPSs) might provide an incentive under the IPF per diem payment system to increase LOS in order to receive additional payments. After establishing the loss sharing ratios, we determined the current fixed dollar loss threshold amount of \$6,372 through payment simulations designed to compute a dollar loss beyond which payments are estimated to meet the 2 percent outlier spending target.

a. Update to the Outlier Fixed Dollar Loss Threshold Amount

In accordance with the update methodology described in § 412.428(d), we proposed to update the fixed dollar loss threshold amount used under the IPF PPS outlier policy. Based on the regression analysis and payment simulations used to develop the IPF PPS, we established a 2 percent outlier policy which strikes an appropriate balance between protecting IPFs from extraordinarily costly cases while ensuring the adequacy of the Federal per diem base rate for all other cases that are not outlier cases.

We believe it is necessary to update the fixed dollar loss threshold amount because an analysis of the latest available data (that is, FY 2009 IPF claims) and rate increases indicates that adjusting the fixed dollar loss amount is necessary in order to maintain an outlier percentage that equals 2 percent of total estimated IPF PPS payments.

In the May 2006 IPF PPS final rule (71 FR 27072), we describe the process by which we calculate the outlier fixed dollar loss threshold amount. We will continue to use this process for RY 2012. We begin by simulating aggregate payments with and without an outlier policy, and applying an iterative process to determine an outlier fixed dollar loss threshold amount that will result in outlier payments being equal to 2 percent of total estimated payments under the simulation. Based on this process, using the FY 2009 claims data, we estimate that IPF outlier payments as a percentage of total estimated payments are approximately 2.2 percent in RY 2011. Thus, for this final rule, we are updating the RY 2012 IPF outlier threshold amount to ensure that estimated RY 2012 outlier payments are approximately 2 percent of total

estimated IPF payments. The outlier fixed dollar loss threshold amount of \$6,372 for RY 2011 will be changed to \$7,340 for RY 2012 to reduce estimated outlier payments and thereby maintain estimated outlier payments at 2 percent of total estimated aggregate IPF payments for RY 2012.

Final Rule Action: In this final rule, we are adopting \$7,340 as the fixed dollar loss threshold for RY 2012.

b. Statistical Accuracy of Cost-to-Charge Ratios

As previously stated, under the IPF PPS, an outlier payment is made if an IPF's cost for a stay exceeds a fixed dollar loss threshold amount. In order to establish an IPF's cost for a particular case, we multiply the IPF's reported charges on the discharge bill by its overall cost-to-charge ratio (CCR). This approach to determining an IPF's cost is consistent with the approach used under the IPPS and other PPSs. In FY 2004, we implemented changes to the IPPS outlier policy used to determine CCRs for acute care hospitals because we became aware that payment vulnerabilities resulted in inappropriate outlier payments. Under the IPPS, we established a statistical measure of accuracy for CCRs in order to ensure that aberrant CCR data did not result in inappropriate outlier payments.

As we indicated in the November 2004 IPF PPS final rule, because we believe that the IPF outlier policy is susceptible to the same payment vulnerabilities as the IPPS, we adopted an approach to ensure the statistical accuracy of CCRs under the IPF PPS (69 FR 66961). Therefore, we adopted the following procedure in the November 2004 IPF PPS final rule:

- We calculated two national ceilings, one for IPFs located in rural areas and one for IPFs located in urban areas. We computed the ceilings by first calculating the national average and the standard deviation of the CCR for both urban and rural IPFs.

To determine the rural and urban ceilings, we multiplied each of the standard deviations by 3 and added the result to the appropriate national CCR average (either rural or urban). The upper threshold CCR for IPFs in RY 2012 is 1.8199 for rural IPFs, and 1.7643 for urban IPFs, based on CBSA-based geographic designations. If an IPF's CCR is above the applicable ceiling, the ratio is considered statistically inaccurate and we assign the appropriate national (either rural or urban) median CCR to the IPF.

We apply the national CCRs to the following situations:

- ++ New IPFs that have not yet submitted their first Medicare cost report.

- ++ IPFs whose overall CCR is in excess of 3 standard deviations above the corresponding national geometric mean (that is, above the ceiling).

- ++ Other IPFs for which the Medicare contractor obtains inaccurate or incomplete data with which to calculate a CCR.

For new IPFs, we are using these national CCRs until the facility's actual CCR can be computed using the first tentatively or final settled cost report.

We are not making any changes to the procedures for ensuring the statistical accuracy of CCRs in RY 2012. However, we are updating the national urban and rural CCRs (ceilings and medians) for IPFs for RY 2012 based on the CCRs entered in the latest available IPF PPS Provider Specific File.

Specifically, for RY 2012, and to be used in each of the three situations listed above, we estimate the national average CCR to be 0.6435 for rural IPFs and the national average CCR of 0.5055 for urban IPFs. These calculations are based on the IPF's location (either urban or rural) using the CBSA-based geographic designations.

A complete discussion regarding the national median CCRs appears in the November 2004 IPF PPS final rule (69 FR 66961 through 66964).

2. Expiration of the Stop-Loss Provision

In the November 2004 IPF PPS final rule, we implemented a stop-loss policy that reduced financial risk to IPFs projected to experience substantial reductions in Medicare payments during the period of transition to the IPF PPS. This stop-loss policy guaranteed that each facility received total IPF PPS payments that were no less than 70 percent of its TEFRA payments had the IPF PPS not been implemented. This policy was applied to the IPF PPS portion of Medicare payments during the 3-year transition.

In the implementation year, the 70 percent of TEFRA payment stop-loss policy required a reduction in the standardized Federal per diem and ECT base rates of 0.39 percent in order to make the stop-loss payments budget neutral. As described in the May 2008 IPF PPS notice for RY 2009, we increased the Federal per diem base rate and ECT rate by 0.39 percent because these rates were reduced by 0.39 percent in the implementation year to ensure stop-loss payments were budget neutral.

The stop-loss provision ended during RY 2009 (that is for discharges occurring on or after July 1, 2008 through June 30,

2009). The stop-loss policy is no longer applicable under the IPF PPS.

3. Future Refinements

As we have noted throughout the RY 2012 IPF PPS proposed rule as well as in this final rule, we have delayed making refinements to the IPF PPS until we have adequate IPF PPS data on which to base those decisions. Now that we are approximately 5 years into the system, we believe that we have enough data to begin that process. We have begun the necessary analysis to better understand IPF industry practices so that we may refine the IPF PPS as appropriate. While we did not propose to make the following refinements in the RY 2012 IPF PPS proposed rulemaking, we believe that in the rulemaking for FY 2013 we will be ready to present the results of our analysis.

Specifically, with the change from ICD-9-CM to ICD-10-CM coming in FY 2013, we are analyzing the comorbidity categories and related codes for utilization and continued suitability. While we would continue to provide for comorbidity adjustments, we are analyzing whether the current groupings and codes continue to be warranted and whether other appropriate codes should be added. Also, we are analyzing our current policies for interrupted stays, readmissions, same-day transfers, and length of stays in order to assess whether these policies continue to be appropriate. Additionally, in accordance with section 1886(s)(4) of the Act, which was added by section 10322 of the Affordable Care Act, IPFs must submit data on quality measures, as specified by the Secretary, for each RY beginning in RY 2014. If data is not submitted, any annual update to a Federal base rate for discharges for the payments shall be reduced by 2 percentage points. Quality measures are currently being developed to effectuate this requirement. Lastly, for the first time MedPAC will become involved in evaluating facility margins and will likely make recommendations regarding the appropriate payment update to IPFs based on their findings. CMS is interested in gaining feedback on these areas for future refinements and therefore we invite comments on these issues described in this section at this time.

Comment: A few commenters strongly supported the need to develop and implement quality measures for the IPF PPS. They strongly encouraged CMS to review and consider the Hospital-Based Inpatient Psychiatric Services (HBIPS) core measures as a foundation for quality measures for the IPF PPS. They pointed out that these quality measures

are now in effect for all Joint Commission-accredited psychiatric hospitals and are available for use by psychiatric units in acute care hospitals.

Response: We appreciate the support for the development and implementation of quality measures, as well as the recommendation regarding the Hospital-Based Inpatient Psychiatric Services (HBIPS) core measures for IPFs. In accordance with section 1886(s)(4) of the SSA (the Act), which was added by section 10322 of the Affordable Care Act, IPFs must submit data on quality measures as specified by the Secretary, for each RY (that coincides with a FY) beginning in FY 2014. Quality measures are currently being developed to effectuate this requirement. To implement this, a Technical Expert Panel (TEP) has been assembled to develop quality measures for inpatient psychiatric hospitals and psychiatric units. The TEP consists of a wide cross-section of today's learned scholars and experts in the field including the Joint Commission on Hospital and Accreditation (formerly Joint Commission on Accreditation of Healthcare Organizations), to provide valued input on quality measure development. The TEP is charged with identifying measures that reflect current knowledge regarding effective, evidenced-based treatments for psychiatric disorders; addressing the range of treatments and care processes provided at IPFs; and identifying measures applicable to all Medicare beneficiaries treated in IPFs. Therefore, consistent with the views of these commenters, CMS is reviewing and taking into consideration those HBIPS core measures to help form a foundation for quality measures as directed under the Act.

Comment: A few commenters stated that although the core adjustments to the system, such as age, length of stay, and comorbidities have been effective in addressing the variability in the costs of treating Medicare patients with psychiatric disorders, they recommend that the key adjustments (such as age, comorbidities, and length of stays) be analyzed to determine if any changes are warranted.

Response: We agree with the commenters on the need to analyze patient characteristics such as age, comorbidities, and length of stays when we refine the IPF PPS system. As explained in the RY 2012 IPF PPS proposed rule, in preparation for the migration from ICD-9-CM to ICD-10-CM in FY 2013, we plan to analyze the comorbidity categories and related codes for utilization and continued suitability. We will make

determinations as to whether the current groupings and codes continue to be warranted and whether other appropriate codes should also be added. We are also analyzing our current policies on interrupted stays, readmissions, same-day transfers, and length of stays in order to assess whether these policies continue to be appropriate. We welcome the support by these commenters for such future refinements.

VII. Regulations Text Corrections

We proposed several minor corrections to the regulations text to address typographical errors. We noted that these proposed changes do not impact policy. We proposed to correct typographical errors at § 412.404, "Conditions for payment" under the prospective payment system for inpatient hospital services of psychiatric facilities; § 412.422, "Basis of payment;" and § 412.426, "Transition period." In addition to these corrections, we proposed to add clarifying language at § 412.426 and § 412.432(d), "Method of payment under the inpatient psychiatric facility prospective payment system." The proposed revisions are described below.

Section 412.404(a)(1)

Under § 412.404, in paragraph (a)(1), "General requirements," we proposed to delete the word "in" between the words "furnished" and "to Medicare".

Section 412.422(b)(2)

Under § 412.422, in paragraph (b)(2), we proposed to correct the reference to § 413.80 to § 413.89. The regulations covered at § 413.89 include bad debts, charity, and courtesy allowances.

Section 412.426(a)

Under § 412.426, in paragraph (a), "Duration of transition period and composition of the blended transition payment," we proposed to replace "Except as provided in paragraph (d) of this section" with "Except as provided in paragraph (c) of this section." There is no paragraph (d); this exception should refer to paragraph (c), "Treatment of new inpatient psychiatric facilities."

Also in paragraph (a), we proposed to add the words "of this part" after "as specified in § 412.424(d)" and "of this section" after "as specified under paragraph (b)." This regulatory language is required by the **Federal Register**.

In each of paragraphs § 412.426(a)(1) through (a)(3), we proposed to delete the words "on or" directly before the words "before January". For example, "For paragraph (a)(1) currently states, "For

cost reporting periods beginning on or after January 1, 2005 and on or before January 1, 2006 * * * We proposed that this statement read: "For cost reporting periods beginning on or after January 1, 2005 and before January 1, 2006 * * * This correction does not represent a change in policy. Rather, it is a correction to conform the regulation text to our policy, which was established in our final rule that appeared in the **Federal Register** on November 15, 2004 (69 FR 66980) (which was subsequently corrected on April 1, 2005 (70 FR 16729)). It is clear that the current regulation text is incorrect. The same January date (for example, January 1, 2007) cannot be both the date on which a new transition period begins and the date on which the previous transition period ends. Our policy, since we established the transition, has been to begin a transition period on or after a January 1 date and to end that transition period before the next transition period begins. Because our regulation text does not accurately reflect our actual policy, we proposed this correction.

At § 412.426(a)(4), we proposed to replace the statement, "For cost reporting periods beginning on or after July 1, 2008, payment is based entirely on the Federal per diem payment amount" with the following statement: "For cost reporting periods beginning on or after January 1, 2008, payment is based entirely on the Federal per diem payment amount." The transition period during which payment was based on a combination of the Federal per diem payment amount and TEFRA payments, ended on January 1, 2008, not July 1, 2008.

Comment: Two commenters expressed serious concern that CMS is making retroactive policy changes to the regulations text for the 3-year transition period for the IPF PPS rather than minor corrections to address typographical errors.

Response: We disagree with the commenters. We are simply making minor corrections to the regulations at § 412.426 covering the transition period to address typographical errors to the IPF PPS. In the November 2004 IPF PPS final rule, we provided for a 3-year transition period. During this 3-year transition period, an IPF's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decreasing percentage of the IPF PPS payment that was based on reasonable cost concepts. However, effective for cost reporting periods beginning on or after January 1, 2008, IPF PPS payments are based on 100 percent of the Federal rate. This

correction does not represent a policy change, and therefore is not a retroactive change. Rather, it is a correction to conform the regulation text to our policy, which was established in our final rule that appeared in the **Federal Register** on November 15, 2004 (69 FR 66980) (which was subsequently corrected on April 1, 2005 (70 FR 16729)). It is clear that the current regulation text is incorrect. The same January date (for example, January 1, 2007) cannot be both the date on which a new transition period begins and the date on which the previous transition period ends. Our policy, since we established the transition, has been to begin a transition period on or after a January 1 date and to end that transition period before the next transition period begins. Because our regulation text does not accurately reflect our actual policy, we proposed this correction.

In addition for § 412.426, in paragraph (a), "Duration of transition period and composition of the blended transition payment," we intended to propose, but did not, to replace "on or after January 1, 2005 through January 1, 2008" with "on or after January 1, 2005 through December 31, 2007". Here again, this correction does not represent a policy change; it is merely a correction to conform the regulation text to our policy, and it is consistent with the other typographical errors we are correcting in § 412.426.

Section 412.432(d)

Under § 412.432, in paragraph (d), "Outlier payments," we proposed to add the words "of this part" after "subject to the cost report settlement specified in § 412.84(i) and § 412.84(m)." This regulatory language is required by the **Federal Register** and clarifies that § 412.84(i) and § 412.84(m) refer to 42 CFR part 412, "Prospective Payment Systems for Inpatient Hospital Services."

VIII. Collection of Information Requirements

This document does not impose any information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

IX. Regulatory Impact Analysis

A. Statement of Need

This final rule will update the prospective payment rates for Medicare inpatient hospital services provided by inpatient psychiatric facilities for

discharges occurring during the RY beginning July 1, 2011 through September 30, 2012. We are applying the 15-month FY 2008-based RPL market basket increase of 3.2 percent, adjusted by the 0.25 percentage point reduction, as required by section 1886(s)(3)(A) of the Act. In addition, the rule implements policy changes affecting the IPF PPS teaching adjustment, as well as makes some clarifications and corrections to terminology and regulations text.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This final rule has been designated an "economically" significant rule, under section 3(f) (1) of Executive Order 12866 and a major rule under the Congressional Review Act. Accordingly, the rule has been reviewed by the Office of Management and Budget.

We estimate that the total impact of these changes for estimated RY 2012 payments compared to estimated RY 2011 payments would be an increase of approximately \$120 million (this reflects a \$130 million increase from the update to the payment rates and a \$10 million decrease due to the update to the outlier threshold amount to decrease outlier payments from approximately 2.2 percent in RY 2011 to 2.0 percent in RY 2012).

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small

governmental jurisdictions. Most IPFs and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$7 million to \$34.5 million in any one year (for details, refer to the SBA Small Business Size Standards found at <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2465b064ba6965cc1fbd2eae60854b11&rgn=div8&view=text&node=13:1.0.1.1.16.1.266.9&idno=13>). Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IPFs or the proportion of IPFs' revenue that is derived from Medicare payments. Therefore, we assume that all IPFs are considered small entities. The Department of Health and Human Services generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA.

As shown in Table 15, we estimate that the revenue impact of this final rule on all IPFs is to increase estimated Medicare payments by about 2.74 percent, with rural IPFs estimated to receive an increase in estimated Medicare payments greater than 3 percent (an aggregate 3.80 percent). As a result, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small entities. Medicare fiscal intermediaries, Medicare Administrative Contractors, and carriers are not considered to be small entities. Individuals and States are not included in the definition of a small entity. We solicited comment on the above analysis.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis, if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. As discussed in detail below, the rates and policies set forth in this final rule will not have an adverse impact on the rural hospitals based on the data of the 320 rural units and 67 rural hospitals in our database of 1,653 IPFs for which data were available. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before

issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately \$136 million. This final rule will not impose spending costs on State, local, or Tribal governments in the aggregate, or by the private sector, of \$136 million.

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. As stated above, this final rule would not have a substantial effect on State and local governments.

C. Anticipated Effects of the Final Rule

We discuss below the historical background of the IPF PPS and the impact of this final rule on the Federal Medicare budget and on IPFs.

1. Budgetary Impact

As discussed in the November 2004 and May 2006 IPF PPS final rules, we applied a budget neutrality factor to the Federal per diem and ECT base rates to ensure that total estimated payments under the IPF PPS in the implementation period would equal the amount that would have been paid if the IPF PPS had not been implemented. The budget neutrality factor includes the following components: Outlier adjustment, stop-loss adjustment, and the behavioral offset. As discussed in the May 2008 IPF PPS notice (73 FR 25711), the stop-loss adjustment is no longer applicable under the IPF PPS.

In accordance with § 412.424(c)(3)(ii), we indicated that we would evaluate the accuracy of the budget neutrality adjustment within the first 5 years after implementation of the payment system. We may make a one-time prospective adjustment to the Federal per diem and ECT base rates to account for differences between the historical data on cost-based TEFRA payments (the basis of the budget neutrality adjustment) and estimates of TEFRA payments based on actual data from the first year of the IPF PPS. As part of that process, we will reassess the accuracy of all of the factors impacting budget neutrality. In addition, as discussed in section IV.C.6 of this final rule, we are using the wage index and labor-related share in a budget neutral manner by applying a wage index budget neutrality factor to the Federal per diem and ECT base rates. Therefore, the budgetary impact to the Medicare program of this final rule will be due to the 15-month market

basket update for RY 2012 of 3.2 percent (see section IV.C.5 of this final rule) as adjusted by the "other adjustment" of -0.25 percentage point according to section 1886(s)(3)(A) of the Act, and the update to the outlier fixed dollar loss threshold amount.

We estimate that the RY 2012 impact would be a net increase of \$120 million in payments to IPF providers. This reflects an estimated \$130 million increase from the update to the payment rates and a \$10 million decrease due to the update to the outlier threshold amount to decrease estimated outlier payments from approximately 2.2 percent in RY 2011 to 2.0 percent in RY 2012.

2. Impact on Providers

To understand the impact of the changes to the IPF PPS on providers, discussed in this final rule, it is necessary to compare estimated payments under the IPF PPS rates and factors for RY 2012 versus those under RY 2011. The estimated payments for RY 2011 and RY 2012 will be 100 percent of the IPF PPS payment, since the transition period has ended and stop-loss payments are no longer paid. We determined the percent change of estimated RY 2012 IPF PPS payments to RY 2011 IPF PPS payments for each category of IPFs. In addition, for each category of IPFs, we have included the estimated percent change in payments resulting from the update to the outlier fixed dollar loss threshold amount, the labor-related share and wage index changes for the RY 2012 IPF PPS, and the 15-month market basket update for RY 2012, as adjusted by the "other adjustment" according to section 1886(s)(3)(A) of the Act.

To illustrate the impacts of the RY 2012 changes in this final rule, our analysis begins with a RY 2011 baseline simulation model based on FY 2009 IPF payments inflated to the midpoint of RY 2011 using IHS Global Insight's most recent forecast of the market basket update (see section IV.C.5 of this final rule); the estimated outlier payments in RY 2011; the CBSA designations for IPFs based on OMB's MSA definitions after June 2003; the FY 2010 pre-floor, pre-reclassified hospital wage index; the RY 2011 labor-related share; and the RY 2011 percentage amount of the rural adjustment. During the simulation, the total estimated outlier payments are maintained at 2 percent of total IPF PPS payments.

Each of the following changes is added incrementally to this baseline model in order for us to isolate the effects of each change:

- The update to the outlier fixed dollar loss threshold amount.

- The FY 2011 pre-floor, pre-reclassified hospital wage index and RY 2012 labor-related share.

- The 15-month market basket update for RY 2012 of 3.2 percent adjusted by the 0.25 percentage point reduction in accordance with section 1886(s)(3)(A) of the Act.

Our final comparison illustrates the percent change in payments from RY 2011 (that is, July 1, 2010 to June 30, 2011) to RY 2012 (that is, July 1, 2011 to September 30, 2012) including all the changes in this final rule.

TABLE 15—IPF Impact Table for RY 2012

| Projected Impacts (Percent Change for RY 2012) | | | | | |
|--|--------------------------------|----------------|--|--|--|
| Facility by Type (1) | Number of Facilities (2) | Outlier (3) | CBSA Wage Index & Labor Share (4) | Adjusted Market Basket Update ¹ (5) | Total Percent Change ² (6) |
| All Facilities | 1,653 | -0.21 | 0.00 | 2.95 | 2.74 |
| Total Urban | 1,266 | -0.21 | -0.16 | 2.95 | 2.57 |
| Total Rural | 387 | -0.18 | 1.02 | 2.95 | 3.80 |
| Urban DPU | 854 | -0.28 | -0.23 | 2.95 | 2.43 |
| Urban CAH unit | 10 | -0.84 | -0.20 | 2.95 | 1.86 |
| Urban hospital | 402 | -0.06 | -0.05 | 2.95 | 2.84 |
| Rural DPU | 267 | -0.24 | 1.05 | 2.95 | 3.77 |
| Rural CAH unit | 53 | -0.13 | 0.64 | 2.95 | 3.47 |
| Rural hospital | 67 | -0.06 | 1.10 | 2.95 | 4.02 |
| Freestanding IPF | | | | | |
| By Type of Ownership: | | | | | |
| Urban Psychiatric Hospitals | | | | | |
| Government | 169 | -0.08 | -0.34 | 2.95 | 2.52 |
| Non-Profit | 117 | -0.07 | 0.01 | 2.95 | 2.88 |
| For-Profit | 116 | -0.04 | 0.20 | 2.95 | 3.12 |
| Rural Psychiatric Hospitals | | | | | |
| Government | 43 | -0.07 | 0.61 | 2.95 | 3.51 |
| Non-Profit | 9 | -0.01 | 1.03 | 2.95 | 4.00 |
| For-Profit | 15 | -0.03 | 2.25 | 2.95 | 5.23 |
| IPF Units | | | | | |
| By Type of Ownership: | | | | | |
| Urban DPU | | | | | |
| Government | 148 | -0.43 | -0.30 | 2.95 | 2.21 |
| Non-Profit | 589 | -0.27 | -0.28 | 2.95 | 2.38 |
| For-Profit | 117 | -0.17 | 0.07 | 2.95 | 2.84 |
| Urban CAH | | | | | |
| Government | 4 | -1.57 | -0.18 | 2.95 | 1.09 |
| Non-Profit | 6 | -0.31 | -0.21 | 2.95 | 2.41 |
| Rural DPU | | | | | |
| Government | 64 | -0.25 | 1.05 | 2.95 | 3.76 |
| Non-Profit | 153 | -0.22 | 0.97 | 2.95 | 3.71 |

| | | | | | | |
|---|--|-------|-------|-------|------|------|
| For-Profit | | 50 | -0.27 | 1.28 | 2.95 | 3.97 |
| Rural CAH | | | | | | |
| Government | | 21 | -0.08 | 0.42 | 2.95 | 3.28 |
| Non-Profit | | 28 | -0.15 | 0.78 | 2.95 | 3.59 |
| For-Profit | | 4 | -0.20 | 0.85 | 2.95 | 3.61 |
| By Teaching Status: | | | | | | |
| Non-teaching | | 1,428 | -0.19 | 0.12 | 2.95 | 2.88 |
| Less than 10% interns and residents to beds | | 130 | -0.18 | -0.53 | 2.95 | 2.22 |
| 10% to 30% interns and residents to beds | | 66 | -0.43 | -0.35 | 2.95 | 2.16 |
| More than 30% interns and residents to beds | | 29 | -0.40 | -0.39 | 2.95 | 2.15 |
| By Region: | | | | | | |
| New England | | 117 | -0.23 | -0.91 | 2.95 | 1.78 |
| Mid-Atlantic | | 273 | -0.19 | -0.74 | 2.95 | 2.00 |
| South Atlantic | | 233 | -0.17 | 0.19 | 2.95 | 2.96 |
| East North Central | | 274 | -0.24 | 0.22 | 2.95 | 2.93 |
| East South Central | | 166 | -0.16 | 0.62 | 2.95 | 3.43 |
| West North Central | | 149 | -0.21 | 0.04 | 2.95 | 2.77 |
| West South Central | | 228 | -0.18 | 1.18 | 2.95 | 3.97 |
| Mountain | | 87 | -0.17 | 0.03 | 2.95 | 2.80 |
| Pacific | | 126 | -0.29 | -0.43 | 2.95 | 2.19 |
| By Bed Size: | | | | | | |
| Psychiatric Hospitals | | | | | | |
| Under 12 beds | | 12 | -0.43 | 0.02 | 2.95 | 2.52 |
| Beds: 12-24 | | 71 | -0.13 | 1.08 | 2.95 | 3.93 |
| Beds: 25-49 | | 70 | -0.15 | 0.32 | 2.95 | 3.11 |
| Beds: 50-75 | | 72 | -0.05 | 0.16 | 2.95 | 3.06 |
| Over 75 beds | | 244 | -0.04 | -0.12 | 2.95 | 2.78 |
| Psychiatric Units | | | | | | |
| Under 12 beds | | 189 | -0.34 | 0.75 | 2.95 | 3.34 |
| Beds: 12-24 | | 515 | -0.26 | 0.15 | 2.95 | 2.83 |
| Beds: 25-49 | | 313 | -0.28 | -0.15 | 2.95 | 2.50 |
| Beds: 50-75 | | 105 | -0.27 | -0.05 | 2.95 | 2.62 |
| Over 75 beds | | 62 | -0.27 | -0.57 | 2.95 | 2.11 |

¹ This column reflects the impact of the 15-month market basket update for RY 2012 of 3.2 percent, reduced by 0.25 percentage point in accordance with section 1886(s)(3)(A) of the Act.

² Percent changes in estimated payments from RY 2011 to RY 2012 include all changes of this rule. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

3. Results

Table 15 above displays the results of our analysis. The table groups IPFs into the categories listed below based on characteristics provided in the Provider of Services (POS) file, the IPF provider specific file, and cost report data from HCRIS:

- Facility Type
- Location
- Teaching Status Adjustment
- Census Region
- Size

The top row of the table shows the overall impact on the 1,653 IPFs included in this analysis.

In column 3, we present the effects of the update to the outlier fixed dollar loss threshold amount. We estimate that IPF outlier payments as a percentage of total IPF payments are 2.2 percent in RY 2011. Therefore, we are adjusting the outlier threshold amount from \$6,372 in RY 2011 to \$7,340 in RY 2012 in order to set total estimated outlier payments equal to 2 percent of total payments in RY 2012. The estimated change in total IPF payments for RY 2012, therefore, includes an approximate 0.2 percent decrease in payments because the outlier portion of total payments is expected to decrease from approximately 2.2 percent to 2 percent.

The overall aggregate effect of this outlier adjustment update (as shown in column 3 of table 15), across all hospital groups, is to decrease total estimated payments to IPFs by 0.21 percent. We do not estimate that any group of IPFs will experience an increase in payments from this update. The largest decrease in payments is estimated to reflect a 1.57 percent decrease in payments to urban government IPF units located in CAHs which is due to the small number of IPFs of that type and the high volume of outlier payments made to those IPFs.

In column 4, we present the effects of the budget-neutral update to the labor-related share and the wage index adjustment under the CBSA geographic area definitions announced by OMB in June 2003. This is a comparison of the simulated RY 2012 payments under the FY 2011 hospital wage index under CBSA classification and associated labor-related share to the simulated RY 2011 payments under the FY 2010 hospital wage index under CBSA classifications and associated labor-related share. We note that there is no projected change in aggregate payments to IPFs, as indicated in the first row of column 4. However, there will be distributional effects among different categories of IPFs. For example, we estimate a 1.02 percent increase in overall payments to rural IPFs, with the

largest increase in payments of 2.25 percent for rural, for-profit freestanding psychiatric hospitals. In addition, we estimate the largest decrease in payments to be a 0.91 percent decrease for IPFs in the New England region.

Column 5 shows the estimated effect of the update to the IPF PPS payment rates, which includes a 3.2 percent 15-month market basket update adjusted by the 0.25 percentage point reduction in accordance with section 1886(s)(3)(A).

Column 6 compares our estimates of the changes reflected in this final rule for RY 2012, to our payments for RY 2011 (without these changes). This column reflects all RY 2012 changes relative to RY 2011. The average estimated increase for all IPFs is approximately 2.74 percent. This estimated net increase includes the effects of the 3.2 percent 15-month market basket update adjusted by the “other adjustment” of –0.25 percentage point, as required by section 1886(s)(3)(A) of the Act. It also includes the overall estimated 0.2 percent decrease in estimated IPF outlier payments from the update to the outlier fixed dollar loss threshold amount. Since we are making the updates to the IPF labor-related share and wage index in a budget-neutral manner, they will not affect total estimated IPF payments in the aggregate. However, they will affect the estimated distribution of payments among providers.

Overall, no IPFs are estimated to experience a net decrease in payments as a result of the updates in this rule. IPFs in urban areas will experience a 2.57 percent increase and IPFs in rural areas will experience a 3.80 percent increase. The largest payment increase is estimated at 5.23 percent for rural, for-profit freestanding psychiatric hospitals. This is due to the larger than average positive effect of the FY 2011 CBSA wage index and labor-related share updates for rural IPFs in this category.

4. Effect on the Medicare Program

Based on actuarial projections resulting from our experience with other PPSs, we estimate that Medicare spending (total Medicare program payments) for IPF services over the next 5 years would be as shown in Table 16 below.

TABLE 16—ESTIMATED PAYMENTS

| Rate year | Dollars in millions |
|-------------------------------|---------------------|
| July 1, 2011 to June 30, 2012 | \$4,615 |
| July 1, 2012 to June 30, 2013 | 4,945 |
| July 1, 2013 to June 30, 2014 | 5,330 |
| July 1, 2014 to June 30, 2015 | 5,775 |

TABLE 16—ESTIMATED PAYMENTS—Continued

| Rate year | Dollars in millions |
|-------------------------------|---------------------|
| July 1, 2015 to June 30, 2016 | 6,273 |

These estimates are based on the current forecast of the increases in the RPL market basket, including an adjustment for productivity, for the RY beginning in 2012 and each subsequent RY, as required by section 1886(s)(3)(A) of the Act, as follows:

- 2.8 percent for rate years beginning in 2011 (RY 2012).
- 1.7 percent for rate years beginning in 2012 (RY 2013).
- 2.0 percent for rate years beginning in 2013 (RY 2014).
- 2.2 percent for rate years beginning in 2014 (RY 2015).
- 2.4 percent for rate years beginning in 2015 (RY 2016).

The estimates in Table 16 also include the application of the “other adjustment,” as required by section 1886(s)(3)(A) of the Act, as follows:

- –0.25 percentage point for rate years beginning in 2011.
- –0.1 percentage point for rate years beginning in 2012.
- –0.1 percentage point for rate years beginning in 2013.
- –0.3 percentage point for rate years beginning in 2014.
- –0.2 percentage point for rate years beginning in 2015.

We estimate that there would be a change in fee-for-service Medicare beneficiary enrollment as follows:

- 3.3 percent in RY 2012.
- 3.7 percent in RY 2013.
- 4.3 percent in RY 2014.
- 4.9 percent in RY 2015.
- 5.6 percent in RY 2016.

5. Effect on Beneficiaries

Under the IPF PPS, IPFs would receive payment based on the average resources consumed by patients for each day. We do not expect changes in the quality of care or access to services for Medicare beneficiaries under the RY 2012 IPF PPS. In fact, we believe that access to IPF services will be enhanced due to the patient- and facility-level adjustment factors, all of which are intended to adequately reimburse IPFs for expensive cases. Finally, the outlier policy is intended to assist IPFs that experience high-cost cases.

D. Alternatives Considered

The statute does not specify an update strategy for the IPF PPS and is broadly written to give the Secretary discretion in establishing an update methodology.

Therefore, we are updating the IPF PPS using the methodology published in the November 2004 IPF PPS final rule.

We note that this final rule initiates policy changes with regard to the IPF PPS, and it also provides an update to the rates for RY 2012. We considered making refinements to the IPF PPS in this final rule. However, more time is required to assess the data and will therefore once again delay running the regression analysis until we have adequate IPF PPS data. We have initiated the necessary analysis to better understand IPF industry practices. We did not consider rebasing the IPF PPS for concerns that rebasing would be too costly (re-calculate the cost-per-day) and time consuming.

E. Accounting Statement

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in Table 17 below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. This table provides our best estimate of the increase in Medicare payments under the IPF PPS as a result of the proposed changes presented in this final rule and based on the data for 1,653 IPFs in our database. All expenditures are classified as transfers to IPF Medicare providers.

TABLE 17—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2011 IPF PPS RY TO THE 2012 IPF PPS RY
[In millions]

| Category | Transfers |
|---------------------------------|---|
| Annualized Monetized Transfers. | \$120. |
| From Whom To Whom? | Federal Government to IPF Medicare Providers. |

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 continues to read as follows:

Authority: Secs 1102, 1862, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395y, and 1395hh).

Subpart N—Prospective Payment System for Inpatient Hospital Services of Inpatient Psychiatric Facilities

■ 2. In § 412.402, the definition of “*Inpatient psychiatric facilities prospective payment system rate year*” is added in alphabetical order to read as follows:

§ 412.402 Definitions.

* * * * *

Inpatient psychiatric facilities prospective payment system rate year means—

(1) Through June 30, 2011, the 12-month period of July 1 through June 30.

(2) Beginning July 1, 2011, the 15-month period of July 1, 2011 through September 30, 2012.

(3) Beginning October 1, 2012, the 12-month period of October 1 through September 30, referred to as Fiscal Year (FY).

* * * * *

■ 3. Section 412.404 is amended by revising paragraph (a)(1) to read as follows:

§ 412.404 Conditions for payment under the prospective payment system for inpatient hospital services of psychiatric facilities.

(a) * * *

(1) Effective for cost reporting periods beginning on or after January 1, 2005, an inpatient psychiatric facility must meet the conditions of this section to receive payment under the prospective payment system described in this subpart for inpatient hospital services furnished to Medicare Part A fee-for-service beneficiaries.

* * * * *

■ 4. Section 412.422 is amended by revising paragraph (b)(2) to read as follows:

§ 412.422 Basis of payment.

* * * * *

(b) * * *

(2) In addition to the Federal per diem payment amounts, inpatient psychiatric facilities receive payment for bad debts of Medicare beneficiaries, as specified in § 413.89 of this chapter.

■ 5. Section 412.424 is amended by adding a new paragraph (d)(1)(iii)(F) to read as follows:

§ 412.424 Methodology for calculating the Federal per diem payment amount.

* * * * *

(d) * * *

(1) * * *

(iii) * * *

(F) *Closure of an IPF.* (1) For cost reporting periods beginning on or after July 1, 2011, an IPF may receive a temporary adjustment to its FTE cap to reflect residents added because of another IPF's closure if the IPF meets the following criteria:

(i) The IPF is training additional residents from an IPF that closed on or after July 1, 2011.

(ii) No later than 60 days after the IPF begins to train the residents, the IPF submits a request to its Medicare contractor for a temporary adjustment to its cap, documents that the IPF is eligible for this temporary adjustment by identifying the residents who have come from the closed IPF and have caused the IPF to exceed its cap, and specifies the length of time the adjustment is needed.

(2) *Closure of an IPF's residency training program.* If an IPF that closes its residency training program on or after July 1, 2011, agrees to temporarily reduce its FTE cap according to the criteria specified in paragraph (d)(1)(iii)(F)(2)(ii) of this section, another IPF(s) may receive a temporary adjustment to its FTE cap to reflect residents added because of the closure of the residency training program if the criteria specified in paragraph (d)(1)(iii)(F)(2)(i) of this section are met.

(i) *Receiving IPF(s).* For cost reporting periods beginning on or after July 1, 2011, an IPF may receive a temporary adjustment to its FTE cap to reflect residents added because of the closure of another IPF's residency training program if the IPF is training additional residents from the residency training program of an IPF that closed a program; and if no later than 60 days after the IPF begins to train the residents, the IPF submits to its Medicare Contractor a request for a temporary adjustment to its FTE cap, documents that it is eligible for this temporary adjustment by identifying the residents who have come from another IPF's closed program and have caused the IPF to exceed its cap, specifies the length of time the adjustment is needed, and submits to its Medicare contractor a copy of the FTE reduction statement by the hospital that closed its program, as specified in paragraph (d)(1)(iii)(F)(2)(ii) of this section.

(ii) *IPF that closed its program.* An IPF that agrees to train residents who have been displaced by the closure of another IPF's program may receive a

temporary FTE cap adjustment only if the hospital with the closed program temporarily reduces its FTE cap based on the FTE residents in each program year training in the program at the time of the program's closure. This yearly reduction in the FTE cap will be determined based on the number of those residents who would have been training in the program during that year had the program not closed. No later than 60 days after the residents who were in the closed program begin training at another hospital, the hospital with the closed program must submit to its Medicare contractor a statement signed and dated by its representative that specifies that it agrees to the temporary reduction in its FTE cap to allow the IPF training the displaced residents to obtain a temporary adjustment to its cap; identifies the residents who were in training at the time of the program's closure; identifies the IPFs to which the residents are transferring once the program closes; and specifies the reduction for the applicable program years.

* * * * *

■ 6. Section 412.426 is amended by revising paragraph (a) to read as follows:

§ 412.426 Transition period.

(a) *Duration of transition period and composition of the blended transition payment.* Except as provided in

paragraph (c) of this section, for cost reporting periods beginning on or after January 1, 2005 through December 31, 2007, an inpatient psychiatric facility receives a payment comprised of a blend of the estimated Federal per diem payment amount, as specified in § 412.424(d) of this subpart and a facility-specific payment as specified under paragraph (b) of this section.

(1) For cost reporting periods beginning on or after January 1, 2005 and before January 1, 2006, payment is based on 75 percent of the facility-specific payment and 25 percent is based on the Federal per diem payment amount.

(2) For cost reporting periods beginning on or after January 1, 2006 and before January 1, 2007, payment is based on 50 percent of the facility-specific payment and 50 percent is based on the Federal per diem payment amount.

(3) For cost reporting periods beginning on or after January 1, 2007 and before January 1, 2008, payment is based on 25 percent of the facility-specific payment and 75 percent is based on the Federal per diem payment amount.

(4) For cost reporting periods beginning on or after January 1, 2008, payment is based entirely on the Federal per diem payment amount.

* * * * *

■ 7. Section 412.432 is amended by revising paragraph (d) to read as follows:

§ 412.432 Method of payment under the inpatient psychiatric facility prospective payment system.

* * * * *

(d) *Outlier payments.* Additional payments for outliers are not made on an interim basis. Outlier payments are made based on the submission of a discharge bill and represents final payment subject to the cost report settlement specified in § 412.84(i) and § 412.84(m) of this part.

* * * * *

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

Dated: April 21, 2011.

Donald Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: April 26, 2011.

Kathleen Sebelius,

Secretary.

Note: The following Addendums will not appear in the Code of Federal Regulations.

BILLING CODE 4120-01-P

Addendum A-Rate and Adjustment Factors

Per Diem Rate:

| | |
|----------------------------|----------|
| Federal Per Diem Base Rate | \$685.01 |
| Labor Share (0.70317) | \$481.68 |
| Non-Labor Share (0.29683) | \$203.33 |

Fixed Dollar Loss Threshold Amount:

\$7,340

Wage Index Budget Neutrality Factor:

0.9995

Facility Adjustments:

| | |
|----------------------------|--|
| Rural Adjustment Factor | 1.17 |
| Teaching Adjustment Factor | 0.5150 |
| Wage Index | Pre-reclass Hospital Wage Index (FY2011) |

Cost of Living Adjustments (COLAs):

| Area | Cost of Living Adjustment Factor |
|---|----------------------------------|
| Alaska: | |
| City of Anchorage and 80-kilometer (50- | 1.23 |

| Area | Cost of Living Adjustment Factor |
|---|----------------------------------|
| mile) radius by road | |
| City of Fairbanks and 80-kilometer (50-mile) radius by road | 1.23 |
| City of Juneau and 80-kilometer (50-mile) radius by road | 1.23 |
| Rest of Alaska | 1.25 |
| Hawaii: | |
| City and County of Honolulu | 1.25 |
| County of Hawaii | 1.18 |
| County of Kauai | 1.25 |
| County of Maui and County of Kalawao | 1.25 |

Patient Adjustments:

ECT - Per Treatment \$294.91

Variable Per Diem Adjustments:

| | Adjustment Factor |
|---|-------------------|
| Day 1 -- Facility Without a Qualifying Emergency Department | 1.19 |
| Day 1 -- Facility With a Qualifying Emergency Department | 1.31 |
| Day 2 | 1.12 |
| Day 3 | 1.08 |
| Day 4 | 1.05 |
| Day 5 | 1.04 |
| Day 6 | 1.02 |
| Day 7 | 1.01 |
| Day 8 | 1.01 |
| Day 9 | 1.00 |
| Day 10 | 1.00 |
| Day 11 | 0.99 |
| Day 12 | 0.99 |
| Day 13 | 0.99 |
| Day 14 | 0.99 |
| Day 15 | 0.98 |
| Day 16 | 0.97 |
| Day 17 | 0.97 |
| Day 18 | 0.96 |
| Day 19 | 0.95 |
| Day 20 | 0.95 |
| Day 21 | 0.95 |
| After Day 21 | 0.92 |

Age Adjustments:

| Age (in years) | Adjustment Factor |
|-----------------|-------------------|
| Under 45 | 1.00 |
| 45 and under 50 | 1.01 |
| 50 and under 55 | 1.02 |
| 55 and under 60 | 1.04 |
| 60 and under 65 | 1.07 |
| 65 and under 70 | 1.10 |
| 70 and under 75 | 1.13 |
| 75 and under 80 | 1.15 |
| 80 and over | 1.17 |

DRG Adjustments:

| MS-DRG | MS-DRG Descriptions | Adjustment Factor |
|--------|---|-------------------|
| 056 | Degenerative nervous system disorders w MCC | 1.05 |
| 057 | Degenerative nervous system disorders w/o MCC | |
| 080 | Nontraumatic stupor & coma w MCC | 1.07 |
| 081 | Nontraumatic stupor & coma w/o MCC | |
| 876 | O.R. procedure w principal diagnoses of mental illness | 1.22 |
| 880 | Acute adjustment reaction & psychosocial dysfunction | 1.05 |
| 881 | Depressive neuroses | 0.99 |
| 882 | Neuroses except depressive | 1.02 |
| 883 | Disorders of personality & impulse control | 1.02 |
| 884 | Organic disturbances & mental retardation | 1.03 |
| 885 | Psychoses | 1.00 |
| 886 | Behavioral & developmental disorders | 0.99 |
| 887 | Other mental disorder diagnoses | 0.92 |
| 894 | Alcohol/drug abuse or dependence, left AMA | 0.97 |
| 895 | Alcohol/drug abuse or dependence w rehabilitation therapy | 1.02 |
| 896 | Alcohol/drug abuse or dependence w/o rehabilitation therapy w MCC | 0.88 |
| 897 | Alcohol/drug abuse or dependence w/o rehabilitation therapy w/o MCC | |

Comorbidity Adjustments:

| Comorbidity | Adjustment Factor |
|--------------------------------|-------------------|
| Developmental Disabilities | 1.04 |
| Coagulation Factor Deficit | 1.13 |
| Tracheostomy | 1.06 |
| Eating and Conduct Disorders | 1.12 |
| Infectious Diseases | 1.07 |
| Renal Failure, Acute | 1.11 |
| Renal Failure, Chronic | 1.11 |
| Oncology Treatment | 1.07 |
| Uncontrolled Diabetes Mellitus | 1.05 |

| Comorbidity | Adjustment Factor |
|---|-------------------|
| Severe Protein Malnutrition | 1.13 |
| Drug/Alcohol Induced Mental Disorders | 1.03 |
| Cardiac Conditions | 1.11 |
| Gangrene | 1.10 |
| Chronic Obstructive Pulmonary Disease | 1.12 |
| Artificial Openings – Digestive & Urinary | 1.08 |
| Severe Musculoskeletal & Connective Tissue Diseases | 1.09 |
| Poisoning | 1.11 |

Addendum B-RY 2012 CBSA Wage Index Tables

In this addendum, we provide the wage index tables referred to in the preamble to this notice. Tables 1 and 2 display the CBSA-based wage index values for urban and rural providers.

Table 1—RY 2012 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|---|------------|
| 10180 | Abilene, TX Callahan County, TX Jones County, TX Taylor County, TX | 0.8003 |
| 10380 | Aguadilla-Isabela-San Sebastián, PR Aguadilla Municipio, PR Añasco Municipio, PR Isabela Municipio, PR Lares Municipio, PR Moca Municipio, PR Rincón Municipio, PR San Sebastián Municipio, PR | |
| 10420 | Akron, OH Portage County, OH Summit County, OH | 0.3471 |
| 10500 | Albany, GA Baker County, GA Dougherty County, GA Lee County, GA Terrell County, GA Worth County, GA | 0.8843 |
| | | 0.9036 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 11700 | Asheville, NC Buncombe County, NC Haywood County, NC Henderson County, NC Madison County, NC | 0.9001 |
| 12020 | Athens-Clarke County, GA Clarke County, GA Madison County, GA Oconee County, GA Oglethorpe County, GA | 0.9659 |
| 12060 | Atlanta-Sandy Springs-Marietta, GA Barrow County, GA Barrow County, GA Bulks County, GA Carroll County, GA Cherokee County, GA Clayton County, GA Cobb County, GA Coweta County, GA Dawson County, GA DeKalb County, GA Douglas County, GA Fayette County, GA Forsyth County, GA Fulton County, GA Gwinnett County, GA Haralson County, GA Heard County, GA Henry County, GA Jasper County, GA Lamar County, GA Meriwether County, GA Newton County, GA Paulding County, GA Pickens County, GA Pike County, GA Rockdale County, GA Spalding County, GA Walton County, GA | 0.9549 |
| 12100 | Atlantic City-Hammonton, NJ Atlantic County, NJ | 1.1129 |
| 12220 | Auburn-Opelika, AL Lee County, AL | 0.7190 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 10560 | Albany-Schenectady-Troy, NY Albany County, NY Rensselaer County, NY Saratoga County, NY Schenectady County, NY Schoharie County, NY | 0.8653 |
| 10740 | Albuquerque, NM Bernalillo County, NM Sandoval County, NM Torrance County, NM Valencia County, NM | 0.9456 |
| 10780 | Alexandria, LA Grant Parish, LA Rapides Parish, LA | 0.7995 |
| 10900 | Allentown-Bethlehem-Easton, PA-NJ Warren County, NJ Carbon County, PA Lehigh County, PA Northampton County, PA | 0.9194 |
| 11020 | Altoona, PA Blair County, PA | 0.8620 |
| 11100 | Amarillo, TX Armstrong County, TX Carson County, TX Potter County, TX Randall County, TX | 0.8644 |
| 11180 | Ames, IA Story County, IA | 0.9970 |
| 11260 | Anchorage, AK Anchorage Municipality, AK Matanuska-Susitna Borough, AK | 1.1964 |
| 11300 | Anderson, IN Madison County, IN | 0.9192 |
| 11340 | Anderson, SC Anderson County, SC | 0.8691 |
| 11460 | Ann Arbor, MI Washtenaw County, MI | 1.0124 |
| 11500 | Anniston-Oxford, AL Calhoun County, AL | 0.7918 |
| 11540 | Appleton, WI Calumet County, WI Outagamie County, WI | 0.9361 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 13380 | Bellingham, WA Whatcom County, WA | 1.1390 |
| 13460 | Bend, OR Deschutes County, OR | 1.1372 |
| 13644 | Bethesda-Fredrick-Gaithersburg, MD Frederick County, MD Montgomery County, MD | 1.0525 |
| 13740 | Billings, MT Carbon County, MT Yellowstone County, MT | 0.8674 |
| 13780 | Binghamton, NY Broome County, NY Tioga County, NY | 0.8719 |
| 13820 | Birmingham-Hoover, AL Blount County, AL Chilton County, AL Jefferson County, AL St. Clair County, AL Shelby County, AL Walker County, AL | 0.8611 |
| 13900 | Bismarck, ND Burleigh County, ND Morton County, ND | 0.7348 |
| 13980 | Blacksburg-Christiansburg-Radford, VA Giles County, VA Montgomery County, VA Pulaski County, VA Radford City, VA | 0.8314 |
| 14020 | Bloomington, IN Greene County, IN Monroe County, IN Owen County, IN | 0.8989 |
| 14060 | Bloomington-Normal, IL McLean County, IL | 0.9439 |
| 14260 | Boise City-Nampa, ID Ada County, ID Boise County, ID Canyon County, ID Gem County, ID Owyhee County, ID | 0.9273 |
| 14484 | Boston-Quincy, MA Norfolk County, MA Plymouth County, MA Suffolk County, MA | 1.2178 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|---|------------|
| 12260 | Augusta-Richmond County, GA-SC Burke County, GA Columbia County, GA McDuffie County, GA Richmond County, GA Aiken County, SC Edgefield County, SC | 0.9538 |
| 12420 | Austin-Round Rock, TX Bastrop County, TX Caldwell County, TX Hays County, TX Travis County, TX Williamson County, TX | 0.9514 |
| 12540 | Bakersfield, CA Kern County, CA | 1.1707 |
| 12580 | Baltimore-Towson, MD Anne Arundel County, MD Baltimore County, MD Carroll County, MD Harford County, MD Howard County, MD Queen Anne's County, MD Baltimore City, MD | 1.0255 |
| 12620 | Bangor, ME Penobscot County, ME | 0.9777 |
| 12700 | Barnstable Town, MA Barnstable County, MA | 1.2823 |
| 12940 | Baton Rouge, LA Ascension Parish, LA East Baton Rouge Parish, LA East Feliciana Parish, LA Iberville Parish, LA Livingston Parish, LA Pointe Coupee Parish, LA St. Helena Parish, LA West Baton Rouge Parish, LA West Feliciana Parish, LA | 0.8583 |
| 12980 | Battle Creek, MI Calhoun County, MI | 0.9656 |
| 13020 | Bay City, MI Bay County, MI | 0.9221 |
| 13140 | Beaumont-Port Arthur, TX Hardin County, TX Jefferson County, TX Orange County, TX | 0.8488 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 16220 | Casper, WY Natrona County, WY | 0.9655 |
| 16300 | Cedar Rapids, IA Benton County, IA Jones County, IA Linn County, IA | 0.8844 |
| 16580 | Champaign-Urbana, IL Champaign County, IL Ford County, IL Platt County, IL | 1.0235 |
| 16620 | Charleston, WV Boone County, WV Clay County, WV Kanawha County, WV Lincoln County, WV Putnam County, WV | 0.7895 |
| 16700 | Charleston-North Charleston-Summerville, SC Berkeley County, SC Charleston County, SC Dorchester County, SC | 0.9354 |
| 16740 | Charlotte-Gastonia-Concord, NC-SC Anson County, NC Cabarrus County, NC Gaston County, NC Mecklenburg County, NC Union County, NC York County, SC | 0.9420 |
| 16820 | Charlottesville, VA Albemarle County, VA Fluvanna County, VA Greene County, VA Nelson County, VA Charlottesville City, VA | 0.9342 |
| 16860 | Chattanooga, TN-GA Catoosa County, GA Dade County, GA Walker County, GA Hamilton County, TN Marion County, TN Sequatchie County, TN | 0.8829 |
| 16940 | Cheyenne, WY Laramie County, WY | 0.9392 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 14500 | Boulder, CO Boulder County, CO | 1.0065 |
| 14540 | Bowling Green, KY Edmonson County, KY Warren County, KY | 0.8666 |
| 14740 | Bremerton-Silverdale, WA Kitsap County, WA | 1.0667 |
| 14860 | Bridgeport-Stamford-Norwalk, CT Fairfield County, CT | 1.2547 |
| 15180 | Brownsville-Harlingen, TX Cameron County, TX | 0.9173 |
| 15260 | Brunswick, GA Branley County, GA Glynn County, GA McIntosh County, GA | 0.9209 |
| 15380 | Buffalo-Niagara Falls, NY Erie County, NY Niagara County, NY | 0.9530 |
| 15500 | Burlington, NC Alamance County, NC | 0.8863 |
| 15540 | Burlington-South Burlington, VT Chittenden County, VT Franklin County, VT Grand Isle County, VT | 0.9947 |
| 15764 | Cambridge-Newton-Framingham, MA Middlesex County, MA | 1.1250 |
| 15804 | Camden, NJ Burlington County, NJ Camden County, NJ Gloucester County, NJ | 1.0386 |
| 15940 | Canton-Massillon, OH Carroll County, OH Stark County, OH | 0.8749 |
| 15980 | Cape Coral-Fort Myers, FL Lee County, FL | 0.9195 |
| 16020 | Cape Girardeau-Jackson, MO-IL Alexander County, IL Boiling County, MO Cape Girardeau County, MO | 0.8983 |
| 16180 | Carson City, NV Carson City, NV | 1.0465 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 17820 | Colorado Springs, CO El Paso County, CO Teller County, CO | 0.9481 |
| 17860 | Columbia, MO Boone County, MO Howard County, MO | 0.8282 |
| 17900 | Columbia, SC Calhoun County, SC Fairfield County, SC Kershaw County, SC Lexington County, SC Richland County, SC Saluda County, SC | |
| 17980 | Columbus, GA-AL Russell County, AL Chattahoochee County, GA Harris County, GA Marion County, GA Muscookee County, GA | 0.8733 |
| 18020 | Columbus, IN Bartholomew County, IN | 0.9027 |
| 18140 | Columbus, OH Delaware County, OH Fairfield County, OH Franklin County, OH Licking County, OH Madison County, OH Morrow County, OH Pickaway County, OH Union County, OH | 0.9434 |
| 18580 | Corpus Christi, TX Aransas County, TX Nueces County, TX San Patricio County, TX | 1.0141 |
| 18700 | Corvallis, OR Benton County, OR | 0.8585 |
| 18880 | Crestview-Fort Walton Beach-Destin, FL Okaloosa County, FL | 1.0455 |
| 19060 | Cumberland, MD-WV Allegany County, MD Mineral County, WV | 0.8842 |
| | | 0.8186 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|---|------------|
| 16974 | Chicago-Naperville-Joliet, IL Cook County, IL DeKalb County, IL DuPage County, IL Grundy County, IL Kane County, IL Kendall County, IL McHenry County, IL Will County, IL | 1.0593 |
| 17020 | Chico, CA Butte County, CA | 1.1533 |
| 17140 | Cincinnati-Middletown, OH-KY-IN Dearborn County, IN Franklin County, IN Ohio County, IN Boone County, KY Bracken County, KY Campbell County, KY Gallatin County, KY Grant County, KY Kenton County, KY Pendleton County, KY Brown County, OH Butler County, OH Clermont County, OH Hamilton County, OH Warren County, OH | 0.9699 |
| 17300 | Clarksville, TN-KY Christian County, KY Trigg County, KY Montgomery County, TN Stewart County, TN | |
| 17420 | Cleveland, TN Bradley County, TN Polk County, TN | 0.7888 |
| 17460 | Cleveland-Elyria-Mentor, OH Cuyahoga County, OH Geauga County, OH Lake County, OH Lorain County, OH Medina County, OH | 0.7731 |
| 17660 | Coeur d'Alene, ID Kootenai County, ID | 0.9050 |
| 17780 | College Station-Bryan, TX Brazos County, TX Burlinson County, TX Robertson County, TX | 0.9364 |
| | | 0.9588 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|---|------------|
| 19780 | Des Moines-West Des Moines, IA Dallas County, IA Guthrie County, IA Madison County, IA Polk County, IA Warren County, IA | 0.9621 |
| 19804 | Detroit-Livonia-Dearborn, MI Wayne County, MI | 0.9699 |
| 20020 | Dothan, AL Geneva County, AL Henry County, AL Houston County, AL | 0.7435 |
| 20100 | Dover, DE Kent County, DE | 0.9921 |
| 20220 | Dubuque, IA Dubuque County, IA | 0.8774 |
| 20260 | Duluth, MN-WI Carlton County, MN St. Louis County, MN Douglas County, WI | 1.0565 |
| 20500 | Durham-Chapel Hill, NC Chatham County, NC Durham County, NC Orange County, NC Person County, NC | 0.9664 |
| 20740 | Eau Claire, WI Chippewa County, WI Eau Claire County, WI | 0.9639 |
| 20764 | Edison-New Brunswick, NJ Middlesex County, NJ Monmouth County, NJ Ocean County, NJ Somerset County, NJ | 1.1006 |
| 20940 | El Centro, CA Imperial County, CA | 0.9258 |
| 21060 | Elizabethtown, KY Hardin County, KY Larue County, KY | 0.8449 |
| 21140 | Elkhart-Goshen, IN Elkhart County, IN | 0.9465 |
| 21300 | Elmira, NY Chemung County, NY | 0.8445 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 19124 | Dallas-Plano-Irving, TX Collin County, TX Dallas County, TX Delta County, TX Denton County, TX Ellis County, TX Hunt County, TX Kaufman County, TX Rockwall County, TX | 0.9860 |
| 19140 | Dallam, GA Murray County, GA Whitfield County, GA | 0.8622 |
| 19180 | Danville, IL Vermilion County, IL | 0.9693 |
| 19260 | Danville, VA Pittsylvania County, VA Danville City, VA | 0.8168 |
| 19340 | Davenport-Moline-Rock Island, IA-IL Henry County, IL Mercer County, IL Rock Island County, IL Scott County, IA | 0.8400 |
| 19380 | Dayton, OH Greene County, OH Miami County, OH Montgomery County, OH Preble County, OH | 0.9140 |
| 19460 | Decatur, AL Lawrence County, AL Morgan County, AL | 0.7621 |
| 19500 | Decatur, IL Macon County, IL | 0.7916 |
| 19660 | Deltona-Daytona Beach-Ormond Beach, FL Volusia County, FL | 0.8736 |
| 19740 | Denver-Aurora-Broomfield, CO Adams County, CO Arapahoe County, CO Broomfield County, CO Clear Creek County, CO Denver County, CO Douglas County, CO Elbert County, CO Gilpin County, CO Jefferson County, CO Park County, CO | 1.0718 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 22540 | Fond du Lac, WI Fond du Lac County, WI | 0.9223 |
| 22660 | Fort Collins-Loveland, CO Larimer County, CO | 0.9892 |
| 22744 | Fort Lauderdale-Pompano Beach-Deerfield Beach, FL Broward County, FL | 1.0160 |
| 22900 | Fort Smith, AR-OK Crawford County, AR Franklin County, AR Sebastian County, AR Le Flore County, OK Squoyah County, OK | 0.7599 |
| 23060 | Fort Wayne, IN Allen County, IN Wells County, IN Whitley County, IN | 0.9362 |
| 23104 | Fort Worth-Arlington, TX Johnson County, TX Parker County, TX Tarrant County, TX Wise County, TX | 0.9474 |
| 23420 | Fresno, CA Fresno County, CA | 1.1422 |
| 23460 | Gadsden, AL Etowah County, AL | 0.7180 |
| 23540 | Gainesville, FL Alachua County, FL Gilchrist County, FL | 0.9160 |
| 23580 | Gainesville, GA Hall County, GA | 0.9223 |
| 23844 | Gary, IN Jasper County, IN Lake County, IN Newton County, IN Porter County, IN | 0.9084 |
| 24020 | Glens Falls, NY Warren County, NY Washington County, NY | 0.8507 |
| 24140 | Goldboro, NC Wayne County, NC | 0.9067 |
| 24220 | Grand Forks, ND-MN Polk County, MN Grand Forks County, ND | 0.7717 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 21340 | El Paso, TX El Paso County, TX | 0.8475 |
| 21500 | Erie, PA Erie County, PA | 0.8360 |
| 21660 | Eugene-Springfield, OR Lane County, OR | 1.1384 |
| 21780 | Evansville, IN-KY Gibson County, IN Posey County, IN Vanderburgh County, IN Warrick County, IN Henderson County, KY Webster County, KY | 0.8433 |
| 21820 | Fairbanks, AK Fairbanks North Star Borough, AK | 1.1060 |
| 21940 | Fajardo, PR Ceiba Municipio, PR Fajardo Municipio, PR Luquillo Municipio, PR | 0.3883 |
| 22020 | Fargo, ND-MN Cass County, ND Clay County, MN | 0.8064 |
| 22140 | Farmington, NM San Juan County, NM | 0.9339 |
| 22180 | Fayetteville, NC Cumberland County, NC Hoke County, NC | 0.9323 |
| 22220 | Fayetteville-Springdale-Rogers, AR-MO Benton County, AR Madison County, AR Washington County, AR McDonald County, MO | 0.8616 |
| 22380 | Flagstaff, AZ Coconino County, AZ | 1.2443 |
| 22420 | Flint, MI Genesee County, MI | 1.1496 |
| 22500 | Florence, SC Darlington County, SC Florence County, SC | 0.8252 |
| 22520 | Florence-Muscle Shoals, AL Colbert County, AL Lauderdale County, AL | 0.8144 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 25500 | Harrisonburg, VA Rockingham County, VA Harrisonburg City, VA | 0.9158 |
| 25540 | Hartford-West Hartford-East Hartford, CT Hartford County, CT Middlesex County, CT Tolland County, CT | 1.0927 |
| 25620 | Hattiesburg, MS Forrest County, MS Lamar County, MS Perry County, MS | 0.7714 |
| 25860 | Hickory-Lenoir-Morganton, NC Alexander County, NC Burke County, NC Caldwell County, NC Catawba County, NC | 0.8693 |
| 25980 | Hinesville-Fort Stewart, GA ¹ Liberty County, GA Long County, GA | 0.8958 |
| 26100 | Holland-Grand Haven, MI Ottawa County, MI | 0.8632 |
| 26180 | Honolulu, HI Honolulu County, HI | 1.1807 |
| 26300 | Hot Springs, AR Garland County, AR | 0.9151 |
| 26380 | Houma-Bayou Cane-Thibodaux, LA Lafourche Parish, LA Terrebonne Parish, LA | 0.7852 |
| 26420 | Houston-Sugar Land-Baytown, TX Austin County, TX Brazoria County, TX Chambers County, TX Fort Bend County, TX Galveston County, TX Harris County, TX Liberty County, TX Montgomery County, TX San Jacinto County, TX Waller County, TX | 0.9824 |
| 26580 | Huntington-Ashland, WV-KY-OH Boyd County, KY Greenup County, KY Lawrence County, OH Cabell County, WV Wayne County, WV | 0.8953 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|---|------------|
| 24300 | Grand Junction, CO Mesa County, CO | 0.9850 |
| 24340 | Grand Rapids-Wyoming, MI Barry County, MI Ionia County, MI Kent County, MI Newaygo County, MI | 0.9169 |
| 24500 | Great Falls, MT Cascade County, MT | 0.8289 |
| 24540 | Greeley, CO Weld County, CO | 0.9496 |
| 24580 | Green Bay, WI Brown County, WI Kewaunee County, WI Oconto County, WI | 0.9586 |
| 24660 | Greensboro-High Point, NC Guilford County, NC Randolph County, NC Rockingham County, NC | 0.8882 |
| 24780 | Greenville, NC Greene County, NC Pitt County, NC | 0.9370 |
| 24860 | Greenville-Mauldin-Easley, SC Greenville County, SC Laurens County, SC Pickens County, SC | 0.9644 |
| 25020 | Guayama, PR Arroyo Municipio, PR Guayama Municipio, PR Patillas Municipio, PR | 0.3686 |
| 25060 | Gulfport-Biloxi, MS Hancock County, MS Harrison County, MS Stone County, MS | 0.8877 |
| 25180 | Hagerstown-Martinsburg, MD-WV Washington County, MD Berkeley County, WV Morgan County, WV | 0.9254 |
| 25260 | Hanford-Corcoran, CA Kings County, CA | 1.1205 |
| 25420 | Harrisburg-Carlisle, PA Cumberland County, PA Dauphin County, PA Perry County, PA | 0.9296 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 27620 | Jefferson City, MO Callaway County, MO Cole County, MO Monteau County, MO Osage County, MO | 0.8434 |
| 27740 | Johnson City, TN Carter County, TN Unicoi County, TN Washington County, TN | 0.8105 |
| 27780 | Johnstown, PA Cambria County, PA | 0.8090 |
| 27860 | Jonesboro, AR Craighead County, AR | 0.7757 |
| 27900 | Poinsett County, AR Joplin, MO Jasper County, MO Newton County, MO | 0.8214 |
| 28020 | Kalamazoo-Portage, MI Kalamazoo County, MI Van Buren County, MI | 1.0292 |
| 28100 | Kankakee-Bradley, IL Kankakee County, IL | 1.0619 |
| 28140 | Kansas City, MO-KS Franklin County, KS Johnson County, KS Leavenworth County, KS Linn County, KS Miami County, KS Wyandotte County, KS Bates County, MO Caldwell County, MO Cass County, MO Clay County, MO Clinton County, MO Jackson County, MO Lafayette County, MO Platte County, MO Ray County, MO | 0.9652 |
| 28420 | Kennewick-Pasco-Richland, WA Benton County, WA Franklin County, WA | 0.9976 |
| 28660 | Killeen-Temple-Fort Hood, TX Bell County, TX Coryell County, TX Lampasas County, TX | 0.8798 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 26620 | Huntsville, AL Limestone County, AL Madison County, AL | 0.9191 |
| 26820 | Idaho Falls, ID Bonneville County, ID Jefferson County, ID | 0.9653 |
| 26900 | Indianapolis-Carmel, IN Boone County, IN Brown County, IN Hamilton County, IN Hancock County, IN Hendricks County, IN Johnson County, IN Marion County, IN Morgan County, IN Putnam County, IN Shelby County, IN | 0.9672 |
| 26980 | Iowa City, IA Johnson County, IA Washington County, IA | 0.9657 |
| 27060 | Ithaca, NY Tompkins County, NY | 0.9842 |
| 27100 | Jackson, MI Jackson County, MI | 0.9155 |
| 27140 | Jackson, MS Copiah County, MS Hinds County, MS Madison County, MS Rankin County, MS Simpson County, MS | 0.8042 |
| 27180 | Jackson, TN Chester County, TN Madison County, TN | 0.8404 |
| 27260 | Jacksonville, FL Baker County, FL Clay County, FL Duval County, FL Nassau County, FL St. Johns County, FL | 0.8884 |
| 27340 | Jacksonville, NC Onslow County, NC | 0.7807 |
| 27500 | Janesville, WI Rock County, WI | 0.9415 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|---|------------|
| 29740 | Las Cruces, NM Dona Ana County, NM | 0.9296 |
| 29820 | Las Vegas-Paradise, NV Clark County, NV | 1.2099 |
| 29940 | Lawrence, KS Douglas County, KS | 0.8533 |
| 30020 | Lawton, OK Comanche County, OK | 0.8285 |
| 30140 | Lebanon, PA Lebanon County, PA | 0.7807 |
| 30300 | Lewiston, ID-WA Nez Perce County, ID Asotin County, WA | 0.9358 |
| 30340 | Lewiston-Auburn, ME Androscoggin County, ME | 0.8903 |
| 30460 | Lexington-Fayette, KY Bourbon County, KY Clark County, KY Fayette County, KY Jessamine County, KY Scott County, KY Woodford County, KY | 0.8817 |
| 30620 | Lima, OH Allen County, OH | 0.9271 |
| 30700 | Lincoln, NE Lancaster County, NE Seward County, NE | 0.9617 |
| 30780 | Little Rock-North Little Rock-Conway, AR Faulkner County, AR Grant County, AR Lonoke County, AR Perry County, AR Pulaski County, AR Saline County, AR | 0.8546 |
| 30860 | Logan, UT-ID Franklin County, ID Cache County, UT | 0.8794 |
| 30980 | Longview, TX Gregg County, TX Rusk County, TX Upshur County, TX | 0.8563 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 28700 | Kingsport-Bristol-Bristol, TN-VA Hawkins County, TN Sullivan County, TN Bristol City, VA Scott County, VA Washington County, VA | 0.7588 |
| 28740 | Kingston, NY Ulster County, NY | 0.9075 |
| 28940 | Knoxville, TN Anderson County, TN Blount County, TN Knox County, TN Loudon County, TN Union County, TN | 0.7842 |
| 29020 | Kokomo, IN Howard County, IN Tipton County, IN | 0.9130 |
| 29100 | La Crosse, WI-MN Harrison County, MN La Crosse County, WI | 0.9803 |
| 29140 | Lafayette, IN Benton County, IN Carroll County, IN Tippecanoe County, IN | 0.9289 |
| 29180 | Lafayette, LA Lafayette Parish, LA St. Martin Parish, LA | 0.8489 |
| 29340 | Lake Charles, LA Calcasieu Parish, LA Cameron Parish, LA | 0.8196 |
| 29404 | Lake County-Kenosha County, IL-WI Lake County, IL Kenosha County, WI | 1.0781 |
| 29420 | Lake Havasu City-Kingman, AZ Mohave County, AZ | 1.0235 |
| 29460 | Lakeland-Winter Haven, FL Polk County, FL | 0.8447 |
| 29540 | Lancaster, PA Lancaster County, PA | 0.9344 |
| 29620 | Lansing-East Lansing, MI Clinton County, MI Eaton County, MI Ingham County, MI | 1.0298 |
| 29700 | Laredo, TX Webb County, TX | 0.7914 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 31860 | Mankato-North Mankato, MN Blue Earth County, MN Nicollet County, MN | 0.9083 |
| 31900 | Mansfield, OH Richland County, OH | 0.8918 |
| 32420 | Mayaguez, PR Hormigueros Municipio, PR Mayaguez Municipio, PR | 0.3640 |
| 32580 | McAllen-Edinburg-Mission, TX Hidalgo County, TX | 0.8837 |
| 32780 | Medford, OR Jackson County, OR | 1.0061 |
| 32820 | Memphis, TN-MS-AR Crittenden County, AR DeSoto County, MS Marshall County, MS Tate County, MS Tunica County, MS Fayette County, TN Shelby County, TN Tipton County, TN | 0.9268 |
| 32900 | Merced, CA Merced County, CA | 1.2359 |
| 33124 | Miami-Miami Beach-Kendall, FL Miami-Dade County, FL | 1.0128 |
| 33140 | Michigan City-La Porte, IN LaPorte County, IN | 0.9470 |
| 33260 | Midland, TX Midland County, TX | 0.9711 |
| 33340 | Milwaukee-Waukesha-West Allis, WI Milwaukee County, WI Ozaukee County, WI Washington County, WI Waukesha County, WI | 1.0183 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|---|------------|
| 31020 | Longview, WA Cowlitz County, WA | 1.0296 |
| 31084 | Los Angeles-Long Beach-Glendale, CA Los Angeles County, CA | 1.2130 |
| 31140 | Louisville-Jefferson County, KY-IN Clark County, IN Floyd County, IN Harrison County, IN Washington County, IN Bullitt County, KY Henry County, KY Meade County, KY Nelson County, KY Oldham County, KY Shelby County, KY Spencer County, KY Trimble County, KY | 0.8896 |
| 31180 | Lubbock, TX Crosby County, TX Lubbock County, TX | 0.8847 |
| 31340 | Lynchburg, VA Amherst County, VA Appomattox County, VA Bedford County, VA Campbell County, VA Bedford City, VA Lynchburg City, VA | 0.8694 |
| 31420 | Macon, GA Bibb County, GA Crawford County, GA Jones County, GA Monroe County, GA Twiggs County, GA | 0.9202 |
| 31460 | Madera-Chowchilla, CA Madera County, CA | 0.7986 |
| 31540 | Madison, WI Columbia County, WI Dane County, WI Iowa County, WI | 1.1294 |
| 31700 | Manchester-Nashua, NH Hillsborough County, NH | 0.9869 |
| 31740 | Manhattan, KS Geary County, KS Pottawatomie County, KS Riley County, KS | 0.7647 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|---|------------|
| 34920 | Myrtle Beach-North Myrtle Beach-Conway, SC Horry County, SC | 0.8738 |
| 34900 | Napa, CA Napa County, CA | 1.4604 |
| 34940 | Naples-Marco Island, FL Collier County, FL | 0.9698 |
| 34980 | Nashville-Davidson—Murfreesboro-Franklin, TN Cannon County, TN Crenshaw County, TN Davidson County, TN Dickson County, TN Hickman County, TN Macon County, TN Robertson County, TN Rutherford County, TN Smith County, TN Sumner County, TN Trousdale County, TN Williamson County, TN Wilson County, TN | 0.9457 |
| 35004 | Nassau-Suffolk, NY Nassau County, NY Suffolk County, NY | 1.2315 |
| 35084 | Newark-Union, NJ-PA Essex County, NJ Hunterdon County, NJ Morris County, NJ Sussex County, NJ Union County, NJ Pike County, PA | 1.1460 |
| 35300 | New Haven-Milford, CT New Haven County, CT | 1.1515 |
| 35380 | New Orleans-Metairie-Kenner, LA Jefferson Parish, LA Orleans Parish, LA Plaquemines Parish, LA St. Bernard Parish, LA St. Charles Parish, LA St. John the Baptist Parish, LA St. Tammany Parish, LA | 0.9070 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|---|------------|
| 33460 | Minneapolis-St. Paul-Bloomington, MN-WI Anoka County, MN Carver County, MN Chisago County, MN Dakota County, MN Hennepin County, MN Isanti County, MN Ramsey County, MN Scott County, MN Sherburne County, MN Washington County, MN Wright County, MN Pierce County, WI St. Croix County, WI | 1.1143 |
| 33540 | Missoula, MT Missoula County, MT | 0.8921 |
| 33680 | Mobile, AL Mobile County, AL | 0.7960 |
| 33700 | Modesto, CA Stanislaus County, CA | 1.2104 |
| 33740 | Monroe, LA Ouachita Parish, LA Union Parish, LA | 0.7993 |
| 33780 | Monroe, MI Monroe County, MI | 0.8684 |
| 33860 | Montgomery, AL Autauga County, AL Elmore County, AL Lowndes County, AL Montgomery County, AL | 0.8442 |
| 34060 | Morgantown, WV Monongalia County, WV Preston County, WV | 0.8137 |
| 34100 | Morristown, TN Grainger County, TN Hamblen County, TN Jefferson County, TN | 0.7041 |
| 34580 | Mount Vernon-Anacortes, WA Skagit County, WA | 1.0363 |
| 34620 | Muncie, IN Delaware County, IN | 0.8206 |
| 34740 | Muskegon-Norton Shores, MI Muskegon County, MI | 0.9809 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|---|------------|
| 36540 | Omaha-Council Bluffs, NE-IA Harrison County, IA Mills County, IA Pottawattamie County, IA Cass County, NE Douglas County, NE Sarpy County, NE Saunders County, NE Washington County, NE | 0.9583 |
| 36740 | Orlando-Kissimmee, FL Lake County, FL Orange County, FL Osceola County, FL Seminole County, FL | 0.9163 |
| 36780 | Oshkosh-Neenah, WI Winnebago County, WI | 0.9566 |
| 36980 | Owensboro, KY Davies County, KY Hancock County, KY McLean County, KY | 0.8370 |
| 37100 | Oxnard-Thousand Oaks-Ventura, CA Ventura County, CA | 1.2377 |
| 37340 | Palm Bay-Melbourne-Titusville, FL Brevard County, FL | 0.9211 |
| 37380 | Palm Coast, FL Flagler County, FL | 0.8405 |
| 37460 | Panama City-Lynn Haven-Panama City Beach, FL Bay County, FL | 0.7954 |
| 37620 | Parkersburg-Marietta-Vienna, WV-OH Washington County, OH Pleasant County, WV Wirt County, WV Wood County, WV | 0.7455 |
| 37700 | Pascagoula, MS George County, MS Jackson County, MS | 0.8299 |
| 37764 | Peabody, MA Essex County, MA | 1.0979 |
| 37860 | Pensacola-Ferry Pass-Brent, FL Escambia County, FL Santa Rosa County, FL | 0.8254 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 35644 | New York-White Plains-Wayne, NY-NJ Bergen County, NJ Hudson County, NJ Passaic County, NJ Bronx County, NY Kings County, NY New York County, NY Putnam County, NY Queens County, NY Richmond County, NY Rockland County, NY Westchester County, NY Niles-Benton Harbor, MI Berrien County, MI | 1.2955 |
| 35660 | | 0.8872 |
| 35840 | North Port-Bradenton-Sarasota-Venice, FL Manatee County, FL Sarasota County, FL | 0.9481 |
| 35980 | Norwich-New London, CT New London County, CT | 1.1215 |
| 36084 | Oakland-Fremont-Hayward, CA Alameda County, CA Contra Costa County, CA | 1.6354 |
| 36100 | Ocala, FL Marion County, FL | 0.8468 |
| 36140 | Ocean City, NJ Cape May County, NJ | 1.0879 |
| 36220 | Odessa, TX Ector County, TX | 0.9436 |
| 36260 | Ogden-Clearfield, UT Davis County, UT Morgan County, UT Weber County, UT | 0.9267 |
| 36420 | Oklahoma City, OK Canadian County, OK Cleveland County, OK Grady County, OK Lincoln County, OK Logan County, OK McCain County, OK Oklahoma County, OK | 0.8877 |
| 36500 | Olympia, WA Thurston County, WA | 1.1269 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|---|------------|
| 38940 | Port St. Lucie, FL Martin County, FL St. Lucie County, FL | 1.0723 |
| 39100 | Poughkeepsie-Newburgh-Middletown, NY Dutchess County, NY Orange County, NY | 1.1354 |
| 39140 | Prescott, AZ Yavapai County, AZ | 1.2234 |
| 39300 | Providence-New Bedford-Fall River, RI-MA Bristol County, MA Bristol County, RI Kent County, RI Newport County, RI Providence County, RI Washington County, RI | 1.0714 |
| 39340 | Provo-Orem, UT Juab County, UT Utah County, UT | 0.9321 |
| 39380 | Pueblo, CO Pueblo County, CO | 0.8721 |
| 39460 | Punta Gorda, FL Charlotte County, FL | 0.8759 |
| 39540 | Racine, WI Racine County, WI | 1.0580 |
| 39580 | Raleigh-Cary, NC Franklin County, NC Johnston County, NC Wake County, NC | 0.9811 |
| 39660 | Rapid City, SD Meade County, SD Pennington County, SD | 1.0442 |
| 39740 | Reading, PA Berks County, PA | 0.8904 |
| 39820 | Redding, CA Shasta County, CA | 1.4134 |
| 39900 | Reno-Sparks, NV Storey County, NV Washoe County, NV | 1.0419 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 37900 | Peoria, IL Marshall County, IL Peoria County, IL Stark County, IL Tazewell County, IL Woodford County, IL | 0.9149 |
| 37964 | Philadelphia, PA Bucks County, PA Chester County, PA Delaware County, PA Montgomery County, PA Philadelphia County, PA | 1.0803 |
| 38060 | Phoenix-Mesa-Scottsdale, AZ Maricopa County, AZ Pinal County, AZ | 1.0842 |
| 38220 | Pine Bluff, AR Cleveland County, AR Jefferson County, AR Lincoln County, AR | 0.8012 |
| 38300 | Pittsburgh, PA Allegheny County, PA Armstrong County, PA Beaver County, PA Butler County, PA Fayette County, PA Washington County, PA Westmoreland County, PA | 0.8605 |
| 38340 | Pittsfield, MA Berkshire County, MA | 1.0371 |
| 38540 | Pocatello, ID Bannock County, ID Power County, ID | 0.9507 |
| 38660 | Ponce, PR Juana Diaz Municipio, PR Ponce Municipio, PR Villalba Municipio, PR | 0.4326 |
| 38860 | Portland-South Portland-Biddeford, ME Cumberland County, ME Sagadahoc County, ME York County, ME | 0.9889 |
| 38900 | Portland-Vancouver-Beaverton, OR-WA Clackamas County, OR Columbia County, OR Multnomah County, OR Washington County, OR Yamhill County, OR Clark County, WA Skamania County, WA | 1.1476 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 40660 | Rome, GA Floyd County, GA | 0.8635 |
| 40900 | Sacramento-Arden-Arcade-Roseville, CA El Dorado County, CA Placer County, CA Sacramento County, CA Yolo County, CA | 1.4053 |
| 40980 | Saginaw-Saginaw Township North, MI Saginaw County, MI | 0.8728 |
| 41060 | St. Cloud, MN Benton County, MN Stearns County, MN | 1.1042 |
| 41100 | St. George, UT Washington County, UT | 0.9133 |
| 41140 | St. Joseph, MO-KS Doniphan County, KS Andrew County, MO Buchanan County, MO DeKalb County, MO | 1.0302 |
| 41180 | St. Louis, MO-IL Bond County, IL Calhoun County, IL Clinton County, IL Jersey County, IL Macoupin County, IL Madison County, IL Monroe County, IL St. Clair County, IL Crawford County, MO Franklin County, MO Jefferson County, MO Lincoln County, MO St. Charles County, MO St. Louis County, MO Warren County, MO Washington County, MO St. Louis City, MO | 0.9090 |
| 41420 | Salem, OR Marion County, OR Polk County, OR | 1.1133 |
| 41500 | Salinas, CA Monterey County, CA | 1.5686 |
| 41540 | Salisbury, MD Somerset County, MD Wicomico County, MD | 0.9005 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|---|------------|
| 40060 | Richmond, VA Amelia County, VA Caroline County, VA Charles City County, VA Cheslerfield County, VA Cumberland County, VA Dinwiddie County, VA Goochland County, VA Hanover County, VA Henrico County, VA King and Queen County, VA King William County, VA Louisa County, VA New Kent County, VA Powhatan County, VA Prince George County, VA Sussex County, VA Colonial Heights City, VA Hopewell City, VA Petersburg City, VA Richmond City, VA | 0.9661 |
| 40140 | Riverside-San Bernardino-Ontario, CA Riverside County, CA San Bernardino County, CA | 1.1570 |
| 40220 | Roanoke, VA Botetourt County, VA Craig County, VA Franklin County, VA Roanoke County, VA Roanoke City, VA Salem City, VA | 0.8827 |
| 40340 | Rochester, MN Dodge County, MN Olmsted County, MN Wabasha County, MN | 1.0942 |
| 40380 | Rochester, NY Livingston County, NY Monroe County, NY Ontario County, NY Orleans County, NY Wayne County, NY | 0.8595 |
| 40420 | Rockford, IL Boone County, IL Winnebago County, IL | 1.0033 |
| 40484 | Rockingham County-Strafford County, NH Rockingham County, NH Strafford County, NH | 1.0026 |
| 40580 | Rocky Mount, NC Edgecombe County, NC Nash County, NC | 0.9034 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|---|------------|
| 41980 | San Juan-Caguas-Guaynabo, PR Agua Buenas Municipio, PR Albionito Municipio, PR Arecibo Municipio, PR Barceloneta Municipio, PR Barranquitas Municipio, PR Bayamon Municipio, PR Caguas Municipio, PR Camuy Municipio, PR Canóvanas Municipio, PR Carolina Municipio, PR Cataño Municipio, PR Cayey Municipio, PR Ciales Municipio, PR Cidra Municipio, PR Comerio Municipio, PR Corozal Municipio, PR Dorado Municipio, PR Florida Municipio, PR Guaynabo Municipio, PR Gurabo Municipio, PR Hatillo Municipio, PR Humacao Municipio, PR Juncos Municipio, PR Las Piedras Municipio, PR Loíza Municipio, PR Manatí Municipio, PR Maunabo Municipio, PR Morovis Municipio, PR Naguabo Municipio, PR Naranjito Municipio, PR Orocovis Municipio, PR Quebradillas Municipio, PR Rio Grande Municipio, PR San Juan Municipio, PR San Lorenzo Municipio, PR Toa Alta Municipio, PR Toa Baja Municipio, PR Trujillo Alto Municipio, PR Vega Alta Municipio, PR Vega Baja Municipio, PR Yabucoa Municipio, PR | 0.4296 |
| 42020 | San Luis Obispo-Paso Robles, CA San Luis Obispo County, CA | 1.2915 |
| 42044 | Santa Ana-Anaheim-Irvine, CA Orange County, CA | 1.2162 |
| 42060 | Santa Barbara-Santa Maria-Goleta, CA Santa Barbara County, CA | 1.1909 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 41620 | Salt Lake City, UT Salt Lake County, UT Summit County, UT Tooele County, UT | 0.9266 |
| 41660 | San Angelo, TX Iron County, TX Tom Green County, TX | 0.8303 |
| 41700 | San Antonio, TX Atascosa County, TX Bandera County, TX Bexar County, TX Comal County, TX Guadalupe County, TX Kendall County, TX Medina County, TX Wilson County, TX | 0.8998 |
| 41740 | San Diego-Carlsbad-San Marcos, CA San Diego County, CA | 1.1979 |
| 41780 | Sandusky, OH Erie County, OH | 0.8686 |
| 41884 | San Francisco-San Mateo-Redwood City, CA Marin County, CA San Francisco County, CA San Mateo County, CA | 1.5733 |
| 41900 | San Germán-Cabo Rojo, PR Cabo Rojo Municipio, PR Lajas Municipio, PR Sabana Grande Municipio, PR San Germán Municipio, PR | 0.4560 |
| 41940 | San Jose-Sunnyvale-Santa Clara, CA San Benito County, CA Santa Clara County, CA | 1.6703 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 44060 | Spokane, WA Spokane County, WA | 1.0571 |
| 44100 | Springfield, IL Menard County, IL Sangamon County, IL | 0.9130 |
| 44140 | Springfield, MA Franklin County, MA Hampden County, MA Hampshire County, MA | 1.0251 |
| 44180 | Springfield, MO Christian County, MO Dallas County, MO Greene County, MO Polk County, MO Webster County, MO | 0.8371 |
| 44220 | Springfield, OH Clark County, OH | 0.9234 |
| 44300 | State College, PA Centre County, PA | 0.8779 |
| 44600 | Staubenville-Weirton, OH-WV Jefferson County, OH Brooke County, WV Hancock County, WV | 0.7315 |
| 44700 | Stockton, CA San Joaquin County, CA | 1.2644 |
| 44940 | Sumter, SC Sumter County, SC | 0.7860 |
| 45060 | Syracuse, NY Madison County, NY Orondaga County, NY Oswego County, NY | 0.9905 |
| 45104 | Tacoma, WA Pierce County, WA | 1.1343 |
| 45220 | Tallahassee, FL Gadsden County, FL Jefferson County, FL Leon County, FL | 0.8806 |
| 45300 | Tampa-St. Petersburg-Clearwater, FL Hernando County, FL Hillsborough County, FL Pasco County, FL Pinellas County, FL | 0.9054 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 42100 | Santa Cruz-Watsonville, CA Santa Cruz County, CA | 1.6740 |
| 42140 | Santa Fe, NM Santa Fe County, NM | 1.0847 |
| 42220 | Santa Rosa-Petaluma, CA Sonoma County, CA | 1.6143 |
| 42340 | Savannah, GA Bryan County, GA Chatham County, GA Effingham County, GA | 0.8907 |
| 42540 | Scranton-Wilkes-Barre, PA Lackawanna County, PA Luzerne County, PA Wyoming County, PA | 0.8238 |
| 42644 | Seattle-Bellevue-Everett, WA King County, WA Snohomish County, WA Sebastian-Vero Beach, FL Indian River County, FL | 1.1556 |
| 43100 | Sheboygan, WI Sheboygan County, WI | 0.9097 |
| 43300 | Sherman-Denison, TX Grayson County, TX | 0.9233 |
| 43340 | Shreveport-Bossier City, LA Bossier Parish, LA Caddo Parish, LA De Soto Parish, LA | 0.8279 |
| 43580 | Sioux City, IA-NE-SD Woodbury County, IA Dakota County, NE Dixon County, NE Union County, SD | 0.8536 |
| 43620 | Sioux Falls, SD Lincoln County, SD McCook County, SD Minnehaha County, SD Turner County, SD | 0.9091 |
| 43780 | South Bend-Mishawaka, IN-MI St. Joseph County, IN Cass County, MI | 0.9299 |
| 43900 | Spartanburg, SC Spartanburg County, SC | 0.9948 |
| | | 0.9383 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 46700 | Vallejo-Fairfield, CA Solano County, CA | 1.4931 |
| 47020 | Victoria, TX Calhoun County, TX Goliad County, TX Victoria County, TX | 0.8219 |
| 47220 | Vineland-Millville-Bridgeton, NJ Cumberland County, NJ | 1.0534 |
| 47260 | Virginia Beach-Norfolk-Newport News, VA-NC Currituck County, NC Gloucester County, VA Isle of Wight County, VA James City County, VA Mathews County, VA Surrey County, VA York County, VA Chesapeake City, VA Hampton City, VA Newport News City, VA Norfolk City, VA Poquoson City, VA Portsmouth City, VA Suffolk City, VA Virginia Beach City, VA Williamsburg City, VA | 0.8961 |
| 47300 | Visalia-Porterville, CA Tulare County, CA | 1.0738 |
| 47380 | Waco, TX McLennan County, TX | 0.8403 |
| 47580 | Warner Robins, GA Houston County, GA | 0.8028 |
| 47644 | Warren-Troy-Farmington Hills, MI Lapeer County, MI Livingston County, MI Macomb County, MI Oakland County, MI St. Clair County, MI | 0.9648 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 45460 | Terre Haute, IN Clay County, IN Sullivan County, IN Vermillion County, IN Vigo County, IN | 0.9205 |
| 45500 | Texarkana, TX-Texarkana, AR Miller County, AR Bowie County, TX | 0.7748 |
| 45780 | Toledo, OH Fulton County, OH Lucas County, OH Ottawa County, OH Wood County, OH | 0.9432 |
| 45820 | Topeka, KS Jackson County, KS Jefferson County, KS Osage County, KS Shawnee County, KS Wabaunsee County, KS | 0.8952 |
| 45940 | Trenton-Ewing, NJ Mercer County, NJ | 1.0150 |
| 46060 | Tucson, AZ Pima County, AZ | 0.9480 |
| 46140 | Tulsa, OK Creek County, OK Okmulgee County, OK Osage County, OK Pawnee County, OK Rogers County, OK Tulsa County, OK Wagoner County, OK | 0.8793 |
| 46220 | Tuscaloosa, AL Greene County, AL Hale County, AL Tuscaloosa County, AL | 0.8843 |
| 46340 | Tyler, TX Smith County, TX | 0.8065 |
| 46540 | Utica-Rome, NY Herkimer County, NY Oneida County, NY | 0.8471 |
| 46660 | Valdosta, GA Brooks County, GA Echols County, GA Lanier County, GA Lowndes County, GA | 0.7941 |

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|---|------------|
| 48864 | Wilmington, DE-MD-NJ New Castle County, DE Cecil County, MD Salem County, NJ | 1.0580 |
| 48900 | Wilmington, NC Brunswick County, NC New Hanover County, NC Pender County, NC | 0.9202 |
| 49020 | Winchester, VA-WV Frederick County, VA Winchester City, VA Hampshire County, WV | 1.0002 |
| 49180 | Winston-Salem, NC Davie County, NC Forsyth County, NC Stokes County, NC Yadkin County, NC | 0.8939 |
| 49340 | Worcester, MA Worcester County, MA | 1.1012 |
| 49420 | Yakima, WA Yakima County, WA | 1.0067 |
| 49500 | Yauco, PR Guanica Municipio, PR Guayanilla Municipio, PR Pefuelas Municipio, PR Yauco Municipio, PR | 0.3536 |
| 49620 | York-Hanover, PA York County, PA | 0.9983 |
| 49660 | Youngstown-Warren-Boardman, OH-PA Mahoning County, OH Trumbull County, OH Mercer County, PA | 0.8625 |
| 49700 | Yuba City, CA Sutter County, CA Yuba County, CA | 1.1043 |
| 49740 | Yuma, AZ Yuma County, AZ | 0.9283 |

¹ At this time, there are no hospitals located in this urban area on which to base a wage index.

| CBSA Code | Urban Area (Constituent Counties) | Wage Index |
|-----------|--|------------|
| 47894 | Washington-Arlington-Alexandria, DC-VA-MD-WV District of Columbia, DC Calvert County, MD Charles County, MD Prince George's County, MD Arlington County, VA Clarke County, VA Fairfax County, VA Fauquier County, VA Loudoun County, VA Prince William County, VA Spotsylvania County, VA Stafford County, VA Warren County, VA Alexandria City, VA Fairfax City, VA Falls Church City, VA Fredericksburg City, VA Manassas City, VA Manassas Park City, VA Jefferson County, WV | 1.0723 |
| 47940 | Waterloo-Cedar Falls, IA Black Hawk County, IA Bremer County, IA Grundy County, IA | 0.8462 |
| 48140 | Wausau, WI Marathon County, WI | 0.9563 |
| 48300 | Wenatchee-East Wenatchee, WA Chelan County, WA Douglas County, WA | 0.9615 |
| 48424 | West Palm Beach-Boca Raton-Boynton Beach, FL Palm Beach County, FL | 0.9934 |
| 48540 | Wheeling, WV-OH Belmont County, OH Marshall County, WV Ohio County, WV | 0.6675 |
| 48620 | Wichita, KS Butler County, KS Harvey County, KS Sedgwick County, KS Sumner County, KS | 0.8898 |
| 48660 | Wichita Falls, TX Archer County, TX Clay County, TX Wichita County, TX | 0.9566 |
| 48700 | Williamsport, PA Lycoming County, PA | 0.7256 |

Table 2-RY 2012 WAGE INDEX BASED ON CBSA LABOR MARKET AREAS
FOR RURAL AREAS

| State Code | Nonurban Area | Wage Index |
|------------|----------------------------|------------|
| 1 | Alabama | 0.7380 |
| 2 | Alaska | 1.2626 |
| 3 | Arizona | 0.9095 |
| 4 | Arkansas | 0.7222 |
| 5 | California | 1.2056 |
| 6 | Colorado | 0.9933 |
| 7 | Connecticut | 1.1128 |
| 8 | Delaware | 0.9757 |
| 10 | Florida | 0.8409 |
| 11 | Georgia | 0.7566 |
| 12 | Hawaii | 1.1189 |
| 13 | Idaho | 0.7556 |
| 14 | Illinois | 0.8343 |
| 15 | Indiana | 0.8391 |
| 16 | Iowa | 0.8545 |
| 17 | Kansas | 0.7981 |
| 18 | Kentucky | 0.7830 |
| 19 | Louisiana | 0.7712 |
| 20 | Maine | 0.8588 |
| 21 | Maryland | 0.9175 |
| 22 | Massachusetts ¹ | 1.1769 |
| 23 | Michigan | 0.8555 |
| 24 | Minnesota | 0.9038 |
| 25 | Mississippi | 0.7620 |
| 26 | Missouri | 0.7655 |
| 27 | Montana | 0.8517 |
| 28 | Nebraska | 0.8911 |
| 29 | Nevada | 0.9350 |
| 30 | New Hampshire | 1.0207 |
| 31 | New Jersey ¹ | 0.9611 |

| State Code | Nonurban Area | Wage Index |
|------------|---------------------------|------------|
| 32 | New Mexico | 0.8911 |
| 33 | New York | 0.8185 |
| 34 | North Carolina | 0.8359 |
| 35 | North Dakota | 0.6831 |
| 36 | Ohio | 0.8561 |
| 37 | Oklahoma | 0.7860 |
| 38 | Oregon | 1.0029 |
| 39 | Pennsylvania | 0.8480 |
| 40 | Puerto Rico ¹ | 0.4047 |
| 41 | Rhode Island ¹ | ----- |
| 42 | South Carolina | 0.8413 |
| 43 | South Dakota | 0.8536 |
| 44 | Tennessee | 0.7886 |
| 45 | Texas | 0.7806 |
| 46 | Utah | 0.8649 |
| 47 | Vermont | 0.9591 |
| 48 | Virgin Islands | 0.7993 |
| 49 | Virginia | 0.7841 |
| 50 | Washington | 1.0184 |
| 51 | West Virginia | 0.7474 |
| 52 | Wisconsin | 0.9186 |
| 53 | Wyoming | 0.9528 |
| 65 | Guam | 0.9611 |

¹ All counties within the State are classified as urban, with the exception of Massachusetts and Puerto Rico. Massachusetts and Puerto Rico have areas designated as rural; however, no short-term, acute care hospitals are located in the area(s) for FY 2011. The rural Massachusetts wage index is calculated as the average of all contiguous CBSAs. The Puerto Rico wage index is the same as FY 2010.



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Part V

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 480

Medicare Program; Hospital Inpatient Value-Based Purchasing Program;
Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 480

[CMS–3239–F]

RIN 0938–AQ55

Medicare Program; Hospital Inpatient Value-Based Purchasing Program

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

ACTION: Final rule.

SUMMARY: This final rule implements a Hospital Inpatient Value-Based Purchasing program (Hospital VBP program or the program) under section 1886(o) of the Social Security Act (the Act), under which value-based incentive payments will be made in a fiscal year to hospitals that meet performance standards with respect to a performance period for the fiscal year involved. The program will apply to payments for discharges occurring on or after October 1, 2012, in accordance with section 1886(o) (as added by section 3001(a) of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act)). Scoring in the Hospital VBP program will be based on whether a hospital meets or exceeds the performance standards established with respect to the measures. By adopting this program, we will reward hospitals based on actual quality performance on measures, rather than simply reporting data for those measures.

DATES: *Effective Date:* These regulations are effective on July 1, 2011.

FOR FURTHER INFORMATION CONTACT: Allison Lee, (410) 786–8691.

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Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

- ACM Appropriate Care Model
- AHRQ Agency for Healthcare Research and Quality
- AMI Acute Myocardial Infarction
- CCN CMS Certification number
- CLABSI Central line-associated bloodstream infections
- CMMI Center for Medicare and Medicaid Innovation
- CMS Centers for Medicare & Medicaid Services
- CV Coefficient of variation
- DRA Deficit Reduction Act of 2005
- DRG Diagnosis-Related Group
- EHR Electronic Health Record
- EKG Electrocardiogram
- FISMA Federal Information Security and Management Act
- HAC Hospital acquired conditions
- HAI Healthcare-associated infections
- HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
- HF Heart Failure
- HIPAA Health Insurance Portability and Accountability Act
- HOP QDRP Hospital Outpatient Quality Data Reporting Program
- IPPS Inpatient prospective payment systems
- IQI Inpatient Quality Indicator
- IQR Inpatient Quality Reporting
- MMA Medicare Prescription Drug, Improvement and Modernization Act of 2003
- NQF National Quality Forum
- PMA Patient-mix adjustment
- PN Pneumonia
- POA Present on Admission
- PQRI Physician Quality Reporting Initiative
- PRRB Provider Reimbursement Review Board
- PSI Patient Safety Indicator
- QIO Quality Improvement Organization
- QRS Quality Review Study
- RFA Regulatory Flexibility Act
- RHQDAPU Reporting Hospital Quality Data for the Annual Payment Update Program
- RIA Regulatory Impact Analysis
- SCIP Surgical Care Improvement

- SDPS Standard Data Processing System
- SES Socioeconomic status
- SSI Surgical site infections
- VBP Value-Based Purchasing

I. Background

A. Overview

The Centers for Medicare & Medicaid Services (CMS) promotes higher quality and more efficient health care for Medicare beneficiaries. In recent years, we have undertaken a number of initiatives to lay the foundation for rewarding health care providers and suppliers for the quality of care they provide by tying a portion of their Medicare payments to their performance on quality measures. These initiatives, which include demonstration projects and quality reporting programs, have been applied to various health care settings, including physicians' offices, ambulatory care facilities, hospitals, nursing homes, home health agencies, and dialysis facilities. The overarching goal of these initiatives is to transform Medicare from a passive payer of claims to an active purchaser of quality health care for its beneficiaries.

This effort is supported by our adoption of an increasing number of widely-agreed upon quality measures for purposes of our existing quality reporting programs. We have worked with stakeholders to define measures of quality in almost every setting. These measures assess structural aspects of care, clinical processes, patient experiences with care, and, increasingly, outcomes.

We have implemented quality measure reporting programs that apply to various settings of care. With regard to hospital inpatient services, we implemented the Hospital IQR program. In addition, we have implemented quality reporting programs for hospital outpatient services through the Hospital Outpatient Quality Reporting program (HOQR), formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), and for physicians and other eligible professionals through the Physician Quality Reporting System (formerly referred to as the Physician Quality Reporting Initiative or PQRI). We have also implemented quality reporting programs for home health agencies and skilled nursing facilities based on conditions of participation, and an end-stage renal disease quality incentive program that links payment to performance.

This new program will necessarily be a fluid model, subject to change as knowledge, measures and tools evolve. We view the Hospital VBP program under section 1886(o) as the next step

in promoting higher quality care for Medicare beneficiaries and transforming Medicare into an active purchaser of quality health care for its beneficiaries.

In developing this rule as well as other value-based quality initiatives, CMS applied the following principles for the development and use of measures and scoring methodologies.

Purpose

CMS views value-based purchasing as an important step toward revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations instead of merely volume.

Use of Measures

- Public reporting and value-based payment systems should rely on a mix of standards, process, outcomes, and patient experience measures, including measures of care transitions and changes in patient functional status. Across all programs, CMS seeks to move as quickly as possible to using primarily outcome and patient experience measures.

- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across Medicare's and Medicaid's public reporting and payment systems. CMS also seeks to develop a focused core-set of measures appropriate to each specific provider category that reflects the level of care and the most important areas of service furnished by that provider.

- The collection of information should minimize the burden on providers to the extent possible. As part of that effort, CMS will continuously seek to align its measures with the adoption of meaningful use standards for health information technology (HIT).

- To the extent practicable, measures used by CMS should be nationally endorsed by a multi-stakeholder organization. Measures should also be aligned with best practices among other payers and the needs of the end users of the measures.

Scoring Methodology

- Providers should be scored on their overall achievement relative to national or other appropriate benchmarks. In addition, scoring methodologies should consider improvement as an independent goal.

- Measures or measurement domains need not be given equal weight, but over time, scoring methodologies should be weighted more heavily towards outcome, patient experience, and functional status measures.

- Scoring methodologies should be reliable, as straightforward as possible, and stable over time and enable consumers, providers, and payers to make meaningful distinctions among providers' performance.

Comment: A number of commenters expressed their general support for these principles. One commenter provided additional remarks on the principles and made a number of comments on the interactions between the principles, including risk adjustment, measure reliability, patient experience of care measures, and measure endorsement. For example, this commenter expressed agreement with our stated principle that public reporting and value-based payment systems should rely on a mix of standards, processes, outcome and payment experience measures. In supporting this principle, the commenter related that health and health care are complex, which requires a multifaceted accountability framework. This commenter also supported our statement that scoring methodologies should be reliable, as straightforward as possible, and stable over time. The commenter further remarked that VBP relies on the support of consumers in the marketplace to drive improvement, and that consumers must understand the measures and how they are used in order to make informed decisions.

Response: We appreciate the comments and input on these principles, and will keep them in mind as we continue to enhance, develop and implement the Hospital VBP program, other quality reporting programs, and other value-based incentive programs.

Comment: A number of commenters stated that CMS must ensure that value-based purchasing programs foster the development of innovative, quality care and provide an adequate level of reimbursement for innovative medical technologies. One commenter reiterated that value-based purchasing programs should not place the provision of lower cost services and products in conflict with what is best for the patient.

Response: We agree that value-based purchasing programs should not hinder innovation and should result in improved patient care. We believe that the Hospital VBP program will drive improvements in the quality of care for Medicare beneficiaries, including the provision of innovative technologies, because of its financial incentives for providers to provide high-quality, patient-centered care coupled with high levels of patient satisfaction. We note that our measure development and selection activities take into account national priorities, including those

established by the National Priorities Partnership and the Department of Health and Human Services, as well as other widely accepted criteria established in the medical literature. We will continue to seek to align all of our quality initiatives to promote high-quality care and continued innovation. We intend to monitor this program over time for unintended consequences.

Comment: One commenter requested that CMS extend the 60-day comment period.

Response: We decline to extend the comment period. Based on the volume and depth of comments we received in response to the Hospital Inpatient VBP proposed rule, we believe that commenters had ample opportunity to submit meaningful comments on our proposals and did so. Specifically, we received comments discussing a wide range of issues on nearly every aspect of that proposed rule, including its potential impact on the health care system, the provision of high-quality medical care and effects on patient satisfaction. We received comments from a wide range of stakeholders, including hospitals, health care providers, professional associations, trade groups, advocacy organizations, Medicare beneficiaries, private citizens, and others. We have had a sufficient opportunity to consider the issues raised by the commenters and have taken their comments into account in developing this final rule.

Comment: One commenter stated that "the specific process for how the agency proposes to achieve 'transparency' is not described or attained," and that the proposed rule did not offer sufficient information and disclosure of the "methods and data the agency proposes to use" in developing the Hospital VBP program.

Response: We disagree. We believe that we have been transparent in making public our goals for the Hospital VBP program and numerous documents that informed our rulemaking on this program, including the 2007 Report to Congress, Congressional testimony and public listening session transcripts. We also believe that the proposed rule contains detailed information regarding the data and analyses we considered in developing our proposals.

However, because we seek to ensure that the continued development of the Hospital VBP program take place in as transparent a manner as possible, we will make available additional information regarding our analyses, study results, and methods and will inform the public accordingly.

We have addressed specific issues relating to the use of measures, scoring

methodology, and other aspects of the Hospital VBP program below.

B. Hospital Inpatient Quality Data Reporting Under Section 501(b) of Public Law 108–173

Section 501(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, added section 1886(b)(3)(B)(vii) to the Act. This section established the original authority for the Hospital IQR program and revised the mechanism used to update the standardized amount for inpatient hospital operating costs. Specifically, section 1886(b)(3)(B)(vii)(I) of the Act provided for a reduction of 0.4 percentage points to the applicable percentage increase (sometimes referred to at that time as the market basket update) for FY 2005 through FY 2007 for a subsection (d) hospital if the hospital did not submit data on a set of 10 quality indicators established by the Secretary as of November 1, 2003. It also provided that any reduction applied only to the fiscal year involved, and would not be taken into account in computing the applicable percentage increase for a subsequent fiscal year. The statute thereby established an incentive for many subsection (d) hospitals to submit data on the quality measures established by the Secretary.

We implemented section 1886(b)(3)(B)(vii) of the Act in the FY 2005 IPPS final rule (69 FR 49078) and codified the applicable percentage increase change in § 412.64(d) of our regulations. We adopted additional requirements for the Hospital IQR program in the FY 2006 IPPS final rule (70 FR 47420).

C. Hospital Inpatient Quality Reporting Under Section 5001(a) of Public Law 109–171

1. Change in the Reduction to the Applicable Percentage Increase

Section 5001(a) of the Deficit Reduction Act of 2005 (DRA), Public Law 109–171, further amended section 1886(b)(3)(B) of the Act to, among other things, revise the mechanism used to update the standardized amount for hospital inpatient operating costs by adding a new section 1886(b)(3)(B)(viii) to the Act. Specifically, sections 1886(b)(3)(B)(viii)(I) and (II) of the Act, as added by the DRA, provided in part that the applicable percentage increase for FY 2007 and each subsequent fiscal year shall be reduced by 2.0 percentage points for a subsection (d) hospital that does not submit quality data in a form and manner and at a time specified by the Secretary. Section

1886(b)(3)(B)(viii)(I) of the Act also provided that any reduction in a hospital's applicable percentage increase will apply only with respect to the fiscal year involved, and will not be taken into account for computing the applicable percentage increase for a subsequent fiscal year.

In the FY 2007 IPPS final rule (71 FR 48045), we amended our regulations at § 412.64(d)(2) to reflect the 2.0 percentage point reduction required under the DRA.

2. Selection of Quality Measures

Section 1886(b)(3)(B)(viii)(V) of the Act, before it was amended by section 3001(a)(2)(B) of the Affordable Care Act, required that, effective for payments beginning FY 2008, the Secretary add other measures that reflect consensus among affected parties, and to the extent feasible and practicable, have been set forth by one or more national consensus building entities. The National Quality Forum (NQF) is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The NQF was established to standardize health care quality measurement and reporting through its consensus development process. We have generally adopted NQF-endorsed measures for purposes of the Hospital IQR program. However, we believe that consensus among affected parties also can be reflected by other means, including consensus achieved during the measure development process, consensus shown through broad acceptance and use of measures, and consensus achieved through public comment.

Section 1886(b)(3)(B)(viii)(VI) of the Act authorizes the Secretary to replace any quality measures or indicators in appropriate cases, such as when all hospitals are effectively in compliance with a measure, or the measures or indicators have been subsequently shown to not represent the best clinical practice. We interpreted this provision to give us broad discretion to replace measures that are no longer appropriate for the Hospital IQR program.

We adopted 45 measures under the Hospital IQR program for the FY 2011 payment determination. Of these measures, 27 are chart-abstracted process of care measures, which assess the quality of care furnished by hospitals in connection with four topics: Acute Myocardial Infarction (AMI); Heart Failure (HF); Pneumonia (PN); and Surgical Care Improvement (SCIP) (75 FR 50182). Fifteen of the measures are claims-based measures, which assess

the quality of care furnished by hospitals on the following topics: 30-day mortality and 30-day readmission rates for Medicare patients diagnosed with AMI, HF, or PN; Patient Safety Indicators/Inpatient Quality Indicators/Composite Measures; and Patient Safety Indicators/Nursing Sensitive Care. Three of the measures are structural measures that assess hospital participation in cardiac surgery, stroke care, and nursing sensitive care systemic databases. Finally, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience of care survey is included as a measure for the FY 2011 payment determination.

The technical specifications for the Hospital IQR program measures, or links to Web sites hosting technical specifications, are contained in the CMS/The Joint Commission Specifications Manual for National Hospital Inpatient Quality Measures (Specifications Manual). This Specifications Manual is posted on the CMS QualityNet Web site at <https://www.QualityNet.org/>. We maintain the technical specifications by updating this Specifications Manual semiannually, or more frequently in unusual cases, and include detailed instructions and calculation algorithms for hospitals to use when collecting and submitting data on required measures. These semiannual updates are accompanied by notifications to users, providing sufficient time before the effective date of the change in order to allow users to incorporate changes and updates to the specifications into data collection systems.

3. Public Display of Quality Measures

Section 1886(b)(3)(B)(viii)(VII) of the Act, as amended by section 3001(a)(2)(C) of the Affordable Care Act, requires that the Secretary establish procedures for making information regarding measures submitted under the Hospital IQR program available to the public after ensuring a hospital has the opportunity to review its data. To meet this requirement, we display most Hospital IQR program data on the *Hospital Compare* Web site, <http://www.hospitalcompare.hhs.gov>, after a 30-day preview period. An interactive Web tool, this Web site assists beneficiaries by providing information on hospital quality of care to those who need to select a hospital. It further serves to encourage beneficiaries to work with their doctors and hospitals to discuss the quality of care hospitals provide to patients, thereby providing an additional incentive to hospitals to improve the quality of care that they

furnish. The *Hospital Compare* Web site currently makes public information on a wide range of measures, including clinical process of care measures, risk adjusted outcome measures, the HCAHPS patient experience of care survey, and structural measures. However, data that we believe is not suitable for inclusion on *Hospital Compare* because it is not salient or will not be fully understood by beneficiaries, as well as data for which there are unresolved display or design issues, may be made available on other CMS Web sites that are not intended to be used as an interactive Web tool, such as <http://www.cms.hhs.gov/HospitalQualityInits/>. In such circumstances, affected parties are notified via CMS listservs, CMS e-mail blasts, national provider calls, and QualityNet announcements regarding the release of preview reports followed by the posting of data on a Web site other than *Hospital Compare*.

D. 2007 Report to Congress: Plan To Implement a Medicare Hospital Value-Based Purchasing Program

Section 5001(b) of the DRA required the Secretary to develop a plan to implement a value-based purchasing program for subsection (d) hospitals. In developing the plan, we were required to consider the on-going development, selection, and modification process for measures of quality and efficiency in hospital inpatient settings; the reporting, collection, and validation of quality data; the structure, size, and sources of funding of value-based payment adjustments; and the disclosure of information on hospital performance.

On November 21, 2007, we submitted the Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program, which is available on the CMS Web site. The report discusses options for a plan to implement a Medicare hospital value-based purchasing program that builds on the Hospital IQR program. We recommended replacing the Hospital IQR program with a new program that would include both a public reporting requirement and financial incentives for better performance. We also recommended that a hospital value-based purchasing program be implemented in a manner that would not increase Medicare spending.

To calculate a hospital's total performance score under the plan, we analyzed a potential performance scoring model that incorporated measures from different quality "domains," including clinical process of care and patient experience of care. We

examined ways to translate that score into an incentive payment by making a portion of the base DRG payment contingent on performance. We analyzed criteria for selecting performance measures and considered a potential phased approach to transition from Hospital IQR to value-based purchasing. In addition, we examined redesigning the current data transmission process and validation infrastructure, including making enhancements to the *Hospital Compare* Web site, as well as an approach to monitor the impact of value-based purchasing.

E. Provisions of the Affordable Care Act

Section 3001(a) of the Affordable Care Act added a new section 1886(o) to the Act, which requires the Secretary to establish a hospital value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary. Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital VBP program to hospitals for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2013 through a reduction to FY 2013 base operating DRG payments for each discharge of 1.0 percent, as required by section 1886(o)(7). Section 1886(o)(1)(C) provides that the Hospital VBP program applies to subsection (d) hospitals (as defined in section 1886(d)(1)(B)), but excludes from the definition of the term "hospital," with respect to a fiscal year: (1) A hospital that is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) for such fiscal year; (2) a hospital for which, during the performance period for the fiscal year, the Secretary cited deficiencies that pose immediate jeopardy to the health and safety of patients; and (3) a hospital for which there is not a minimum number (as determined by the Secretary) of applicable measures for the performance period for the fiscal year involved, or for which there is not a minimum number (as determined by the Secretary) of cases for the applicable measures for the performance period for such fiscal year.

II. Provisions of the Final Rule and Response to Comments

A. Overview of the January 7, 2011 Hospital Inpatient VBP Program Proposed Rule

On January 7, 2011, we issued a proposed rule that proposes to implement a Hospital VBP program under section 1886(o) of the Act (76 FR 2454, January 13, 2011). Specifically, we proposed to initially adopt for the FY 2013 Hospital VBP program 18 measures that we have already adopted for the Hospital IQR program, categorized into two domains, as follows: 17 of the measures would be clinical process of care measures, which we would group into a clinical process of care domain, and 1 measure would be the HCAHPS survey, which would fall under a patient experience of care domain. With respect to the clinical process of care and HCAHPS measures, we proposed to use a three-quarter performance period from July 1, 2011 through March 31, 2012 for the FY 2013 Hospital VBP payment determination. We proposed to determine whether hospitals meet the performance standards for the selected measures by comparing their performance during the performance period to their performance during a three-quarter baseline period of July 1, 2009 through March 31, 2010. We also proposed to initially adopt for the FY 2014 Hospital VBP program three outcome measures. With respect to the outcome measures, we proposed to use an 18-month performance period from July 1, 2011 to December 31, 2012. Furthermore, for these outcome measures, we proposed to establish performance standards and to determine whether hospitals meet those standards by comparing their performance during the performance period to their performance during a baseline period of July 1, 2008 to December 31, 2009.

We also proposed to adopt 8 Hospital Acquired Condition measures and 9 AHRQ Patient Safety Indicator and Inpatient Quality Indicator outcome measures. We further proposed to begin the performance period for each of these proposed measures 1 year after we included the measure on the *Hospital Compare* Web site.

In general, we proposed to implement a methodology for assessing the total performance of each hospital based on performance standards, under which we would score each hospital based on achievement and improvement ranges for each applicable measure. Additionally, we proposed to calculate a total performance score for each hospital by combining the greater of the

hospital's achievement or improvement points for each measure to determine a score for each domain, multiplying each domain score by a proposed weight (clinical process of care: 70 percent, patient experience of care: 30 percent), and adding together the weighted domain scores. We proposed to convert each hospital's Total Performance Score into a value-based incentive payment utilizing a linear exchange function.

We provided a 60-day public comment period in which we received approximately 319 timely comments from hospitals, health care facilities, advocacy organizations, researchers, patients, and other individuals and organizations. Summaries of the public comments, as well as our responses to those comments, are set forth below.

Comment: A number of commenters requested clarification on the interaction between the Hospital IQR program and the Hospital VBP program. Commenters specifically requested that we explain more fully how the penalties under the two programs will interact, as well as clarify if we intend to continue the Hospital IQR program in the future.

Response: The Affordable Care Act did not repeal section 1886(b)(3)(B)(viii), the statutory authority for the Hospital IQR program, and that program will continue to exist side-by-side with the Hospital VBP program. However, we note that beginning in FY 2015, the reduction to the applicable percentage increase under the Hospital IQR program changes from a straight 2.0 percentage point reduction to a reduction equal to "one quarter of such applicable percentage increase" (determined without regard to several other applicable statutory reductions).

We also note that under section 1886(o)(1)(C)(I), hospitals that are subject to the Hospital IQR program payment reduction for a fiscal year are excluded from the definition of "hospital" for purposes of the Hospital VBP program for that fiscal year. We interpret this provision to mean that a hospital that does not meet the requirements of the Hospital IQR program with respect to a fiscal year and, as a result, will receive a reduction to the applicable percentage increase for that fiscal year, will not be subject to the reduction to its base operating DRG payment amount under the Hospital VBP program for that fiscal year or be eligible to receive a value-based incentive payment for that fiscal year.

Comment: Some commenters requested that CMS delay implementation of the Hospital VBP program. A number of commenters urged CMS to adopt the implementation

calendar discussed in 2007 Report to Congress, in which the first performance period would begin April 1, 2013.

Response: We are statutorily required to begin making value-based incentive payments under the Hospital VBP program to hospitals for discharges occurring on or after October 1, 2012 under section 1886(o)(1)(B) of the Act. Thus, the first performance period must begin before April 1, 2013, which is the time suggested by the commenters. As we stated in the proposed rule, in determining what performance period to propose to adopt, we were cognizant that hospitals submit data on the chart abstracted measures adopted for the Hospital IQR Program on a quarterly basis, and for that reason, we believed that the performance period should commence at the beginning of a quarter. We also recognized that we needed to balance the length of the performance period for collecting measure data with the need to undertake the rulemaking process in order to establish the performance period and provide the public with an opportunity to meaningfully comment on that proposal. With these considerations in mind, we proposed July 1, 2011 as the start of the performance period.

Comment: Some commenters requested additional information on how we will educate consumers about the Hospital VBP program.

Response: We understand how crucial it is to communicate clearly and consistently with all stakeholders in order to provide accurate and timely information about the Hospital VBP program. We believe that communicating in a way that promotes transparency and understanding of the Hospital VBP program will help reduce confusion and misunderstanding while enhancing the program's success.

To this end, we will be undertaking an extensive outreach and education campaign to ensure that all stakeholders understand how the Hospital VBP program works. In addition to providing information on www.cms.gov and www.medicare.gov, as well as through other existing mechanisms that we use to communicate with the public such as newsletters, e-mail blasts, listserv communications, special forums, and webinars, an important element of this campaign will be a new Hospital VBP page on <http://www.cms.gov>. In addition, as required under sections 1886(o)(10)(A) and (B), hospital specific and aggregate information for the Hospital VBP program will be made available on the Hospital Compare Web site.

Comment: One commenter stated that the Hospital VBP program statutory

authority overlaps with other provisions of the Affordable Care Act and asked CMS to address the various incentives created by the Affordable Care Act, how it intends to differentiate among separate policies, and how it will ensure that incentives will not overlap or be duplicative. The commenter specifically cited efforts to increase productivity and efficiency through Accountable Care Organizations, market basket reductions for productivity, penalties related to hospital-acquired conditions, and payment reductions for readmissions.

Response: While there may be specific areas of overlap addressed by the various statutory provisions and policies, the legislative requirements, programs, and policies cited by the commenter represent interrelated but distinct areas of efforts to improve quality in the Medicare program. We will continue to monitor the interactions between the policies cited by the commenter and will continue discussions with stakeholders on this topic.

Comment: One commenter stated that all purchaser/payer value-based strategies and programs should be supported and encouraged through the Center for Medicare and Medicaid Innovation (CMMI).

Response: Created by the Affordable Care Act and launched on November 16, 2010, the CMMI will examine new ways of delivering health care and paying health care providers that can save money for Medicare and Medicaid while improving the quality of care. CMMI will consult a diverse group of stakeholders including hospitals, doctors, consumers, payers, States, employers, advocates, relevant federal agencies and others to obtain direct input and build partnerships for its upcoming work. We agree that CMMI is an important contributor in developing innovative strategies for value-based purchasing programs, and look forward to continuing to leverage the Center's resources and expertise in future years of the Hospital VBP program.

Comment: One commenter suggested that we establish a "Pay to Share" pool under which funding would be provided to enable higher-rated hospitals to instruct lower-rated hospitals on best practices.

Response: While we appreciate the comment, we do not believe we have the statutory authority under the Act to implement such a program at this time.

C. Performance Period

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for a fiscal year that begins and ends prior to the beginning of such

fiscal year. In considering various performance periods that could apply for purposes of the fiscal year 2013 payment adjustments, we recognized that hospitals submit data on the chart-abstracted measures adopted for the Hospital IQR program on a quarterly basis, and for that reason, we proposed that the performance period commence at the beginning of a quarter. We also recognized that we must balance the length of the period for collecting measure data with the need to undertake the rulemaking process in order to propose a performance period and provide the public with an opportunity to meaningfully comment on that proposal. With these considerations in mind, we concluded that July 1, 2011 is the earliest date that the performance period could begin.

Therefore, we proposed to use the fourth quarter of FY 2011 (July 1, 2011 through September 30, 2011) and the first and second quarters of FY 2012 (October 1, 2011 through March 31, 2012) as the performance period for the clinical process of care and HCAHPS measures we proposed to initially adopt for the FY 2013 Hospital VBP program. Under the proposed approach, hospitals would be scored based on how well they perform on the clinical process of care and patient experience measures during this performance period. For the three mortality outcome measures currently specified for the Hospital IQR program for the FY 2011 payment determination (MORT-30-AMI, MORT-30-HF, MORT-30-PN) that we proposed to adopt for the FY 2014 Hospital VBP program payment determination, we proposed to establish a performance period of July 1, 2011 to December 31, 2012. We also proposed to begin the performance period for the 8 proposed HAC measures and 9 proposed AHRQ Patient Safety Indicator (PSI) and Inpatient Quality Indicator (IQI) outcome measures 1 year after those measures were included on the *Hospital Compare* Web site. The proposed HAC and AHRQ measures were included on *Hospital Compare* on March 3, 2011.

Comment: A number of commenters requested that we adopt a 12-month performance period for the proposed mortality measures rather than the proposed 18-month performance period. Some were concerned that seasonal fluctuations in mortality rates would impact the measure rates if an 18-month performance period were used instead of a 12-month period.

Response: We proposed to use an 18-month performance period (July 1, 2011 through December 31, 2012) for the three proposed mortality measures in

order to be able to increase the reliability of the measure rates by including more cases. However, in response to the commenters' concern about how the use of a period that is not equal to a year (or multiple years) could introduce seasonal fluctuations into the measure rates, we conducted additional reliability analyses on the hospital-level risk standardized mortality rates for the proposed 30-day mortality measures using 12 months, 18 months, and 24 months, and have concluded that 12 months of data provides moderate to high reliability for the Heart Failure and Pneumonia 30-day mortality measures, and is sufficiently reliable for the AMI 30-day mortality measure. Therefore, we are finalizing a 12-month performance period of July 1, 2011 to June 30, 2012 for the three proposed 30-day mortality measures for the FY 2014 Hospital VBP payment determination.

Comment: Some commenters expressed concern about the proposed baseline period for the FY 2014 mortality outcome measures. Commenters noted that the proposed 18-month baseline period would lead to data overlap during each program year.

Response: For the reasons noted above, we are finalizing a 12-month performance period of July 1, 2011 to June 30, 2012 for the three proposed 30-day mortality measures for the FY 2014 Hospital VBP payment determination. In accordance with our proposal that hospital performance should be evaluated based on how well hospitals performed during the same quarters in a baseline period, we are finalizing a 12-month baseline period for the mortality outcomes measures' performance standards calculations from July 1, 2009 to June 30, 2010. We believe that this change will address commenters' concerns about seasonal fluctuations in the data or overlap between program years.

Comment: Some comments requested that we require 2–3 years' worth of data for outcome measures to ensure that the measures do not result in any unintended consequences.

Response: As noted above, our reliability analyses for the proposed 30-day mortality measures indicate that using 12-months of data yields sufficient reliability (moderate to high) for the HF, PN and AMI 30-day mortality measures. We believe this time frame will enable us to calculate the measures using reliable data. CMS will monitor this policy to ensure that negative consequences do not occur as a result of the shortened performance period and, if indicated, would consider proposing to lengthen the performance period for future program years.

Comment: Many commenters generally supported our performance period proposals given the statutory deadlines.

Response: We thank commenters for their support.

Comment: Some commenters suggested that we use 12-month performance periods for all measures as soon as possible.

Response: We anticipate proposing to use a full year as the performance period for all measures in the future.

After considering the public comments, we are finalizing a performance period of July 1, 2011 through March 31, 2012 that will apply to the clinical process of care and patient experience measures for the FY 2013 Hospital VBP program. With respect to the FY 2014 Hospital VBP program, we are finalizing a 12-month performance period of July 1, 2011 through June 30, 2012 that will apply to the three 30-day mortality measures (AMI, HF, PN) that we are finalizing below. We are also finalizing our proposal to adopt a performance period that begins 1 year after any HAC and/or AHRQ measures that are specified for the Hospital IQR program are included on Hospital Compare, and in accordance with that finalized policy, the performance period for the 8 finalized HAC measures and 2 finalized AHRQ measures (discussed below) will begin on March 3, 2012. We intend to propose the end performance period date for the 8 finalized HAC measures and 2 finalized AHRQ measures in the CY 2012 Outpatient Prospective Payment System proposed rule.

D. Measures

Section 1886(o)(2)(A) of the Act requires the Secretary to select for the Hospital VBP program measures, other than readmission measures, from the measures specified for the Hospital IQR program. Section 1886(o)(2)(B)(i) of the Act requires the Secretary to ensure that the selected measures for FY 2013 include measures on the following specified conditions or topics: AMI; HF; PN; surgeries, as measured by the Surgical Care Improvement Project (SCIP); HAIs; and the HCAHPS survey. Section 1886(o)(2)(C)(i) of the Act provides that the Secretary may not select a measure with respect to a performance period for a fiscal year unless the measure has been specified under section 1886(b)(3)(B)(viii) of the Act and included on the *Hospital Compare* Web site for at least 1 year prior to the beginning of the performance period. Section 1886(o)(2)(C)(ii) of the Act provides that a measure selected under section

1886(o)(2)(A) of the Act shall not apply to a hospital if the hospital does not furnish services appropriate to the measure.

In the FY 2011 IPPS/RV 2011 LTCHPPS Final Rule (75 FR 50188), we stated that in future expansions and updates to the Hospital IQR program measure set, we will be taking into consideration several important goals. These goals include: (1) Expanding the types of measures beyond process of care measures to include an increased number of outcome measures, efficiency measures, and patients' experience of care measures; (2) expanding the scope of hospital services to which the measures apply; (3) considering the burden on hospitals in collecting chart-abstracted data; (4) harmonizing the measures used in the Hospital IQR program with other CMS quality programs to align incentives and promote coordinated efforts to improve quality; (5) seeking to use measures based on alternative sources of data that do not require chart abstraction or that utilize data already being reported by many hospitals, such as data that hospitals report to clinical data registries, or all payer claims databases; and (6) weighing the relevance and utility of the measures compared to the burden on hospitals in submitting data under the Hospital IQR program.

In addition, we stated in the proposed rule our belief that we must act with all speed and deliberateness to expand the pool of measures used in the Hospital VBP program. This goal is supported by at least two Federal reports documenting that tens of thousands of patients do not receive safe care in the nation's hospitals. For this reason, we proposed to adopt measures for the Hospital VBP program relevant to improving care, particularly as these measures are directed toward improving patient safety, as quickly as possible. We believe that speed of implementation is a critical factor in the success and effectiveness of this program.

The Hospital VBP program that we proposed to implement has been developed with the focused intention to motivate all subsection (d) hospitals to which the program applies to take immediate action to improve the quality of care they furnish to their patients. Because we view as urgent the necessity to improve the quality of care furnished by these hospitals, and because we believe that hospitalized patients in the United States currently face patient safety risks on a daily basis, we proposed to adopt an initial measure set for the Hospital VBP program. However, we also proposed to add additional

measures to the Hospital VBP program in the future in such a way that their performance period would begin immediately after they are displayed on Hospital Compare for a period of time of at least one year, but without the necessity of notice and comment rulemaking. We proposed this because of the urgency to improve the quality of hospital care, and in order to minimize any delay to take substantive action in favor of patient safety.

We stated that for the Hospital IQR Program, we give priority to quality measures that assess performance on: (a) Conditions that result in the greatest mortality and morbidity in the Medicare population; (b) conditions that are high volume and high cost for the Medicare program; and (c) conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. In addition, we stated that we seek to select measures that address the six quality aims of effective, safe, timely, efficient, patient centered, and equitable healthcare. Current and long term priority topics include: Prevention and population health; safety; chronic conditions; high cost and high volume conditions; elimination of health disparities; healthcare-associated infections and other adverse healthcare outcomes; improved care coordination; improved efficiency; improved patient and family experience of care; effective management of acute and chronic episodes of care; reduced unwarranted geographic variation in quality and efficiency; and adoption and use of interoperable health information technology.

We also stated that these criteria, priorities, and goals are consistent with section 1886(b)(3)(B)(viii)(X) of the Act, as added by section 3001(a)(2)(D) of the Affordable Care Act, which requires the Secretary, to the extent practicable and with input from consensus organizations and other stakeholders, to take steps to ensure that the Hospital IQR program measures are coordinated and aligned with quality measures applicable to physicians and other providers of services and suppliers under Medicare.

As discussed in the Hospital Inpatient VBP Program proposed rule (76 FR 2459), to determine which measures to propose to initially adopt for the FY 2013 Hospital VBP program, we examined whether any of the eligible Hospital IQR measures should be excluded from the Hospital VBP program measure set because hospital performance on them is "topped out," meaning that all but a few hospitals have achieved a similarly high level of

performance on them. We stated our belief that measuring hospital performance on topped-out measures would have no meaningful effect on a hospital's total performance score.

We also stated that scoring a topped-out measure for purposes of the Hospital VBP program would present a number of challenges. First, as discussed below, we proposed that the benchmark performance standard for all measures would be performance at the mean of the top decile of hospital performance during the baseline period. We noted in the Hospital Inpatient VBP Program proposed rule that, when applied to a topped-out measure, this proposed benchmark would be statistically indistinguishable from the highest attainable score for the measure and, in our view, could lead to unintended consequences as hospitals strive to meet the benchmark. Examples of unintended consequences could include, but would not be limited to, inappropriate delivery of a service to some patients (such as delivery of antibiotics to patients without a confirmed diagnosis of pneumonia), unduly conservative decisions on whether to exclude some patients from the measure denominator, and a focus on meeting the benchmark at the expense of actual improvements in quality or patient outcomes. Second, we stated that we have found that for topped-out measures, it is significantly more difficult to differentiate among hospitals performing above the median. Third, because a measure cannot be applied to a hospital unless the hospital furnishes services appropriate to the measure, we stated our belief that data reporting under the Hospital VBP program would not be the same for all hospitals. To the extent that a hospital could report a higher proportion of topped-out measures, for which its scores would likely be high, we stated that we believed such a hospital would be unfairly advantaged in the determination of its Total Performance Score.

To determine whether an eligible Hospital IQR measure is topped out, we initially focused on the top distribution of hospital performance on each measure and noted if their 75th and 90th percentiles were statistically indistinguishable. Based on our analysis, we identified 7 topped-out measures: AMI-1 Aspirin at Arrival; AMI-5 Beta Blocker at Discharge; AMI-3 ACEI or ARB at Discharge; AMI-4 Smoking Cessation; HF-4 Smoking Cessation; PN-4 Smoking Cessation; and SCIP-Inf-6 Surgery Patients with Appropriate Hair Removal. We then observed that two of these measures identified as topped out (AMI-3 ACEI or

ARB at Discharge and HF-4 Smoking Cessation) had significantly lower mean scores than the others, which led us to question whether our analysis was too focused on the top ends of distributions and whether additional criteria that could account for the entire distribution might be more appropriate. To address this, we analyzed the truncated coefficient of variation (CV) for each of the measures. The CV is a common statistic that expresses the standard deviation as a percentage of the sample mean in a way that is independent of the units of observation. Applied to this analysis, a large CV would indicate a broad distribution of individual hospital scores, with large and presumably meaningful differences between hospitals in relative performance. A small CV would indicate that the distribution of individual hospital scores is clustered tightly around the mean value, suggesting that it is not useful to draw distinctions between individual hospital performance scores. We used a modified version of the CV, namely a truncated CV, for each measure, in which the 5 percent of hospitals with the lowest scores, and the 5 percent of hospitals with highest scores were first truncated (set aside) before calculating the CV. This was done to avoid undue effects of the highest and lowest outlier hospitals, which if included, would tend to greatly widen the dispersion of the distribution and make the measure appear to be more reliable or discerning. For example, a measure for which most hospital scores are tightly clustered around the mean value (a small CV) might actually reflect a more robust dispersion if there were also a number of hospitals with extreme outlier values, which would greatly increase the perceived variance in the measure. Accordingly, the truncated CV was added as an additional criterion requiring that a topped-out measure also exhibit a truncated CV < 0.10. Using both the truncated CV and data showing whether hospital performance at the 75th and 90th percentiles was statistically indistinguishable, we reexamined the available measures and determined that the same seven measures continue to meet our proposed definition for being topped-out.

Our analysis of the impact of including the topped-out measures discussed above indicated that their use would mask true performance differences among hospitals and, as a result, would fail to advance our priorities for the Hospital VBP program. We therefore proposed to not include these 7 topped-out measures (AMI-1

Aspirin at Arrival; AMI-5 Beta Blocker at Discharge; AMI-3 ACEI or ARB at Discharge; AMI-4 Smoking Cessation; HF-4 Smoking Cessation; PN-4 Smoking Cessation; and SCIP-Inf-6 Surgery Patients with Appropriate Hair Removal) in the list of measures we proposed to initially adopt for the FY 2013 Hospital VBP program. We sought comment on that proposal.

We also examined and sought comment on whether the following outcome measures adopted for the Hospital IQR program were appropriate for inclusion in the FY 2013 Hospital VBP program. These measures are as follows: (1) AHRQ PSIs, IQIs and composite measures; (2) AHRQ PSI and nursing sensitive care measure; and (3) AMI, HF, and PN mortality measures (Medicare patients). We stated our belief that these outcome measures provide important information relating to treatment outcomes and patient safety. We also stated in the proposed rule that we believe that adding these outcome measures would significantly improve the correlation between patient outcomes and Hospital VBP performance. However, because under section 1886(o)(2)(C)(i) of the Act, we may only select measures if they have been included on Hospital Compare for a least 1 year prior to the beginning of the performance period, we stated that the AHRQ PSIs, IQIs and composite measures, and the AHRQ Nursing Sensitive Care measure were not yet eligible for inclusion in the FY 2013 Hospital VBP program. Although these measures are currently specified for the Hospital IQR program, we acknowledged that as of the time we issued the proposed rule, they did not meet the one year Hospital Compare inclusion requirement.

We also considered whether the current publicly-reported 30-day mortality claims-based measures (Mort-30-AMI, Mort-30-HF, Mort-30-PN) should be included in the FY 2013 Hospital VBP program. The mortality measures assess hospital-specific, risk-standardized, all-cause 30-day mortality rates for patients hospitalized with a principal diagnosis of heart attack, heart failure, and pneumonia. All-cause mortality is defined for purposes of these measures as death from any cause within 30 days after the index admission date, regardless of whether the patient died while still in the hospital or after discharge. The eligible clinical process of care measures we considered covered AMI, HF, PN, and surgeries as measured by the SCIP. Therefore, we believe that they meet the requirements of section 1886(o)(2)(B)(i)(I)(aa)-(dd) of the Act,

which requires us to include measures covering these conditions or procedures. Section 1886(o)(2)(B)(i)(ee) of the Act also requires the Secretary to select for purposes of the FY 2013 Hospital VBP program measures that cover HAIs “as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent Healthcare-Associated Infections (or any successor plan) of the Department of Health and Human Services.” The SCIP measures discussed above were developed to support practices that have demonstrated an ability to significantly reduce surgical complications such as HAIs. Compliance with the selected SCIP infection measures is also included as a targeted metric in the HHS *Action Plan to Prevent Healthcare-Associated Infections* issued in 2009, available on the HHS Web site. As a result, we believe that the SCIP-Inf-1; SCIP-Inf-2; SCIP-Inf-3; and SCIP-Inf-4 measures we have adopted for the Hospital IQR program meet the requirement in section 1886(o)(2)(B)(i)(I)(ee); we proposed to adopt them for the FY 2013 Hospital VBP program and to categorize them under the HAI condition topic instead of under the SCIP condition topic.

Under section 1886(o)(2)(B)(i)(II), the Secretary must select measures for the FY 2013 Hospital VBP program related to the HCAHPS survey. CMS partnered with AHRQ to develop HCAHPS. The HCAHPS survey is the first national, standardized, publicly reported survey of patients’ experience of hospital care, and we proposed to adopt it for the FY 2013 Hospital VBP program. HCAHPS, also known as the CAHPS® Hospital Survey, is a survey instrument and data collection methodology for measuring patients’ perceptions of their hospital experience.

The HCAHPS survey asks discharged patients 27 questions about their recent hospital stay that are used to measure the experience of patients across 10 dimensions in the Hospital IQR program. The survey contains 18 core questions about critical aspects of patients’ hospital experiences (communication with nurses and doctors, the responsiveness of hospital staff, the cleanliness and quietness of the hospital environment, pain management, communication about medicines, discharge information, overall rating of the hospital, and whether they would recommend the hospital). The survey also includes four items to direct patients to relevant questions if a patient did not have a particular experience covered by the survey, such as taking new medications or needing medicine for pain. Three

items in the survey are used to adjust for the mix of patients across hospitals, and two items related to race and ethnicity support congressionally-mandated reports on disparities in health care.

The HCAHPS survey is administered to a random sample of adult patients across medical conditions between 48 hours and 6 weeks after discharge; the survey is not restricted to Medicare beneficiaries. Hospitals must survey patients throughout each month of the year. The survey is available in official English, Spanish, Chinese, Russian and Vietnamese versions. The survey and its protocols for sampling, data collection and coding, and file submission can be found in the HCAHPS *Quality Assurance Guidelines, Version 5.0*, which is available on the official HCAHPS Web site, <http://www.hcahpsonline.org>.

AHRQ carried out a rigorous, scientific process to develop and test the HCAHPS instrument. This process entailed multiple steps, including: A public call for measures; literature review; cognitive interviews; consumer focus groups; stakeholder input; a three-state pilot test; small-scale field tests; and soliciting public comments via several **Federal Register** notices. In May

2005, the HCAHPS survey was endorsed by the NQF, and in December 2005, the Federal Office of Management and Budget gave its final approval for the national implementation of HCAHPS for public reporting purposes. CMS adopted the entire HCAHPS survey as a measure in the Hospital IQR program in October 2006, and the first public reporting of HCAHPS results occurred in March 2008. The survey, its methodology, and the results it produces are in the public domain.

As previously discussed, in determining what clinical process of care measures to propose, we analyzed the impact of including topped-out measures and determined that their use would mask true performance differences among hospitals, thus failing to advance our quality priorities. As a result, we proposed to exclude 7 topped-out measures (AMI-1 Aspirin at Arrival; AMI-5 Beta Blocker at Discharge; AMI-3 ACEI or ARB at Discharge; AMI-4 Smoking Cessation; HF-4 Smoking Cessation; PN-4 Smoking Cessation; and SCIP-Inf-6 Surgery Patients with Appropriate Hair Removal) from the list of measures we proposed to initially adopt for the FY 2013 Hospital VBP program.

We did not propose to adopt the current Hospital IQR structural measures because we believe that these measures require further development if they are to be used for the Hospital VBP program. Therefore, we solicited public comment on the possible utility of adopting structural measures for the Hospital VBP program measure set and how these measures might contribute to the improvement of patient safety and quality of care.

Finally, we proposed to exclude the PN-5c measure from the Hospital VBP program. We do not believe that this measure is appropriate for inclusion because it could lead to inappropriate antibiotic use. We proposed retiring this measure, as well as several other measures that we will not adopt for the Hospital VBP program, from the Hospital IQR program in the FY 2012 IPPS/LTCH PPS proposed rule scheduled for publication on May 5, 2011.

We proposed to initially select 17 clinical process of care measures and the HCAHPS measure for inclusion in the FY 2013 Hospital VBP program. The proposed list of initial measures is provided in Table 1.

TABLE 1—PROPOSED MEASURES FOR FY 2013 HOSPITAL VBP PROGRAM

| Measure ID | Measure description |
|--|--|
| Clinical Process of Care Measures | |
| Acute myocardial infarction | |
| AMI-2 | Aspirin Prescribed at Discharge. |
| AMI-7a | Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival. |
| AMI-8a | Primary PCI Received Within 90 Minutes of Hospital Arrival. |
| Heart Failure | |
| HF-1 | Discharge Instructions. |
| HF-2 | Evaluation of LVS Function. |
| HF-3 | ACEI or ARB for LVSD. |
| Pneumonia | |
| PN-2 | Pneumococcal Vaccination. |
| PN-3b | Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital. |
| PN-6 | Initial Antibiotic Selection for CAP in Immunocompetent Patient. |
| PN-7 | Influenza Vaccination. |
| Healthcare-associated infections | |
| SCIP-Inf-1 | Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision. |
| SCIP-Inf-2 | Prophylactic Antibiotic Selection for Surgical Patients. |
| SCIP-Inf-3 | Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time. |
| SCIP-Inf-4 | Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose. |
| Surgeries | |
| SCIP-Card-2 | Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period. |
| SCIP-VTE-1 | Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered. |
| SCIP-VTE-2 | Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery. |

TABLE 1—PROPOSED MEASURES FOR FY 2013 HOSPITAL VBP PROGRAM—Continued

| Measure ID | Measure description |
|--|---|
| Patient Experience of Care Measures | |
| HCAHPS | Hospital Consumer Assessment of Healthcare Providers and Systems Survey. ¹ |

In the Hospital Inpatient VBP Program proposed rule, we solicited public comments on our intention to add measures to the Hospital VBP Program as rapidly as possible for their availability in future performance periods. To that end, we proposed to implement a subregulatory process to expedite the timeline for adding measures to the Hospital VBP program beginning with the FY 2013 program. Under this proposed process, we could add any measure to the Hospital VBP program if that measure is adopted under the Hospital IQR program and has been included on Hospital Compare for at least 1 year. We proposed that the performance period for all of these measures would start exactly 1 year after the date these measures were publicly posted on Hospital Compare, consistent with section 1886(o)(2)(C)(i). Under this proposed subregulatory process for adopting new Hospital VBP program measures, we would solicit comments from the public on the appropriateness of adopting 1 or more Hospital IQR measures for the Hospital VBP program. We would also assess the reported Hospital IQR measure rates using the criteria we used to select the measures for the initial FY 2013 Hospital VBP measure set and would notify the public regarding our findings. We stated that we would propose to set performance period end dates for any measure we selected for future Hospital VBP program years in rulemaking.

We also proposed to implement a subregulatory process to retire Hospital VBP measures. Under the proposed process, we would post our intention to retire measures on the CMS Web site at least 60 days prior to the date that we would retire the measure. Also, as we do with respect to Hospital IQR measures that we believe pose immediate patient safety concerns if reporting on them is continued, we proposed that we would notify hospitals and the public of the retirement of the measure and the reasons for its

retirement through the usual hospital and QIO communication channels used for the Hospital IQR program, which include e-mail blasts to hospitals and the dissemination of Standard Data Processing System (SDPS) memoranda to QIOs, as well as post the information on the QualityNet Web site. We would then confirm the retirement of the measure from the Hospital VBP program measure set in a rulemaking vehicle. We made this proposal because it would allow us to ensure that the Hospital VBP program measure set focuses on the most current quality improvement and patient safety priorities. We solicited public comment on our proposals and other methods that allow for the addition of measures to the Hospital VBP program as rapidly as possible in order to improve quality and safety for patients.

In addition, we sought public comment on efficiency measures required for inclusion in the Hospital VBP program for value-based incentive payments made with respect to discharges occurring during FY 2014 or a subsequent fiscal year. Specifically, we requested comment on what services should be included and what should be excluded in a “Medicare spending per beneficiary” calculation, and what, if any, type(s) of hospital segmentation or adjustment should be considered in such a measure. We also solicited comment on approaches for measuring internal hospital efficiency. We took these comments into account in the development of the Medicare spending per beneficiary measure that we proposed to adopt in the FY 2012 IPPS/LTCH PPS proposed rule scheduled for publication on May 5, 2011, available at <http://www.ofr.gov/inspection.aspx?AspxAutoDetectCookieSupport=1>.

The public comments we received are set forth below.

Comment: Some commenters agreed with our proposed measure set and our proposal to exclude PN–5c and structural measures.

Response: We thank the commenters for their support. We believe that the structural measures we have adopted for the Hospital IQR program require further development before we can consider adopting them for the Hospital VBP program, including the development of an appropriate scoring

methodology. We also believe that the inclusion of PN–5c measure could lead to inappropriate antibiotic use. We also note that we have proposed to retire the PN–5c measure from the Hospital IQR program in the FY 2012 IPPS/LTCH PPS proposed rule scheduled for publication on May 5, 2011 for the same reason that we proposed to not include it in the Hospital VBP program measure set.

Comments: Some commenters noted that CMS is retiring PN–2 (Pneumococcal Vaccination) and PN–7 (Influenza Vaccination) from the Hospital IQR Program and asked why these measures were included in the proposed rule. These commenters wanted to know how the retirement of these measures from the Hospital IQR Program would affect how these measures were collected and scored under the Hospital VBP program. Other commenters were concerned about including pneumonia vaccination measures in the Hospital VBP program measure set because they stated that there may be clinical reasons why a physician does not want a patient to receive the vaccination. The commenters suggested adding an “allowable value” or allowable code to the measure specifications to avoid penalizing the hospital for that situation.

Response: Commenters are correct in that we finalized our retirement of PN–2 (Pneumococcal Vaccination) and PN–7 (Influenza Vaccination) beginning with the FY 2014 Hospital IQR program payment determination (75 FR 50211), and hospitals will no longer be required to submit data on these measures beginning with January 1, 2012 discharges (75 FR 50221). Because these measures will cease to continue being Hospital IQR program measures midway through the performance period we are finalizing for the FY 2013 Hospital VBP program, we do not believe that we can include them in the FY 2013 Hospital VBP measure set.

Comment: One commenter requested clarification on whether we proposed to include SCIP–Inf–6 in the FY 2013 Hospital VBP measure set.

Response: Table 2 of the Hospital Inpatient VBP proposed rule (76 FR 2462) listed our proposed measures for FY 2013, and Table 2 of this Final Rule lists the finalized measures. As we

¹ Proposed dimensions of the HCAHPS survey for use in the FY 2013 Hospital VBP program are: Communication with Nurses, Communication with Doctors, Responsiveness of Hospital Staff, Pain Management, Communication about Medicines, Cleanliness and Quietness of Hospital Environment, Discharge Information and Overall Rating of Hospital.

explained in the Hospital Inpatient VBP proposed rule (76 FR 2461), we proposed not to adopt SCIP-Inf-6 for the Hospital VBP program because we concluded that the measure had achieved a “topped out” status.

Comment: A commenter suggested that the proposed clinical process of care measures are flawed, suggesting that hospitals might choose not to submit records that could adversely impact their total performance score when submitting quality data.

Response: All Hospital VBP program measures must be selected from the measures specified under the Hospital IQR program, and the data that we will use to calculate a hospital’s total performance score for the clinical process of care measures will be the same data that the hospital submitted on those measures under the Hospital IQR program.

We allow hospitals to submit Hospital IQR clinical process of care measure data either by abstracting the necessary data elements from all qualifying cases or by submitting data elements taken from a sample of those cases. If the hospital chooses to submit a sample, the sample must meet the population and sample requirements outlined in the Specifications Manual. This Specifications Manual is posted on the CMS QualityNet Web site at <https://www.QualityNet.org/>. The purpose of these requirements is to ensure that the sample is statistically valid. We also note that we have adopted a process for validating clinical process of care measure data submitted under the Hospital IQR program, and we stated in the Hospital Inpatient VBP program proposed rule our belief that this process will also assure us that the same data is accurate for purposes of assessing hospital performance under the Hospital VBP program.

Comment: Several commenters asked if CMS will monitor “topped-out” measures to ensure that they remain “topped-out”.

Response: At this time, we do not have a mechanism in place to monitor whether measures we do not adopt for the Hospital VBP program on the basis that they are topped-out remain topped-out. We will consider such monitoring in the future.

Comment: Some commenters suggested that CMS include in the Hospital VBP program measures that meet the definition of “topped out” because some hospitals will still be able to demonstrate improvement on them.

Response: As detailed in the Hospital Inpatient VBP proposed rule (76 FR 2460), we proposed to define a “topped out” measure as a measure for which

hospital performance at the 75th and 90th percentiles are statistically indistinguishable, and the truncated CV was set at <0.10. We believe that if a measure is “topped out,” there is no room for improvement for the vast majority of hospitals, and that measuring hospital performance on that measure will not have a meaningful effect on a hospital’s Total Performance Score. For that reason, we proposed to exclude 7 topped-out measures from the FY 2013 Hospital VBP measure set.

Comment: We received several comments asking us to re-run our analysis of “topped-out” measures using more recent data to determine if any other measures also met that status.

Response: At the time we issued the Hospital Inpatient VBP proposed rule, the most recent data that was available to assess whether the proposed measures met our proposed definition of “topped out” was data from July 1, 2008 through March 31, 2009 which was the most recent validated data available and publicly displayed under the Hospital IQR program. However, since that time, data from the period that we proposed to set as the baseline period for the FY 2013 proposed measures has been validated (that is, data from the period July 1, 2009 to March 31, 2010). Therefore, in response to these comments, we analyzed all of the proposed FY 2013 measures to see if any of them met our proposed definition of “topped out” using this more recent data. We determined that three additional measures: AMI-2: Aspirin Prescribed at Discharge; HF-2: Evaluation of LVS Function; and HF-3: ACEI or ARB for LVSD meet our proposed definition of “topped-out” based on this more recent data. Because one of our goals for the Hospital VBP program is to ensure that hospital performance can be meaningfully measured and distinguished, we believe that it is appropriate to exclude these three additional measures from the FY 2013 Hospital VBP measure set based on this more recent analysis.

Comment: Some commenters suggested that we consider SCIP-Inf-2 and PN-3b for “topped out” status. Other commenters stated, generally, that other measures should be considered for “topped-out” status, particularly those on which the difference between median performance and top performance is small. One commenter stated that it had calculated achievement thresholds and benchmark scores for the proposed measures using data available on *Hospital Compare* that most closely matched data from CMS’ proposed baseline period. The commenter stated that its analysis

showed that with respect to several measures, hospital scores were clustered at a high level of achievement, and suggested that such measures should also be considered as “topped out.”

Response: As discussed above, we examined all of the proposed measures using data from the baseline period that we are finalizing in this final rule, and determined that three additional measures (AMI-2, HF-2, HF-3) are topped-out based on this data. As for other measures, including SCIP-Inf-2 and PN-3b, for which performance is high but which do not meet the proposed definition of “topped-out” based on the more recent data, the data show that hospital performance on these measures can still be meaningfully distinguished. For this reason, we believe that it is appropriate to include these measures in the FY 2013 Hospital VBP measure set.

Comment: One commenter suggested that we not include the HF-1 measure (Discharge Instructions) from the Hospital VBP program because the measure does not measure clinical care provided, but instead measures administrative processes. Another commenter suggested that we exclude AMI-2, HF-1, HF-2 and SCIP-VTE-2 from the Hospital VBP program because these measures do not represent a significant improvement in the clinical practices required to deliver high value health care.

Response: We disagree. The HF-1 measure, Discharge Instructions, assesses several critical elements important to a discharged patient: Activity level, diet, discharge medications, follow-up appointment, weight monitoring, and what to do if symptoms worsen. These elements are critical to ensuring that patients continue to receive appropriate, high-quality health care services after their discharge from the hospital. We believe that SCIP-VTE-2 is important for the Hospital VBP program because the optimal start of pharmacologic prophylaxis in surgical patients can significantly decrease the mortality and morbidity associated with blood clot formation.

As described above, we are not finalizing our proposal to include AMI-2 and HF-2 in the FY 2013 Hospital VBP measure set because based on an analysis involving data from the proposed baseline period, these measures meet our proposed definition of “topped-out.”

Comment: One commenter suggested that we review the technical specifications for AMI-7a and AMI-8a to ensure that intervention timing is based on diagnosis by EKG.

Response: The intervention timing for both AMI-7a and AMI-8a runs from the time of arrival, not the time of diagnosis by EKG. Specifically, the specifications for the AMI-7a measure state that AMI patients with ST-segment elevation or Left bundle branch block (LBBB) on the EKG closest to arrival time receiving fibrinolytic therapy during the hospital stay have a time from hospital arrival to fibrinolysis of 30 minutes or less. Similarly, the specifications for the AMI-8a measure state that AMI patients with ST-segment elevation or LBBB on the ECG closest to arrival time receiving primary PCI during the hospital stay have a time from hospital arrival to PCI of 90 minutes or less. These specifications can be found on the QualityNet Web site (<http://www.qualitynet.org>). We note that these specifications are based on clinical guidelines adopted by the American College of Cardiology (ACC) clinical guidelines for ST elevation MI.

Comment: Some commenters expressed support for our exclusion of structural measures. Others suggested that we consider using specific structural measures in the future such as participation in a systematic database or registry.

Response: We believe these measures require further analysis of how they could be scored, and how they would impact a hospital's total performance score before they can be adopted for the Hospital VBP program. We intend to consider these issues as the Hospital VBP program evolves.

Comment: One commenter suggested including the three smoking cessation measures adopted for the Hospital IQR program (AMI-4, HF-4, PN-4), despite their "topped out" status, because of the risk that hospitals will not focus on these measures and overall performance could begin to decline.

Response: These measures meet our proposed definition of topped-out status. As we have stated, we do not believe that measuring performance on a topped-out measure produces a meaningful differentiation of hospital performance. We also note that we have proposed to retire these measures from the Hospital IQR measure set in the FY 2012 IPPS/LTCH PPS proposed rule scheduled for publication on May 5, 2011. Therefore, we are excluding these measures from the Hospital VBP measure set. We will consider the feasibility of proposing to adopt a global smoking cessation measure for the Hospital VBP program.

Comment: A number of commenters supported our proposal to include PN-6 and PN-3b in the Hospital VBP measure set, stating that these measures

encourage use of new technologies after patient diagnosis.

Response: We appreciate the support, and we believe that the inclusion of these measures will help promote the provision of quality care by promoting appropriate laboratory testing (taking of blood cultures to facilitate selection of the most effective antibiotic for the patient) and actual selection of appropriate antibiotics based on patient data.

Comment: Some commenters supported our proposal to use SCIP measures to capture HAIs.

Response: We thank commenters for their support. As discussed in the Hospital Inpatient VBP Program proposed rule (76 FR 2461), the SCIP measures were developed to support practices that have demonstrated an ability to significantly reduce surgical complications such as HAIs. Compliance with the proposed SCIP infection measures is also included as a targeted metric in the HHS *Action Plan to Prevent Healthcare-Associated Infections* issued in 2009, a copy of which is available on the HHS Web site.

Comment: One commenter suggested that measures should assess services regularly provided by rural hospitals and hospitals that do not perform surgeries.

Response: The measures selected for the Hospital VBP program address services provided by subsection (d) hospitals, including rural hospitals and hospitals that do not perform surgeries. For example, the HCAHPS dimensions measure patients' experiences of care at hospitals; none of the dimensions are surgery-specific. Additionally, pneumonia and other conditions such as heart failure and acute myocardial infarction are treated by rural hospitals.

Comment: A number of commenters called on CMS to use the Joint Commission's accountability criteria for measure selection, which include strong scientific evidence of improved outcomes, proximity to impacted outcomes, accurate assessment of evidence-based processes and minimal adverse effects.

Response: In August 2010, The Joint Commission published an article in the New England Journal of Medicine discussing the criteria that should be used to define a measure that is used for accountability and public reporting purposes versus criteria that is used to define measures used strictly for performance improvement. The Joint Commission identified four criteria a measure must have in order to have the greatest positive impact on patient outcomes. These criteria include: Research, Proximity, Accuracy, and

Adverse Effects. Further information on the Joint Commission's accountability criteria may be found at <http://www.jointcommission.org/about/jointcommissionfaqs.aspx?CategoryId=31>. We generally agree with the Joint Commission's list of criteria that would apply to measures used for accountability purposes and considered this criteria in determining whether certain measures may warrant retirement from the Hospital IQR program. However, we do not agree with their exclusion of HF-1 from the list of accountability measures as we believe HF-1 assesses a hospital's compliance with providing critical information to patients at the time of their discharge, including instructions regarding activity level, diet, discharge medications, follow-up appointment, weight monitoring, and what to do if symptoms worsen. As stated above, we believe that this information is critical for hospitals to provide in order to facilitate appropriate self-care and provider follow up care after a patient is discharged from the hospital.

Comment: A number of commenters recommended that we analyze measures against pre-established, agreed-upon criteria to ensure that they are relevant to value-based purchasing and will improve health outcomes for patients. Some commenters suggested that our goal should be to find the most appropriate ways to tie measures to patient benefits. Some commenters argued that current measures which we have proposed to adopt for the Hospital VBP program do not sufficiently impact health outcomes. Other commenters wondered if any measures are "paper-only" and do not reflect the actual provision of quality medical care.

Response: To ensure that measures assess the quality of care provided to Medicare beneficiaries, we agree that measures should be scrutinized by experts and evaluated against objective criteria. We believe that these elements have been incorporated into our measure selection process in a variety of ways, including through endorsement by consensus-developing entities and through notice and public comment rulemaking. For example, most of the measures that we have selected for the Hospital IQR program, (which make them candidates for the Hospital VBP program) are endorsed by the NQF, the entity with a contract with the Secretary under Section 1890(a) of the Act. To the extent that we have determined that measurement is needed in a specified area for which there are no NQF endorsed measures, we give due consideration to measures endorsed or adopted by different consensus

organizations before specifying the measure. We also consider whether the measures meet the goals of the National Priorities Partnership, enable the Department to further its strategic goals and initiatives, and whether they are adopted by the HQA. This has resulted in our adoption of meaningful measures that assess the quality of care furnished by hospitals.

Comment: A few commenters were concerned that the HCAHPS scores publicly reported on Hospital Compare differ by bed size, type of hospital and geography and thought the HCAHPS scores should be adjusted for these factors. These commenters thought HCAHPS needs to be vetted more to understand these differences to ensure that HCAHPS is a reliable measure.

Response: Although we recognize that HCAHPS results differ by bed size and other hospital characteristics, we do not interpret these differing results to mean that the survey should be risk adjusted. HCAHPS results also differ among hospitals with the same characteristics, which we view as evidence that the results account for differences in the quality of care received by patients. In general, risk adjustment models control for exogenous factors that are beyond the control of a hospital, not for hospital characteristics that are endogenous, or within their control.

We also believe that the HCAHPS survey has been thoroughly vetted, including through reviews in peer-reviewed journals and through notice and comment rulemaking when we adopted it for the Hospital IQR program, and it is endorsed by the NQF.

Comment: One commenter questioned whether top-box responses in the HCAHPS survey are appropriate for urban, safety net hospitals that serve culturally diverse patients and may not be able to “always” communicate well with their patients.

Response: The “top-box” response to HCAHPS survey items is the most positive response that a patient can provide (often presented in the survey as “Always”). Medicare does not have an indicator for a “safety net hospital.” However, we have examined the HCAHPS results submitted by urban hospitals, which we believe can serve as a rough proxy for a “safety net hospital.” Urban hospitals, particularly large ones, have historically not performed as well on HCAHPS as rural hospitals. However, our internal studies of HCAHPS results show that hospitals in the following urban areas scored in the top 25 percent of hospitals overall: New York City, Boston, Baltimore, Atlanta, Chicago, Los Angeles, San Francisco, San Diego, Phoenix, Dallas, Houston,

and San Antonio. We believe that these results suggest that urban hospitals are not being disadvantaged by the HCAHPS measurement.

Comment: Several commenters questioned the reliability of HCAHPS data. Some suggested that we consider possible negative consequences associated with its use.

Response: Since its national implementation in October 2006, when hospitals began to administer the HCAHPS survey, our analyses of HCAHPS results has shown that this standardized, publicly reported survey of patients’ experience of hospital care is satisfactorily reliable at 100 completed surveys using statistical measures of reliability that calculate the proportion of the variance in reported hospital scores that is due to true variation between hospitals, rather than within hospital variation that reflects limited sample size.

We also note that since public reporting of HCAHPS scores began under the Hospital IQR program[?] in March 2008 there have been small but statistically significant improvements in 9 of 10 HCAHPS dimensions.² In addition, we are aware of abundant anecdotal evidence that hospitals are engaging in quality improvement efforts aimed at improving the quality of the inpatient experience. We believe that HCAHPS, in part, motivates these efforts and expect that hospitals will continue to improve their patients’ experience of care as the incentives for doing so become more salient.

We believe that setting the minimum number of measures and cases as low as is reasonable is an essential component of implementing the Hospital VBP program and will help to minimize the number of hospitals unable to participate due to not having the minimum number of cases for a measure or the minimum number of measures. Therefore, we also proposed that, for inclusion in the Hospital VBP program for FY 2013, hospitals must report a minimum of 100 HCAHPS surveys during the performance period. Our statistical analyses show that HCAHPS is a reliable measure of patient experience and, therefore, we see no negative consequences with its use.

Comment: One commenter provided suggestions for additional items regarding palliative care that could be added to the HCAHPS instrument; another commenter suggested that CMS add questions about patient activation

(patients’ knowledge, skills, and confidence for self-management), care coordination, shared decision-making and support for patient self-management.

Response: As part of our ongoing maintenance activities for the HCAHPS survey, which include assessing whether it needs to be updated, we will consider the feasibility of adding the suggested survey items.

Comment: One commenter wanted to exclude the doctor communication dimension from the HCAHPS measure, reasoning that hospital payment under the IPPS should not be based in part upon physician behavior that it cannot control.

Response: We are including the doctor communication dimension as an HCAHPS dimension because it is a key aspect of care from the perspective of consumers. In addition, many hospitals employ their own doctors (hospitalists) who are directly under the hospitals’ control.

Comment: Some commenters opposed combining the cleanliness and quiet items because they are conceptually different and the cleanliness item is important for patient safety.

Response: We thank commenters for their input. Although these two items were originally proposed to be one composite in the survey, we separated them into two individual measures for public reporting prior to the 2006 national implementation because it made more sense for consumers to see “clean” and “quiet” as distinct environmental aspects of hospitals. The “clean” and “quiet” HCAHPS measures will continue to be publicly reported separately on Hospital Compare for the Hospital Inpatient Quality Reporting program.

For purposes of the Hospital VBP program, these two items were combined so as not to put more weight on the environmental items compared to the rest of the HCAHPS items, which are composite measures (with the exception of Overall Rating). If the environmental items were separated, quietness of the hospital environment, for example, would receive as much weight as nurse communication, which includes 3 items from the HCAHPS survey. The combined “cleanliness and quietness” HCAHPS dimension will be publicly reported on Hospital Compare as part of the Hospital VBP program.

Comment: Some commenters were concerned that the risk adjustment models for the HCAHPS survey are not adequate and do not control for the severity of a patient’s condition, socioeconomic status, and geographic differences

² See “Hospital Survey Shows Improvements in Patient Experience.” M.N. Elliott, W.G. Lehrman, E.H. Goldstein, L.A. Giordano, M.K. Beckett, C.W. Cohea and P.D. Cleary. *Health Affairs*, 29 (11): 2061–2067. 2010.

Response: HCAHPS dimensions are currently patient-mix adjusted. We adjust HCAHPS data for patient characteristics that are not under the control of the hospital that may affect patient reports of hospital experiences. The goal of adjusting for patient-mix is to estimate how different hospitals would be rated if they all provided care to comparable groups of patients. As part of the endorsement process for HCAHPS, the NQF endorsed the HCAHPS patient-mix adjustment currently in use.

The HCAHPS patient-mix adjustment (PMA) model incorporates important and statistically significant predictors of patients' HCAHPS ratings that also vary meaningfully across hospitals (O'Malley et al., 2005). The PMA model includes seven variables, as follows: Self-reported health status, education, service line (medical, surgical, or maternity care), age, response percentile order (also known as "relative lag time," which is based on the time between discharge and survey completion), service line by linear age interactions, and primary language other than English. Initially the model also included admission through an emergency room, but because admission through an emergency room is no longer available on the UB-92 Form, this adjuster is no longer available for the patient-mix model. We are exploring other options to obtain that information in the future. We have found that evaluations of care increase with self-rated health and age (at least through age 74), and decrease with educational attainment. Maternity service has generally more positive evaluations than medical and surgical services. Percentile response order (relative lag time) findings show that late responders tend to provide less positive evaluations than earlier responders. From research conducted during the development of HCAHPS, we found little evidence that DRG matters beyond the service line, which is included in the patient mix model.

To further address specific concerns about the adjustment model, it is important to note that self-reported health status is a widely accepted measure of a person's overall health status. In general, "how would you rate your health" is the most widely used single self-reported health item and is used in a plethora of national health surveys. Education also captures important aspects of socio-economic status. Income is generally not available to adjust survey data.

Patient-mix adjustment is based on variation by patient-level factors within hospitals so that true differences

between hospitals are not included in the adjustment.³ Controlling for geographic region (a hospital-level factor) as part of a patient-mix adjustment model could mask important differences in quality across the country.

Comment: Several commenters suggested changing the HCAHPS requirements to reduce the number of required mailings and telephone attempts, allow survey administration while patients are still in the hospital, and allow electronic administration of the survey to reduce the cost of survey administration.

Response: We know from our HCAHPS research that, on average, late responders report less positive experiences. For this reason, we believe that allowing hospitals to reduce their effort to obtain completed surveys by reducing the required number of mailings and telephone attempts would bias the HCAHPS results. Under the current HCAHPS requirements, which can be found in the HCAHPS Quality Assurance Guidelines available at www.hcahpsonline.org, the administration of the HCAHPS survey begins 48 hours following discharge to ensure that the patient has had an opportunity to return home or go to an alternative location. We also believe that allowing a hospital to administer the survey while the patient is still in the hospital has the potential to create biased results because the patient might not feel that he or she can freely answer the questions with hospital staff nearby.

We note that we have tested an Internet version of HCAHPS. However, at this point, we do not believe that hospitals routinely collect e-mail addresses or that the Medicare population has enough experience with the Internet to support allowing hospitals to administer the survey via the Internet. This is a technology that we will continue to explore because we agree with the commenters that electronic administration of the survey would be less expensive for hospitals.

Comment: One commenter was concerned that patients would be more likely to recommend larger hospitals due to the spectrum of services offered by them and, thus, smaller and rural hospitals would be disadvantaged by HCAHPS.

Response: Because HCAHPS focuses on the actual experiences of care by asking patients about what happened during the hospital stay, the HCAHPS

data are not biased by the perceptions of patients in terms of the range of services offered by different hospitals. In fact, smaller hospitals generally tend to do better on HCAHPS relative to larger ones.

While most HCAHPS survey items assess the patient's actual experience in the hospital, two survey items ask for the patient's overall impressions of the hospital stay. Because these items are highly correlated and potentially draw on wider influences, we have proposed to include only one global dimension, Overall Rating, in the Hospital VBP program scoring for the HCAHPS measure.

Comment: Some commenters called on us to make HCAHPS patient mix adjustment formulas public.

Response: The HCAHPS patient-mix adjustment formulas are publicly available on <http://www.hcahpsonline.org>. The data on <http://www.hcahpsonline.org> regarding the adjustments are updated quarterly.

Comment: Some commenters opposed the use of 30-day mortality rates in the Hospital VBP program because they are "all-cause" measures and do not exclude deaths that are not attributable to a hospital's quality of care. One commenter questioned the use of the mortality measures, citing the possibility of unintended consequences and remarking that, "unless hospitals are provided with specific interventions which have been demonstrated to reduce mortality, penalizing a hospital for an increase in mortality (or rewarding one for a decrease in mortality) is not rationally related to the operations of the hospital." Other commenters argued that the Hospital VBP program should focus on outcome measures that are risk adjusted to account for extremely ill patients.

Response: We appreciate commenters' input on measures for use in the Hospital VBP program. The proposed all-cause risk adjusted 30-day mortality measures are endorsed by the National Quality Forum (NQF). There are several reasons why we believe it is appropriate for us to adopt the NQF-endorsed all-cause mortality measures for the Hospital VBP program.

First, from the patient perspective, death is the key outcome regardless of its cause. Second, cause of death may be unreliably recorded. Third, the cause of death may represent a complication related to the underlying condition. For example, a patient with HF who develops a hospital-acquired infection may ultimately die of sepsis and multi-organ failure. It would be inappropriate to consider the death as unrelated to the care the patient received for HF.

³ See "Adjusting Performance Measures To Ensure Equitable Plan Comparisons," Zaslavsky, A.M., L.B. Zaboriski, D.J.A. Shaul, M.J. Cioffi, and P.D. Cleary. *Health Care Financing Review* 22(3): 109-26. 2001.

Another patient might have a complication leading to renal failure, resulting in death, and yet quality of care could have reduced the risk of the complication. A patient with PN who did not receive deep vein thrombosis prophylaxis may ultimately die of a pulmonary embolism. It would be inappropriate to consider the death as unrelated to the care the patient received for PN. Although this approach will include some patients whose death may be unrelated to their care (for example, a casualty in a motor vehicle accident), events completely unrelated to the admission are expected to be uncommon and should not be clustered unevenly among hospitals.

Furthermore the NQF-endorsed measure methodology for all three of these all-cause mortality measures includes a risk adjustment for protein-calorie malnutrition, dementia, and metastatic cancer that are common among extremely ill patients.

Comment: Some commenters suggested that we should ensure that measures, particularly those added in FY 2014, appropriately capture services provided by hospitals, as not all hospitals treat all conditions.

Response: We agree and note that we proposed that hospitals must have at least 10 cases per measure in order to be scored on that measure and report on at least 4 measures to be included in the Hospital VBP program. We also believe that the finalized Hospital VBP measures capture a broad range of hospital services, which will enable a large number of hospitals to participate in the program.

Comment: One commenter suggested that we proceed cautiously in seeking to adopt outcome measures for the Hospital VBP program, and that we first demonstrate their statistical reliability for low-volume hospitals.

Response: We agree that acceptable statistical reliability is important to our analysis in determining what measures to adopt for the Hospital VBP program. As stated above, we conducted analyses on the 30-day outcome measures we are adopting for this program and have found them to be reliable for all hospitals for purposes of Hospital VBP scoring.

Comment: One commenter suggested that CMS use an error bar or other visual display of the confidence intervals surrounding mortality rate performance similar to the displays currently used on *Hospital Compare* for mortality measures.

Response: The confidence intervals currently shown on *Hospital Compare* are used to classify hospitals into broad categories for purposes of that display.

For the Hospital VBP program, we will score all of the Hospital VBP measures using the scoring methodology that we finalize for the program. The use of this scoring methodology will result in each hospital being assigned a point estimate that reflects its score on each of the mortality measures, and it is those scores, rather than broad confidence intervals, that will be used for purposes of the public reporting.

Comment: Some commenters expressed general support for the 3 proposed 30-day mortality measures.

Response: We thank commenters for their support.

Comment: Some commenters suggested that we exclude some types of cases, including hospice or palliative care, from the mortality measure calculations. They also suggested that this “new” mortality rate measurement without hospice and palliative care patients should be displayed on *Hospital Compare* for one year prior to implementation.

Response: The risk-adjusted mortality measure methodology excludes admissions for Medicare fee-for-service patients who elect hospice care any time in the 12 months prior to the index hospitalization, including the first day of the index admission. Information on the methodology used to calculate the measures can be found at <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1163010398556>.

Comment: Many commenters opposed our proposal to adopt HAC measures for the FY 2014 Hospital VBP program, arguing that we will be penalizing hospitals on those measures both under the Hospital VBP program, the HAC policy required by Section 3008 of the Affordable Care Act and the Medicaid penalties required by Section 2702 of the Affordable Care Act.

Response: We view the program authorized by section 3008 of the Affordable Care Act and the Hospital VBP Program as being related but separate efforts to reduce HACs. Although the Hospital VBP program is an incentive program that provides incentive-based payments to hospitals based on quality performance, the program established by section 3008 of ACA creates a payment adjustment resulting in payment reductions for the lowest performing hospitals. We also view programs that could potentially affect a hospital’s Medicaid payment as separate from programs that could potentially affect a hospital’s Medicare payment, although we intend to monitor the various interactions of programs authorized by the Affordable Care Act

and their overall impact on providers and suppliers.

Comment: Several commenters requested that we ensure the harmonization of new programs and any overlay or duplication in the Affordable Care Act, generally.

Response: We are coordinating the development and implementation of all of these programs and will continue to monitor their impacts on providers and suppliers.

Comment: Some commenters argued that CMS should analyze HAC measures more closely to test the validity of “present on admission” (POA) diagnosis coding. The commenters suggested that CMS compare POA coding to chart-review to test the appropriateness of using claims-based measures for payment purposes. Commenters more generally argued that the current measure format does not allow for valid comparisons due to coding issues and physician behavior.

Response: The purpose of POA coding is to allow better discernment of whether a diagnosis is a complication of care received in the hospital or an adverse event occurring in the hospital. Beginning in FY 2007, we have proposed, solicited, and responded to public comments and have implemented the Hospital Acquired Condition Program under section 1886(d)(4)(D) of the Act and its accompanying POA coding requirement through the IPPS annual rulemaking process. For specific policies addressed in each rulemaking cycle, we direct readers to the following publications: the FY 2007 IPPS proposed rule (71 FR 24100) and final rule (71 FR 48051 through 48053); the FY 2008 IPPS proposed rule (72 FR 24716 through 24726) and final rule with comment period (72 FR 47200 through 47218); the FY 2009 IPPS proposed rule (73 FR 23547), and final rule (73 FR 48471); and the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24106) and final rule (74 FR 43782). A complete list of the 10 current categories of HACs is included in section II.F.2. of FY 2011 IPPS/RY 2011 LTCH PPS (75 FR 50080 through 50101).

POA coding is also used in the specifications for the component indicators for the AHRQ Patient Safety composite measure we proposed to adopt for the Hospital VBP program for FY 2014. This composite measure consists of 8 component indicators, including PSI–3 (Pressure ulcer), PSI–6 (Iatrogenic Pneumothorax), PSI–7 (Central venous catheter-related bloodstream infections), PSI–8 (Postoperative hip fracture), PSI–12 (Postoperative pulmonary embolism or

deep vein thrombosis), PSI-13 (Postoperative sepsis), PSI-14 (Postoperative wound dehiscence), and PSI-15 (Accidental Puncture or Laceration). For each of these component indicators, present-on-admission coding is one of the exclusion criteria used to indicate whether a condition or an injury occurred before or after the patient was admitted to the hospital. Please refer to www.qualityindicators.ahrq.gov for further details about the technical specifications for these measures. We are using the POA information on the final adjudicated claim submitted by the hospital. These data are subject to the same scrutiny as other information on Medicare claims.

We also note that we are currently evaluating the Hospital Acquired Condition-Present on Admission (HAC-POA) Program. We appreciate the commenters' interest and will take it into consideration as we proceed with this evaluation.

Comment: Some commenters noted that the proposed HAC measures are limited to the Medicare fee-for-service population and suggested that these measures should not be used in Hospital VBP.

Response: The proposed HAC measures are calculated using only Medicare fee-for-service data because we do not currently have access to claims data that is submitted by hospitals to other payers. We also note that POA codes, which are required to calculate all of the proposed HAC measures and which must be included on Medicare Part A claims submitted to CMS by hospitals, may not be required to be included on inpatient claims submitted by hospitals to other payers. Despite this data limitation, we believe that the proposed HAC measures provide important information regarding patient safety events occurring during hospitalization, which reflect the quality of patient care provided, and we believe these measures should be included in the Hospital VBP program.

Comment: Some commenters questioned whether value-based incentive payments will be available only to Medicare FFS and Medicare cost payers and not Medicare Advantage Organization (MAO) payers.

Response: Value-based incentive payments made under the Hospital VBP program can be made only in the form of an adjustment to a subsection (d) hospital's base operating DRG payment amount under the IPPS.

Comment: Some commenters noted that the proposed HAC measures do not capture more than 9 diagnoses.

Response: CMS' current system limitations allow for the processing of only the first 9 diagnoses and 6 procedures. While CMS accepts all 25 diagnoses and 25 procedures submitted on the claims, we do not process all of the codes because of these system limitations.

In the FY 2011 IPPS/LTCH-PPS final rule, we discussed our plans to accept and process up to 25 diagnoses and procedures on the hospital inpatient claims submitted on the 5010 format beginning January 1, 2011 (75 FR 50127 through 50128). In the FY 2010 IPPS/R 2010 LTCH PPS final rule, we responded to hospitals' requests that we process up to 25 diagnosis codes and 25 procedure codes (74 FR 43798). In that FY 2010 IPPS/R 2010 LTCH PPS final rule, we referred readers to the ICD-10 final rule (74 FR 3328 through 3362) where we discuss the updating of Medicare systems prior to the implementation of ICD-10 on October 1, 2013. We mentioned that part of the system updates in preparation for ICD-10 is the "expansion of our ability to process more diagnosis and procedure codes." In the FY 2009 IPPS final rule (73 FR 48433 through 48444), we also responded to multiple requests to increase the number of codes processed from 9 diagnosis and 6 procedure codes to 25 diagnosis and 25 procedure codes.

We are currently making extensive system updates as part of the move to 5010, which includes the ability to accept ICD-10 codes. This complicated transition involves converting many internal systems prior to October 1, 2013, when ICD-10 will be implemented. One important step in this planned conversion process is the expansion of our ability to process additional diagnosis and procedure codes. We are currently planning to complete the expansion of this internal system capability so that we are able to process up to 25 diagnoses and 25 procedures on hospital inpatient claims as part of the HIPAA ASC X12 Technical Reports Type 3, Version 005010 (Version 5010) standards system update.

Comment: Many commenters recommended that CMS develop risk adjustment methods, measure exclusion criteria, or stratified scoring methods to account for variations in measure rates related to patient factors or hospital function. Commenters argued that many of the proposed outcome, patient experience, and other measures including HCAHPS, HACs, and mortality measures are not valid because they lack appropriate risk adjustment and exclusion criteria and called for their exclusion from the

Hospital VBP program. One commenter suggested risk adjustments should specifically be employed for trauma patients. A number of commenters suggested that CMS consider other risk adjustment models used by the industry, such as those promulgated by the Society of Thoracic Surgeons. One commenter suggested that we include "median income of ZIP code of residence" in a risk adjustment methodology for mortality measures in order to account for socioeconomic variables that may lead to a greater rate of mortality. Additionally, some commenters suggested that CMS convene experts to develop a "population adjustment" and adopt only HACs that do not rely on claims data for the Hospital VBP program.

Response: For the measures that currently employ risk adjustment, we are using the risk adjustment models that are part of the NQF-endorsed measure specifications. In developing its risk adjustment model for the 30-day measures, the NQF performed an extensive literature review of risk factors employed by other models to inform the development of its model. We note that the current risk adjustment methodology for the three proposed mortality measures for FY 2014 was recently reevaluated and approved by an NQF steering committee. There is no risk adjustment for race and socioeconomic status, which we believe is appropriate because we do not want to hold hospitals with different racial or SES mixes to different performance standards. Adjusting for race or SES would also obscure differences that are important to identify if we want to reduce disparities where they do exist. We note that the NQF has issued guidance recommending against adjusting for patient characteristics such as socioeconomic status in outcomes measures, located at: http://www.qualityforum.org/docs/measure_evaluation_criteria.aspx. We welcome collaboration on this issue with providers that serve unique patient populations and functions.

Furthermore, while we understand that claims-based measures such as HAC measures have certain limitations, as discussed below, HAC measures were defined in prior rulemaking, during which we conducted several listening sessions and had the benefit of receiving public comment. We note that some of the HACs are "never" events and therefore should not be risk adjusted. We will consider refinements to the HAC measures in future years. We will monitor the impact of the Hospital VBP program on the care provided to

vulnerable subpopulations of patients, including trauma patients.

Comment: Some commenters argued that the proposed HAC measures should be risk-adjusted before they are used in Hospital VBP.

Response: Six of the 8 HACs adopted for the Hospital VBP program are considered “never events,” for which risk adjustment would not be appropriate because, in our view, such events should never happen under any circumstances. In the event that we do decide that some type of risk adjustment would be appropriate, we will seek input from the NQF as to whether or not this constitutes a substantive change to the measures, in which a formal consensus development process will be initiated. We will consider further refinements to the HAC measures in future years. We note that when we adopted the HAC vascular catheter-associated infection measure and the catheter-associated urinary tract infection measure in the FY 2008 IPPS final rule with comment period (72 FR 47202 through 47218), there were no related risk-adjustments under the DRG payment policy reforms (72 FR 47141).

Comment: Some commenters suggested that measures should be approved by the Hospital Quality Alliance (HQA) before use in the Hospital VBP program.

Response: In developing the Hospital VBP program, we took into account the input of a multitude of stakeholders, including the HQA. The HQA is a national, public-private collaboration committed to making meaningful, relevant, and easily understood information about hospital performance accessible to the public and to informing and encouraging efforts to improve quality. We will also continue to consider HQA input as part of our ongoing measure selection process for the Hospital VBP program.

Comment: Some commenters argued that the low incidence rates of HACs, particularly in academic medical centers, would lead to unstable statistics on which to base comparisons between hospitals.

Response: Low incidence of events does not equate to unstable rates for those events. We acknowledge that the rates of some of the HACs, particularly the ones measuring ‘never events’, may be rare. However, because these are considered events that should never happen, reporting their prevalence, though rare, is still meaningful. We have not found that HAC incidence is particularly low in academic medical centers. We believe that all of the proposed HAC measures are important to measure and report, despite their low

incidence rates, and that the public reporting of the HACs on the *Hospital Compare* Web site will encourage improvement. We believe that the Hospital VBP program must emphasize patient safety and improved quality of health care, and we believe that holding hospitals accountable for HACs will further those goals.

Comment: Some commenters asked us to discuss the inclusion of HAIs in HACs. Specifically, the commenters asked us to include additional detail on how CMS plans to implement HHS’s HAI Action Plan.

Response: Two of the eight proposed HAC measures (Vascular Catheter-Associated Infection and Catheter-Associated Urinary Tract Infection) capture HAIs. We are considering the feasibility of proposing to adopt all of the metrics listed in the HAI Action Plan for the Hospital IQR program in future years. In the FY 2011 IPPS/LTCH PPS final rule, we adopted two of the HAI measures from the HHS HAI Action Plan: the central line-associated bloodstream infection measure, for which reporting began with respect to January 2011 events; and the surgical site infection measure, which hospitals will begin reporting with respect to January 2012 events. In addition, we have proposed in the FY 2012 IPPS/LTCH PPS proposed rule scheduled for publication on May 5, 2011, to adopt additional HAI measures: Catheter-associated urinary tract infection measure, central line insertion practices adherence percentage; Methicillin-resistant *Staphylococcus aureus* (MRSA), *Clostridium difficile* (C-Diff), and Health Care Personnel Influenza Vaccination measures. All of these measures, if finalized for the Hospital IQR program, will be eligible for inclusion in the Hospital VBP program, and would allow CMS to better address the important topic area of Healthcare Associated Infections.

Comment: Some commenters noted that HACs are not entirely preventable and argued that they should not be a component of quality measurement.

Response: We believe that all 8 proposed HAC measures assess the presence of hospital acquired conditions that are reasonably preventable if high quality care is furnished to the patient. We also believe that the incidence of HACs in general raise major patient safety issues for Medicare beneficiaries. According to the 2010 Department of Health and Human Services Office of the Inspector General Report, entitled “Adverse Events in Hospitals: National Incidence among Medicare Beneficiaries,” an estimated 13.5 percent of hospitalized Medicare beneficiaries

experienced adverse events during their hospital stays (OIG, November 2010, OEI-06-09-00090). We proposed to adopt 8 HAC measures for the Hospital VBP program because they are outcome measures (which are widely regarded by the provider community as strongly indicative of quality of medical care) that assess whether certain adverse events occurred during hospitalization. We believe that the adoption of these measures will facilitate our on-going efforts to hold hospitals accountable for these events, as well as reduce the incidence of these adverse events that result in harm to Medicare beneficiaries and higher costs of care.

Comment: Some commenters asked us to explain why HACs are appropriate for quality measurement and scoring given that they are derived from billing and payment methods.

Response: We believe that public reporting of the HACs on the *Hospital Compare* Web site will encourage improvement. We acknowledge that the incidence of HACs may be rare. However, many of the HACs are considered events that should never happen; reporting their prevalence, though rare, is still meaningful.

Medicare fee for service claims data is the source for many measures that are NQF endorsed. This data source was reviewed as part of the NQF endorsement process for such measures, and has been found to be an appropriate data source. We also refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47202 through 47218); section II.F. of the FY 2009 IPPS final rule with comment period (73 FR 48474 through 48486); and section II.F. of the FY 2010 IPPS/RV 2010 LTCH PPS final rule (74 FR 43782 through 43785) for detailed discussions regarding the selection of the current 10 HAC categories.

Comment: Some commenters suggested that CMS consider integrating HACs, complications and other causes of waste into an efficiency domain rather than in clinical process or outcomes.

Response: We believe that the proposed HAC measures best capture health care quality outcomes rather than efficiency and are therefore best included in the outcome domain.

Comment: One commenter suggested that we revise the definition of Falls and(?) Trauma. Specifically, the commenter suggested that the definition should be revised to require not only these injury codes, but also an e-code related to falls that are not POA.

Response: We appreciate the suggestion to refine the definition of this

HAC, and will consider refinements for future implementation.

Comment: Some commenters requested that we provide detailed measure specifications for the proposed HAC measures immediately if we intend to use them in the Hospital VBP program.

Response: The specifications for these proposed measures were made available on *QualityNet* at <http://www.qualitynet.org> earlier in the year.

Comment: Some commenters were opposed to the use of Nursing Sensitive measures in the Hospital VBP measure set while others, noting that nurses provide numerous services to patients, argued that nursing sensitive measures are essential quality indicators.

Response: We agree that nurses provide numerous services to their patients, and we are interested in nursing sensitive measures because those measures capture many processes and outcomes that are influenced by nursing practice. Currently, we only have one nursing sensitive measure in the Hospital IQR Program: Death among surgical inpatients with serious treatable complications (AHRQ PSI-04). We are also collecting the structural measure "Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care". We will consider adopting one or more measures in the nursing sensitive category for the Hospital IQR and Hospital VBP programs in the future.

Comment: Some commenters opposed the use of any AHRQ PSI and IQI measures or their composites in Hospital VBP. Others suggested that those measures should be evaluated for validity and reliability as they were not developed to be performance measures and are based on claims data. Others noted that hospitals have encountered technical and programming issues with respect to the proposed AHRQ measures.

Response: We thank commenters for their input. The AHRQ PSI and IQI measures that we proposed to adopt for the Hospital VBP measure set are NQF endorsed. In order to achieve NQF endorsement, measures must meet all of the criteria of the NQF consensus development process. Information on this process can be found at: http://www.qualityforum.org/Masuring_Performance/Consensus_Development_Process.aspx. We believe this consensus development process includes the necessary steps to assure that measures that are NQF endorsed have been tested for validity and reliability of the data. This endorsement includes the data source needed to calculate the measures (Medicare fee for service claims). We believe these measures are appropriate

for use in the Hospital VBP program as they meet the statutory requirements for inclusion and address the topic of patient safety, which is a high priority that we believe should be addressed in the Hospital VBP program. We also note that because these measures are claims-based, no separate data reporting is needed.

Comment: One commenter objected to the use of PSI 4, arguing that about 25 percent of surgical patients are admitted with sepsis or acute illness and multiple organ failure for surgical exploration, then coded as surgical patients even if the surgery doesn't find anything and doesn't contribute to death.

Response: We have not proposed to adopt PSI 4, Death among surgical inpatients with serious, treatable complications, for inclusion in the Hospital VBP program. However, we note that the specifications for that measure specifically exclude patients with a diagnosis of sepsis or infection in the primary diagnosis field and patients who are immunosuppressed.

Comment: Some commenters argued that the proposed AHRQ measures amount to double-counting for purposes of scoring, as two of the proposed AHRQ measures are composites of the other AHRQ measures.

Response: We appreciate commenters' concerns. We agree that the use of all of the proposed AHRQ measures, including the two composite measures, would result in "double-counting" each of the individual measures. While each of the individual AHRQ measures capture important components of quality care, we believe that scoring hospital performance on the two composite measures simply and clearly captures the provision of high quality care that we wish to incentivize in the Hospital VBP program. Therefore, we are only finalizing the 2 proposed AHRQ composite measures, which will avoid any double-counting.

Comment: Some commenters argued that all outcome, process, and patient experience measures should be posted on *Hospital Compare* for one year prior to use in the Hospital VBP program, and that, during this year, CMS should provide quarterly hospital preview reports on *qualitynet.org* with a percentile ranking for each measure in order to prepare for public reporting.

Response: In accordance with statutory requirements, all measures will be included on *Hospital Compare* for at least one year prior to the beginning of the performance period for which we propose to adopt them under the Hospital VBP program. The process of care measures and HCAHPS are updated quarterly, and facilities that

submit data are provided a 30-day preview of their data before public reporting occurs. The outcomes of care measures are updated annually, usually in July. The new outcomes data is included in the preview reports for this display period. As stated below, we will provide details on the information to be reported on *Hospital Compare* in future rulemaking. We will consider commenters' suggestion for quarterly preview reports on *qualitynet.org* before public reporting. However, we believe that providing robust quality information to the public as soon as possible is a desired outcome of quality reporting and performance scoring.

Comment: One commenter noted that the requirement that measures be included on *Hospital Compare* appears to be a significant barrier to timely adoption of the HAI Action Plan metrics in the Hospital VBP program. Other commenters encouraged us to accelerate the adoption of those metrics for the Hospital IQR program, *Hospital Compare*, and NQF endorsement.

Response: We agree that the requirement that measures be included on the Hospital Compare Web site for at least one year before the performance period for them can begin under the Hospital VBP program has the potential to limit the speed at which we can adopt measures for the program, however we intend to propose to adopt measures that drive quality improvements and improve patient safety, such as the prevention metrics included in the HHS Action Plan to Prevent HAIs, as quickly as possible within that constraint.

Comment: Some commenters argued that CMS's data collection system does not adequately differentiate among conditions acquired in the hospital and those that are "present on admission" (POA) for purposes of scoring outcome measures. Commenters recommended that CMS allow hospitals to use POA claims indicators or consider other methods for outcome measure scoring, particularly since certain types of hospitals such as trauma centers or tertiary referral centers could be penalized on those measures because they receive a disproportionate share of transfers from other hospitals. Some commenters suggested that transferee and transferor hospitals should share in mortality rates for transferred patients.

Response: We are currently using the POA indicator to calculate the proposed HAC and AHRQ patient safety composite measures, and we believe that the use of this indicator will better enable us to identify patient safety events, conditions and complications arising during hospital stays. We also

note that, under the specifications for the 30-day mortality measures, if the primary discharge diagnosis at the receiving hospital matches the primary discharge diagnosis at the transferring hospital, the patients are included in the transferring hospital's mortality measure calculations. We believe this approach encourages coordination between hospitals and their referral networks. Further, we believe that this approach promotes the best interests of the patient because it does not create an incentive for hospitals to transfer patients who are critically ill or at high risk of dying.

Comment: Some commenters were concerned about the accuracy of claims-based quality measures. In particular, they questioned how claims-based quality measurements will be accurate given hospitals' technical and programming issues with the AHRQ measures, which are claims based rather than chart abstracted.

Response: Both the AHRQ measures and their data source have been endorsed by NQF. We note that other quality initiatives, such as the Medicare End-Stage Renal Disease Quality Incentive Program, require reporting on claims-based measures. While they have certain limitations, claims-based measures provide important information on hospital quality of care. We also note that hospitals are not required to submit data for the AHRQ measures; rather, the calculations are derived from Medicare fee-for-service claims data. Thus, neither technical nor programming issues should arise. For the reasons discussed above, we are only finalizing the two composite AHRQ measures.

Comment: Some commenters opposed our proposal to implement a subregulatory process for adding or retiring measures, calling on CMS to use full notice and comment rulemaking instead. A few commenters supported the proposed subregulatory process.

Response: We appreciate the comments, and understand that stakeholder input is critical to ensuring that the Hospital VBP program and measure set improves the quality of care and patient safety. As stated in the Hospital Inpatient VBP proposed rule (76 FR 2458 through 2459), we believe that we must act with all speed and deliberateness to expand the pool of measures used in the Hospital VBP program. This goal is supported by at least two Federal reports documenting that tens of thousands of patients do not receive safe care in the nation's hospitals.⁴

For this reason, we believe that we should adopt measures for the Hospital VBP program relevant to improving care, particularly as these measures are directed toward improving patient safety, as quickly as possible. Additionally, we believe that we should retire measures from the Hospital VBP program as quickly as possible to ensure that they do not detract from other measures that we believe will be more impactful in improving patient health. We believe that speed of implementation is a critical factor in the success and effectiveness of this program.

However, we are aware of stakeholders' concerns about the proposed subregulatory process. We understand commenters' point that notice-and-comment rulemaking is important to ensure that hospitals are aware of the applicable measures. In response to those comments, we will not finalize the proposed subregulatory process for adding or retiring measures. Instead, we have proposed in the FY 2012 IPPS/LTCH PPS proposed rule scheduled for publication on May 5, 2011 that we might choose to propose to simultaneously adopt one or more measures for both the Hospital IQR Program and the Hospital VBP program. We refer readers to that proposal for further information.

Comment: Some commenters suggested that we consider adopting quality measures covering more conditions to ensure that hospitals improve the quality of care that they furnish to all patients, not just those diagnosed with conditions covered by current quality measures.

Response: We thank commenters for the suggestion. The Affordable Care Act specifically names AMI, HF, PN, SCIP, HAIs and HCAHPS as initial topics to be included in the Hospital VBP program in FY 2013. We will consider other measures and conditions for inclusion in the Hospital VBP program for future years.

Comment: Some commenters strongly opposed use of the IQI stroke mortality measure, arguing that it is not adjusted for stroke severity.

Response: We thank commenters for their suggestion. The current methodology for this measure, including the risk adjustment methodology is NQF endorsed.

Comment: A number of commenters asked how hospitals will be scored and payments will be adjusted when measure specifications change.

Response: We understand that from time to time measure specifications require updating. We maintain the technical specifications by updating the Specifications Manual semiannually, or more frequently in unusual cases, and include detailed instructions and calculation algorithms for hospitals to use when collecting and submitting data on required measures. While many of these updates or changes do not impact the calculation of the measures, we are aware that substantive changes to the specifications for a measure may impact the score a hospital receives.

Comment: Some commenters asked if measure adoption will expand at a rate that keeps pace with hospital resources. Other commenters expressed concern that measure reporting might burden hospitals, while others suggested that we consider how difficult measures are for hospitals to improve upon.

Response: We are cognizant of the reporting burden on hospitals associated with the adoption of new measures under both the Hospital IQR program and the Hospital VBP program. In proposing to adopt new measures for the Hospital IQR program, which make them candidates for the Hospital VBP program, we have emphasized on many occasions that we take into consideration the burden that additional reporting will have on hospitals, and we seek, for that reason, to limit our proposals to adopt chart-abstracted measures. We also carefully consider whether the benefit that we believe will be realized from adopting additional measures (such as encouraging hospitals to improve their performance on those measures) will outweigh the burden associated with their collection.

Comment: Some commenters asked if 30-day readmission rates will be included in the Hospital VBP program.

Response: Measures of readmissions are statutorily excluded under section 1886(o)(2)(A) of the Act and therefore cannot be included in the Hospital VBP program.

Comment: A commenter asked if measure scores will be based on all-payer data or Medicare data only. Some commenters argued that the Hospital VBP program's measures should capture data for all patients, not Medicare patients only so that hospitals are ranked and incentivized according to their care for all patients, rather than for Medicare patients only.

Response: Measures in the clinical process and patient experience domains are scored using all-patient data while measures in the outcome domain will be scored using Medicare claims data only. Although we generally agree that all-patient data would be a preferable

⁴ See OEI-06-09-00090 "Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries." Department of Health and Human

Services, Office of Inspector General, November 2010. See also, 2009 National Healthcare Quality Report, pp. 107-122. "Patient Safety," Agency for Healthcare Research and Quality.

source of data for purposes of calculating all Hospital VBP measures, we currently do not have access to claims data submitted by hospitals to other payers.

Comment: Some commenters suggested that we more forcefully endorse the NQF process, expressing concern that marginalizing the NQF endorsement process might discourage hundreds of hard working volunteers.

Response: We work closely with the NQF on issues related to measure endorsement because that entity holds the contract under section 1890(a) of the Act. However, we note that in the case of a specified area or medical topic determined appropriate by the Secretary for which there is no NQF-endorsed measure, section 1886(b)(3)(B)(viii)(IX)(bb) of the Act allows us to specify a measure that is not NQF-endorsed so long as due consideration has been given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

Comment: Several commenters suggested that we consider adopting a central line-associated blood stream infections measure, a surgical site infections measure, and/or the National Database of Nursing Quality Indicators for the Hospital VBP program.

Response: We thank commenters for their input. We note that we have adopted a central line-associated blood stream infection measure (CLABSI) and surgical site infection measure (SSI) for the Hospital IQR program, and we anticipate proposing to adopt these measures for the Hospital VBP program in the future. The National Database of Nursing Quality Indicators (NDNQI) were previously considered for Hospital IQR program adoption (See 72 FR 47351), and we remain interested in these measures.

Comment: Some commenters asked us to explain why the current requirement by CMS for NHSN reporting begins with January 2011 events for CLABSI and with January 2012 events for SSI.

Response: In response to public comments on the FY 2011 IPPS/LTCH PPS proposed rule, we adopted one NHSN collected measure (the CLABSI measure) for the FY 2013 Hospital IQR payment determination (with reporting beginning with respect to January 2011 events) to allow hospitals to gain experience with the NHSN collection mechanism for one year before requiring hospitals to begin reporting a second measure (SSI) using that mechanism (75 FR 50202).

Comment: Some commenters argued that the FY 2013 measures do not reflect nurses' contributions to patient care.

Response: We disagree. Many of the process of care measures reflect the contributions of a broad range of healthcare professionals, including nurses. Furthermore, a number of measures rely heavily on nursing input and documentation. Additionally, one of the eight HCAHPS dimensions focuses exclusively on nurses' role in communicating with patients regarding their care.

Comment: One commenter suggested that we post measure information on *Hospital Compare* for 2 years prior to adopting them in the Hospital VBP program.

Response: We thank the commenter for the input. Although we acknowledge that section 1886(o)(2)(C)(i) provides, in part, that measures must be included on the Hospital Compare Web site for at least one year prior to the performance period, we believe that a one year period is sufficient to ensure that hospitals, Medicare beneficiaries and other stakeholders are fully aware of and familiar with the measures before they are added to the Hospital VBP program. We also believe that any further delay would unnecessarily postpone the adoption of important measures for the Hospital VBP program.

Comment: One commenter noted that care coordination measures are not included in the Hospital VBP measure set.

Response: We will consider this comment as we seek to expand the Hospital VBP measure set in the future.

Comment: One commenter called on us not to use the Krumholtz methodology for mortality measures. The commenter noted that this methodology has only been applied in very narrow ranges of diagnoses; may not be useful for comparing mortality rates; has weak explanatory power; omits variables that should be considered; and would be difficult if not impossible to generalize.

Response: We disagree. The risk-standardized mortality rates for the three proposed mortality measures are derived from administrative data for Medicare patients with a principal discharge diagnosis of AMI, HF, and PN from all acute care and critical access hospitals in the nation. The model used for calculation includes several variables and has a relatively high discrimination rate. As a result we believe this methodology is appropriate to use. Additionally, this methodology falls within the scope of the NQF-endorsement for the three proposed mortality measures.

Comment: One commenter asked us to clarify whether hospital data reported on *Hospital Compare* that are also

collected by the Joint Commission will continue to be included on *Hospital Compare*.

Response: Yes. Many of the AMI, Heart Failure, Pneumonia and SCIP measures reported to CMS for Hospital IQR and publicly reported on *Hospital Compare* are also collected and utilized by the Joint Commission. In addition, hospitals can voluntarily choose to allow CMS to publicly report the Joint Commission's children's asthma care measures, which are not part of Hospital IQR, on *Hospital Compare*. We will continue to publicly report all Hospital IQR measures and other quality information on *Hospital Compare*.

Comment: One commenter questioned whether the proposed clinical process of care measures have been tested in older patients and women to assure applicability to Medicare's patient subpopulations.

Response: The clinical process of care measures proposed for the Hospital VBP program have been tested and used in all patients 18 years and older which includes older patients and women if they meet criteria for inclusion in the measure.

Comment: Some commenters recommended that CMS and outside experts study the measures' actual impact on patients and caregivers. Commenters also expressed concern about possible unintended consequences for patient care due to measure design, such as some hospitals refusing to admit high-risk patients in an effort to improve their Total Performance Score.

Response: We thank commenters for their input. We intend to monitor the initial impacts of the Hospital VBP program, including its impacts on costs, quality, outcomes, and patient experiences with care. We believe the Hospital VBP program represents a significant next step in aligning payment with the quality of care delivered to beneficiaries. We firmly believe that these efforts will increase the quality of care provided, resulting in improved health outcomes. However, we will monitor and evaluate the impact of the Hospital VBP program on access to and quality of care, including monitoring any unintended consequences.

Comment: One commenter stated that the proposal to use electronic submission for measures in future years was misaligned with one of the potential future measures. The measure, "median time from admit decision time to time of departure from the emergency department (ED) for ED patients admitted to inpatient status" differs from the specifications put forth by

HITSP (Health Information Technology Standards) which specifies the measure as, Admit Decision Time to ED Departure Time. The difference is that the former does not allow for the use of Admit Orders Date (or Admit Orders Time) in the measures specification while the HITSP specifications do allow the use of this data.

Response: We agree that the measure specifications for “median time from admit decision time to time of departure from the emergency department (ED) for ED patients admitted to inpatient status” require manual chart abstraction, and is specified slightly different than electronic health record version of the measure. This is because of the availability of the data. When abstracting data manually, a human abstractor uses specific guidelines for

abstraction. Admit order date/time are not included in the chart abstracted version as the intent of the measure is to calculate throughput time (that is, how long the patient is in the ED) which is calculated from admit decision to departure from the Emergency Department. The admit decision time is generally found in a note written in the chart, and therefore, a human abstractor can interpret that data element per the guidelines for abstractions. In contrast, admit date/time are used in the electronic specifications as the two fields are readily available in the electronic health record (EHR), and there is no human interpretation. At this time, data from a progress note is not considered a discreet data element and therefore cannot be used for EHR abstraction.

After consideration of public comments, we are finalizing our proposed definition of “topped out” for purposes of measure selection under the Hospital VBP program. We will use this definition to inform our measure proposals for future Hospital VBP program years and will use the most recently available data at the time to conduct our analysis. Additionally, we are finalizing our proposal to adopt 12 of the 17 proposed clinical process of care measures for the FY 2013 Hospital VBP program, but for the reasons discussed above, are not finalizing our proposal to adopt the following measures: PN–2, PN–7, AMI–2, HF–2 and HF–3.

Table 2 lists the 13 measures we are finalizing for the FY 2013 Hospital VBP measure set.

TABLE 2—FINAL MEASURES FOR FY 2013 HOSPITAL VBP PROGRAM

| Measure ID | Measure description |
|--|--|
| Clinical Process of Care Measures | |
| Acute myocardial infarction | |
| AMI–7a | Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival. |
| AMI–8a | Primary PCI Received Within 90 Minutes of Hospital Arrival. |
| Heart Failure | |
| HF–1 | Discharge Instructions. |
| Pneumonia | |
| PN–3b | Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital. |
| PN–6 | Initial Antibiotic Selection for CAP in Immunocompetent Patient. |
| Healthcare-associated infections | |
| SCIP–Inf–1 | Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision. |
| SCIP–Inf–2 | Prophylactic Antibiotic Selection for Surgical Patients. |
| SCIP–Inf–3 | Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time. |
| SCIP–Inf–4 | Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose. |
| Surgeries | |
| SCIP–Card–2 | Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period. |
| SCIP–VTE–1 | Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered. |
| SCIP–VTE–2 | Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery. |
| Patient Experience of Care Measures | |
| HCAHPS | Hospital Consumer Assessment of Healthcare Providers and Systems Survey. ⁵ |

With respect to the FY 2014 Hospital VBP measure set, we are finalizing our proposal to adopt the three 30-day mortality claims-based measures, MORT–30–AMI, MORT–30–HF, and MORT–30–PN, as well as the 8

proposed HAC measures. In light of the public comments we received regarding the proposed AHRQ measures and as discussed above, we are only finalizing the 2 composite measures: Complication/patient safety for selected

indicators (composite) and Mortality for selected medical conditions (composite). The measures that we are finalizing in this final rule for the FY 2014 Hospital VBP Program are listed in Table 3 below.

⁵ Proposed dimensions of the HCAHPS survey for use in the FY 2013 Hospital VBP program are: Communication with Nurses, Communication with

Doctors, Responsiveness of Hospital Staff, Pain Management, Communication about Medicines, Cleanliness and Quietness of Hospital Environment,

Discharge Information and Overall Rating of Hospital.

TABLE 3—FINALIZED OUTCOME MEASURES FOR THE FY 2014 HOSPITAL VBP PROGRAM

Mortality Measures (Medicare Patients):

- Acute Myocardial Infarction (AMI) 30-day mortality rate.
- Heart Failure (HF) 30-day mortality rate.
- Pneumonia (PN) 30-day mortality rate.

AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) Composite Measures:

- Complication/patient safety for selected indicators (composite).
- Mortality for selected medical conditions (composite).

Hospital Acquired Condition Measures:

- Foreign Object Retained After Surgery.
- Air Embolism.
- Blood Incompatibility.
- Pressure Ulcer Stages III & IV.
- Falls and Trauma: (Includes: Fracture Dislocation Intracranial Injury Crushing Injury Burn Electric Shock).
- Vascular Catheter-Associated Infection.
- Catheter-Associated Urinary Tract Infection (UTI).
- Manifestations of Poor Glycemic Control.

As noted above, we have proposed in the FY 2012 IPPS/LTCH PPS proposed rule scheduled for publication on May 5, 2011 to adopt an additional measure, Medicare spending per beneficiary, for the FY 2014 Hospital VBP program. We also intend to propose to adopt additional measures for the FY 2014 Hospital VBP program in the CY 2012 OPPTS proposed rule.

E. Performance Standards

To determine what the performance standard for each proposed clinical process of care measure and the proposed HCAHPS measure should be for purposes of the FY 2013 Hospital VBP program, we analyzed the most reliable and current hospital data that we had on each of these measures by virtue of the Hospital IQR program. Because we proposed to adopt a performance period that was less than a full year for FY 2013, we were sensitive to the fact that hospital performance on the proposed measures could be affected by seasonal variations in patient mix, case severity, and other factors. To address this potential variation and ensure that the hospital scores reflect their actual performance on the measures, we believe that the performance standard for each clinical process of care measure and HCAHPS should be based on how well hospitals performed on the measure during the same time period in the applicable baseline period. In determining what three-quarter baseline period would be the most appropriate to propose to use for the FY 2013 Hospital VBP program, we wanted to ensure that the baseline would be as close in time to the proposed performance period as possible. We stated our belief that selecting a three-quarter baseline period from July 1, 2009 to March 31, 2010 will enable us to achieve this goal. We also believe that an essential goal of the

Hospital VBP program is to provide incentives to all hospitals to improve the quality of care that they furnish to their patients. In determining what level of hospital performance would be appropriate to select as the performance standards for each measure, we focused on selecting levels that would challenge hospitals to continuously improve or maintain high levels of performance.

As required by Section 1886(o)(3)(D), we specifically considered hospitals' practical experience with the measures, particularly through the Hospital IQR program, examining how different achievement and improvement thresholds would have historically impacted hospitals, how hospital performance may have changed over time, and how hospitals could continue to improve.

We proposed to set the achievement performance standard (achievement threshold) for each proposed FY 2013 Hospital VBP measure at the median of hospital performance (50th percentile) during the baseline period of July 1, 2009 through March 31, 2010. As proposed in the Hospital Inpatient VBP proposed rule (76 FR 2463 through 2464), hospitals would receive achievement points only if they exceed the achievement performance standard and could increase their achievement score based on higher levels of performance. We believe these achievement performance standards represent achievable standards of excellence and will reward hospitals for meritorious performance on quality measures. We also proposed to set the improvement performance standard (improvement threshold) for each measure at each specific hospital's performance on the measure during the baseline period of July 1, 2009 through March 31, 2010. We believe that these proposed improvement performance

standards ensure that hospitals will be adequately incentivized to improve.

We proposed to set the achievement performance standard (achievement threshold) for each of the proposed FY 2014 Hospital VBP mortality measures at the median of hospital performance (50th percentile) during the baseline period. We proposed to set the improvement performance standard (improvement threshold) for each mortality measure at each specific hospital's performance on each measure during the baseline period of July 1, 2008 to December 31, 2009. The comments we received on these proposals and our responses are set forth below.

Comment: A number of commenters suggested that we publish baseline achievement thresholds and benchmarks for clinical process measures and HCAHPS dimensions on *Hospital Compare*.

Response: The finalized achievement thresholds and benchmarks that apply to the FY 2013 Hospital VBP program are provided in Table 4 of this final rule. We will consider the commenters suggestion to publish baseline achievement thresholds and benchmarks on *Hospital Compare* in the future.

Comment: One commenter requested that CMS clarify whether hospitals lacking the minimum number of patients or measures would be included in baseline period calculations of thresholds and benchmarks.

Response: The achievement thresholds and benchmarks will be calculated using data from a baseline period comparable in length to the performance period. For this reason, we believe that we should also use the same minimums for purposes of those calculations.

Comment: One commenter suggested that we compare performance among similar hospitals rather than against

national data. Other commenters asked if CMS was going to adjust the baseline period data based on any factors such as geographic region.

Response: We believe that achievement thresholds and benchmarks based on national data provide balanced, appropriate standards of high quality care for hospitals to work towards under the Hospital VBP program. Some groups of hospitals may perform better or worse than other hospitals on certain measures, but we do not believe it would appropriate to raise or lower the performance standards based on such observations. For example, we do not wish to lower the performance standards for a hospital simply because average performance in its local region is subpar compared to national performance. Similarly, we do not wish to raise or lower the performance standards for large

hospitals, teaching hospitals, or others based on any observations that classes of hospitals differed in their average performance on individual measures. We note that consumers will be able to compare geographically and demographically similar hospitals' performance on measures as they currently do on the *Hospital Compare* Web site.

Comment: One commenter asked us to clarify the baseline periods for Hospital VBP program years after FY 2013.

Response: We intend to propose all future baseline periods in future rulemaking and specifically, intend to propose the FY 2014 Hospital VBP payment determination baseline period in the CY 2012 OPPS rule.

Comment: One commenter asked how CMS will address hospital mergers that occur during the performance period.

Response: The issue of how to address the calculation of the total performance score in the context of hospital mergers will be the subject of future rulemaking.

After considering the public comments, we are finalizing the proposed definitions of the achievement performance standard (achievement threshold) and the improvement performance standard (improvement threshold) for the FY 2013 Hospital VBP program as displayed below in Table 4. Because our process for validating the proposed baseline period of data was not yet complete at the time we issued the proposed rule, we were unable to provide the precise achievement threshold values; instead we provided example achievement performance standards. We also stated that these values would be specified in the final rule (76 FR 2464), and they are shown below.

TABLE 4—ACHIEVEMENT THRESHOLDS THAT APPLY TO THE FY 2013 HOSPITAL VBP PROGRAM MEASURES

| Measure ID | Measure description | Performance standard (achievement threshold) |
|--|--|--|
| Clinical Process of Care Measures | | |
| AMI-7a | Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival | 0.6548 |
| AMI-8a | Primary PCI Received Within 90 Minutes of Hospital Arrival | 0.9186 |
| HF-1 | Discharge Instructions | 0.9077 |
| PN-3b | Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital. | 0.9643 |
| PN-6 | Initial Antibiotic Selection for CAP in Immunocompetent Patient | 0.9277 |
| SCIP-Inf-1 | Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision | 0.9735 |
| SCIP-Inf-2 | Prophylactic Antibiotic Selection for Surgical Patients | 0.9766 |
| SCIP-Inf-3 | Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time | 0.9507 |
| SCIP-Inf-4 | Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose | 0.9428 |
| SCIP-VTE-1 | Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered | 0.9500 |
| SCIP-VTE-2 | Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery. | 0.9307 |
| SCIP-Card-2 | Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period. | 0.9399 |
| Patient Experience of Care Measures | | |
| HCAHPS | Communication with Nurses | 75.18% |
| | Communication with Doctors | 79.42% |
| | Responsiveness of Hospital Staff | 61.82% |
| | Pain Management | 68.75% |
| | Communication About Medicines | 59.28% |
| | Cleanliness and Quietness of Hospital Environment | 62.80% |
| | Discharge Information | 81.93% |
| | Overall Rating of Hospital | 66.02% |

We are also finalizing the achievement thresholds for the three

mortality measures, (displayed as survival rates) in Table 5 below based

on a 12-month baseline period from July 1, 2009 to June 30, 2010:

TABLE 5—ACHIEVEMENT THRESHOLDS FOR THE FY 2014 HOSPITAL VBP PROGRAM MORTALITY OUTCOME MEASURES (DISPLAYED AS SURVIVAL RATES)

| Measure ID | Measure description | Performance standard (achievement threshold) |
|-----------------------------------|---|--|
| Mortality Outcome Measures | | |
| MORT-30-AMI | Acute Myocardial Infarction (AMI) 30-Day Mortality Rate | 84.8082% |
| MORT-30-HF | Heart Failure (HF) 30-Day Mortality Rate | 88.6109% |
| MORT-30 PN | Pneumonia (PN) 30-Day Mortality Rate | 88.1795% |

F. Methodology for Calculating the Total Performance Score

1. Statutory Provisions

Section 1886(o)(5)(A) of the Act requires the Secretary to develop a methodology for assessing each hospital's total performance based on performance standards with respect to the measures selected for a performance period. Using such methodology, the Secretary must provide for an assessment for each hospital for each performance period.

Section 1886(o)(5)(B) of the Act sets forth 5 requirements related to the scoring methodology developed by the Secretary under section 1886(o)(5)(A). Specifically, section 1886(o)(5)(B)(i) requires the Secretary to ensure that the application of the scoring methodology results in an appropriate distribution of value-based incentive payments among hospitals receiving different levels of hospital performance scores, with hospitals achieving the highest hospital Total Performance Scores receiving the largest value-based incentive payments.

Section 1886(o)(5)(B)(ii) provides that, under the methodology, the hospital Total Performance Score must be determined using the higher of the applicable hospital's achievement or improvement score for each measure. Section 1886(o)(5)(B)(iii) requires that the hospital scoring methodology provide for the assignment of weights for categories of measures as the Secretary deems appropriate. Section 1886(o)(5)(B)(iv) prohibits the Secretary from setting a minimum performance standard in determining the hospital performance score for any hospital. Finally, section 1886(o)(5)(B)(v) requires that the hospital performance score for a hospital reflect the measures that apply to the hospital.

2. Additional Factors for Consideration

As discussed in the Hospital Inpatient VBP Program proposed rule, in addition to statutory requirements, we also considered several additional factors when developing the proposed performance scoring methodology for

the Hospital VBP program. First, we stated our belief that it is important that the performance scoring methodology is straightforward and transparent to hospitals, patients, and other stakeholders.

Hospitals must be able to clearly understand performance scoring methods and performance expectations to maximize quality improvement efforts.

The public must understand performance score methods to utilize publicly reported information when choosing hospitals.

Second, we stated our belief that the scoring methodologies for all Medicare Value-Based Purchasing programs, including (but not limited to) the End Stage Renal Disease Quality Incentive Program should be aligned as appropriate given their specific statutory requirements. This alignment will facilitate the public's understanding of quality information disseminated in these programs and foster more informed consumer decision making about health care. Third, we stated our belief that differences in performance scores must reflect true differences in performance. In order to ensure this in the proposed Hospital VBP Program, we assessed the quantitative characteristics of the measures we are proposing to use to calculate the Total Performance Score, including the current state of measure development, distribution of current hospital performance in the proposed measure set, number of measures, and the number and grouping of measure domains. Fourth, we stated that we must appropriately measure both quality achievement and improvement in the Hospital VBP program. Section 1886(o)(5)(B)(ii) of the Act specifies that performance scores under the Hospital VBP program be calculated utilizing the higher of achievement and improvement scores for each measure; that explicit direction has implications for the design of the performance scoring methodology. We must also consider the impact of performance scores utilizing

achievement and improvement on hospital behavior due to payment implications. Fifth, we stated that we wished to eliminate unintended consequences for rewarding inappropriate hospital behavior and outcomes to patients in our performance scoring methodology. Sixth, we stated that we wished to utilize the most currently available data to assess hospital improvement in a performance score methodology. We believe that more current data would result in a more accurate performance score, but recognize that hospitals require time to abstract and collect quality information. We also require time to process this information accurately.

The methodology proposed in the Hospital Inpatient VBP Program proposed rule for calculating the improvement score relies on a comparison of the hospital's performance during the performance period against its performance during a baseline period rather than a comparison of the hospital's performance during a particular year against its performance during a previous year (as was outlined in the 2007 Report to Congress).

We stated that we planned to propose future annual updates to the baseline period through future rulemaking. We recognize that comparing a payment year's performance period with the previous year's performance period may be a better estimate of incremental improvement.

In the Hospital Inpatient VBP Program proposed rule, we solicited comment on the merits and impact of all of the factors related to our performance score methodology alternatives, including the choice of how to define the baseline year.

We welcomed suggestions on improving the simplicity of the Hospital VBP program performance score methodology and its alignment with other CMS quality initiatives.

3. Background

In November 2007, CMS published the 2007 Report to Congress.⁶ In addition to laying the groundwork for hospital value-based purchasing, the 2007 Report to Congress analyzed and presented a potential performance scoring methodology (called the Performance Assessment Model) for the Hospital VBP program. The Performance Assessment Model combines scores on individual measures across different quality categories or “domains” (for example, clinical process of care, patient experience of care) to calculate a hospital’s Total Performance Score.

The Performance Assessment Model provides a methodology for evaluating a hospital’s performance on each measure based on the higher of an attainment score in the measurement period or an improvement score, which is determined by comparing the hospital’s current measure score with a baseline period of performance.

The use of an improvement score is intended to provide an incentive for a broad range of hospitals that participate in the Hospital VBP program by awarding points for showing improvement on measures, not solely for outperforming other hospitals.

Under the Performance Assessment Model, measures are grouped into domains, for example, clinical process of care (which could include AMI, HF, PN, and SCIP) and patient experience of care (for example, HCAHPS).

A score is calculated for each domain by combining the measure scores within that domain, weighting each measure equally. The domain score reflects the percentage of points earned out of the total possible points for which a hospital is eligible. A hospital’s Total Performance Score is determined by aggregating the scores across all domains. In aggregating the scores across domains, the domains could be weighted equally or unequally, depending on the policy goals. The Total Performance Score is then translated into the percentage of the Hospital VBP incentive payment earned using an exchange function, which aligns payments with desired policy goals.

4. FY 2013 Hospital VBP Program Scoring Methodology

As stated in the Hospital Inpatient VBP Program proposed rule, we believe that the Performance Assessment Model presented and analyzed in the 2007 Report to Congress provides a useful

foundation for developing the FY 2013 Hospital VBP program performance scoring methodology that comports with the requirements in section 1886(o) of the Act. The Performance Assessment Model outlines an approach that we believe is well-understood by patient advocates, hospitals and other stakeholders, was developed during a year-long process that involved extensive stakeholder input, and was presented by us to Congress. Since issuing the report, we have conducted further, extensive research on a number of important methodology issues for the Hospital VBP program, including the impact of topped-out measures on scoring, appropriate case minimum thresholds for measures, appropriate measure minimum thresholds per domain, and other issues required to ensure a high level of confidence in the scoring methodology (all of which we discussed in this Final Rule).

After carefully reviewing and evaluating a number of potential performance scoring methodologies for the Hospital VBP program, we proposed to use a Three-Domain Performance Scoring Model, although we proposed that only two domains would receive weight in FY 2013. This methodology is very similar to the Performance Assessment Model; however, it incorporates an outcome measure domain in addition to the clinical process of care and patient experience of care domains.

While we did not propose to adopt any outcome measures for the FY 2013 Hospital VBP program, we proposed to adopt these measures as part of an outcome measures domain for FY 2014. The proposed Three-Domain Performance Scoring Model includes setting benchmarks and thresholds, scoring hospitals on achievement and improvement for three domains (clinical process of care, patient experience of care, and outcomes), weighting the domains, and calculating the hospital Total Performance Score.

a. Setting Performance Benchmarks and Thresholds

As stated above, section 1886(o)(5)(B)(ii) of the Act requires that under the Hospital VBP program performance scoring methodology, hospital performance scores be determined using the higher of achievement or improvement scores for each measure. With respect to scoring hospital performance on the proposed clinical process of care and outcome measures, we propose to use a methodology based on the scoring methodology set forth in the 2007

Report to Congress Performance Assessment Model.

In the Hospital Inpatient VBP Program proposed rule, we proposed that hospitals will receive points along an achievement range, which is a scale between the achievement threshold (the minimum level of hospital performance required to receive achievement points) and the benchmark (the mean of the top decile of hospital performance during the baseline period). In determining the improvement score, we proposed that hospitals will receive points along an improvement range, which is a scale between the hospital’s prior score on the measure during the baseline period and the benchmark.

Under this methodology, we proposed to establish the benchmarks and achievement thresholds for the FY 2013 Hospital VBP program using national data from a three-quarter baseline period of July 1, 2009 through March 31, 2010.

To define a high level of hospital performance on a given measure, we proposed to set the benchmark at the mean of the top decile of hospital scores on the clinical process of care, and outcome measures during the baseline period. For the patient experience of care measures, we proposed to set the benchmark at the 95th percentile of hospital performance during the baseline period. We stated that this would ensure that the benchmark represents demonstrably high but achievable standards of excellence; in other words, the benchmark will reflect observed scores for the highest-performing hospitals on a given measure.

We proposed to set the achievement threshold at the 50th percentile of hospital performance on the measure during the baseline period. Hospitals will have to score at or above this achievement threshold to earn achievement points.

Comment: We received many comments stating that the proposed benchmarks were too high. Some commenters stated that this was evidenced by the fact that for many of the proposed measures, performance at the benchmark would require hospitals to achieve 100 percent success on the measure. In addition to stating that this level of performance could be too difficult for some hospitals to achieve, some commented that this would serve as an inappropriate benchmark in light of the fact that the measures do not incorporate all clinically relevant exclusion criteria based on every patient’s particular situation. One commenter supported setting the benchmark at the 80th percentile in the

⁶The report may be found at <http://www.cms.gov/AcuteInpatientPPS/downloads/HospitalVBPPlanRTCFINALSUBMITTED2007.pdf>.

baseline period for the patient experience of care domain to ensure that every hospital has a chance of exceeding the benchmark.

Response: As we stated in the Hospital Inpatient VBP program proposed rule, the benchmark is intended to represent an empirically-demonstrated level of excellent performance during the baseline period (76 FR 2471), and we believe that this standard represents achievable excellence for all hospitals during the performance period. We recognize that some of the proposed clinical process of care measures do not meet our criteria for topped-out status but still have a benchmark of 100 percent success.

We consider a benchmark to be an empirically-observed level of excellent performance to which we believe hospitals generally should aspire. Using the proposed definition of a benchmark (mean value for the top 10 percent of hospitals during the baseline period), typically only about 5 percent of all hospitals will be observed to have achieved the benchmark level for an individual measure during the baseline period. However, any number of hospitals could score at or above the benchmark during the performance period, and under the proposed performance scoring methodology, such hospitals would receive the full 10 points on the measure. A benchmark level of 100 percent is a special case in which at least 10 percent of hospitals achieved a 100 percent success rate on the measure during the baseline period. When a benchmark for a measure is 100 percent, at least half of all reporting hospitals will receive at least some achievement points on the measure (assuming no general degradation of performance among hospitals), which is the same as every other measure. Arbitrarily setting benchmark levels (for example, at 80th percentile) would undermine its empirically-based definition, as would, for example, arbitrarily setting the benchmark at 100 percent for every measure.

As stated above, when a benchmark is 100 percent, at least 10 percent of hospitals would have to have achieved 100 percent on the measure during the baseline period; this suggests that achieving 100 percent success on a measure is not prohibitively difficult as

a portion of hospitals will have actually achieved that standard. In rare instances, a hospital might not provide a process covered by a clinical process of care measure because none of those measures currently allow for blanket discretionary exclusions that would enable a hospital to exclude a case based on any conceivable set of circumstances. As a result, a measure calculation might capture a rare case that arguably could have been excluded, such as a case where the patient was allergic to all indicated drugs, or the patient refused services and/or asked to be discharged against medical advice. As new information becomes available concerning possible unintended consequences of measures, their specifications can be reviewed and revised as necessary, including the addition of supplemental exclusion criteria. This process is ongoing and, we believe, is a better way to deal with rare cases instead of setting a benchmark at an indiscriminate, low value such as the 80th percentile.

All measures have limitations and it is therefore possible that a hospital, in the unfortunate but rare instance in which it provides what it believes is the best quality of care, will fail to achieve the benchmark. It is partly for this reason that we proposed to set the achievement performance standard for each measure at the achievement threshold rather than the benchmark. We also emphasize that a hospital's value-based incentive payment is based on its Total Performance Score, not on performance at the benchmark for every measure. Our analysis indicates that small differences in points on a single measure caused by missing the benchmark have little impact on the distribution of incentive payments and rank correlation of hospitals.

Comment: One commenter argued that high-performing hospitals "who already beat national benchmarks" have incentives to perform poorly "in the short term" so that they can then win improvement points and receive higher payments.

Response: We assume that the commenter is suggesting a scenario in which a high-performing hospital might attempt to intentionally score lower on one or more measures during the baseline period in order to score

improvement points during the performance period. First, we expect all Medicare hospitals to provide high-quality care to their patients regardless of whether they are included in the Hospital VBP program or not. Furthermore, we disagree that high-achieving hospitals would have an incentive to lower their performance in order to win improvement points in the Hospital VBP program. We note that under the proposed Three-Domain Scoring Methodology, the maximum number of achievement points possible on a given measure is higher (10 points) for achieving the benchmark, than the maximum number of improvement points possible (9 points). It is difficult to envision a scenario in which a high-performing hospital would earn more overall points on a measure (that is, the higher of achievement and improvement points) by intentionally lowering its performance during the baseline period and increasing performance during the performance period versus simply maintaining high performance during the baseline period and seeking to maintain or improve on that performance during the performance period. However, we plan to closely monitor and evaluate the impact of the Hospital VBP program on the quality of care provided to Medicare beneficiaries.

After consideration of the public comments, we are finalizing as proposed the definition of the benchmark as the mean of the top decile of hospital performance during the baseline period for the clinical process of care and outcome measures. In response to numerous public comments (further discussed below) requesting greater uniformity between the scoring of clinical process of care measures, outcome measures, and HCAHPS dimensions, we are also finalizing the definition of the benchmark as the mean of the top decile of performance during the baseline period for the patient experience of care domain.

The finalized benchmarks for the clinical process of care and patient experience of care domains for the FY 2013 Hospital VBP Program are provided below in Table 6. The finalized benchmarks for the three 30-day mortality outcome measures for the FY 2014 Hospital VBP Program are provided below in Table 7.

TABLE 6—BENCHMARKS THAT APPLY TO THE FY 2013 HOSPITAL VBP PROGRAM MEASURES

| Measure ID | Measure description | Benchmark |
|--|---|-----------|
| Clinical Process of Care Measures | | |
| AMI-7a | Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival | 0.9191 |
| AMI-8a | Primary PCI Received Within 90 Minutes of Hospital Arrival | 1.0 |

TABLE 6—BENCHMARKS THAT APPLY TO THE FY 2013 HOSPITAL VBP PROGRAM MEASURES—Continued

| Measure ID | Measure description | Benchmark |
|-------------------|--|-----------|
| HF-1 | Discharge Instructions | 1.0 |
| PN-3b | Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital. | 1.0 |
| PN-6 | Initial Antibiotic Selection for CAP in Immunocompetent Patient | 0.9958 |
| SCIP-Inf-1 | Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision | 0.9998 |
| SCIP-Inf-2 | Prophylactic Antibiotic Selection for Surgical Patients | 1.0 |
| SCIP-Inf-3 | Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time | 0.9968 |
| SCIP-Inf-4 | Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose | 0.9963 |
| SCIP-VTE-1 | Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered | 1.0 |
| SCIP-VTE-2 | Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery. | 0.9985 |
| SCIP-Card-2 | Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period. | 1.0 |
| HCAHPS | Communication With Nurses | 84.70% |
| | Communication With Doctors | 88.95% |
| | Responsiveness of Hospital Staff | 77.69% |
| | Pain Management | 77.90% |
| | Communication About Medicines | 70.42% |
| | Cleanliness and Quietness of Hospital Environment | 77.64% |
| | Discharge Information | 89.09% |
| | Overall Rating of Hospital | 82.52% |

TABLE 7—FINAL BENCHMARKS FOR THE FY 2014 HOSPITAL VBP PROGRAM MORTALITY OUTCOME MEASURES (DISPLAYED AS SURVIVAL RATES)

| Measure ID | Measure description | Benchmark |
|-----------------------------------|---|-----------|
| Mortality Outcome Measures | | |
| MORT-30-AMI | Acute Myocardial Infarction (AMI) 30-Day Mortality Rate | 86.9098% |
| MORT-30-HF | Heart Failure (HF) 30-Day Mortality Rate | 90.4861% |
| MORT-30 PN | Pneumonia (PN) 30-Day Mortality Rate | 90.2563% |

b. Calculating Achievement, Improvement Points, and Consistency Points

We proposed a scoring methodology that would assign an achievement and improvement score to each hospital for each of the clinical process of care and outcome measures that apply to the hospital, and for each HCAHPS dimension. We proposed that a hospital will earn 0–10 points for achievement based on where its performance for the measure fell relative to the achievement threshold and the benchmark.

We proposed that a hospital would earn 0–9 points based on how much its performance on the measure during the performance period improved from its performance on the measure during the baseline period. A unique improvement range for each measure would be established for each hospital that defines the distance between the hospital's baseline period score and the national benchmark for the measure.

The scoring methodology we proposed to implement for HCAHPS includes achievement, improvement, and consistency points. We proposed that for the FY 2013 Hospital VBP program hospitals may earn from 0–20

consistency points based on the lowest of its 8 HCAHPS dimension scores.

We refer readers to the Hospital Inpatient VBP Program proposed rule (76 FR 2470–2487) for the details of the proposed scoring methodologies and examples of how hospital total performance scores are calculated under the Three-Domain Performance Scoring Model.

Our responses to public comments are provided below.

Comment: One commenter asked us to outline the scoring model for outcome measures before proposing their use.

Response: As detailed in the Hospital Inpatient VBP Program proposed rule (76 FR 2466), we proposed that the outcome domain would be scored using the same methodology that we proposed to use to score the clinical process of care domain. That methodology is finalized in this final rule.

Comment: We received numerous comments asking CMS to more closely align the scoring methodologies and formulas used to calculate points in the clinical process of care and patient experience of care domains. Commenters specifically suggested that we use percentages rather than

percentiles in the HCAHPS scoring methodology and questioned why we chose different methodologies to calculate the benchmarks in the clinical process of care and patient experience of care domains. These commenters suggested that the patient experience of care scoring model laid out in the proposed rule was too complex and differed too greatly from the clinical process of care scoring model. Commenters also suggested that CMS create greater uniformity in Hospital VBP scoring formulas across the domains, including the formulation of the benchmarks.

Response: In the initial analyses of HCAHPS data for the 2007 Report to Congress, which was based on about 500 hospitals and three quarters of HCAHPS results, we found that a few small hospitals achieved much higher HCAHPS scores than most. Thus, a non-percentile approach for HCAHPS would have led to a skewed distribution of achievement points (most clustered at the low end and few high scores). At the time of the 2007 Report to Congress, the percentile approach did a better job of spreading out the achievement points.

When we re-examined this issue in response to comments to the Hospital Inpatient VBP Program proposed rule, we found that our current data, which is based upon over 3,000 hospitals with several years of experience using HCAHPS, show that the distribution of scores has changed over time and that there is no longer a skewed distribution of achievement points using a non-percentile approach.

Therefore, we will abandon the use of percentiles for calculating the benchmark in HCAHPS in Hospital VBP and instead will finalize the use of percentages of top-box scores in our HCAHPS calculations. As stated below, we believe that this change will both simplify the calculation of HCAHPS

scores and will make HCAHPS scoring more comparable to that of the clinical process of care and outcome measures in the Hospital VBP program.

In response to numerous comments received, we are finalizing the definition of the benchmark for each measure in the patient experience of care domain as the mean of the top decile of hospital performance on the measure (for purposes of the HCAHPS measure, this would be each HCAHPS dimension) during the baseline period. We believe this policy results in more uniform scoring methodologies across domains and appropriately reflects our decision to abandon the use of percentiles in the patient experience of care domain. We have made technical changes to the

formulas used to calculate achievement and improvement points reflecting these finalized policies below.

As shown in Table 8, for each of the 8 HCAHPS dimensions we are finalizing for the FY 2013 Hospital VBP program, scores will be based on the publicly-reported proportions of best category (“top-box”) responses. (As noted above, top-box responses, as publicly reported on the *Hospital Compare* Web site, are the most positive responses to HCAHPS survey questions and are adjusted for patient-mix and survey mode). Please note that the “Cleanliness and Quietness” dimension is the average of the publicly reported stand-alone “Cleanliness” and “Quietness” ratings.

TABLE 8—EIGHT HCAHPS DIMENSIONS FOR THE FY 2013 HOSPITAL VBP PROGRAM

| Dimension (composite or stand-alone item) | Constituent HCAHPS survey items |
|--|---|
| 1. Communication with Nurses (% “Always”) | Nurse—Courtesy/Respect. Nurse—Listen. Nurse—Explain. |
| 2. Communication with Doctors (% “Always”) | Doctor—Courtesy/Respect. Doctor—Listen. Doctor—Explain. |
| 3. Responsiveness of hospital staff (% “Always”) | Bathroom Help. Call Button. |
| 4. Pain management (% “Always”) | Pain Control. Help with Pain. |
| 5. Communication about Medicines (% “Always”) | New Medicine—Reason. New Medicine—Side Effects. |
| 6. Hospital Cleanliness & Quietness (% “Always”) | Cleanliness and Quietness. Discharge—Help. |
| I. Discharge Information (% “Yes”). | |
| 7. Overall rating (% “9 or 10”) | Discharge—Systems. |
| 8. Overall Rating of Hospital (% “9 or 10”) | Overall Rating. |

Comment: Some commenters recommended that HCAHPS be excluded from the Hospital VBP program until an examination and public vetting of the scoring methodology takes place.

Response: The scoring methodology proposed for HCAHPS was part of the original Report to Congress in 2007 and was subject to stakeholder input through multiple listening sessions. The final methodology described in this final rule is more similar to the clinical process of care scoring methodology since it now uses percentages not percentiles. The notice and comment rulemaking process for this rule has allowed the public to vet CMS’ proposals. In response to public comments, CMS is making an additional change to the HCAHPS scoring methodology (this change is discussed below).

Comment: Many commenters opposed our proposal to use consistency points in the patient experience of care domain. Others suggested that we

consider using consistency points in the clinical process of care domain.

Response: For reasons detailed in the 2007 Report to Congress and the Hospital Inpatient VBP Program proposed rule (76 FR 2472), we believe that consistency points recognize and reward consistent achievement across HCAHPS dimensions. By offering hospitals additional incentives to achieve across all HCAHPS dimensions, consistency points promote wider systems changes within hospitals to improve quality. We will consider developing consistency points for the clinical process of care domain in the future. However, we note that applying consistency points in that domain would be methodologically challenging. All hospitals must report all dimensions of the HCAHPS survey, and for that reason, all hospitals will earn scores on all dimensions on which we can use to fairly reward consistency. Applying consistency points to the clinical process of care domain when different numbers of measures might apply to

different hospitals may result in unfair distributions of consistency points. We welcome input on an appropriate methodology for clinical process of care consistency points.

Comment: A number of commenters suggested technical changes to the formulas proposed to be used to calculate achievement and improvement points. In suggesting these technical changes, commenters pointed out that under the proposed formulas for clinical process of care and outcome measure scoring, a hospital with a score equal to the achievement threshold would receive a score of .5, which rounds to 1, while a hospital with a score equal to the benchmark would receive a score of 9.5, which rounds to 10. Commenters pointed out that this formula effectively creates a scale of 0.5 to 9.5 instead of a scale from 1 to 10. These commenters urged CMS to modify the formula so that the scale “starts” at 1 instead of 0.5, and urged CMS to make similar modifications for the formula used to calculate improvement points for the

clinical process of care and outcome measures.

Response: The formula for achievement points reflects the description of how points are assigned to hospitals with scores between the threshold and benchmark values. For such hospitals, the range between the achievement threshold and benchmark values is partitioned into 9 equally spaced intervals and a hospital is awarded from 1 to 9 points, depending on which of the nine equally spaced intervals its score falls. The offered alternatives satisfy much of this description, but fail to meet the equal-spacing property. In particular, if we revised the scale along the lines suggested by the commenters, the interval of scores needed to receive one point would be only half as large as the remaining eight intervals. As a result, the number of hospitals receiving one point would be reduced and our ability to distinguish among hospitals on the lower end of the scale would also be reduced.

Regarding the specific comment that the scoring scale starts with only 0.5, we note that, in fact, hospitals scoring within the achievement range start with a score of “round (.5).” The “round” function is part of the formula and cannot be ignored without significantly altering the resulting calculations, which would prevent us from implementing equal spacing within the achievement and improvement ranges as described above. We note that within the formula, any value that ends in .5 rounds to the next higher integer, so “round(.5)” equals 1 and a hospital scoring at the achievement threshold receives 1 point on that measure. Likewise, a score of 4.5 rounds to 5, and so on.

The formula for improvement points is similar except that it divides the range between the hospital’s baseline score and the benchmark into 9 equally-spaced intervals and awards a hospital a score between 0 and 9 improvement points. Again, the round function is part of the formula and needs to be acknowledged (with the similar stipulation that values ending in .5 round to the next higher integer). Thus, a hospital with a score exactly equal to its improvement threshold receives a score of round (–.5), which would equal 0 points.

Comment: One commenter recommended that the point conversions and reconversion steps be removed from the mathematical calculations, and that CMS develop a more direct calculation method rather than scoring hospitals with points based

on measure rates and later converting point totals into domain scores.

Response: The point calculations used to score hospitals on performance measures reflect our intent to provide a more[?] robust measure scoring methodology than[?] is possible with a more direct score calculation. We believe that the point conversions from raw measure scores to the 0–10 and 0–9 achievement and improvement ranges, respectively, enable us to more clearly communicate assessments of hospital performance to hospitals and the public. We note that the point calculations allow us to easily calculate and combine points earned for both achievement and improvement, as well as compare hospitals earning points on different measures in cases when the relevant achievement ranges may differ substantially. We will evaluate the impact of the scoring methodology and will continue to examine alternative scoring methodologies for future years of the program.

Comment: Some commenters suggested that the proposed scoring methodology undervalues improvement, and that establishing a lower “improvement benchmark” would be more appropriate so that the improvement range is the same for every hospital.

Response: We believe establishing a lower benchmark would undervalue achievement by lowering the standard by which hospitals may achieve 10 points as well as the importance of improving to the highest level of care. Setting a separate, lower benchmark for the improvement range might also encourage higher achieving hospitals to underperform, as they would be rewarded more highly for achieving a lower level of improvement. A higher benchmark also allows every hospital to improve as much as possible and to the highest level of care.

Comment: Some commenters agreed with our proposal to exclude the “Would You Recommend” item in the HCAHPS performance score and to include only the Overall Rating because they believe that “recommend” is properly characterized as a measure of expectations. Other commenters thought both the Overall Rating and “Would You Recommend” should be included. One commenter thought the Overall Rating should receive more weight than the other HCAHPS dimensions because the commenter viewed it as an outcome measure.

Response: We decided to include only the Overall Rating and not the “Would You Recommend” item in the HCAHPS measure because the two global ratings are highly correlated and the “Would

You Recommend” item is more likely to measure expectations and other factors rather than the actual patient experience. It is important to note that, while there is a high correlation between these items overall, there can still be divergence for some hospitals. Thus for purposes of the Hospital IQR program, these two dimensions will be reported separately.

With regard to giving greater weight to the Overall Rating item, we believe that the Overall Rating item is no more of an outcome than the other HCAHPS items, so it has been given the same weight as the other HCAHPS dimensions in the Hospital VBP scoring formula. Compared to the other HCAHPS dimensions, the Overall Rating focuses on the overall experience, while the other dimensions focus on specific aspects of the hospital stay.

As discussed above, we are finalizing an HCAHPS scoring approach that does not use percentiles, and instead will adopt an approach that uses the percentage of top-box scores for scoring a hospital’s HCAHPS calculations. We believe that this change will both simplify the calculation of HCAHPS scores and will make the HCAHPS scoring more comparable to that of the clinical process of care and outcome measures.

Accordingly, after considering public comments, we are finalizing the scoring methodology as follows:

Hospitals will receive an achievement and improvement score for each of the clinical process of care and outcome measures that apply to them, and for each HCAHPS dimension. Hospital will earn between 0–10 points for achievement based on where its performance for the measure falls relative to the achievement threshold and the benchmark according to the following formula:

$$[9 * ((\text{Hospital's performance period score} - \text{achievement threshold}) / (\text{benchmark} - \text{achievement threshold})) + .5, \text{ where the hospital performance period score falls in the range from the achievement threshold to the benchmark}]$$

All achievement points will be rounded to the nearest whole number (for example, an achievement score of 4.5 would be rounded to 5). If a hospital’s score is:

- Equal to or greater than the benchmark, the hospital will receive 10 points for achievement.
- Equal to or greater than the achievement threshold (but below the benchmark), the hospital will receive a score of 1–9 based on a linear scale established for the achievement range

(which distributes all points proportionately between the achievement threshold and the benchmark so that the interval in performance between the score needed to receive a given number of achievement points and one additional achievement point is the same throughout the range of performance from the achievement threshold to the benchmark).

- Less than the achievement threshold (that is, the lower bound of the achievement range), the hospital will receive 0 points for achievement.

Hospitals will earn between 0–9 points based on how much their performance on the measure during the performance period improves from their performance on the measure during the baseline period according to the following formula:

$$[10 * ((\text{Hospital performance period score} - \text{Hospital baseline period score}) / (\text{Benchmark} - \text{Hospital baseline period score})) - .5], \text{ where the hospital performance score falls in the range from the hospital's baseline period score to the benchmark}$$

All improvement points will be rounded to the nearest whole number.

If a hospital's score on the measure during the performance period is:

- Greater than its baseline period score but below the benchmark (within the improvement range), the hospital will receive a score of 0–9 based on the linear scale that defines the improvement range.

- Equal to or lower than its baseline period score on the measure, the hospital will receive 0 points for improvement.

Hospitals will earn between 0–20 consistency points on the HCAHPS measure based on the lowest of its 8 HCAHPS dimension scores.

A hospital will receive 0 consistency points if its performance on one or more HCAHPS dimensions during the performance period is at least as poor as the worst-performing hospital's performance on that dimension during the baseline period. A hospital will receive a maximum score of 20 consistency points if its performance on all 8 HCAHPS dimensions is at or above the achievement threshold.

Based on comments discussed above, consistency points will be awarded proportionately based on the single lowest of a hospital's 8 HCAHPS dimension scores during the performance period compared to the achievement threshold (the 50th percentile of the baseline performance score) for that specific HCAHPS dimension. If the lowest score is less than the achievement threshold, then the score is based on the distance between the achievement threshold (50th percentile of baseline) and the floor (0th percentile of baseline). If all 8 of a hospital's dimension scores during the performance period are at or above the achievement threshold (50th percentile of hospital performance in the baseline period), then that hospital will earn all 20 consistency points. (That is, if the lowest of a hospital's eight HCAHPS dimension scores is at or

above the 50th percentile of hospital performance on that dimension during the baseline period, then that hospital will earn the maximum of 20 consistency points). If the lowest score a hospital receives on an HCAHPS dimension is at or below the floor of hospital performance on that dimension during the baseline period, then 0 consistency points will be awarded to that hospital. Otherwise, consistency points will be awarded proportionately according to the distance of the performance period score for that dimension between the floor and the achievement threshold.

We define the *lowest dimension score* as the lowest value across the eight HCAHPS dimensions using the following formula:

$$((\text{Hospital's performance period score} - \text{floor}) / (\text{achievement threshold} - \text{floor})).$$

The formula for the HCAHPS consistency points score is as follows: $(20 * (\text{lowest dimension score} - 0.5))$, rounded to the nearest whole number, with a minimum of zero and a maximum of 20 consistency points.

Consistency points will be rounded to the nearest whole number (for example, 9.5 consistency points would be rounded to 10 points).

Table 9 below displays floors, achievement thresholds, and benchmarks for HCAHPS consistency points applicable to FY 2013 using a baseline period of July 1, 2009–March 31, 2010.

TABLE 9—HCAHPS¹ TOP-BOX SCORES² REPRESENTING THE FLOOR (MINIMUM), ACHIEVEMENT THRESHOLD (50TH PERCENTILE) AND BENCHMARK (MEAN OF TOP DECILE) FOR HOSPITAL VALUE-BASED PURCHASING: BASELINE PERIOD (JULY 1, 2009–MARCH 31, 2010)

| HCAHPS dimension | Floor (minimum) | Achievement threshold (50th percentile) | Benchmark (mean of top decile) |
|--|-----------------|---|--------------------------------|
| Communication with Nurses | 38.98 | 75.18 | 84.70 |
| Communication with Doctors | 51.51 | 79.42 | 88.95 |
| Responsiveness of Hospital Staff | 30.25 | 61.82 | 77.69 |
| Pain Management | 34.76 | 68.75 | 77.90 |
| Communication about Medicines | 29.27 | 59.28 | 70.42 |
| Hospital Cleanliness & Quietness | 36.88 | 62.80 | 77.64 |
| Discharge Information | 50.47 | 81.93 | 89.09 |
| Overall Rating of Hospital | 29.32 | 66.02 | 82.52 |

¹ Includes IPPS hospitals with 100+ completed surveys from patients discharged between July 2009 and March 2010 (3,211 hospitals). Scores have been adjusted for survey mode and patient-mix.

² "Top-box" score is the percentage of patients who chose the most positive response to HCAHPS survey items.

As stated above, we also note that, to achieve greater uniformity of scoring for all of the domains, we are finalizing the definition of the benchmark as the mean of the top decile of performance on the HCAHPS dimensions, rather than the

95th percentile of performance as we had proposed.

We have provided three examples describing how the clinical process of care and outcome measures will be scored. These examples are similar to

those that were provided in the Hospital Inpatient VBP proposed rule (76 FR 2467–2470), but illustrate scoring on a different measure since PN–2, used in the proposed rule, is now topped-out. Three more examples illustrate how the

finalized scoring methodology will be applied to the HCAHPS dimensions. The clinical process of care examples use AMI-7a “Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival,” while the HCAHPS examples are based on the “Doctor Communication” dimension.

Figure 1 shows measure scoring for Hospital B. The benchmark calculated for AMI-7a in this case was 0.9191 (the mean value of the top decile during the baseline period), and the achievement threshold was 0.6548 (the performance of the median or the 50th percentile hospital during the baseline period). Hospital B’s performance rate of 0.93 during the performance period for this measure exceeds the benchmark, so Hospital B would earn 10 points (the maximum) for achievement. The measure is expressed as a decimal. In the illustration, Hospital B’s performance rate of 0.93 means that 93 percent of applicable patients received Fibrinolytic Therapy within 30 minutes of arrival. (Because Hospital B has earned the maximum number of points possible for this measure, its improvement score would be irrelevant.)

Figure 1. Example of Hospital Earning Points by Exceeding Benchmark, Clinical Process of Care and Outcome Measure Scoring Under Three-Domain Performance Scoring Model

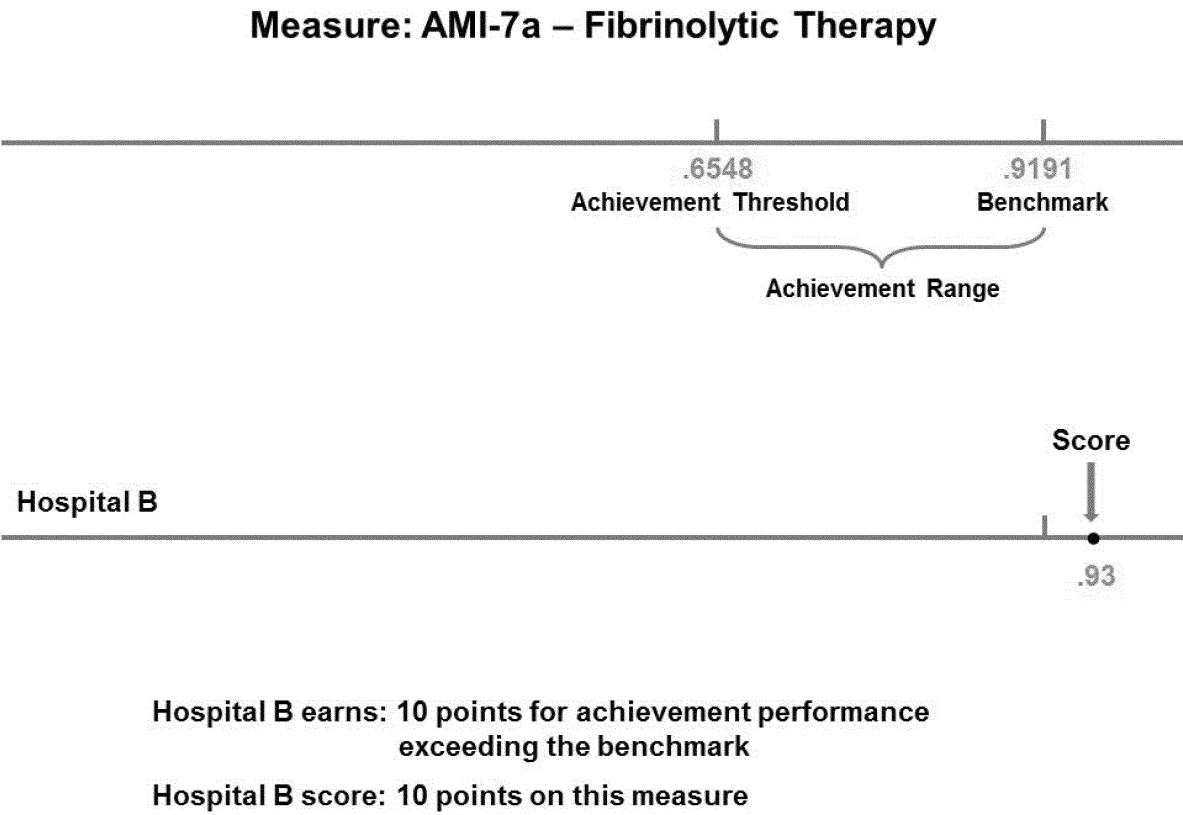


Figure 2 shows the scoring for another hospital, Hospital I. As can be seen below, the hospital’s performance on this measure went from 0.4297 (below the achievement threshold) in the baseline period to 0.8163 (above the achievement threshold) in the performance period. Applying the achievement formula, Hospital I would earn 6 points for this measure, calculated as follows:

$$[9 * ((0.8163 - 0.6548) / (0.9191 - 0.6548))] + 0.5 = 5.5 + 0.5 = 6 \text{ points.}$$

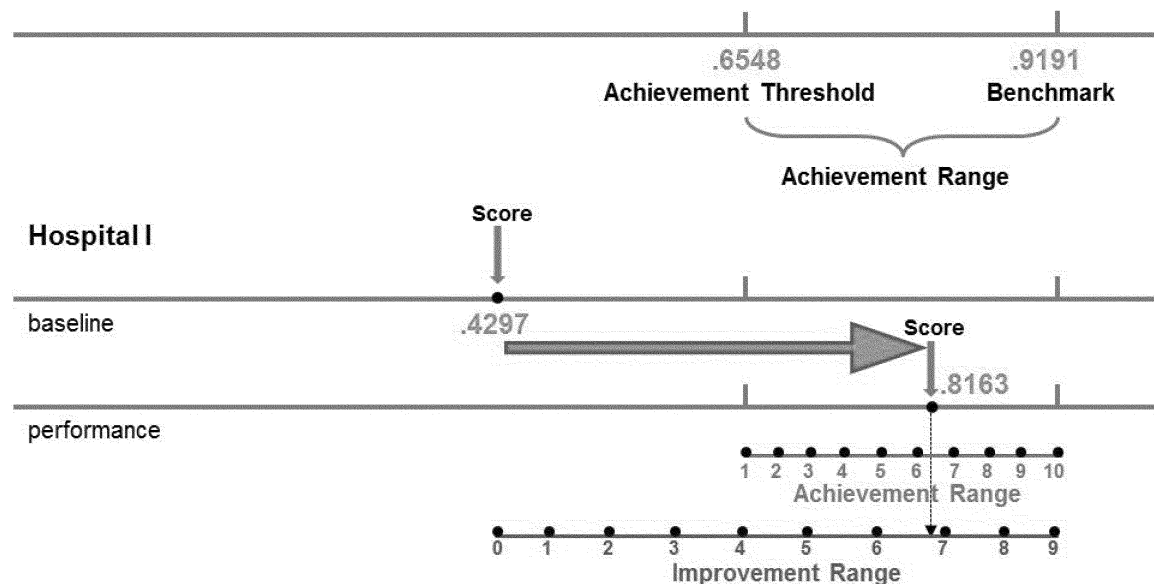
However, because Hospital I’s performance during the performance period is also greater than its performance during the baseline period, it would be scored based on improvement as well. According to the improvement formula, based on Hospital I’s period-to-period improvement, from 0.4297 to 0.8163, Hospital I would earn 7 points, calculated as follows:

$$[10 * ((0.8163 - 0.4297) / (0.9191 - 0.4297))] - 0.5 = 7.9 - 0.5 = 7.4, \text{ rounded to 7 points.}$$

Because the higher of the two scores is used for determining the measure score, Hospital I would receive 7 points for this measure (rounded to the nearest whole number).

Figure 2. Example of Hospital Earning Points by Achievement or Improvement, Clinical Process of Care and Outcome Measure Scoring Under Three-Domain Performance Scoring Model

Measure: AMI-7a – Fibrinolytic Therapy



**Hospital I earns: 6 points for achievement
7 points for improvement**

**Hospital I score: maximum of either achievement or improvement
= 7 points on this measure**

In Figure 3 shown below, Hospital L's performance on AMI-7a drops from 0.72 to 0.64 (a decline of 0.08 points). Because this hospital's performance during the performance period is lower

than the achievement threshold of 0.6548, it receives 0 points based on achievement. It would also receive 0 points for improvement, because its performance during the performance

period is lower than its performance during the baseline period. In this example, Hospital L would receive 0 points for the measure.

Figure 3. Example of Hospital Earning No Points, Clinical Process of Care and Outcome Measure Scoring Under Three-Domain Performance Scoring Model

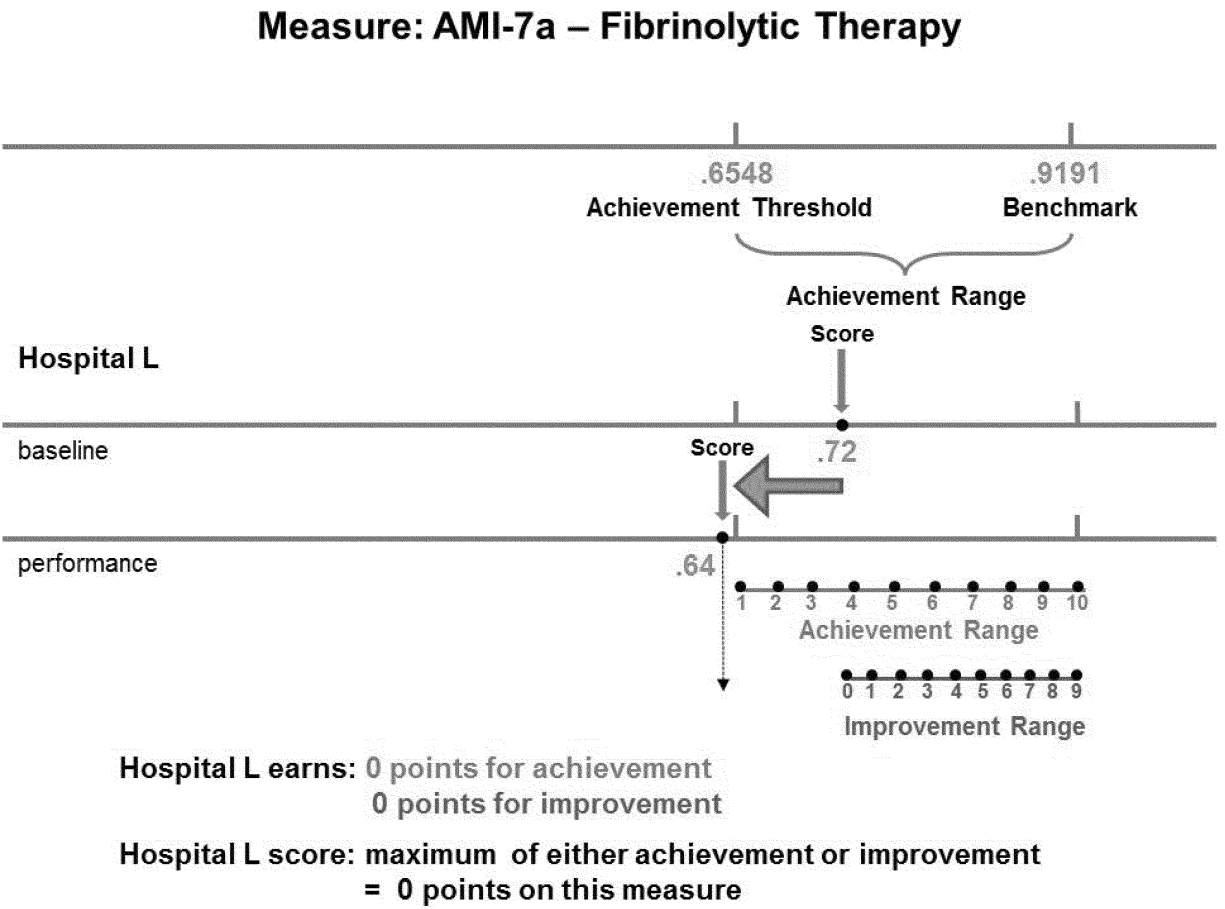
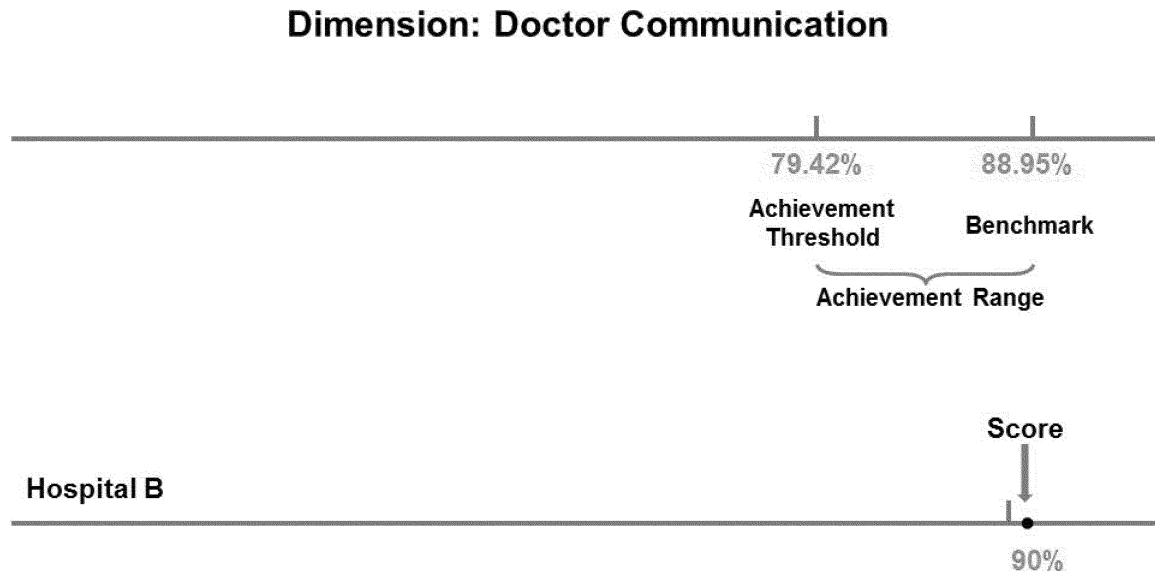


Figure 4 shows Hospital B’s scoring on the doctor communication dimension. It scores a 90 percent, which exceeded the benchmark. Thus,

Hospital B would earn the maximum of 10 points for achievement. Because this is the highest number of achievement points the hospital could attain for this

dimension, its improvement from its baseline period score on this measure would not be relevant.

Figure 4. Example of Hospital Earning Points by Exceeding Benchmark, HCAHPS Measure Scoring Under the Three-Domain Performance Scoring Model



Hospital B's performance in measurement period equates to 90 percent in the baseline period.

Hospital B earns: 10 points for achievement performance exceeding the benchmark

Hospital B score: 10 points on this dimension

Figure 5 shows that Hospital I's performance on the doctor communication dimension rose from 77.19 percent during the baseline period to 82.07 percent during the performance period. Because Hospital I's performance during the performance period exceeds the achievement threshold of 79.42 percent, Hospital I's score would fall within the achievement range. According to the achievement scale, Hospital I would earn 3

achievement points, calculated as follows:

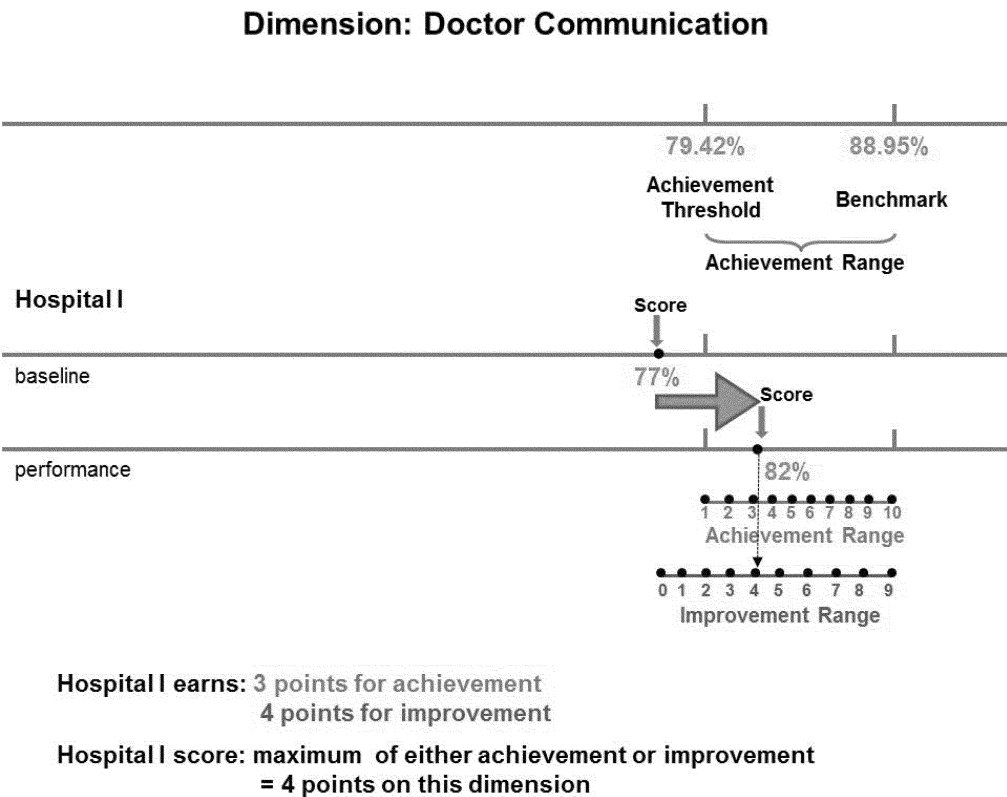
$$[9 * ((82.07 - 79.42) / (88.95 - 79.42))] + 0.5 = 2.5 + 0.5 = 3$$
 However, in this case, the hospital's performance in the performance period has improved from its performance during the baseline period, so Hospital I would be scored based on improvement as well as achievement. Applying the improvement scale, Hospital I's period-to-period

improvement from 77.19 percent to 82.07 percent would earn 3.65 improvement points, which would be rounded to 4 points calculated as follows:

$$[10 * ((82.07 - 77.19) / (88.95 - 77.19))] - 0.5 = 3.65$$

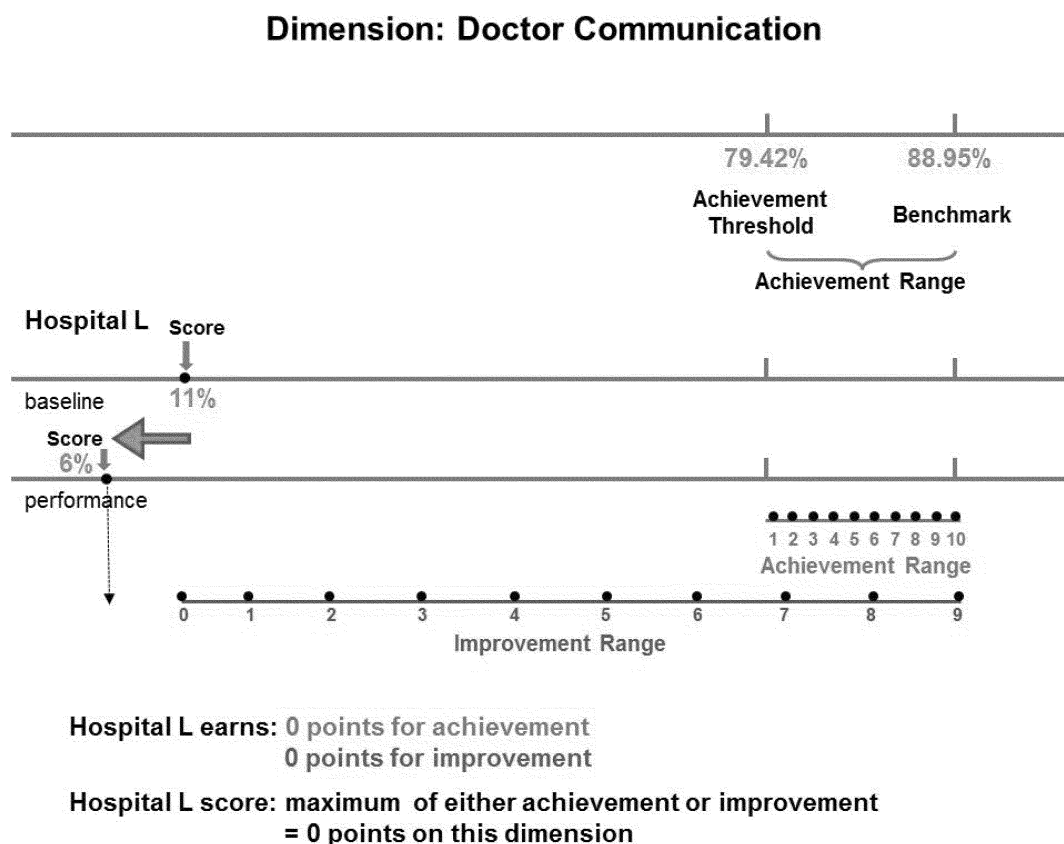
Using the greater of the two scores, Hospital I would receive 4 points for this dimension (rounded to the nearest whole number).

Figure 5. Example of Hospital Earning Points By Achievement or Improvement, HCAHPS Measure Scoring Under the Three-Domain Performance Scoring Model



In Figure 6, Hospital L's performance in the baseline period was at 11 percent, and its performance declined in the performance period to 6 percent. Because Hospital L's performance during the performance period is lower than the achievement threshold of 79.42 percent, it would receive 0 points based on achievement. Hospital L would also receive 0 points for improvement because its performance during the performance period is lower than its performance during the baseline period.

Figure 6. Example of Hospital Earning Zero Points, HCAHPS Measure Scoring Under the Three-Domain Performance Scoring Model



c. The Total Domain Score and the Total Performance Score

We proposed to group the measures for the Hospital VBP program into domains, which we proposed to define as categories of measures by measure type. Because the clinical process of care and outcome measure performance scores will be based only on the measures that apply to the hospital, we proposed to normalize the domain scores across hospitals by converting the points earned for each domain to a percentage of total points. We proposed that the points earned for each measure that applies to the hospital would be summed (weighted equally) to determine the total earned points for the domain.

For purposes of the Hospital VBP program in FY 2013, we also proposed that only two domains will be scored, the clinical process of care and patient experience of care. In determining how to appropriately weight quality measure domains, we considered a number of criteria. Specifically, we considered the number of measures that we proposed to include in each domain and the reliability of individual measure data. We also considered the systematic

effects of alternative weighting schemes on hospitals according to their location and characteristics (for example, by region, size, and teaching status) and Departmental quality improvement priorities. We strongly believe that outcome measures are important in assessing the overall quality of care provided by hospitals. However, for reasons outlined in the Hospital Inpatient VBP Program proposed rule (76 FR 2461), we did not propose to include outcome measures in the FY 2013 Hospital VBP program. Taking all of these considerations into account, we proposed the use of a 70 percent clinical process of care and 30 percent patient experience of care (HCAHPS) weighting scheme for the FY 2013 Hospital VBP program. We proposed this weighting scheme because the proposed clinical process of care measures comprise all but one of the measures we proposed to include in the FY 2013 Hospital VBP program. We believe assigning a 30 percent weight to the patient experience of care domain is appropriate because the HCAHPS measure is comprised of eight dimensions that address different aspects of patient satisfaction.

We solicited public comment on the domain weighting approach and calculation of the total performance score, as well as the utility and appropriateness of alternative methods.

Comment: Some commenters suggested that we weight Total Performance scores by “opportunities to provide care,” rather than equally weighting each measure within each domain.

Response: We thank commenters for their suggestion. However, we believe that weighting each measure within a domain equally will encourage hospitals to consider each of them equally in their quality improvement initiatives. We also believe that weighting by the number of opportunities, the suggested alternative, would overemphasize the SCIP measures, which often have opportunity counts that are much larger than the corresponding counts for measures related to other topics or conditions.

Comment: Many commenters opposed our proposal to weight the patient experience of care domain at 30 percent, arguing that the HCAHPS survey composing the domain is subjective, and is not sufficiently risk adjusted for

patient characteristics or other factors. Those commenters suggested various proposed weights but generally called on us to lower the patient experience of care domain weight. One commenter suggested that we weight the patient experience of care domain higher than 30 percent of the Total Performance Score. A few commenters supported our proposal.

Response: We appreciate the commenters' suggestions. However, we disagree with weighting the patient experience of care domain either higher or lower than proposed. As we detailed in the Hospital Inpatient VBP Program proposed rule (76 FR 2475), we considered many factors when determining the appropriate domain weights for the FY 2013 program, including the number of measures in each domain, the reliability of individual measure data, systematic effects of alternative weighting schemes on hospitals according to their location and characteristics, and Departmental quality improvement priorities. We also believe that delivery of high-quality, patient-centered care requires us to carefully consider the patient's experience in the hospital inpatient setting.

Comment: Some commenters suggested that CMS should convene focus groups of Medicare beneficiaries to determine the relative importance of clinical process of care and patient experience of care domains for weighting.

Response: We believe that we have received significant public input to inform our approach for weighing each domain. Many public comments on the proposed rule discussed the weighing and relative importance of the domains, and supported the proposed weighting distribution. We will, however, continue to monitor the weighing distribution between domains and will consider commenters' suggestions as the program goes forward and new measures and domains are added.

Comment: Commenters suggested that we place greater weight on outcome measures compared to clinical process of care measures and that we emphasize overall rating dimensions of the HCAHPS survey over other dimensions.

Response: We will take the commenters' suggestion to weight the outcome domain more heavily than the clinical process of care domain as we develop our weighting proposals for the FY2014 Hospital VBP program.

However, as we stated earlier, we believe that all measures within a domain should be weighted equally in order to encourage hospitals to improve their performance on all of them.

Based on the comments we received, we are finalizing the calculation of the clinical process of care and outcome domain scores as follows:

1. For each domain:

Total earned points for domain = Sum of points earned for all applicable domain measures

2. Each hospital also has a corresponding universe of total possible points for each of the clinical process and outcome domains calculated as follows:

Total possible points for domain = Total number of domain measures that apply to the hospital multiplied by 10 points

3. For each domain, the total domain score would be calculated as a percentage, as follows:

Domain score = Total earned points for domain divided by Total possible points for domain multiplied by 100 percent.

We are also finalizing the calculation of the patient experience of care domain score as follows:

1. For each of the eight dimensions, determine the larger of the 0–10 achievement score and the 0–9 improvement score;
2. Sum these 8 values to arrive at a 0–80 HCAHPS base score;
3. Calculate the 0–20 HCAHPS consistency score;
4. To arrive at the HCAHPS total earned points, or HCAHPS overall score, sum the HCAHPS base score and the consistency score.

In summary, the overall HCAHPS performance score is calculated as follows:

HCAHPS total earned points = HCAHPS base score + consistency score.

After consideration of public comments, we are finalizing the calculation of a hospital's Total Performance Score as follows:

Multiply the hospital's performance score for each domain by the weight for that domain (70 percent clinical process of care, 30 percent patient experience of care), and add those weighted scores together.

d. Alternative Performance Scoring Models

We discussed our analysis of several alternative performance scoring models in addition to the model proposed (76 FR 2476–2478). We solicited public comments on the proposed model as well as the other potential performance scoring models. The comments we received on these models and our responses are set forth below.

Comment: While agreeing with the analysis of scoring models considered in

the proposed rule, one commenter asked that CMS consider including aspects of the Appropriate Care Model (ACM) in the Hospital VBP program scoring methodology, perhaps by creating a hybrid model in which a portion of the overall performance score is determined by an ACM-like measure of patient-level appropriate care.

Response: The ACM, also referred to as the “all-or-none” model, is intended to be a more patient-centric method of assessing hospital performance on the clinical process of care measures (see 76 FR 2476–2478).

The ACM creates sub-domains by topic for the clinical process measures and is distinguished from the other two models described in the Hospital Inpatient VBP Program proposed rule (namely, the Three-Domain Performance Scoring Model and the Six-Domain Performance Scoring Model) in that it requires complete mastery for each topic area (“all-or-none”) in the clinical process of care domain at the patient level.

Under the ACM, the patient encounter, rather than the clinical process of care measure itself, becomes the scored “event,” with a hospital receiving 1 point if it successfully provides to a patient the applicable processes under all of the measures within an applicable topic area, or 0 points if it fails to furnish one or more of the applicable processes. The hospital's condition-specific ACM score is the proportion of patients with the condition who receive the appropriate care as captured by the process measures that fall within the topic area. As discussed in the proposed rule, in the Three-Domain Performance Scoring Model, the scoring of the clinical process of care measures in a single clinical process of care domain is consistent with the current level of precision on the measures.

We believe that given the current set of measures available for adoption into the Hospital VBP program at this time, the intermediate scores created at the condition or topic level under the ACM would convey a false sense of precision about the quality of care provided for that condition. The ACM sets a high bar for quality improvement and sends a strong signal about complete mastery for each individual topic area (“all-or-none”) at the patient level.

On the other hand, we stated our belief that for complex patients or patients for whom one or more processes are not needed, the ACM model may provide a disincentive to providing quality care. The ACM is considered to be “patient focused” rather than “opportunity focused.” Due

to its all-or-nothing scoring approach, the ACM loses patient information that would have some effect on the total performance score under the Three-Domain Performance Scoring Model, under which hospitals would receive credit for all of the measures for which it met the performance standard. Furthermore, as a result of all-or-nothing scoring, the ACM approach captures whether a patient received appropriate care, but it does not describe the extent of lacking care. Since the unit of scoring is the patient encounter, and the hospital earns a clinical process of care domain score of zero for a patient if the hospital fails to provide any of the applicable processes covered by the measures in the applicable topic area, we believe that the hospital is likely to become aware of all of the processes the patient requires in order to treat the condition, rather than thinking in terms of individual opportunities.

We will continue analyzing alternative performance scoring models, including the ACM, and will consider proposing to implement scoring models other than the Three-Domain Performance Scoring Model in the future. As the industry continues to develop sets of measures that capture many aspects of quality for various conditions, we will seek to examine more patient-centered scoring methodologies and measures, and will certainly consider hybrid models such as the one described by the commenter.

G. Applicability of the Value-Based Purchasing Program to Hospitals

Section 1886(o)(1)(C) of the Act specifies how the value-based purchasing program applies to hospitals. For purposes of the Hospital VBP program, the term “hospital” is defined under section 1886(o)(1)(C)(i) as a “subsection (d) hospital,” (as defined in section 1886(d)(1)(B) of the Act). Section 1886(d)(1)(B) of the Act defines a “subsection (d) hospital” as a “hospital located in one of the fifty States or the District of Columbia.” The term therefore does not include hospitals located in the territories or hospitals located in Puerto Rico. Section 1886(d)(9)(A) of the Act separately defines a “subsection (d) Puerto Rico hospital” as a hospital that is located in Puerto Rico and that “would be a subsection (d) hospital if it were located in one of the 50 states.” Therefore, because 1886(o)(1)(C) does not refer to “subsection (d) Puerto Rico hospitals,” the Hospital VBP program would not apply to hospitals located in Puerto Rico. The statutory definition of a subsection (d) hospital under section

1886(d)(1)(B), however, does include inpatient, acute care hospitals located in the State of Maryland. These hospitals are not currently paid under the IPPS in accordance with a special waiver provided by section 1814(b)(3) of the Act. Despite this waiver, the Maryland hospitals continue to meet the definition of a “subsection (d) hospital” because they are hospitals located in one of the 50 states. Therefore we proposed that the Hospital VBP program will apply to acute care hospitals located in the State of Maryland unless the Secretary exercises discretion pursuant to 1886(o)(1)(C)(iv), which states that “the Secretary may exempt such hospitals from the application of this subsection if the State which is paid under such section submits an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under this subsection.”

The statutory definition of a subsection (d) hospital also does not apply to hospitals and hospital units excluded from the IPPS under section 1886(d)(1)(B) of the Act, such as psychiatric, rehabilitation, long term care, children’s, and cancer hospitals. In order to identify hospitals, we proposed that, for purposes of this provision, we would adjust payments to hospitals as they are distinguished by provider number in hospital cost reports. We proposed that payment adjustments for hospitals be calculated based on the provider number used for cost reporting purposes, which is the CMS Certification Number (CCN) of the main provider (also referred to as OSCAR number). Payments to hospitals are made to each provider of record.

Comment: Several commenters, including national and state hospital associations, expressed their support of our proposal to apply the Hospital VBP program to subsection (d) hospitals in accordance with the statutory requirement. Clarification was requested regarding whether critical access hospitals (CAHs) and subsection (d) hospitals that are in CMS demonstrations for their inpatient payment, such as the Rural Community Hospital Demonstration Program, are to be included in the Hospital VBP program.

Response: For purposes of the Hospital VBP program, the term “hospital” is defined under section 1886(o)(1)(C)(i) as a “subsection (d) hospital,” (as defined in section 1886(d)(1)(B) of the Act). Section 1886(d)(1)(B) of the Act defines a

“subsection (d) hospital” as a “hospital located in one of the fifty States or the District of Columbia.” This does not include IPPS hospitals in Puerto Rico. We are finalizing that we shall identify these hospitals by the CMS Certification Number (CCN) of the main Provider (also referred to as OSCAR number), calculate, and make the payment adjustments based on this identification.

CAHs are designated under section 1820(c); therefore, consistent with section 1886(o)(1)(C)(i), which limits participation in the Hospital VBP program to subsection (d) hospitals, they are ineligible to participate in the Hospital VBP program.

Hospitals that participate in the Rural Community Hospital Demonstration Program are subsection (d) hospitals; therefore, the Hospital VBP program would apply to them. To the extent there are other demonstrations involving subsection (d) hospitals, we will need to evaluate each individual demonstration to determine how it might potentially overlap with the Hospital VBP program.

Comment: Several commenters requested that CMS exempt hospitals in Maryland from the Hospital VBP program. Commenters described current quality efforts in Maryland relating to quality reporting, hospital-acquired conditions, and readmissions. Some stated that “requiring Maryland to comply with the federal program in addition to the existing State programs would be burdensome and duplicative.” Several commenters noted that the State intended to submit a report pursuant to section 1886(o)(1)(C)(iv).

Response: Our proposal was to apply the Hospital VBP program to acute care hospitals in Maryland paid under the 1814(b)(3) waiver unless the Secretary exercised her discretion to exempt these hospitals. We intend to make this the subject of future rulemaking.

Inpatient acute care hospitals located in the State of Maryland are not currently paid under the IPPS in accordance with a special waiver provided by section 1814(b)(3) of the Act. Despite this waiver, Maryland hospitals continue to meet the definition of a “subsection (d) hospital” under section 1886(d)(1)(B) of the Act because they are hospitals located in one of the 50 states. While these hospitals are not subject to the payment reduction under the Hospital IQR program, all or nearly all of them submit data to *Hospital Compare* on a voluntary basis. Therefore, we do not believe that requiring these hospitals to participate in the Hospital VBP program would create an additional or duplicative burden for them. Section

1886(o)(1)(C)(iv) of the Act grants the Secretary discretion to exempt hospitals paid under section 1814(b)(3) from the Hospital VBP program, but only if the State which is paid under such section submits “an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under this subsection.” To facilitate future rulemaking on this topic, we believe that this report should be received prior to the Secretary’s consideration of whether to exercise discretion under section 1886(o)(1)(C)(iv) of the Act.

According to section 1886(o)(1)(B) of the Act, the Hospital VBP program applies to discharges occurring on or after October 1, 2012. Therefore, in response to public comment, we are adopting the following procedure for submission of the state report in order for a hospital within the state to be exempt from the Hospital VBP program: a State shall submit, in writing and electronically, a report pursuant to section 1886(o)(1)(C)(iv) in a timeframe such that allows it to be received no later than October 1, 2011, which is the beginning of the fiscal year prior to the beginning of FY 2013. The statute requires the report to describe how a “similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings.” We request that the report be as specific as possible in describing the quality (and other) measures included and in describing the results achieved over an applicable time period, noting that for the initial report the applicable time period would likely be before and after implementation of the State program. In response to commenters’ discussion of readmissions-related quality efforts in Maryland, we point out that 1886(o)(2)(A) specifically excludes measures of readmissions from the Hospital VBP program.

Section 1886(o)(1)(C)(ii) sets forth a number of exclusions to the definition of the term “hospital.” First, under section 1886(o)(1)(C)(ii)(I), a hospital is excluded if it is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) (the Hospital IQR program) for the applicable fiscal year. Therefore, any hospital that is subject to the Hospital IQR program payment reduction because it does not meet the requirements for the Hospital IQR program will be excluded from the Hospital VBP program for such fiscal year. We are concerned about the

possibility of hospitals deciding to “opt out” of the Hospital VBP program by choosing to not submit data under the Hospital IQR program, thereby avoiding both the base operating DRG payment reduction and the possibility to receive a value-based incentive payment, although we recognize that these hospitals would still be subject to the Hospital IQR program reduction to their applicable percentage increase for the fiscal year. We intend to track hospital participation in the Hospital IQR program and welcome public input on this issue.

With respect to hospitals for which we have measure data from the performance period but no measure data from the baseline period (perhaps because these hospitals were either not open during the baseline period or otherwise did not participate in the Hospital IQR program during that period), we proposed that these hospitals will still be included in the Hospital VBP program, but that they will be scored based only on achievement. We invited public comments on this approach and requested input on how to score hospitals without baseline performance data using this and other approaches.

Under section 1886(o)(1)(C)(ii)(II), a hospital is excluded if it has been cited by the Secretary for deficiencies during the performance period that pose immediate jeopardy to the health or safety of patients. We proposed to interpret this provision to mean that any hospital that is cited by CMS through the Medicare State Survey and Certification process for deficiencies during the performance period (for purposes of the FY 2013 Hospital VBP program, the performance period is July 1, 2011–March 31, 2012) that pose immediate jeopardy to patients will be excluded from the Hospital VBP program for the fiscal year. We also proposed to use the definition of the term “immediate jeopardy” that appears in 42 CFR 489.3.

Section 1886(o)(1)(C)(ii)(III) requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of measures that apply to the hospital for the performance period for the fiscal year.

Section 1886(o)(1)(C)(ii)(IV) requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year.

In determining the minimum number of reported measures and cases under sections 1886(o)(1)(C)(ii)(III) and (IV),

the statute requires the Secretary to conduct an independent analysis of what minimum numbers would be appropriate. To fulfill this requirement, we commissioned Brandeis University to perform an independent analysis that examined technical issues concerning the minimum number of cases per measure and the minimum number of measures per hospital needed to derive reliable performance scores. This analysis examined hospital performance scores using data from 2007 through 2008 and 2008 through 2009. The researchers tested different minimum numbers of cases and measures and concluded that the most important factor in setting minimum thresholds for the Hospital VBP program is to determine a combination of thresholds that allows the maximum number of hospitals to be scored reliably. We note that such reliability depends on the combination of the two thresholds. For example, if we allowed the number of cases per measure to be small (for example, 5 cases), we might still have reliable overall scores if there were a sufficiently large number of measures.

The independent analysis indicated that a smaller number of cases would yield less reliable results for any given measure, ultimately affecting results, when the measures were combined to create the domain scores. Because the finalized Hospital VBP program scoring methodology aggregates information across all of the measures, the analysis considered various thresholds for the minimum number of cases to include in a measure. We recognized that lowering the minimum number of cases required for each measure would allow a greater number of hospitals to participate in the Hospital VBP program. The analysis explored whether a lower threshold for each individual measure might be sufficient to make composite measures (that is, measures based on aggregations of individual measures), more statistically reliable.

Brandeis researchers checked the reliability of the total performance score for hospitals with only 4 measures. One approach was to randomly select 4, 6, 10, or 14 measures and to compare the reliabilities that are determined using these different sets of measures per hospitals. The research found that using 4 randomly selected measures per hospital did not greatly reduce between-hospital reliability (particularly in terms of rank ordering) from what would have been determined using 10 or 14 measures. Examining hospitals with at least 10 cases for each clinical process measure, the analysis compared the reliability of clinical process measure scores for hospitals according to the

number of such measures reported. Whisker plots and reliability scores revealed comparable levels of variation in the process scores for hospitals reporting even a small number of measures as long as the minimum of 10 cases per clinical process measure was met. Based on this analysis, we proposed to establish the minimum number of cases required for each measure under the proposed Three Domain Performance Scoring Model at 10, which we believe will allow us to include more hospitals in the Hospital VBP program.

When examining the minimum number of measures necessary to derive reliable performance scores, the independent analysis revealed that the distribution of performance scores varied depending on the number of measures reported per hospital. The whisker plots and reliability scores demonstrated a clear difference in the distribution of scores for hospitals reporting 4 or more measures compared with those reporting fewer than 4 measures.

We believe that setting the minimum number of measures and cases as low as is reasonable is an essential component of implementing the Hospital VBP program and will help to minimize the number of hospitals unable to participate due to not having the minimum number of cases for a measure or the minimum number of measures. Therefore, as we stated above, we proposed to exclude from hospitals' Total Performance Score calculation any measures on which they report fewer than 10 cases. We also proposed to exclude from the Hospital VBP program any hospitals to which less than 4 of the measures apply.

We also proposed that, for inclusion in the Hospital VBP program for FY 2013, hospitals must report a minimum of 100 HCAHPS surveys during the performance period. The reliability of HCAHPS scores was determined through statistical analyses conducted by RAND, the statistical consultant for HCAHPS. RAND's analysis indicates that HCAHPS data does not achieve adequate reliability with a sample of less than 100 completed surveys to ensure that true hospital performance rather than random "noise" is measured. RAND's analysis indicates that HCAHPS data are significantly below 85 percent reliability levels across all HCAHPS dimensions with a sample of less than 100 completed surveys.

As proposed in the Hospital Inpatient VBP Program proposed rule (76 FR 2481), hospitals reporting insufficient data to receive a score on either the clinical process of care or HCAHPS

domains will not receive a Total Performance Score for the FY 2013 Hospital VBP program.

We solicited public comments on our proposals regarding the minimum numbers of cases and measures necessary for hospitals' inclusion in the Hospital VBP program. We note that hospitals excluded from the Hospital VBP program will be exempt from the base operating DRG payment reduction required under section 1886(o)(7) as well as the possibility for value-based incentive payments.

We also note that the independent analysis conducted by Brandeis only looked at clinical process of care measures and for that reason, we intended that our proposal for the 10 case and 4 measure minimums apply only to those measures. We intend to make a separate proposal on what specific minimum numbers of cases and measures should apply to the outcome domain in future rulemaking. To the extent that the comments to the Hospital Inpatient VBP proposed rule pertained to what specific minimums would be appropriate for the outcome domain, we will take them into consideration as we develop our proposal. We will address the comments in this final rule insofar as they relate to what minimum numbers would be appropriate for the clinical process of care and patient experience of care domains.

Comment: Some commenters asked if very small hospitals will be subjected to the 1.0 percent reduction in base operating DRG amounts without being eligible for value-based incentive payments.

Response: Hospitals to which the Hospital VBP program does not apply will not receive a reduction to their base operating DRG amounts.

Comment: Many commenters asked that new hospitals not be included in the Hospital VBP program until they have sufficient time to implement all of their quality initiatives and begin meeting the requirements under the Hospital IQR program, and that new hospitals be given the opportunity to be scored on improvement during their first year of participation in the Hospital VBP program. Several other commenters objected to the inclusion of any hospitals that did not have sufficient measure data from the baseline period with which to calculate improvement scores, claiming that it would be unfair to deny these hospitals the opportunity to receive potentially higher scores based on improvement points. One commenter asked whether a hospital assigned a CCN in January 2010 would be scored based on a shorter baseline

period or scored based only on achievement.

Response: We recognize the commenters' concerns regarding the fair treatment of all hospitals in the Hospital VBP program and the desire that all hospitals be given the opportunity to earn improvement points. However, we do not believe that we have authority to exclude these hospitals from the Hospital VBP program; section 1886(o)(1)(C)(ii) of the Act sets forth specific exclusions to the term "hospital" for purposes of the program, and none of these exclusions relate to hospitals that do not have baseline performance measure data. If a hospital does not have a minimum number of cases on a given measure in the baseline period, then we interpret the hospital to have "no measure data from the baseline period" with which to calculate an improvement threshold. In such a case, the hospital would not be scored on improvement for that measure. If, however, a hospital reports the minimum number of cases during the applicable baseline period on a given measure—whether such data was obtained throughout the entire baseline period or only over a portion of such period—then the hospital's data during the performance period would be compared to its baseline period performance for the purpose of determining improvement points for that measure. Hospitals not scored on improvement for a given measure will still have the opportunity to score up to 10 achievement points on that measure. As noted above, we believe it is important to include as many hospitals as possible in order to successfully implement the Hospital VBP program and succeed in achieving the Hospital VBP program goals. Thus, the program will apply to hospitals, as that term is defined in section 1886(o)(1)(C)(i), and provided that none of the exclusions in section 1886(o)(1)(C)(ii) apply.

Comment: Commenters suggested that CMS should develop a new value-based purchasing program specific to cancer centers. Other commenters suggested that CMS consider promoting disease-specific quality programs across all care settings.

Response: We thank the commenters for their input. We will certainly take their suggestions under advisement for future quality improvement efforts. We note that the Affordable Care Act requires the Secretary to implement a number of new value-based purchasing and quality reporting initiatives across various health care settings, including quality reporting programs for cancer care hospitals and psychiatric hospitals, as well as to develop plans for value-

based purchasing efforts in the home health and skilled nursing settings.

Comment: Several commenters requested improvements to or clarification of the Medicare State Survey and Certification Process prior to its use in the Hospital VBP program.

Response: We proposed to interpret the statutory exclusion at Section 1886(o)(1)(C)(ii)(II) to mean that any hospital that is cited by CMS through the Medicare State Survey and Certification process for deficiencies during the performance period that pose immediate jeopardy to patients will be excluded from the Hospital VBP program for the fiscal year. We proposed to use the definition of the term “immediate jeopardy” that appears in 42 CFR § 489.3. We intend to further evaluate the application of this definition to the Hospital VBP context and may make additional proposals related to the “immediate jeopardy” exclusion in section 1886(o)(1)(C)(ii)(II) in future rulemaking.

Comment: Many commenters suggested different numbers of minimum cases for hospitals to be included in Hospital VBP, arguing that 10 cases per clinical process measure are insufficient to produce reliable measure scores. A number of commenters argued that CMS should use the same reliability criteria it uses for purposes of displaying measure information on *Hospital Compare* for purposes of defining the minimum case threshold for the Hospital VBP program.

Response: There are currently no minimum case thresholds for the clinical process of care measures reported on *Hospital Compare*, and all clinical process of care data, regardless of sample size, are made publicly available. We recognize that there is currently a footnote added where the Hospital IQR reported clinical process of care measure rates are based on less than 25 cases, and we note that we originally believed that this footnote was appropriate based on the work we did in developing the Hospital Compare display parameters for Hospital IQR data. However, the more recent independent analysis that was completed as part of the development of the Hospital Inpatient VBP proposed rule indicates that the clinical process of care measure data is reliable with fewer than 25 cases, and we plan to revise the footnote on Hospital Compare.

Comment: Many commenters called on us to publish the independent analysis we used to determine the appropriate minimum numbers of cases and measures for the Hospital VBP program.

Response: To the extent that these analyses are not subject to privilege, we will make available additional information, including the study results and methods, and will inform the public when such information is available.

Comment: One commenter asked whether we had considered the impacts of the proposed measure and case minimums on hospitals’ ability to compete for value-based incentive payments.

Response: As detailed in the Hospital Inpatient VBP proposed rule (76 FR 2480), we considered many factors when developing the measure and case minimums, including the reliability of Total Performance Scores, the number of hospitals included in the program, and the impact on small hospitals under various scenarios. We believe that reliable clinical process of care and patient experience of care domain scores can be generated based on the proposed minimum numbers of cases, measures, and completed HCAHPS surveys, and that hospitals will be able to fairly compete for value-based incentive payments.

Comment: Some commenters suggested that we should consider other performance measures for hospitals with few cases.

Response: We note that section 3001(b)(2) of the Affordable Care Act requires the Secretary to establish a value-based purchasing demonstration program for hospitals that are excluded from the Hospital VBP program because they do not have the minimum number of cases or measures.

Comment: One commenter suggested that CMS require hospitals to submit a minimum of 300 HCAHPS surveys per year in order to be included in Hospital VBP; another commenter questioned whether 100 completed HCAHPS surveys will still be the minimum number required in the future should Hospital VBP move to a 12-month performance period rather than the 9-month performance period finalized for the FY 2013 Hospital VBP program. Another commenter was concerned that the HCAHPS exclusion of patients discharged to a nursing home would not permit hospitals to achieve a sufficient number of completed surveys.

Response: Because of reliability concerns, if a hospital has less than 100 completed surveys, we will not calculate an HCAHPS performance score for the Hospital VBP program (and thus will exclude the hospital from the Hospital VBP program). The requirement for 100 completed surveys pertains to both the 9 month and 12 month performance periods as the 100 survey requirement is based upon the

reliability of the data, not the number of calendar quarters. In either time period, we want to ensure that we have reliable data to measure performance. Using statistical measures of reliability that calculate the proportion of the variance in reported hospital scores that is due to true variation between hospitals, rather than within hospital variation that reflects limited sample size, HCAHPS data have been found to be unreliable when a hospital achieves under 100 survey completes.

Patients that are discharged to nursing homes are excluded from the survey due to numerous problems that have been encountered by HCAHPS survey vendors and self-administering hospitals in contacting nursing home patients. We have also found, based on our own research on this topic, that the response rate for nursing home residents is extremely low. By increasing their sampling of patients not discharged to nursing homes, hospitals can achieve a sufficient number of completed surveys.

Based on the comments we received, we are finalizing our proposals regarding the applicability of the Hospital VBP program to hospitals, including calculating and making payment adjustments for this provision using the CCN of the main provider and making payments to each provider of record. Further, we adopt the procedures noted above for submission of the report required under section 1886(o)(1)(C)(iv) and note that we intend to make the question of whether to exempt Maryland hospitals from the Hospital VBP program the subject of future rulemaking.

We are also finalizing a policy to exclude from a hospital’s total performance score its score on any clinical process measure for which it reports fewer than 10 cases, and to exclude from the Hospital VBP program any hospital to which less than 4 of the clinical process measures apply. We are also finalizing our proposal to exclude from the FY 2013 Hospital VBP program a hospital that reports fewer than 100 HCAHPS surveys during the performance period. Finally, we are finalizing our proposal to score hospitals only based on achievement if we have measure data from the performance period but no measure data from the baseline period. However, as discussed above, we will interpret “no measure data from the baseline period” to include data that does not meet the minimum measure and case thresholds that we are adopting in this final rule for the clinical process of care and patient experience of care domains. We believe that calculating an improvement threshold requires at least as much data

as is required for calculating measure scores during the performance period in order to ensure valid comparisons between the two periods. We further believe that the analyses we commissioned to determine the minimum number of cases, measures, and completed HCAHPS surveys during the performance period can be appropriately applied to requiring these minimums in the baseline period to create an improvement threshold.

H. The Exchange Function

Section 1886(o)(6) of the Act governs the calculation of value-based incentive payments under the Hospital VBP program. Specifically, section 1886(o)(6)(A) requires that in the case of a hospital that meets or exceeds the performance standards for the performance period for a fiscal year, the Secretary shall increase the base operating DRG payment amount (as defined in section 1886(o)(7)(D)), as determined after application of a payment adjustment described in section 1886(o)(7)(B)(i), for a hospital for each discharge occurring in the fiscal year by the value-based incentive payment amount. Section 1886(o)(6)(B) defines the value-based incentive payment amount for each discharge in a fiscal year as the product of (1) the

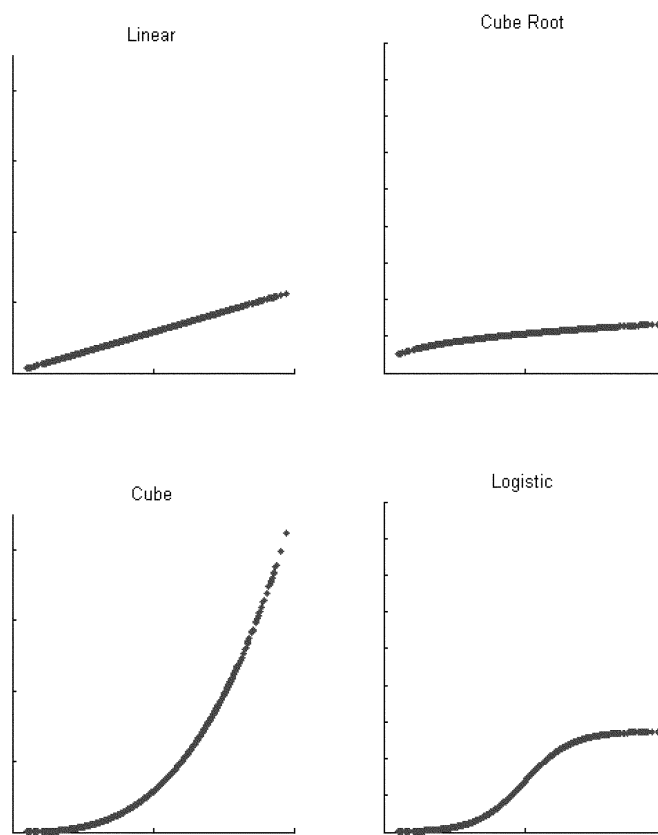
base operating DRG payment amount for the discharge for the hospital for such fiscal year, and (2) the value-based incentive payment percentage for the hospital for such fiscal year. Section 1886(o)(6)(C)(i) provides that the Secretary must specify a value-based incentive payment percentage for each hospital for a fiscal year, and section 1886(o)(6)(C)(ii) provides that in specifying the value-based incentive payment percentage, the Secretary must ensure (1) that the percentage is based on the hospital's performance score, and (2) that the total amount of value-based incentive payments to all hospitals in a fiscal year is equal to the total amount available for value-based incentive payments for such fiscal year under section 1886(o)(7)(A), as specified by the Secretary.

Section 1886(o)(7) of the Act describes how the value-based incentive payments are to be funded. Under section 1886(o)(7)(A), the total amount available for value-based incentive payments for all hospitals for a fiscal year must be equal to the total amount of reduced payments for all hospitals under section 1886(o)(7)(B), as estimated by the Secretary. Section 1886(o)(7)(B)(i) requires the Secretary to adjust the base operating DRG payment amount for each hospital for each

discharge in a fiscal year by an amount equal to the applicable percent of the base operating DRG payment amount for the discharge for the hospital for such fiscal year, and further requires that the Secretary make these reductions for all hospitals in the fiscal year involved, regardless of whether or not the hospital has been determined to have earned a value-based incentive payment for the fiscal year. With respect to FY 2013, the term "applicable percent" is defined as 1.0 percent, but the amount gradually rises to 2.0 percent by FY 2017 (section 1886(o)(7)(C)).

The 2007 Report to Congress introduced the exchange function as the means to translate a hospital's total performance score into the percentage of the value-based incentive payment earned by the hospital. We believe that the selection of the exact form and slope of the exchange function is of critical importance to how the incentive payments reward performance and encourage hospitals to improve the quality of care they provide.

As illustrated in Figure 7, we considered four mathematical exchange function options: straight line (linear); concave curve (cube root function); convex curve (cube function); and S-shape (logistic function).

Figure 7. Exchange Function Options.

In determining which of these exchange functions would be most appropriate for translating a hospital's Total Performance Score into a value-based incentive payment percentage, we carefully considered four aspects of each option.

First, we considered how each option would distribute the value-based incentive payments among hospitals. Under section 1886(o)(7)(A) of the Act, the total amount available for value-based incentive payments for all hospitals for a fiscal year must be equal to the total amount of reduced payments for all hospitals for such fiscal year, as estimated by the Secretary. We interpreted this section to mean that the redistribution of a portion of the IPPS payments to all hospitals under the Hospital VBP program must be accomplished in a way that is estimated to be budget neutral, without increasing or decreasing the aggregate overall IPPS payments made to all hospitals. As a result, if we award higher value-based incentive payments to higher performing hospitals, less money is available to make value-based incentive payments to lower performing hospitals. The reverse is also true. If we give higher value-based incentive payments

to lower performing hospitals, less money is available to reward higher performing hospitals. The form and slope of each exchange function also affects the level of value-based incentive payments available to hospitals at various performance levels. Under both the cube and logistic functions, lower incentive payments are available to lower performing hospitals and aggressively higher payments are available for higher performing hospitals. These functions therefore distribute more incentive payments to higher performing hospitals. Under the cube root function, payments stay at relatively lower levels for higher performing hospitals; this function distributes more incentive payments to lower performing hospitals. The linear function moves more aggressively to higher levels for higher performing hospitals than the cube root function, but not as aggressively as the logistic and cube functions. It therefore distributes more incentive payments to higher performing hospitals than the cube root function, but not as aggressively as the logistic and cube functions.

Second, we considered the potential differences between the value-based

incentive payment amounts for hospitals that do poorly and hospitals that do very well. Due to the fact that the cube root function distributes lower payment amounts to higher performing hospitals, the cube root function creates the narrowest distribution of incentive payments across hospitals. The linear is next, followed by the logistic. The cube function, which most aggressively moves to higher payment levels for higher performing hospitals, creates the widest distribution.

Third, we considered the different marginal incentives created by the different exchange function shapes. In the case of the linear shape, the marginal incentive does not vary for higher or lower performing hospitals. The slope of the linear function is constant, so any hospital with a Total Performance Score that is 0.1 higher than another hospital would receive the same increase in its value-based incentive payment across the entire Total Performance Score range. For the other shapes, the slope of the exchange function creates a higher or lower marginal incentive for higher or lower performing hospitals. Steeper slopes at any given point on the function indicate greater marginal incentives for hospitals

to improve scores and obtain higher payments at that point, while flatter slopes indicate smaller marginal incentives. If the slope is steeper at the low end of performance scores than at the high end, as with the cube root function, hospitals at the low end have a higher marginal incentive to improve than hospitals at the high end. If the slope is steeper at the high end, as with the cube function, hospitals have a higher marginal incentive to improve at the high end than they do at the low end.

Fourth, we weighed the relative importance of having the exchange function be as simple and straightforward as possible.

Taking all of these factors into account, we proposed to adopt a linear exchange function for the purpose of calculating the percentage of the value-based incentive payment earned by each hospital under the Hospital VBP program. The linear function is the simplest and most straightforward of the mathematical exchange functions discussed above. The linear function provides all hospitals the same marginal incentive to continually improve. The linear function rewards higher performing hospitals more aggressively than the cube root function, but not as aggressively as the logistic and cube functions. We proposed the function's intercept at zero, meaning that hospitals with scores of zero will not receive any incentive payment. Payment for each hospital with a score above zero will be determined by the slope of the linear exchange function, which will be set to meet the budget neutrality requirement of section 1886(o)(6)(C)(ii)(II) of the Act, that the total amount of value-based incentive payments equal the estimated amount available under section 1886(o)(7)(A). In other words, we proposed to set the slope of the linear exchange function for FY 2013 so that the estimated aggregate value-based incentive payments for FY 2013 are equal to 1.0 percent of the estimated aggregate base operating DRG payment amounts for FY 2013. We proposed that analogous estimates will be done for subsequent fiscal years.

We believe that our proposed linear exchange function ensures that all hospitals have strong incentives to continually improve the quality of care they provide to their patients. We may revisit the issue of the most appropriate exchange function in future rulemaking as we gain more experience under the Hospital VBP program. We solicited public comments on our exchange function and the resulting distribution of value-based incentive payments.

We noted in the Hospital Inpatient VBP Program proposed rule that, in order to evaluate the different exchange functions, we needed to estimate the value-based incentive payment amount. As stated above, section 1886(o)(6)(B) of the Act defines the value-based incentive payment amount as equal to the product of the base operating DRG payment amount for each discharge for the hospital for the fiscal year and the value-based incentive payment percentage specified by the Secretary for the hospital for the fiscal year. Section 1886(o)(7)(D)(i) defines the base operating DRG payment with respect to a hospital for a fiscal year as, unless certain special rules apply, "the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (q)) for a discharge if [subsection (o)] did not apply; reduced by any portion of such payment amount that is attributable to payments under paragraphs (5)(A), (5)(B), (5)(F) and (12) of subsection (d); and such other payments under subsection (d) determined appropriate by the Secretary." Therefore, for estimation purposes, to calculate base operating DRG payments, we estimated the total payments using Medicare Part A claims data and subtracted from this number the estimates of payments made as outlier payments (authorized under section 1886(d)(5)(A)), indirect medical education payments (authorized under section 1886(d)(5)(B)), disproportionate share hospital payments (authorized under section 1886(d)(5)(F)), and low-volume hospital adjustment payments (authorized under section 1886(d)(12)). We note that this approximation of base operating DRG payments made for the purpose of estimating the value-based payment amount to evaluate the different exchange functions is not a policy proposal. We will propose a definition of the term "base operating DRG payment amount" under section 1886(o)(7)(D), as well as how we would implement the special rules for certain hospitals described in section 1886(o)(7)(D)(ii), in future rulemaking. We solicited public comment to inform our intended future policymaking on this issue.

Furthermore, section 1886(o)(7)(A) states that the total amount available for value-based incentive payments for all hospitals for a fiscal year shall be equal to the total amount of reduced payments for all hospitals for such fiscal year. To calculate the total amount of reduced payments, section 1886(o)(7)(B) states that the base operating DRG payment amount shall be reduced by an

applicable percent as defined under section 1886(o)(7)(C). This applicable percent is 1.0 percent for FY 2013, 1.25 percent for FY 2014, 1.5 percent for FY 2015, 1.75 percent for FY 2016, and 2.0 percent for FY 2017 and subsequent years. To develop an estimation of the value-based incentive payment amount for the purposes of evaluating the different exchange functions, we used the FY 2013 1.0 percent as the applicable percent. We multiplied an estimate (described above) of the total aggregate base operating DRG payments for hospitals as defined under section 1886(o)(1)(C) by 1.0 percent in order to derive the total amount available for value-based incentive payments that was used in the evaluation of the four exchange functions.

The comments we received on this proposal and our responses are set forth below.

Comment: The majority of commenters, including MedPAC, expressed support for our proposed linear exchange function with an intercept of zero during the initial years of the Hospital VBP program. The reasons cited by these commenters included that a linear exchange function appropriately incentivizes both high- and low-performing hospitals; it is more straightforward than the alternative functional forms discussed in the Hospital Inpatient VBP Program proposed rule (that is cube, cube root, and logistic); and it provides a relatively more even distribution of incentive payments. Many commenters indicated that we should consider revisiting the issue of the exchange function once we have actual data and experience under an implemented Hospital VBP program. Some of these commenters, including MedPAC, suggested that over time we could consider providing stronger incentives to lower performing hospitals depending on the initial experience and data.

A few commenters did not support the use of the linear exchange function with an intercept of zero. These commenters indicated that we need to provide greater incentives to lower performing hospitals in the initial implementation, such as through the use of a cube root exchange function.

Commenters also requested transparency with respect to the slope of the linear exchange function for FY 2013 and the associated issues of budget neutrality, payment impacts, and the maximum performance-based payment adjustment that can be made to a hospital's base operating DRG payment amount. They also requested additional operational detail on how CMS will distribute the incentive payment

amounts to the hospitals once they have been determined.

Response: We agree with the commenters who supported our proposed linear exchange function. It provides all hospitals with the same marginal incentive to continually improve. It more aggressively rewards higher performing hospitals than the cube root function, but not as aggressively as the logistic and cube functions. It is also the simplest and most straightforward of the mathematical exchange functions discussed in the Hospital Inpatient VBP Program proposed rule.

We disagree with the commenters who stated that we need to provide greater incentives to lower performing hospitals in the initial implementation of the Hospital VBP program, such as through the use of a cube root exchange function. At this time we believe it would be prudent to examine the experience and data from the initial implementation of the program before considering increasing the incentives to lower performing hospitals. We note that increasing the incentives to lower performing hospitals would result in decreased incentives for higher performing hospitals due to the requirement in section 1886(o)(6)(C)(ii)(II) of the Act that the total amount available for value-based incentive payments under section 1886(o)(6) for all hospitals for a fiscal year be equal to the total amount of reduced payments for all hospitals under section 1886(o)(7)(B) for such fiscal year, as estimated by the Secretary.

With respect to the slope of the linear exchange function for FY 2013, we fully intend to provide the final exchange function slope once our actuaries have the data necessary to calculate it. As noted in the Hospital Inpatient VBP Program proposed rule (76 FR 2483), our actuaries will calculate the slope of the linear exchange function for FY 2013 so that the estimated aggregate value-based incentive payments for FY 2013 are equal to 1.0 percent of the estimated aggregate base operating DRG payment amounts for FY 2013. It is not possible for our actuaries to calculate the final slope of the linear exchange function until we have the data from the performance period.

As we have indicated previously, we intend to propose a definition of the base operating DRG payment amount in future rulemaking. We also intend to provide additional operational detail concerning how hospitals will receive the value-based incentive payments in a future rule.

As requested by many commenters, we would consider revisiting the issue of the exchange function depending on the actual data and experience under the implemented Hospital VBP program.

Comment: One commenter argued that an increasing proportion of hospital payments should be tied to performance, eventually even above the 2.0 percent margin.

Response: Section 1886(o)(7)(C) of the Act provides for an annual increase in the funding for available value-based incentive payments from FY 2013 to FY 2017, adjusting the applicable percent of base operating DRG payments available for value-based incentive payments as follows: with respect to FY 2013, 1.0 percent; with respect to FY 2014, 1.25 percent; with respect to FY 2015, 1.5 percent; with respect to FY 2016, 1.75 percent; and with respect to FY 2017 and succeeding fiscal years, 2 percent. In effect, this will tie an increasing proportion of hospital payments to performance on quality measures. CMS does not have authority to increase the base DRG operating payment withhold amount above 2.0 percent.

After considering the public comments, we are finalizing the exchange function as proposed.

I. Hospital Notification and Review Procedures

Section 1886(o)(8) of the Act requires the Secretary to inform each hospital of the adjustments to payments to the hospital for discharges occurring in a fiscal year as a result of the calculation of the value-based incentive payment amount (section 1886(o)(6)) and the reduction of the base operating DRG payment amount (section 1886(o)(7)(B)(i)) not later than 60 days prior to the fiscal year involved. We proposed to notify hospitals of the 1.0 percent reduction to their respective FY 2013 base operating DRG payments for each discharge in the FY 2013 IPPS rule, which will be finalized at least 60 days prior to the beginning of FY 2013. We expect to propose to incorporate this reduction into our claims processing system in January 2013, which will allow the 1.0 percent reduction to be applied to the FY 2013 discharges, including those that have occurred beginning on October 1, 2012. We will address the operational aspects of the reduction as part of the FY 2013 IPPS rule.

Because the performance period would end only six months prior to the beginning of FY 2013, CMS will not know each hospital's exact Total Performance Score or final value-based incentive payment adjustment 60 days prior to the start of the 2013 fiscal year

on October 1, 2012. Therefore, we proposed to inform each hospital through its QualityNet account at least 60 days prior to October 1, 2012 of the estimated amount of its value-based incentive payment for FY 2013 discharges based on estimated performance scoring and value-based incentive payment amounts, which will be derived from the most recently available data. We also proposed that each hospital participating in the Hospital VBP program establish a QualityNet account if it does not already have one for purposes of the Hospital IQR program. We further proposed to notify each hospital of the exact amount of its value-based incentive payment adjustment for FY 2013 discharges on November 1, 2012. The value-based incentive payment adjustment would be incorporated into our claims processing system in January 2013, which will allow the value-based incentive payment adjustment to be applied to the FY 2013 discharges, including those that have occurred beginning on October 1, 2012.

Section 1886(o)(10)(A)(i) of the Act requires the Secretary to make information available to the public regarding individual hospital performance in the Hospital VBP program, including: (1) hospital performance on each measure that applies to the hospital; (2) the performance of the hospital with respect to each condition or procedure; and (3) the hospital's Total Performance Score. To meet this requirement, we proposed to publish hospital scores with respect to each measure, each hospital's condition-specific score (that is, the performance score with respect to each condition or procedure, for example, AMI, HF, PN, SCIP, HAI), each hospital's domain-specific score, and each hospital's Total Performance Score on the *Hospital Compare* Web site. We note that we did not propose to use a hospital's condition-specific score for purposes of calculating its Total Performance Score under the Three-Domain Performance Scoring Model.

Section 1886(o)(10)(A)(ii) of the Act requires the Secretary to ensure that each hospital has the opportunity to review and submit corrections related to the information to be made public with respect to the hospital under section 1886(o)(10)(A)(i) prior to such information being made public. As stated above, we proposed to derive the Hospital VBP measures data directly from measure data submitted by each hospital under the Hospital IQR program. We proposed that the procedures we adopt for the Hospital IQR program will also be the procedures

that hospitals must follow in terms of reviewing and submitting corrections related to the information to be made public under section 1886(o)(10) of the Act.

With respect to the FY 2013 Hospital VBP program, we proposed to make each hospital's Hospital VBP performance measure score, condition-specific score, domain-specific score, and Total Performance Score available on the hospital's QualityNet account on November 1, 2012. We proposed to remind each hospital via the hospital's secure QualityNet account of the availability of its performance information under the Hospital VBP program on this date. Pursuant to section 1886(o)(10)(A)(ii), we proposed to provide hospitals with 30 calendar days to review and submit corrections related to their performance measure scores, condition-specific scores, domain-specific scores and Total Performance Score.

Section 1886(o)(10)(B) requires the Secretary to periodically post on the *Hospital Compare* Web site aggregate information on the Hospital VBP program, including: (1) the number of hospitals receiving value-based incentive payments under the program as well as the range and total amount of such value-based incentive payments; and (2) the number of hospitals receiving less than the maximum value-based incentive payment available for the fiscal year involved and the range and amount of such payments. We proposed to post aggregate Hospital VBP information on the *Hospital Compare* Web site in accordance with Section 1886(o)(10)(B) of the Act. We will provide further details on reporting aggregated information in the future.

The comments we received on this proposal and our responses are set forth below.

Comment: Some commenters expressed general support for our proposals to display hospital's Hospital VBP performance measure score, condition-specific score, domain-specific score, and Total Performance Score available on the hospital's QualityNet account on November 1, 2012 for the FY 2013 Hospital VBP program, specifically noting time limitations in the statutory timeline.

Response: We thank commenters for their support.

Comment: Some commenters called on CMS to translate hospitals' Total Performance Scores into publicly reported data that is meaningful to consumers and those employers sponsoring health care coverage for their employees, specifically by listing data not only for Medicare patients but for all

patients. One commenter additionally requested that hospitals' performance be evaluated and reported on an individual basis, even if hospitals are commonly owned and operating upon one license, and, therefore, reporting as one entity. One commenter asked if CMS will publish hospital-specific incentive payment percentages or amounts.

Response: As discussed in the Hospital Inpatient VBP Program proposed rule (76 FR 2484), section 1886(o)(10)(A)(i) of the Act requires the Secretary to make information available to the public regarding individual hospital performance in the Hospital VBP program. We proposed to publish hospital scores with respect to each measure, each hospital's condition-specific score, each hospital's domain-specific score, and each hospital's Total Performance Score on the *Hospital Compare* Web site. We will make every effort to make the information presented as usable and clear for public use as possible. However, we do not plan at this point to make public hospital-specific incentive payment percentages or amounts because we believe that the information required to be publicly reported adequately describes each hospital's individual performance under the program. With respect to the request that we report performance information for individual hospitals that are commonly owned, CMS currently receives and displays data under the Hospital IQR program by CCN number. One CCN number can apply to multiple campuses of one hospital. Although hospital owners have chosen to enroll these campuses in the Medicare program as one integrated hospital rather than as separate hospitals, we are aware that members of the public tend to view them as separate hospitals. CMS is currently exploring best methods to make data publicly available for each campus of multi-campus hospitals operating under one CCN number and will take this comment into consideration as it seeks to improve transparency of hospital performance for consumers.

Comment: One commenter suggested that we develop a composite quality measurement system for the *Hospital Compare* Web site similar to the Society of Thoracic Surgeons' Adult Cardiac Surgery Database.

Response: We thank the commenter for the suggestion. We are continuing to look for ways to decrease the reporting burden to hospitals and make the information that we include on *Hospital Compare* meaningful for consumers. We will take the suggestion under advisement.

Comment: Commenters questioned how the Hospital VBP program would ease reporting burdens and aid consumers if, although hospitals are required to report measure data, some of the data reported would not be made publicly available on *Hospital Compare*.

Response: We note that all data used to evaluate hospital performance in Hospital VBP will also be submitted by hospitals under the Hospital IQR program. Accordingly, the Hospital VBP program does not impose reporting requirements on hospitals in addition to or different from those imposed by the Hospital IQR program. We believe that the data as reported on *Hospital Compare* adequately reflects each hospital's performance without mirroring the consumer in too much detail. As discussed above, consumers will be able to see each hospital's score with respect to each measure, each hospital's condition-specific score, each hospital's domain-specific score, and each hospital's Total Performance Score on the *Hospital Compare* Web site. We are aware that the score for a measure for purposes of the Hospital VBP program might differ from the rate we display for that measure for purposes of the Hospital IQR program based on differing date ranges used for each program and the fact that the Hospital VBP data will reflect a hospital's performance score on the measure. We will make every effort to ensure that these differences are clearly explained to the public.

Comment: Many commenters asked that frequently updated calculations be provided for each hospital. Some commenters specifically asked for quarterly hospital preview reports with a percentile ranking for each hospital. Other commenters suggested CMS make available a report through QualityNet that would provide constant updates and status about value-based purchasing scoring calculations and each hospital's individual and up-to-date scores.

Response: We believe that yearly updates of Hospital VBP performance information will provide the most simplicity and clarity for hospitals, although we will certainly consider commenters' suggestions as the program moves forward. We note that Total Performance Scores are based on measure data from the entirety of the performance period, not any subset. We are concerned that providing hospitals with a calculation of their scores based on only a portion of the performance period would be misleading because the scores would be based on insufficient data and could be significantly different from the hospitals' Total Performance Scores, which will be based on data from entire performance periods. For

these reasons, we believe calculating Hospital VBP scores based on the data from the entire performance period will provide hospitals with the best and most reliable information for their use.

Comment: Some commenters asked CMS to provide the final, adjusted DRG payments 30 days before October 1, 2012 to avoid claims reprocessing for the value-based incentive payments.

Response: Section 1886(o)(8) requires the Secretary to inform each hospital of the adjustments to payments to the hospital for discharges occurring in a fiscal year as a result of the calculation of the value-based incentive payment amount (section 1886(o)(6)) and the reduction of the base operating diagnosis-related group (DRG) payment amount (section 1886(o)(7)(B)(i)), not later than 60 days prior to the fiscal year involved. We proposed to notify hospitals of the 1.0 percent reduction to their FY 2013 base operating DRG payments for each discharge in the FY 2013 IPPS rule, which will be finalized at least 60 days prior to the beginning of the 2013 fiscal year. We expect to propose to incorporate this reduction into our claims processing system in January 2013, which will allow the 1.0 percent reduction to be applied to the FY 2013 discharges, including those that have occurred beginning on October 1, 2012. We will address the operational aspects of the reduction as part of the FY 2013 IPPS rule.

Because the finalized nine-month performance period will end only six months prior to the beginning of FY 2013, we will not have enough time to calculate each hospital's exact total performance score or final value-based incentive payment adjustment 60 days prior to the start of the 2013 fiscal year on October 1, 2012. Therefore, we proposed to inform each hospital through its QualityNet account at least 60 days prior to October 1, 2012 of the estimated amount of its value-based incentive payment for FY 2013 discharges based on estimated performance scoring and value-based incentive payment amounts, which will be derived from the most recently available data. We also proposed that each hospital participating in the Hospital VBP program establish a QualityNet account if it does not already have one for purposes of the Hospital IQR program.

We further proposed to notify each hospital of the exact amount of its value-based incentive payment adjustment for FY 2013 discharges on November 1, 2012. The value-based incentive payment adjustment would be incorporated into our claims processing system in January 2013, which will

allow the value-based incentive payment adjustment to be applied to the FY 2013 discharges, including those that have occurred beginning on October 1, 2012.

We made these notification proposals because we concluded that using a full year as the FY 2013 performance period would not give us sufficient time to calculate the total performance scores and value-based incentive payments, notify hospitals regarding their payment adjustments, and implement the payment adjustments.

While we generally agree with commenters' suggestion, we believe our finalized performance period and notification policies outlined above appropriately balance the need for a robust FY 2013 performance period with hospitals' desire to receive value-based incentive payments as quickly as possible.

Comment: One commenter asked how often the rankings for each hospital, based on individual Total Performance Scores, will be updated. The commenter also asked if there will be a data backlog for such rankings, and, if so, how great.

Response: We have not proposed to provide "rankings" of hospitals based on their Total Performance Scores. Rather, the hospitals' Total Performance Scores will be calculated annually at least 60 days prior to the beginning of the fiscal year. As stated above, because the Total Performance Scores depend on the entirety of hospitals' data submitted during the performance period, we do not believe that providing more frequent updates to the Total Performance Scores than on an annual basis would be helpful to providers or the public.

While there is a delay between the conclusion of the performance period and the beginning of the fiscal year in which the corresponding value-based incentive payments will be made, this time period is necessary for hospitals to submit the required data, for that data to be validated, for hospitals to review and submit corrections to information that will be made public, and for us to calculate Total Performance Scores. We do not view this delay as a "backlog," which we would interpret in this context as an extraordinary delay in data submission, validation, processing and notifications to hospitals.

As noted above, we will provide further details on information to be made public with respect to hospitals' performance scores in the future. We will consider the commenter's implicit suggestion that we should provide rankings in the future.

After considering the public comments, we are finalizing the notification and review provisions of

the Hospital Inpatient VBP Program proposed rule as proposed.

J. Reconsideration and Appeal Procedures

Section 1886(o)(11)(A) of the Act requires the Secretary to establish a process by which hospitals may appeal the calculation of a hospital's performance assessment with respect to the performance standards (section 1886(o)(3)(A)) and the hospital performance score (section 1886(o)(5)). Under section 1886(o)(11)(B) of the Act, there is no administrative or judicial review under section 1869, section 1878, or otherwise of the following: (1) The methodology used to determine the amount of the value-based incentive payment under section 1886(o)(6) and the determination of such amount; (2) the determination of the amount of funding available for the value-based incentive payments under section 1886(o)(7)(A) and payment reduction under section 1886(o)(7)(B)(i); (3) the establishment of the performance standards under section 1886(o)(3) and the performance period under section 1886(o)(4); (4) the measures specified under section 1886(b)(3)(B)(viii) and the measures selected under section 1886(o)(2); (5) the methodology developed under section 1886(o)(5) that is used to calculate hospital performance scores and the calculation of such scores; or (6) the validation methodology specified in section 1886(b)(3)(B)(viii)(XI).

We solicited public comment, in general, on the structure and procedure of an appropriate appeals process. Specifically, we solicited comment on the appropriateness of a process that would establish an agency-level appeals process under which CMS personnel having appropriate expertise in the Hospital VBP program would decide the appeal. We sought insight on what qualifications such personnel should hold. We solicited comment on how the appeals process should be structured. Finally, we solicited public input on the timeframe in which these appeals should be resolved.

The comments we received on this proposal and our response are set forth below.

Comment: Many commenters called on us to establish an appeals process as soon as possible or prior to FY 2012. Others provided suggestions on the proper form of an appeals process, including a peer-reviewed process similar to QIOs or an informal dispute resolution process such as that outlined in the CMS State Operations Manual, 7212.

Response: We thank commenters for their input. These comments will inform future rulemaking on this issue.

K. FY 2013 Validation Requirements for Hospital Value-Based Purchasing

In the FY 2011 Inpatient Prospective Payment System (IPPS) final rule (75 FR 50225 through 50230), we adopted a validation process for the FY 2013 Hospital IQR program. We proposed that this validation process will also apply to the FY 2013 Hospital VBP program. We believe that using this process for both the Hospital IQR program and the Hospital VBP program is beneficial for both hospitals and CMS because no additional burden will be placed on hospitals to separately return requested medical records for the Hospital VBP program. Because the measure data we are using for the Hospital VBP program is the same as, or a subset of, the data we collect for the Hospital IQR program, we believe that we can ensure that the Hospital VBP program measure data are accurate through the Hospital IQR program validation process.

We note that we recently proposed to shorten the timeframe for submitting medical records for purposes of validation under the Hospital IQR program from 45 days to 30 days. Details regarding that proposal can be found in the FY 2012 IPPS/LTCH PPS proposed rule scheduled for publication on May 5, 2011.

The comments we received on this proposal and our responses are set forth below.

Comment: A number of commenters expressed support for our proposal on data validation.

Response: We thank the commenters for their input.

Comment: Some commenters requested information on how the data validation processes for Hospital VBP would be run and, if issues regarding validation arose, how such problems would be addressed.

Response: We interpret the comments to request more information on validation scoring, sample selection, medical record request deadlines, and measures included in the validation process. Details regarding the validation process that we have adopted for the FY 2013 Hospital IQR program, as well as the change that we recently proposed to adopt for that process, can be found in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50225 through 50230) and in the FY 2012 IPPS/LTCH PPS proposed rule scheduled for publication on May 5, 2011. The public section of the QualityNet Web site (<http://www.qualitynet.org>) also contains

additional technical information about the validation process. As we stated in the Hospital Inpatient VBP Program proposed rule, we believe that using this process for both the Hospital IQR program and the Hospital VBP program will be beneficial for both hospitals and CMS because no additional burden will be placed on hospitals to separately return requested medical records for the Hospital VBP program. Because the measure data we are using for the Hospital VBP program is the same or a subset of the data we collect for the Hospital IQR program, we believe that we can ensure that the Hospital VBP program measure data are accurate through the Hospital IQR program validation process. The data validation for the proposed baseline period was completed at the end of January 2011.

Comment: Some commenters suggested that CMS should conduct targeted validation, studying the overall accuracy of hospitals' calculation of measure performance rather than assessing accuracy of every data element.

Response: As we explain in the FY 2011 IPPS/LTCH PPS Final Rule (75 FR 50225 through 50230), the validation process we have adopted for the Hospital IQR Program uses every data element used to calculate chart abstracted quality measures to assess overall measure accuracy. We interpret the comment to request that we target hospitals for validation that have attained high measure rates, high performance scores, and/or a very high number of improvement points as part of their Hospital VBP total performance score calculation. We believe that targeting validation on the subset of hospitals achieving high performance scores and the highest performance score changes from previous performance periods would improve the data accuracy under the Hospital VBP program. We will consider this suggestion for future rulemaking.

Comment: A commenter asked how we will validate data submitted from hospitals during the initial baseline period.

Response: We interpret this comment to question our validation process for the FY 2013 proposed baseline period for chart abstracted clinical process of care measure data from July 1, 2009 to March 31, 2010. We validated the Hospital IQR data for the 3rd calendar quarter 2009 discharges using the validation process that we adopted in the FY 2010 IPPS final rule (73 FR 43882 through 43889) for the FY 2011 payment determination and for 1st calendar quarter 2010 discharges using the validation process that we adopted

in the FY 2011 IPPS final rule (75 FR 50225 through 50229) for the FY 2012 payment determination. The 4th calendar quarter of 2009 was not among the quarters of data that were used for validation of the FY 2011 or FY 2012 payment determinations. Accordingly, we used the process that we adopted for the FY 2012 payment determination to validate data from this calendar quarter. We completed validation of these data in January 2011.

Comment: A number of commenters suggested that we consider the impact of the ICD-10-CM/PCS reporting implementation on the Hospital VBP program, measure rates, and quality improvement efforts.

Response: We interpret the comment to request additional information on the impact of ICD-10-CM/PCS implementation on Hospital VBP measure populations changing from ICD-9 codes to using ICD-10 codes. While the change in codes used for measure calculation may have some impact on measure rates, this will not happen until the transition to ICD-10 on October 1, 2013. We have not modeled this impact on Hospital VBP measures using statistical analysis at the present time. We will closely monitor the impact of ICD-10 implementation on the Hospital VBP program measure achievement and improvement trends and consider this information in future rulemaking. We agree that this fundamental change in categorizing diagnoses and procedures could potentially impact Hospital VBP performance scores through changes in measure rates due to measure population definition changes and coding definition changes. Additional information regarding ICD-10 implementation can be found at: <http://www.cms.gov/ICD10>.

Comment: Some commenters argued that the proliferation of different electronic reporting requirements and programs and differing chart-abstraction practices may result in inconsistent data collection by hospitals.

Response: We appreciate the comment and understand that differences in abstraction practices and increased use of electronic health records may result in inconsistent interpretations of measure instructions among hospitals in terms of data collection. A principal goal of our validation requirement is to ensure consistency and accuracy in hospital reported measures. We currently validate the accuracy of chart-abstracted measure data reported for the Hospital IQR program and, as explained above, will use this validation process to

ensure the accuracy of the Hospital VBP chart-abstracted measure data.

After considering the public comments, we are finalizing our proposal to use the validation process we use for the FY 2013 Hospital IQR program to ensure that data for the FY 2013 Hospital VBP program are accurate.

L. Additional Information

1. **Monitoring and Evaluation.** As part of our ongoing effort to ensure that Medicare beneficiaries receive high-quality inpatient care, CMS plans to monitor and evaluate the new Hospital VBP program. Monitoring will focus on whether, following implementation of the Hospital VBP program, we observe changes in access to and the quality of care furnished to beneficiaries, especially within vulnerable populations. We will also evaluate the effects of the new Hospital VBP program in areas such as:

- Access to care for beneficiaries, including categories or subgroups of beneficiaries.
- Changes in care practices that might adversely impact the quality of care furnished to beneficiaries.
- Patterns of care suggesting particular effects of the Hospital VBP program (such as whether there are changes in the percentage of patients receiving appropriate care for conditions covered by the measures); or a change in the rate of hospital acquired conditions.
- Best practices of high-performing hospitals that might be adopted by other hospitals. We currently collect data on readmission rates for beneficiaries diagnosed with myocardial infarction, heart failure, and pneumonia. We also collect chart abstracted data on a variety of quality of care indicators related to myocardial infarction, heart failure, pneumonia, and surgical care improvement. These sources and other available data will provide the basis for early examination of trends in care delivery, access, and quality. Assessment of the early experience with the Hospital VBP program will allow us to create an active learning system, building the evidence base essential for guiding the design of future Hospital VBP programs and enabling us to address any disruptions in access or quality that may arise. These ongoing monitoring and evaluation efforts will be part of our larger efforts to promote improvements in quality and efficiency, both within CMS and between CMS and hospitals in the Hospital VBP program.

2. Electronic Health Records (EHRs)

a. Background

Starting with the FY 2006 IPPS final rule, we have encouraged hospitals to take steps toward the adoption of electronic health records (EHRs, also referred to in previous rulemaking documents as electronic medical records) that will allow for reporting of clinical quality data from the EHRs directly to a CMS data repository (70 FR 47420 through 47421). We encouraged hospitals that are implementing, upgrading, or developing EHR systems to ensure that the technology obtained, upgraded, or developed conforms to standards adopted by HHS. We suggested that hospitals also take due care and diligence to ensure that the EHR systems accurately capture quality data and that, ideally, such systems provide point of care decision support that promotes optimal levels of clinical performance.

We also continue to work with standard-setting organizations and other entities to explore processes through which EHRs could speed the collection of data and minimize the resources necessary for quality reporting as we have done in the past.

We note that we have initiated work directed toward enabling EHR submission of quality measures through EHR standards development and adoption. We have sponsored the creation of electronic specifications for quality measures for the hospital inpatient setting, and will also work toward electronically specifying measures selected for the Hospital IQR program and the Hospital VBP program.

b. HITECH Act EHR Provisions

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes payment incentives under Medicare for the adoption and use of certified EHR technology beginning in FY 2011. Hospitals are eligible for these payment incentives if they meet requirements for meaningful use of certified EHR technology, which include reporting on quality measures using certified EHR technology. With respect to the selection of quality measures for this purpose, under section 1886(n)(3)(A)(iii) of the Act, as added by section 4102 of the HITECH Act, the Secretary shall select measures, including clinical quality measures, that hospitals must provide to CMS in order to be eligible for the EHR incentive payments. With respect to the clinical quality measures, section 1886(n)(3)(B)(i) of the Act requires the Secretary to give preference to those clinical quality measures that

have been selected for the Hospital IQR program under section 1886(b)(3)(B)(viii) of the Act or that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act. All clinical quality measures selected for the EHR Incentive Program for eligible hospitals must be proposed for public comment prior to their selection, except in the case of measures previously selected for the Hospital IQR program under section 1886(b)(3)(B)(viii) of the Act. The final rule for the Medicare and Medicaid EHR Incentive Programs includes 15 clinical quality measures for eligible hospitals and critical access hospitals (75 FR 44418), two of which have been selected for the Hospital IQR program under section 1886(b)(3)(B)(viii) of the Act for the FY 2014 payment determination (75 FR 50210 through 75 FR 50211).

Thus, the Hospital IQR and Hospital VBP programs have important areas of overlap and synergy with respect to the EHR-based reporting of quality measures under the HITECH Act. We believe the financial incentives under the HITECH Act for the adoption and meaningful use of certified EHR technology by hospitals will encourage greater EHR-based reporting of clinical quality measures under the Hospital IQR program which are subsequently used for the Hospital VBP Program.

We note that the provisions in this final rule do not implicate or implement any HITECH statutory provisions. Those provisions are the subject of separate rulemaking and public comment.

The comments we received on this proposal and our responses are set forth below.

Comment: Many commenters expressed support or encouragement of EHR use for quality improvement efforts.

Response: We thank commenters for their support.

Comment: Some commenters argued that EHR use in hospitals does not mean that quality of care is improving.

Response: We thank commenters for their input. We agree with commenters' point that possessing electronic health records alone does not constitute quality improvement. However, the criteria for "meaningful use" certified EHR technology are intended to encourage actual improvements in medical care quality associated with health information technology rather than simple possession of new systems. As stated in the Hospital Inpatient VBP proposed rule (76 FR 2485), we believe that electronic reporting of measure information is a necessary step towards a more integrated health care system

and one we intend to encourage in future Hospital VBP rulemaking.

Comment: Some commenters requested clarification on the interaction of the Hospital VBP program initiatives with the EHR incentive programs.

Response: We appreciate the commenters' request. We are actively planning to synchronize the various reporting programs in order to ensure harmony amongst measures across various settings. We hope to have all measure data submitted via EHRs in the future.

Comment: One commenter suggested that CMS ensure that value-based purchasing initiatives foster innovative, quality care with an adequate level of reimbursement for innovative medical technologies.

Response: We thank the commenter for this observation and believe that the Hospital VBP program will drive high quality care for Medicare beneficiaries, including through the provision of innovative technologies and EHRs. As stated above, we will closely monitor the Hospital VBP program for effects on the provision of medical care and on changes to medical practices, including the appropriate use of medical technologies.

Comment: Many commenters suggested that CMS coordinate with the Office of the National Coordinator for Health IT (ONC) so that quality reporting and value-based purchasing data can be collected from certified EHR technology and related health information systems rather than manually extracted from medical records and submitted through a CMS Web site. Many commenters suggested that the first steps in coordination between CMS and ONC should be to clarify the goals and harmonize the measure specifications between CMS quality reporting and value-based purchasing efforts and "meaningful use."

Response: We believe that using the same specifications for similarly-constructed measures for "meaningful use" and value-based purchasing initiatives would reduce confusion from multiple overlapping measures, reduce the costs of developing measures and could potentially address the limitations of CMS data collection methods that impact the ability to risk-adjust measures and distinguish outcomes that are present on admission.

We agree that data required for quality reporting and value-based purchasing should be collected primarily from certified EHR technology rather than manually extracted from medical records when at all possible. We believe

that collecting and transmitting data in this fashion will, in the long term, reduce provider reporting burden, as well as improve the reliability of the data used for public reporting and value-based purchasing. In achieving this objective, we will continue to engage the ONC on a myriad of operational issues and challenges that will need to be addressed when aligning value-based purchasing and "meaningful use," including harmonizing the specifications of overlapping measures between "meaningful use" and value-based purchasing programs and considering developing new policies to protect patient privacy when accessing EHR data.

M. QIO Quality Data Access

In the proposed rule (76 FR 2485), we explained the various changes that have occurred since the QIO program regulations were first issued in 1985 (see 50 FR 15347, April 17, 1985). These include the significant technological changes that have occurred in the last 25 years; the addition of new responsibilities performed by QIOs; changes in the way QIOs—and CMS—conduct business; the establishment of new laws to protect data and information, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Federal Information Security and Management Act (FISMA); the need for improved transparency and focus on quality health care and patient safety; and the realization that CMS needs improved access to better manage and oversee the QIOs. We also noted that these same regulations govern data and information held by End Stage Renal Disease Networks in accordance with section 1881(c)(8) of the Act.

In light of the above, we proposed several changes to the QIO regulations. Specifically, we proposed amending the definition of the QIO review system in § 480.101(b) to include CMS; modifying § 480.130 to clarify the Department's general right to access non-QRS confidential and non-confidential information; removing the onsite limitation placed on CMS' access to QIO internal deliberations in § 480.139(a); and similarly modifying § 480.140 to eliminate the onsite restriction to CMS' access to Quality Review study (QRS) data. We also proposed making corresponding changes in § 422.153 to ensure consistency with § 480.140. In addition, we asked for comments regarding whether the "onsite" restriction should be eliminated entirely from subparagraph (a) of section 480.140 so that other entities who

already have access to this information can obtain it without going to the QIO's site. We also asked for comments on whether researchers should be allowed access to QIO information and the process, including criteria, which should be used to approve or deny these requests.

The comments we received on these changes and our responses are set forth below.

Comment: We received comments expressing concern that the changes to the QIO confidentiality regulations strip many of the confidentiality safeguards and go against Congress' original intent in establishing the confidentiality requirements contained in section 1160 of the Social Security Act. These comments included concerns that making CMS part of the review system and providing CMS with access to confidential QIO deliberations and QRS information would make the information subject to the Freedom of Information Act (FOIA); would not provide "adequate protection" as required by section 1160; would violate other laws, such as the Health Insurance Portability and Accountability Act (HIPAA); and may result in patient, physician, and provider information being released much more broadly than Congress intended, including potential releases of information during discovery in civil proceedings. Other commenters believed that there could be serious unintended consequences for patients, physicians, and providers, including damage to professional reputations.

Response: We thank the commenters for their concerns. While section 1160 does provide a general framework for maintaining the confidentiality of data or information acquired by QIOs, the section gives the Secretary broad discretion on when disclosures are necessary and appropriate. Paragraph (a)(1) provides that disclosures can be made "to the extent that may be necessary to carry out the purposes of [the QIO statute], * * *" Paragraph (a)(2) gives the Secretary authority to allow disclosures in such cases and under such circumstances as the Secretary provides for in regulations to assure the adequate protection of the rights and interests of patients, physicians and providers. As we discussed in the proposed rule, the initial regulatory framework was developed at a time when computers were in their infancy and the work of the QIOs was performed onsite at provider and physician facilities. However, as technology has advanced and the QIOs' workload has expanded, what was deemed "adequate" 25 years ago is no longer the case. CMS has

weighed the concerns of the commenters against the needs of the QIO program, as well as other benefits CMS will gain from these changes. We have determined that the benefits resulting from these changes are extremely important at this time. We believe that these changes are necessary to modernize the regulations to equate with the manner in which QIOs carry out their work. In addition, these changes take into account the increased focus on medical errors and patient safety, which continue to be a major focus of the QIO program and of CMS. These changes, particularly the expanded definition of “QIO review system,” acknowledge the key role CMS plays in quality improvement, including CMS’ role in the Hospital Value Based Purchasing Program, the Hospital Inpatient Quality Reporting Program, and the Hospital Outpatient Quality Data Reporting Program. We also recognize that conveying additional kinds of QIO confidential information to CMS will result in the information being subject to the Freedom of Information Act (FOIA); however, protections remain within FOIA for protecting certain kinds of confidential information from further disclosure. In obtaining any information, CMS strives to adhere to all legal requirements, including those specified in HIPAA and in the Federal Information Security and Management Act (FISMA). Our goals are, among others, to achieve improved management and oversight of the QIO program and greater transparency of physician and provider care. We recognize that these goals must be accomplished while continuing to ensure that QIOs are able to effectively develop reliable methods for identifying medical errors and attain overall improvement in the quality of health care provided to patients.

Comment: Several commenters expressed concerns regarding the negative impact the changes to the confidentiality regulations, and in particular CMS’ expanded access to QIO information, could have on the QIO program. Some commenters suggested that the changes could place the entire QIO review process—and the QIO program—in jeopardy. Some believed that the changes are not in line with the original intent of the confidentiality provisions, which was to ensure “frank and open communication” and that the ability of the QIOs to attain quality improvement would be undermined. Others believed that the changes could create an environment where every discussion between the QIO and a provider or physician would take place

in the presence of the provider’s or practitioner’s legal counsel in an attempt to ensure that the provider or practitioner does not reveal potentially damaging information. Still others believed the changes could result in attorneys using the QIO process as a “screening” tool, gaining access to QIO information to decide whether a lawsuit against an individual or entity identified in the information might be appropriate, or whether the information might bolster an existing suit. The commenters also mentioned that access to QIO information might subject QIO staff to a lawsuit when a jury’s decision ultimately differs from that of the QIO. In addition, QIOs attempting to mediate and/or resolve concerns or complaints could see less willingness by beneficiaries, physicians, and providers to engage in these discussions in light of concerns that information and outcomes may become discoverable and that this could ultimately impact patient safety. In fact, at least one commenter suggested that providers and physicians could be less likely to participate in programs associated with other Federal agencies, such as the Center for Disease Control, and Prevention’s work associated with Healthcare Acquired Infections. Concerns were also raised regarding the ability of QIOs to hire physician reviewers should the names of physician reviewers and their conclusions about the quality of care provided by other physicians and providers become discoverable and that this could drive up costs associated with hiring these physician reviewers.

Response: QIOs perform numerous reviews through their contracts with CMS, including quality of care reviews, medical necessity reviews, readmission reviews, higher-weighted diagnosis related group reviews, appropriateness of settings reviews, admission reviews, as well as appeals of beneficiary discharges from a variety of provider settings. In carrying out these reviews, the QIOs rely on medical and other relevant information supplied by providers, physicians and beneficiaries, and these providers and physicians are required by law to provide QIOs with relevant information upon request. In fact, the QIO regulations at § 480.130 already provide, without any amendments, that the Department of Health and Human Services (including CMS) has full access to all QIO confidential information—except information that qualifies as QRS data and internal deliberations. As such, we do not anticipate that QIO core review operations will be impacted in any significant way through the changes to

the confidentiality regulations. Moreover, while reference was made to a potential negative impact on participation in other Federal programs, the exact nature of this impact was not clear and again, in light of the Department’s existing access, we do not believe that the commenters’ concern is likely. Quality Review Studies is the one area in which the changes could potentially have an impact on provider and physician participation; however, we do not believe that the changes will have the profound impact envisioned by these commenters. In light of CMS’ role in paying claims and the substantial amount of claims data already in CMS’ possession, requestors can already obtain certain information from CMS’s Privacy Act Systems of Records related to providers and physicians from which conclusions about their performance could be gleaned. This is in addition to the performance information that is already made available on providers and physicians through the various quality reporting programs. CMS’ goal is not to serve as the repository of all QIO data and information. We recognize that responsibility is best left to the QIOs, and we are cognizant of the concerns expressed by the commenters. To the extent that we are going to collect information that will be retrieved by an individual’s personal identifier including name, social security number, etc., we will publish a CMS Privacy Act System of Record notice in the **Federal Register**. However, at this time we have not identified such a need.

Additionally, CMS does not disclose patient identifiable data to third party FOIA requesters and will protect this information to the extent allowed by Federal law. As we have noted, one of our major goals is to improve the management and oversight of the QIOs. We do not intend to interfere in the relationships between the QIOs and physicians, providers, etc.

Although providers and physicians could conceivably engage legal counsel, this does not appear likely, particularly given the nature of the review process as detailed below. Providers and physicians have always had the right to consult with their counsel but have not routinely enlisted such assistance. We believe that this is because of the QIOs’ statutory right to medical information, which is normally maintained in the medical records. Moreover, while the impact of the changes will place more emphasis on information in CMS’ possession, section 1157(b) of the QIO statute protects the QIO and its employees from being held to have violated a criminal law or be civilly

liable for performing its statutory and contractual responsibilities, provided due care was exercised. Additionally, while the changes provide CMS with the right to obtain more data off-site, they do not mandate that CMS receive every piece of information in the QIOs' possession, and we will make determinations regarding information needed in line with our stated goals, as articulated above. As such, we do not anticipate routinely obtaining the names of physician reviewers or other information associated with QIO deliberations unless that information is pertinent to a specific identifiable performance initiative.

Comment: Some commenters expressed concern that there could be a lack of control over disclosures once confidential information is provided to other Federal and state agencies and that robust systems are needed to prevent inherent dangers associated with multiple "hand-offs" of information from agency to agency so that the necessary level of responsibility and oversight is maintained and information is not lost, misused or inappropriately disclosed. In addition, a concern was raised that QIO information represents only a subset of all data and information and that CMS and other agencies must consider that the information does not represent the "norm." In particular, commenters raised concerns that the expanded access to quality improvement review activity would allow CMS to use QIO data to determine new methodologies to reduce or deny payments for other initiatives, such as the expansion of the Recovery Audit Program.

Response: We appreciate the comments regarding the need for internal controls related to information provided to other Federal and state agencies. However, QIOs already have the authority to release confidential information to Federal and state agencies in certain instances as defined by the QIO confidentiality regulations in Part 480 (for example, the Office of Inspector General, Federal and State fraud and abuse agencies, and Federal and State agencies responsible for risks to the public health), and necessary controls are already in place to effectuate these provisions and ensure the data is appropriately protected. We believe that any additional controls associated with the potential increased access by Federal and state agencies can be handled through the development of additional program instructions and policy statements. Moreover, CMS already has a well-defined process in place to ensure protection of various types of information, including limited

data sets, identifiable data, and claims data in general, and this includes adherence to specific information technology requirements, as well as HIPAA and FISMA. As we have noted, our goal in expanding the access is, in part, to ensure appropriate oversight and management of the QIO program. However, we recognize that access to this information could have additional benefits and improve our understanding of payment related problems. This includes the ability to use QIO data to determine new methodologies to reduce or deny payments for other initiatives, such as recovery audits. In utilizing the data, we also recognize that careful analysis will need to be conducted to ensure that the scope of the data is clearly recognized so that inaccurate conclusions are not drawn based on the particular "subset" of data being used.

Comment: We received comments advising that making confidential QIO information available to researchers would undermine the QIO program and could drive Hospitals to cease participating in QIO activities. Some commenters recognized that while sharing this data may be beneficial and increase opportunities for improvement within our health care systems, the data and process for obtaining the data could be easily mismanaged if well-defined parameters are not put into place for approving these requests, including the establishment of detailed criteria that ensures the research has value to CMS' and is in line with CMS' goals, and that the research be conducted by credible research entities. Still others commented that QIOs should share only aggregate level data or de-identified data and that rigorous assurances and safeguards be put in place to ensure patient privacy and confidentiality.

Response: We appreciate the comments and suggestions regarding the release of information to researchers. As discussed previously, QIOs perform numerous reviews through their contracts with CMS, including quality of care reviews, medical necessity reviews, readmission reviews, higher-weighted diagnosis related group reviews, appropriateness of settings reviews, admission reviews, as well as appeals of beneficiary discharges from a variety of provider settings. In carrying out these reviews, the QIOs rely on medical and other relevant information supplied by Medicare providers, physicians and beneficiaries, and these providers and physicians are required by law to provide QIOs with medical and other relevant information upon request. As such, we do not anticipate that most QIO core review operations will be negatively impacted through the

changes to the confidentiality regulations. As previously mentioned, although there could be some potential impact on participation in Quality Review Studies, our hope is that the focus will remain on the patients and the quality improvements that can be achieved through these studies. Additionally, the potential benefits attained through the efforts of researchers are significant, particularly as we aim to improve patient safety by reducing medical errors. We recognize that these requests should be thoroughly evaluated, with the release of information based on well-defined criteria. CMS already employs the CMS Privacy Board to review researchers' requests for CMS claims data. The Board reviews the request, and ensures that the request would comply with applicable privacy and security laws and CMS policies governing data disclosure. Only after an affirmative finding is the data released to the researcher. We believe that we should use the CMS Privacy Board to process research requests for QIO data as well. After consideration of the public comments, we have added \$ 480.144 to allow CMS to approve requests from researchers for access to QIO confidential information.

Furthermore, even after the Board determines that the disclosure would comply with applicable laws and CMS' policies, data is only released upon execution of a data use agreement (DUA). These agreements spell out the expectations on data transmission, storage, access, use, re-use and disclosure to downstream entities. CMS conditions research data disclosures on the researchers' acceptance of these terms. DUAs therefore provide ongoing protection of the data after it is released.

Moreover, in order to fully leverage the capabilities of these researchers, it is imperative that full access be given in those situations in which the CMS Privacy Board deems warranted. Our goal will be to develop sub-regulatory requirements, including any additional criteria and requirements necessary to properly evaluate these requests to coincide with the effectuation of this Final Rule.

Comment: We received comments in support of CMS's proposed changes to the regulations governing QIOs, including those providing CMS with broader access to QIO data and the deletion of the "onsite" requirement for CMS and other Federal and state agencies having the right to access the data. These commenters believed that any entity that is entitled to have access to QIO information should be able to get the information without going onsite to

the QIO. The commenters considered the technological advances since 1985 considerable and that new Federal legislation, including HIPAA and FISMA, have made the “on-site” requirement obsolete. Others supported making CMS an identified part of the definition of a “QIO review system” because this would assist CMS in becoming more efficient in exchanging data and enable CMS to better manage and respond to new information. These comments also supported CMS’ modification of § 480.139 and § 480.140 to facilitate CMS’ communication with, and awareness of, QIO activities needed to improve the proper oversight and management of QIOs and the timely access to information.

Response: We thank these commenters for the support. The changes are designed to improve our oversight and management of the QIOs while also better utilizing available data to oversee patient care, and where feasible the Medicare program. We see the recognition of CMS’ role in the QIO review system as an important step towards achieving this goal. Moreover, as we conveyed in the Hospital Inpatient VBP Program proposed rule, the current state of technology, the use of electronic exchanges of data and information, and the speed at which data must be exchanged to ensure accomplishment of our work warrants the elimination of the restriction that data can only be accessed onsite at the QIO by CMS in sections 480.139 and 480.140. For the same reasons, we believe that the onsite restriction should be eliminated for all Federal and state agencies having access to QIO data as specified in section 480.140. In implementing these changes and allowing improved access to this information, CMS will ensure adherence to all legal requirements, including HIPAA and FISMA, and we will establish policies and procedures to ensure appropriate protections are in place in response to the deletion of the onsite requirement from sections 480.139 and 480.140.

Comment: We received several comments in support of giving researchers access to QIO confidential information. Many believed this access would enable researchers to study quality issues and obtain needed insights into ways health care quality could be improved. Commenters also supported leveraging the current CMS Privacy Board structure to evaluate these requests. Others suggested that the process for accessing QIO data be given free of lengthy delays or cumbersome process requirements for approval of these requests. It was also suggested that

an expedited process be created that would grant individual QIOs with the authority to independently assess and release information, would incorporate tightly managed data use agreements and would also allow requestors to appeal declinations to the CMS Privacy Board. Alternatively, comments were received suggesting that CMS utilize a review process similar to “investigational review boards” or the “Limited Data Set Data process.”

Response: We appreciate these comments and agree with the positive insights that could be attained by allowing researcher access to QIO data as well as the benefits of using the already established CMS Privacy Board. Although we have considered other options for evaluating these requests, we believe that using the existing CMS Privacy Board gives us the best opportunity to ensure that all requests are appropriately evaluated in a timely fashion. As necessary, we will consider potential modifications to the specific criteria and processes employed by the CMS Privacy Board should circumstances warrant such changes. Moreover, with regard to the suggestion that QIOs be used to evaluate these requests, we believe that this would create a substantial workload burden for QIOs and could potentially result in different decisions on similar requests, along with the potential for “forum-shopping” for those who have had their requests denied by individual QIOs. While we recognize that other models may exist to evaluate these data requests, we believe the use of the CMS Privacy Board represents the best opportunity to ensure requests are properly and uniformly adjudicated, without placing an undue burden on individual QIOs.

Comment: One commenter requested a change to the QIO confidentiality regulations related to the right of an attending physician to unilaterally decide not to release individual case review results to beneficiaries if the attending physician determines the results could “harm” the beneficiary. The commenter suggested that the regulatory requirement be changed to allow providers to comment on these determinations and that the QIO “finding” be available to the beneficiary in all circumstances and that these changes are important for improvements to the patient, physician and provider relationships.

Response: While we appreciate this suggestion, we believe that it is outside the scope of this Final Rule. As such, we are not taking any action at this time. However, we reserve the right to consider this issue in future rulemaking.

After consideration of the public comments, we are finalizing the proposed changes to the QIO program regulations. In addition, we are eliminating the “onsite” restriction on Quality Review Study information in § 480.140(a) so that all of the entities and individuals listed in that provision are no longer subject to it. We are also establishing regulations governing the ability of researchers to request access to QIO confidential information.

III. Collection of Information Requirements

We will submit a revised information collection and recordkeeping requirements to incorporate CMS access of information from QIOs. CMS intends to modify existing information collection requirements approved on behalf of the Hospital IQR program data collection (OMB 0938–1022) and supporting the Hospital Value Based Purchasing Program, and the QIO quality of care complaint form (OMB 0938–1102) to QIO program confidentiality regulation modification. We estimate that the 53 QIOs will each require approximately 120 hours per QIO per year to modify information technology systems necessary to grant CMS access to the requested information, or a total of 6,360 burden hours per year. We believe that no additional information will be collected from providers and Beneficiaries as a result of this information collection.

IV. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the 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. This rule has been designated an “economically” significant rule, under section 3(f)(1) of Executive Order 12866, and a major rule under the Congressional Review Act. Accordingly, the rule has been reviewed by the Office of Management and Budget.

2. Statement of Need

The objectives of the Hospital VBP program include to transform how Medicare pays for care and to encourage hospitals to continually improve the quality of care they provide. In accordance with section 1886(o) of the Act, we will accomplish these goals by providing incentive payments based on hospital performance on measures. This final rule was developed based on extensive research we conducted on hospital value-based purchasing, some of which formed the basis of the 2007 Report to Congress, as well as extensive stakeholder and public input. The approach reflects the statutory requirements and the intent of Congress to promote increased quality of hospital care for Medicare beneficiaries by aligning a portion of hospital payments with performance.

3. Summary of Impacts

To provide funding for value-based incentive payments, beginning in fiscal year 2013 and in each succeeding fiscal year, section 1886(o)(7) of the Act governs the funding for the value-based

incentive payments and requires the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an amount equal to the applicable percent of the base operating DRG payment amount for the discharge for the hospital for such fiscal year. We anticipate defining the term “base operating DRG payment amount” in future rulemaking. For purposes of this final rule, we have limited our analysis of the economic impacts to the value-based incentive payments. As required by section 1886(o)(7)(A), total reductions for hospitals under section 1886(o)(7)(B) must be equal to the amount available for value-based incentive payments under section 1886(o)(6), as estimated by the Secretary, resulting in a net budget-neutral impact. Overall, the distributive impact of this final rule is estimated at \$850 million for FY 2013.

The objectives of the Hospital VBP program include to transform how Medicare pays for care and to encourage hospitals to continually improve the quality of care they provide. In accordance with section 1886(o) of the Act, we will accomplish these goals by providing incentive payments based on hospital performance on measures. This final rule was developed based on extensive research we conducted on hospital value-based purchasing, some of which formed the basis of the 2007 Report to Congress, as well as extensive stakeholder and public input. The approach reflects the statutory

requirements and the intent of Congress to promote increased quality of hospital care for Medicare beneficiaries by aligning a portion of hospital payments with performance.

4. Detailed Economic Analysis

Table 10 displays our analysis of the distribution of possible total performance scores based on 2009 data, providing information on the estimated impact of this final rule. Value-based incentive payments for the estimated 3,092 hospitals that would participate in Hospital VBP are stratified by hospital characteristic, including geographic region, urban/rural designation, capacity (number of beds), and percentage of Medicare utilization. For example, row 8 of Table 10 shows the estimated value-based incentive payments for the East South Central region, which includes the states of Alabama, Kentucky, Mississippi, and Tennessee. Column 2 relates that, of the 3,092 participating hospitals, 301 are located in the East South Central region. Column 3 provides the estimated mean value-based incentive payment to those hospitals, which is 1.021 percent. The next columns provide the distribution of scores by percentile; we see that the value-based incentive percentage payments for hospitals in the East South Central region range from 0.550 at the 5th percentile to 1.482 at the 95th percentile, while the value-based incentive payment at the 50th percentile is 1.023 percent.

TABLE 10—TWO-DOMAIN IMPACT (CLINICAL PROCESS AND HCAHPS): ESTIMATED INCENTIVE RATES BY HOSPITAL CHARACTERISTIC †

| Hospital characteristic | Percentile | | | | | | | | |
|-----------------------------|------------|-------|-------|-------|-------|-------|-------|-------|-------|
| | N = 3,092 | Mean | 5th | 10th | 25th | 50th | 75th | 90th | 95th |
| Region | | | | | | | | | |
| New England | 138 | 1.083 | 0.660 | 0.751 | 0.935 | 1.088 | 1.276 | 1.391 | 1.434 |
| Middle Atlantic | 370 | 0.955 | 0.542 | 0.619 | 0.766 | 0.963 | 1.152 | 1.288 | 1.352 |
| South Atlantic | 518 | 1.041 | 0.551 | 0.661 | 0.822 | 1.039 | 1.255 | 1.420 | 1.499 |
| East North Central | 475 | 1.022 | 0.555 | 0.652 | 0.840 | 1.025 | 1.214 | 1.380 | 1.472 |
| East South Central | 301 | 1.021 | 0.550 | 0.634 | 0.810 | 1.023 | 1.235 | 1.413 | 1.482 |
| West North Central | 248 | 1.083 | 0.638 | 0.721 | 0.866 | 1.075 | 1.283 | 1.470 | 1.567 |
| West South Central | 457 | 1.014 | 0.477 | 0.597 | 0.784 | 0.997 | 1.248 | 1.432 | 1.563 |
| Mountain | 201 | 0.980 | 0.584 | 0.650 | 0.822 | 0.986 | 1.159 | 1.336 | 1.396 |
| Pacific | 384 | 0.935 | 0.434 | 0.551 | 0.755 | 0.951 | 1.126 | 1.290 | 1.383 |
| Urban/Rural | | | | | | | | | |
| Large Urban | 1,199 | 1.008 | 0.552 | 0.646 | 0.815 | 1.014 | 1.206 | 1.370 | 1.449 |
| Other Urban | 1,010 | 1.016 | 0.551 | 0.646 | 0.817 | 1.015 | 1.209 | 1.379 | 1.484 |
| Rural | 883 | 1.007 | 0.487 | 0.607 | 0.788 | 1.009 | 1.239 | 1.398 | 1.499 |
| Capacity (by # beds) | | | | | | | | | |
| 1 to 99 beds | 1,045 | 1.044 | 0.491 | 0.617 | 0.814 | 1.047 | 1.284 | 1.456 | 1.575 |
| 100 to 199 beds | 939 | 1.002 | 0.500 | 0.598 | 0.815 | 1.015 | 1.201 | 1.360 | 1.452 |
| 200 to 299 beds | 481 | 0.989 | 0.586 | 0.662 | 0.803 | 0.996 | 1.175 | 1.323 | 1.392 |
| 300 to 399 beds | 279 | 0.995 | 0.577 | 0.668 | 0.821 | 1.022 | 1.167 | 1.293 | 1.379 |

TABLE 10—TWO-DOMAIN IMPACT (CLINICAL PROCESS AND HCAHPS): ESTIMATED INCENTIVE RATES BY HOSPITAL CHARACTERISTIC †—Continued

| Hospital characteristic | N = 3,092 | Mean | Percentile | | | | | | |
|-----------------------------|-----------|-------|------------|-------|-------|-------|-------|-------|-------|
| | | | 5th | 10th | 25th | 50th | 75th | 90th | 95th |
| 400 to 499 beds | 151 | 0.985 | 0.575 | 0.700 | 0.837 | 0.982 | 1.135 | 1.307 | 1.414 |
| 500+ beds | 197 | 0.960 | 0.562 | 0.652 | 0.766 | 0.960 | 1.146 | 1.265 | 1.314 |
| Medicare Utilization | | | | | | | | | |
| 0 to 25% | 237 | 0.990 | 0.542 | 0.639 | 0.798 | 1.012 | 1.164 | 1.352 | 1.451 |
| > 25% to 50% | 1,508 | 1.016 | 0.528 | 0.642 | 0.818 | 1.020 | 1.224 | 1.381 | 1.459 |
| > 50% to 65% | 1,148 | 1.005 | 0.524 | 0.637 | 0.804 | 1.008 | 1.206 | 1.381 | 1.482 |
| > 65% | 196 | 1.02 | 0.52 | 0.60 | 0.80 | 1.02 | 1.28 | 1.42 | 1.53 |

† Note: Because sufficient 2009 data was not available at the time of publication of this final rule, the measures SCIP-Card-2 and SCIP-Inf-4 were not included in the calculation of estimated incentive rates. However, we believe that no significant change in estimated incentive rates results from the omission of these measures.

Table 11 below shows the estimated (\$850 million) in the base operating percent distribution by hospital DRG payment for fiscal year 2013. characteristic of the 1 percent reduction

TABLE 11—AVERAGE ESTIMATED PERCENTAGE WITHHOLD AMOUNT (AS REQUIRED BY SECTION 1886(o)(7) OF THE SOCIAL SECURITY ACT) BY HOSPITAL CHARACTERISTIC

| Hospital characteristic | N = 3,092 | Estimated percent withhold amount |
|------------------------------|-----------|-----------------------------------|
| Region: | | |
| New England | 138 | 5.9 |
| Middle Atlantic | 370 | 15.9 |
| South Atlantic | 518 | 19.5 |
| East North Central | 475 | 17.5 |
| East South Central | 301 | 7.8 |
| West North Central | 248 | 7.2 |
| West South Central | 457 | 10.3 |
| Mountain | 201 | 4.8 |
| Pacific | 384 | 11.2 |
| Urban/Rural: | | |
| Large Urban | 1,199 | 49.8 |
| Other Urban | 1,010 | 38.2 |
| Rural | 883 | 11.1 |
| Capacity (by # beds): | | |
| 1 to 99 beds | 1,045 | 8.1 |
| 100 to 199 beds | 939 | 21.2 |
| 200 to 299 beds | 481 | 20.5 |
| 300 to 399 beds | 279 | 16.9 |
| 400 to 499 beds | 151 | 11.0 |
| 500+ beds | 197 | 23.4 |
| Medicare Utilization: | | |
| 0 to 25% | 237 | 3.9 |
| > 25% to 50% | 1,508 | 60.0 |
| > 50% to 65% | 1,148 | 32.8 |
| > 65% | 196 | 3.2 |

We also analyzed the characteristics of hospitals not receiving a Hospital VBP score based on the program requirements, which is shown below in Table 12. We estimate that 353 hospitals will not receive a Hospital VBP score in fiscal year 2013. We note that these hospitals will not be impacted by the reductions in base DRG operating payments under section 1886(o)(7). Hospitals not included in this analysis were excluded due to the complete absence of cases applicable to the

measures included, or due to the absence of a sufficient number of cases to reliably assess the measure.

As might be expected, a significant portion of hospitals not receiving a Hospital VBP score are small providers because such entities are more likely to lack the minimum number of cases or measures required to participate in the Hospital VBP program. We anticipate conducting future research on methods to include small hospitals in the Hospital VBP program.

TABLE 12—PROJECTED NUMBER OF HOSPITALS NOT RECEIVING A HOSPITAL VBP SCORE IN FY 2013, BY HOSPITAL CHARACTERISTIC

| Hospital characteristic | Number of hospitals not receiving hospital VBP score (N = 353) |
|-------------------------|--|
| Region: | |
| New England | 6 |

TABLE 12—PROJECTED NUMBER OF HOSPITALS NOT RECEIVING A HOSPITAL VBP SCORE IN FY 2013, BY HOSPITAL CHARACTERISTIC—Continued

| Hospital characteristic | Number of hospitals not receiving hospital VBP score (N = 353) |
|------------------------------------|--|
| Middle Atlantic | 18 |
| South Atlantic | 14 |
| East North Central | 31 |
| East South Central | 26 |
| West North Central | 17 |
| West South Central | 85 |
| Mountain | 25 |
| Pacific | 26 |
| Puerto Rico | 34 |
| Missing Region | 71 |
| Urban/Rural: | |
| Large Urban | 116 |
| Other Urban | 83 |
| Rural | 83 |
| Missing Urban/Rural | 71 |
| Capacity (by # beds): | |
| 1 to 99 beds | 213 |
| 100 to 199 beds | 47 |
| 200 to 299 beds | 11 |
| 300 to 399 beds | 8 |
| 400 to 499 beds | 2 |
| 500+ beds | 0 |
| Missing Capacity | 72 |
| Medicare Utilization: | |
| 0 to 25% | 78 |
| > 25% to 50% | 75 |
| > 50% to 65% | 43 |
| > 65% | 28 |
| Missing Medicare Utilization | 129 |

We note that a number of hospitals were missing hospital characteristic data, including region, urban/rural classification, size, and Medicare utilization. All 353 hospitals included in Table 9, including those with missing hospital characteristic data, lacked

sufficient clinical process of care data or HCAHPS data needed to calculate a total performance score.

5. Alternatives Considered

The major alternative performance scoring models considered for this final rule were the Six-Domain Performance Scoring Model and the Appropriate Care Model, and both of these models were discussed at length in the proposed rule (76 FR 2476 through 2478).

The Appropriate Care Model (ACM) creates sub-domains by topic for the clinical process of care measures and is distinguished from the Three-Domain Performance Scoring Model in that it requires complete mastery for each topic area (“all-or-none”) in the clinical process of care domain at the patient level. Under the ACM, the patient encounter is the scored “event,” with a hospital receiving 1 point if it successfully provides to a patient the applicable processes under all of the measures within an applicable topic area, or 0 points if it fails to furnish one or more of the applicable processes. The hospital’s condition-specific ACM score is the proportion of patients with the condition who receive the appropriate care as captured by the process

measures that fall within the topic area. The Six-Domain Performance Scoring Model, like the ACM, would create and separately score individual sub-domains at the topic level for the clinical process of care domain would be further broken down into sub-domains characterized by condition. We would assign intermediate scores to each hospital for each of the clinical process sub-domains. Like the Three-Domain Performance Scoring Model, hospitals would be scored on each measure in the

sub-domain and individual measures would still be weighted equally within a sub-domain. Scores across the topic area sub-domains would then be equally weighted and combined to create an overall clinical process score. The total performance score would be computed as an average across domains, calculated by weighting the scores for each of the three domains.

Examining these alternative performance scoring models, our analyses showed only modest differences in financial reimbursements across the separate models considered by the various characteristics listed above. We believe that these observed transfers are within the limits of expected variation and do not reflect significant differences in financial reimbursements between the performance scoring models considered.

6. Accounting Statement

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), we have prepared an accounting statement showing the classification of the impacts associated with the provisions of this final rule.

As required by section 1886(o)(7)(A), total reductions for hospitals under section 1886(o)(7)(B) must be equal to the amount available for value-based incentive payments under section 1886(o)(6), resulting in a net budget-neutral impact. Overall, the distributive impacts of this final rule, resulting from the incentive payments and the 1 percent reduction (withhold) in the base operating DRG payment for fiscal year 2013, are estimated at \$850 million for fiscal year 2013 (reflected in 2010 dollars).

TABLE 13—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR FY 2013

| Category | Transfers |
|--------------------------------------|---|
| Annualized Monetized Transfers | \$0 (Distributive impacts resulting from the incentive payments and the 1 percent reduction (withhold) in the base operating DRG payment are estimated at \$850 million.) |
| From Whom To Whom? | Federal Government to Hospitals. |

B. Regulatory Flexibility Act Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that 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 \$7.0 million to \$34.5 million or less in any 1 year. For purposes of the RFA, among the 3,092 hospitals that would be participating in the Hospital VBP program, we estimate that percent increases in payments resulting from this final rule will range from 0.0236 percent for the lowest-scoring hospital to 1.817 percent for the highest-scoring hospital. When the reduction to base operating DRG payments required under section 1886(o)(7) (one percent in FY 2013,

gradually rising to 2 percent by FY 2017) is taken into account, roughly half of participating hospitals will receive a net increase in payments and half will receive a net decrease in payments. However, we estimate that no participating hospital will receive more than a net 1 percent increase or decrease in total Medicare payments. This falls well below the threshold for economic significance established by HHS for requiring a more detailed impact assessment under the RFA. Thus, we are

not preparing an analysis under the RFA because the Secretary has determined that this final rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. We did not prepare an analysis under section 1102(b) of the Act because the Secretary has determined that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Comment: One commenter disagreed with our analysis, which concluded that the proposed rule will not have an impact on a substantial number of small, rural hospitals. The commenter argued that quality improvement efforts are more costly for small hospitals and was also concerned about the program's reliability in low volume situations.

Response: As discussed throughout the various sections of this Regulatory Impact Analysis, including the discussions of the RFA and section 1102(b), and based on the concluding economic impact findings and tables presented, we believe there will not be a significant impact on the operations of a substantial number of small rural hospitals. Absent any new data, commenters may reference the upcoming demonstration projects such as those required under section 3001(b) of the Affordable Care Act as a tool for better understanding any new economic impacts, including those of small rural hospitals. As described in section II. G. of this Final Rule, we believe that the measure and case minimums allow us to include as many hospitals as possible while calculating reliable Total Performance Scores.

Comment: Another commenter asked for more detail in Table 10, including data to offer a rationale for the incentive rates identified. This commenter stated that the "weights have not been defined or modeled within the rule to allow hospitals to make projections with budgeting and other operational issues." This commenter recommended that CMS provide additional information so that hospitals can replicate the process and calculations for planning purposes.

Response: We believe the data on the two-domain impact of the Hospital VBP program provided in Table 10 are as detailed as possible, along with the

accompanying narrative and analysis provide a description of the number of affected entities and the size of the economic impacts of this final rule, as well as the justification for the Secretary's certification that this final rule will not have a significant economic impact on a substantial number of small entities. We will take the commenter's suggestions for providing additional data under advisement should additional or more detailed data become available and as we continue public outreach and education efforts for the Hospital VBP program.

C. Unfunded Mandates Reform Act Analysis

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 of \$100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately \$136 million. This rule would not mandate any requirements for State, local, or tribal governments, nor would it affect private sector costs.

V. Federalism Analysis

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. As stated above, this final rule would not have a substantial effect on State and local governments.

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 480

Health care, Health professions, Health records, Peer Review Organizations (PRO), Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 1. 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).

Subpart D—Quality Improvement

■ 2. Section 422.153 is revised to read as follows:

§ 422.153 Use of quality improvement organization review information.

CMS will acquire from quality improvement organizations (QIOs) as defined in part 475 of this chapter data collected under section 1886(b)(3)(B)(viii) of the Act and subject to the requirements in § 480.140(g). CMS will acquire this information, as needed, and may use it for the following functions:

(a) Enable beneficiaries to compare health coverage options and select among them.

(b) Evaluate plan performance.

(c) Ensure compliance with plan requirements under this part.

(d) Develop payment models.

(e) Other purposes related to MA plans as specified by CMS.

PART 480—ACQUISITION, PROTECTION, AND DISCLOSURE OF QUALITY IMPROVEMENT ORGANIZATION REVIEW INFORMATION

■ 3. The authority citation for part 480 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Utilization and Quality Control Quality Improvement Organizations (QIOs)

■ 4. Section 480.101(b) is amended by revising the definition of "QIO review system" to read as follows:

§ 480.101 Scope and definitions.

* * * * *

(b) * * *

QIO review system means the QIO and those organizations and individuals who either assist the QIO or are directly responsible for providing medical care or for making determinations with respect to the medical necessity, appropriate level and quality of health care services that may be reimbursed under the Act. The system includes—

(1) The QIO and its officers, members and employees;

(2) QIO subcontractors;

(3) Health care institutions and practitioners whose services are reviewed;

(4) QIO reviewers and supporting staff;

(5) Data support organizations; and

(6) CMS.

* * * * *

■ 5. Section 480.130 is revised to read as follows:

§ 480.130 Disclosure to the Department.

Except as limited by § 480.139(a) and § 480.140 of this subpart, QIOs must disclose to the Department all information requested by the Department in the manner and form requested. The information can include confidential and non-confidential information and requests can include those made by any component of the Department, such as CMS.

■ 6. Section 480.139 is amended by revising paragraph (a)(1) to read as follows:

§ 480.139 Disclosure of QIO deliberations and decisions.

(a) * * *

(1) A QIO must not disclose its deliberations except to—

(i) CMS; or

(ii) The Office of the Inspector General, and the Government

Accountability Office as necessary to carry out statutory responsibilities.

* * * * *

■ 7. Section 480.140 is amended by revising paragraphs (a) introductory text, (a)(1) and paragraph (g) to read as follows:

§ 480.140 Disclosure of quality review study information.

(a) A QIO must disclose quality review study information with identifiers of patients, practitioners or institutions to—

(1) Representatives of authorized licensure, accreditation or certification agencies as is required by the agencies in carrying out functions which are within the jurisdiction of such agencies under state law; to Federal and State agencies responsible for identifying risks to the public health when there is substantial risk to the public health; or to Federal and State fraud and abuse enforcement agencies;

* * * * *

(g) A QIO must disclose quality review study information to CMS with identifiers of patients, practitioners or institutions—

(1) For purposes of quality improvement. Activities include, but are

not limited to, data validation, measurement, reporting, and evaluation.

(2) As requested by CMS when CMS deems it necessary for purposes of overseeing and planning QIO program activities.

■ 8. Section 480.144 is added to read as follows:

§ 480.144 Access to QIO Data and Information.

CMS may approve the requests of researchers for access to QIO confidential information not already authorized by other provisions in 42 CFR part 480.

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

Dated: April 14, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: April 26, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011–10568 Filed 4–29–11; 8:45 am]

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Part VI

Securities and Exchange Commission

17 CFR Parts 240, 242, and 249

Removal of Certain References to Credit Ratings Under the Securities Exchange Act of 1934 Regulation Z; Truth in Lending; Proposed Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 240, 242, and 249

[Release No. 34-64352; File No. S7-15-11]

RIN 3235-AL14

Removal of Certain References to Credit Ratings Under the Securities Exchange Act of 1934

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rule.

SUMMARY: This is one of several proposed rules that the Securities and Exchange Commission (the “Commission”) will be considering relating to the use of credit ratings in Commission rules and forms. Section 939A of the Dodd-Frank Act Wall Street Reform and Consumer Protection Act (the “Dodd-Frank Act”) requires the Commission to remove any references to credit ratings from its regulations and to substitute such standard of creditworthiness as the Commission determines to be appropriate. In this release, the Commission is proposing to amend certain rules and one form under the Securities Exchange Act of 1934 (the “Exchange Act”) applicable to broker-dealer financial responsibility, distributions of securities, and confirmations of transactions. The Commission also is requesting comment on potential standards of creditworthiness for purposes of Exchange Act Sections 3(a)(41) and 3(a)(53), which define the terms “mortgage related security” and “small business related security,” respectively, as the Commission considers how to implement Section 939(e) of the Dodd-Frank Act.

DATES: Comments should be received on or before July 5, 2011.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s Internet comment form (<http://www.sec.gov/rules/proposed.shtml>); or
- Send an e-mail to rule-comments@sec.gov. Please include File Number S7-15-11 on the subject line; or
- Use the Federal eRulemaking Portal (<http://www.regulations.gov>). Follow the instructions for submitting comments.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission,

100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number S7-15-11. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s Internet Web site (<http://www.sec.gov/rules/concept.shtml>). Comments are also available for Web site viewing and printing in the Commission’s Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT:

Michael A. Macchiaroli, Associate Director, at (202) 551-5525; Thomas K. McGowan, Deputy Associate Director, at (202) 551-5521; Randall W. Roy, Assistant Director, at (202) 551-5522; Mark M. Attar, Branch Chief, at (202) 551-5889; Carrie A. O’Brien, Special Counsel, at (202) 551-5640; and Leigh E. Bothe, Attorney, at (202) 551-5511, Office of Financial Responsibility (Net Capital, Customer Protection, and Books and Records Requirements, and Section 939(e) of the Dodd-Frank Act); Josephine J. Tao, Assistant Director, Elizabeth A. Sandoe, Senior Special Counsel, David P. Bloom, Branch Chief, or Bradley Gude, Special Counsel, Office of Trading Practices and Processing at (202) 551-5720 (Regulation M); and Joseph M. Furey, Co-Acting Chief Counsel, and Ignacio Sandoval, Special Counsel, Office of Chief Counsel at (202) 551-5550 (Confirmation of Transactions), Division of Trading and Markets, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-7010.

SUPPLEMENTARY INFORMATION: On July 21, 2010, the President signed the Dodd-Frank Act into law. The Commission is requesting public comment on proposed amendments to Exchange Act Rules 15c3-1, 15c3-3, 17a-4, 101 and 102 of Regulation M, and 10b-10, and one Exchange Act form—Form X-17A-5, Part IIB—to remove references to credit ratings and, in certain cases, substitute alternative standards of creditworthiness as required by Section 939A of the Dodd-Frank Act.¹ The Commission is also requesting public comment on potential standards of

creditworthiness for purposes of Exchange Act Sections 3(a)(41) and 3(a)(53), which define the terms “mortgage related security” and “small business related security,” respectively, as the Commission considers how to implement Section 939(e) of the Dodd-Frank Act.

I. Background

A. Dodd-Frank Wall Street Reform and Consumer Protection Act

The Dodd-Frank Act was enacted to, among other things, promote the financial stability of the United States by improving accountability and transparency in the financial system.² Title IX, Subtitle C, of the Dodd-Frank Act³ includes provisions regarding statutory and regulatory references to credit ratings in Exchange Act rules, as well as in the Exchange Act itself.⁴

Specifically, in Section 939A of the Dodd-Frank Act, Congress requires that the Commission “review any regulation issued by [the Commission] that requires the use of an assessment of the credit-worthiness of a security or money market instrument and any references to or requirements in such regulations regarding credit ratings.”⁵ Once the Commission has completed that review, the statute provides that the Commission “remove any reference to or requirement of reliance on credit ratings, and to substitute in such regulations such standard of creditworthiness” as the Commission determines to be appropriate.⁶

As is discussed in detail below, there are five Exchange Act rules—Rule 15c3-1, Rule 15c3-3, Rules 101 and 102 of Regulation M, and Rule 10b-10—administered by the Commission and one Exchange Act form—Form X-17A-5, Part IIB—that the Commission is proposing to amend in this release as directed by Section 939A of the Dodd-Frank Act. The Commission is also proposing corresponding changes to Exchange Act Rule 17a-4, relating to broker-dealer recordkeeping.

² See Public Law 111-203, 124 Stat. 1376 (2010); Public Law 111-203, Preamble.

³ Public Law 111-203, 124 Stat. 1376 (2010).

⁴ These provisions are designed “to reduce the reliance on ratings.” See *Joint Explanatory Statement of the Committee of Conference*, Conference Committee Report No. 111-517, to accompany H.R. 4173, 864-879, 870 (Jun. 29, 2010).

⁵ Public Law 111-203 § 939A(a)(1)-(2).

⁶ See Public Law 111-203 § 939A(b). The Commission has recently proposed amendments to its rules in other contexts under the federal securities laws to remove references to credit ratings. See *References to Credit Ratings in Certain Investment Company Act Rules and Forms*, Securities Act of 1933 (“Securities Act”) Release No. 9193 (Mar. 3, 2011), 76 FR 12896 (Mar. 9, 2011) and *Security Ratings*, Exchange Act Release No. 63874 (Feb. 9, 2011), 76 FR 8946 (Feb. 16, 2011).

¹ See Public Law 111-203 § 939A.

Further, in Section 939(e) of the Dodd-Frank Act,⁷ Congress deleted Exchange Act references to credit ratings in two sections: (1) In Exchange Act Section 3(a)(41),⁸ which defines the term “mortgage related security,” and (2) in Exchange Act Section 3(a)(53),⁹ which defines the term “small business related security.” In place of the credit rating references, Congress added language stating that a mortgage related security and a small business related security will need to satisfy “standards of credit-worthiness as established by the Commission.”¹⁰ This replacement language becomes effective on July 21, 2012 (*i.e.*, two years after the date the Dodd-Frank Act was signed into law).

As is discussed in detail below, the Commission also is requesting comment on potential standards of creditworthiness for purposes of Exchange Act Sections 3(a)(41) and 3(a)(53), as the Commission considers how to implement Section 939(e) of the Dodd-Frank Act.

B. Previous Commission Action

In 1975, the Commission adopted the term “nationally recognized statistical rating organization” (“NRSRO”) as part of the Commission’s amendments to its broker-dealer net capital rule, Exchange Act Rule 15c3–1 (the “Net Capital Rule”).¹¹ Although the Commission originated the use of the term NRSRO for a narrow purpose in its own regulations, ratings by NRSROs today are widely used as benchmarks in federal and state legislation, rules by financial and other regulators, foreign regulatory schemes, and private financial contracts. The Commission’s initial regulatory use of the term NRSRO was intended solely to provide a method for determining capital charges on different grades of debt securities under the Net Capital Rule. The Commission’s reference to NRSROs for purposes of certain rules increased over time.

Subsequent to the adoption of many of the Commission’s requirements using the NRSRO concept, the Commission—in 2006—obtained registration and oversight authority with respect to credit rating agencies that register to be treated as NRSROs.¹² In response, the

Commission adopted rules to implement a registration and oversight program for NRSROs in June 2007.¹³

The Commission notes that this is not the first time that the Commission has proposed to remove references to credit ratings in Commission rules. The Commission issued a concept release in 1994 on the general idea of removing references to NRSROs in its rules.¹⁴ In 2003, the Commission again sought comment on whether it should eliminate the NRSRO designation from Commission rules, and, if so, what alternatives could be adopted to meet the Commission’s regulatory objectives.¹⁵ Most recently, in July 2008, the Commission made specific proposals to remove rule references to

ratings by NRSROs.¹⁶ In response, the Commission received many comments that raised serious concerns about removing the references.¹⁷ Commenters argued that removing NRSRO references in the context of the Net Capital Rule would decrease the transparency of broker-dealers’ net capital computations and negatively affect market confidence in the financial strength of broker-dealers.¹⁸ In addition, commenters contended that the proposed amendments would place an undue burden on broker-dealers to justify the propriety of internal methods for determining haircuts and on Commission examiners who might be required to review those methods.¹⁹

In October 2009, the Commission adopted several of the proposed reference removals and re-opened for comment the remaining proposals.²⁰ As noted above, in each of these concept releases and rule proposals, commenters generally did not support the removal of references to NRSRO ratings from Commission rules and provided few possible regulatory alternatives. The Commission recognizes the concerns raised by commenters that replacing credit ratings—which provide an objective benchmark—with more subjective approaches could increase costs to broker-dealers and the

(2006). Among other things, the Rating Agency Act of 2006 defined the terms “credit rating agency” and “nationally recognized statistical rating organization” in Exchange Act Sections 3(a)(61) and 3(a)(62), respectively. See Public Law 109–291 § 3. Under Section 3(a)(61), the term “credit rating agency” means any person: (A) engaged in the business of issuing credit ratings on the Internet or through another readily accessible means, for free or for a reasonable fee, but does not include a commercial credit reporting company; (B) employing either a quantitative or qualitative model, or both, to determine credit ratings; and (C) receiving fees from either issuers, investors, or other market participants, or a combination thereof. 15 U.S.C. 78c(a)(61). Under Section 3(a)(62), the term “nationally recognized statistical rating organization” means a credit rating agency that: (A) issues credit ratings certified by qualified institutional buyers, in accordance with section 15E(a)(1)(B)(ix) of the Exchange Act, with respect to (i) financial institutions, brokers, or dealers; (ii) insurance companies; (iii) corporate issuers; (iv) issuers of asset-backed securities (as that term is defined in section 1101(c) of part 229 of title 17, Code of Federal Regulations, as in effect on the date of enactment of this paragraph); (v) issuers of government securities, municipal securities, or securities issued by a foreign government; or (vi) a combination of one or more categories of obligors described in any clauses (i) through (v); and (B) is registered under Exchange Act Section 15E.

¹³ See *Oversight of Credit Rating Agencies Registered as Nationally Recognized Statistical Rating Organizations*, Exchange Act Release No. 55857 (Jun. 5, 2007), 72 FR 33564 (Jun. 18, 2007). The implementing rules were Form NRSRO, Rule 17g–1, Rule 17g–2, Rule 17g–3, Rule 17g–4, Rule 17g–5, and Rule 17g–6. The Commission has twice adopted amendments to some of these rules. See *Amendments to Rules for Nationally Recognized Statistical Rating Organizations*, Exchange Act Release No. 59342 (Feb. 2, 2009), 74 FR 6456 (Feb. 9, 2009); and *Amendments to Rules for Nationally Recognized Statistical Rating Organizations*, Exchange Act Release No. 61050 (Nov. 23, 2009), 74 FR 63832 (Dec. 4, 2009). The Commission also recently added a new NRSRO rule. See *Disclosure for Asset-Backed Securities Required by Section 943 of the Dodd-Frank Wall Street Reform and Consumer Protection Act*, Securities Act Release No. 9175 (Jan. 20, 2011), 76 FR 4489 (Jan. 26, 2011).

¹⁴ See *Concept Release: Nationally Recognized Statistical Rating Organizations*, Exchange Act Release No. 34616 (Aug. 31, 1994), 59 FR 46314 (Sep. 7, 1994).

¹⁵ See *Concept Release: Rating Agencies and the Use of Credit Ratings under the Federal Securities Laws*, Exchange Act Release No. 47972 (Jun. 4, 2003), 68 FR 35258 (Jun. 12, 2003).

¹⁶ See *Proposed Rule: References to Ratings of Nationally Recognized Statistical Rating Organizations*, Exchange Act Release No. 58070 (Jul. 1, 2008), 73 FR 40088 (Jul. 11, 2008).

¹⁷ See *Comments on References to Ratings of NRSROs*, available on the Commission’s Internet Web site at <http://www.sec.gov/comments/s7-17-08/s71708.shtml>.

¹⁸ See, e.g., Letter from Jeffrey T. Brown, Senior Vice President, Charles Schwab & Co., Inc. to Florence E. Harmon, Acting Secretary, Commission, dated Sep. 5, 2008, stating, “we are concerned that the Commission’s proposed amendments to remove references to NRSRO ratings from [R]ule 15c3–1 (the Net Capital Rule) * * * may be destabilizing and inject risk and uncertainty into the operations of broker-dealers, investment advisers and money market mutual funds. We urge the Commission to retain the references to NRSRO ratings as a minimum floor of credit quality.”

¹⁹ See, e.g., Deborah A. Cunningham and Boyce I. Greer, SIFMA Credit Rating Agency Task Force Co-Chair to Elizabeth M. Murphy, Secretary, Commission, dated Dec. 9, 2009.

²⁰ See *References to Ratings of Nationally Recognized Statistical Rating Organizations*, Exchange Act Release No. 60789 (Oct. 5, 2009), 74 FR 52358 (Oct. 9, 2009) (adopting release). In the adopting release, the Commission amended Exchange Act Rule 3a1–1 (17 CFR 240.3a1–1), Exchange Act Rules 300, 301(b)(5) and 301(b)(6) of Regulation ATS (17 CFR 242.300, 242.301(b)(5) and 242.301(b)(6)), Form ATS–R (17 CFR 249.638) and Form PILOT (17 CFR 249.821). The Commission also adopted amendments to Rules 5b–3 and 10f–3 under the Investment Company Act of 1940 (17 CFR 270.5b–3 and 17 CFR 270.10f–3). See *References to Ratings of Nationally Recognized Statistical Rating Organizations*, Exchange Act Release No. 60790 (Oct. 5, 2009), 74 FR 52374 (Oct. 9, 2009) (re-opening comment for Net Capital Rule purposes and various Exchange Act rules).

⁷ Public Law 111–203 § 939(e).

⁸ 15 U.S.C. 78c(a)(41).

⁹ 15 U.S.C. 78c(a)(53).

¹⁰ Public Law 111–203 § 939(e).

¹¹ See *Adoption of Uniform Net Capital Rule and an Alternative Net Capital Requirement for Certain Brokers and Dealers*, Exchange Act Release No. 11497 (Jun. 26, 1975), 40 FR 29795 (Jul. 16, 1975) and 17 CFR 240.15c3–1.

¹² See Credit Rating Agency Reform Act of 2006 (“Rating Agency Act of 2006”); Public Law 109–291

Commission. For example, broker-dealers would be required to allocate resources toward developing and maintaining compliance processes, and the Commission would likewise be required to allocate resources toward examining for compliance. The Commission also recognizes that an alternative approach, if too rigid, could narrow the types of financial instruments that qualify for benefits under existing rules and, if too flexible, could broaden the types of financial instruments that qualify for benefits under existing rules. The Commission, in proposing alternatives to credit ratings, is seeking generally to neither narrow nor broaden the scope of financial instruments that would qualify for the benefits conferred in the existing rules while, at the same time, fulfilling the statutory mandate in Section 939A of the Dodd-Frank Act.²¹ In this regard, the Commission seeks comment below on whether the proposed alternatives achieve this goal and whether more effective alternatives exist.

II. Commission Proposals

A. Proposed Amendments to Exchange Act Rule 15c3-1 and the Appendices to the Rule

1. Amendments to Rule 15c3-1

As noted above, the Commission first developed the NRSRO concept for use in the Net Capital Rule. The Net Capital Rule prescribes minimum regulatory capital requirements for broker-dealers.²² A “net liquid assets test” is the fundamental requirement of the Net Capital Rule. This test is designed to provide that a registered broker-dealer maintain at all times more than one dollar of highly liquid assets for each dollar of liabilities (*e.g.*, money owed to customers and counterparties), excluding liabilities that are subordinated to all other creditors by contractual agreement. Consequently, if the broker-dealer experiences financial difficulty, it should be in a position to meet all obligations to customers and counterparties and generate resources to wind-down its operations in an orderly manner without the need of a formal proceeding. The Net Capital Rule operates by requiring a broker-dealer to perform two calculations: (1) A computation of required minimum net capital; and (2) a computation of actual net capital. A broker-dealer must ensure that its actual net capital exceeds its minimum net capital requirement at all times.

To calculate its actual net capital, a broker-dealer first computes its net worth in accordance with generally accepted accounting principles and then adds to this amount certain subordinated liabilities. From that figure, the broker-dealer subtracts assets not readily convertible into cash, such as intangible assets, fixed assets, and most unsecured receivables. The broker-dealer then subtracts prescribed percentages of the market value of securities owned by the broker-dealer (otherwise known as “haircuts”) to discount for potential market movements. A primary purpose of these haircuts is to provide a margin of safety against losses that might be incurred by the broker-dealer as a result of market fluctuations in the prices of, or lack of liquidity in, its proprietary positions. The resulting figure is the broker-dealer’s net capital.

The Net Capital Rule currently applies a lower haircut to certain types of securities held by a broker-dealer if the securities are rated in higher rating categories by at least two NRSROs, since those securities typically are more liquid and less volatile in price than securities that are rated in the lower categories or are unrated. Currently, to receive the benefit of a reduced haircut on commercial paper, the commercial paper must be rated in one of the three highest rating categories by at least two NRSROs.²³ To receive the benefit of a reduced haircut on a nonconvertible debt security and preferred stock, the security must be rated in one of the four highest rating categories by at least two NRSROs.²⁴

In conformance with the Dodd-Frank Act, the Commission is proposing to remove from the Net Capital Rule all references to credit ratings and substitute an alternative standard of creditworthiness. Specifically, in place of the current Net Capital Rule references to credit ratings, the Commission is proposing that a broker-dealer take a 15% haircut on its proprietary positions in commercial paper, nonconvertible debt, and preferred stock unless the broker-dealer has a process for determining creditworthiness that satisfies the criteria described below. However, commercial paper, nonconvertible debt, and preferred stock without a ready market would remain subject to a 100% haircut.²⁵ The 15% haircut is derived

from the catchall haircut amount that applies to a security not specifically identified in the Net Capital Rule as having an asset-class specific haircut, provided the security is otherwise deemed to have a ready market.²⁶ It is also the haircut applicable to most equity securities.²⁷

If a broker-dealer establishes, maintains, and enforces written policies and procedures for determining creditworthiness under the proposed amendments, the broker-dealer would be permitted to apply the lesser haircut requirement currently specified in the Net Capital Rule for commercial paper (*i.e.*, between zero and ½ of 1%), nonconvertible debt (*i.e.*, between 2% and 9%), and preferred stock (*i.e.*, 10%) when the creditworthiness standard is satisfied. Under this proposal, in order to use these lower haircut percentages for commercial paper, nonconvertible debt, and preferred stock, a broker-dealer would be required to establish, maintain, and enforce written policies and procedures designed to assess the credit and liquidity risks applicable to a security, and based on this process, would have to determine that the investment has only a “minimal amount of credit risk.”

Under the proposed amendments, a broker-dealer, when assessing credit risk, could consider the following factors, to the extent appropriate, with respect to each security:²⁸

- Credit spreads (*i.e.*, whether it is possible to demonstrate that a position in commercial paper, nonconvertible debt, and preferred stock is subject to a minimal amount of credit risk based on the spread between the security’s yield and the yield of Treasury or other securities, or based on credit default swap spreads that reference the security);
- Securities-related research (*i.e.*, whether providers of securities-related research believe the issuer of the security will be able to meet its financial commitments, generally, or specifically, with respect to securities held by the broker-dealer);
- Internal or external credit risk assessments (*i.e.*, whether credit assessments developed internally by the broker-dealer or externally by a credit

current bona fide competitive bid and offer quotations can be determined for a particular security almost instantaneously and where payment will be received in settlement of a sale at such price within a relatively short time conforming to trade custom.” 17 CFR 240.15c3-1(c)(11).

²⁶ 17 CFR 240.15c3-1(c)(2)(vi)(j). Securities without a ready market would remain subject to a 100% haircut. 17 CFR 240.15c3-1(c)(2)(vii).

²⁷ 17 CFR 240.15c3-1(c)(2)(vi)(j).

²⁸ This list of factors is not meant to be exhaustive or mutually exclusive.

²¹ See Public Law 111-203 § 939.

²² See 17 CFR 240.15c3-1(a).

²³ 17 CFR 240.15c3-1(c)(2)(vi)(E).

²⁴ 17 CFR 240.15c3-1(c)(2)(vi)(F)(1) and (c)(2)(vi)(H).

²⁵ The term “ready market” is defined in the Net Capital Rule as “a market in which there exists independent bona fide offers to buy and sell so that a price reasonably related to the last sales price or

rating agency, irrespective of its status as an NRSRO, express a view as to the credit risk associated with a particular security);

- Default statistics (*i.e.*, whether providers of credit information relating to securities express a view that specific securities have a probability of default consistent with other securities with a minimal amount of credit risk);

- Inclusion on an index (*i.e.*, whether a security, or issuer of the security, is included as a component of a recognized index of instruments that are subject to a minimal amount of credit risk);

- Priorities and enhancements (*i.e.*, the extent to which a security is covered by credit enhancements, such as overcollateralization and reserve accounts, or has priority under applicable bankruptcy or creditors' rights provisions);

- Price, yield and/or volume (*i.e.*, whether the price and yield of a security or a credit default swap that references the security are consistent with other securities that the broker-dealer has determined are subject to a minimal amount of credit risk and whether the price resulted from active trading); and
- Asset class-specific factors (*e.g.*, in the case of structured finance products, the quality of the underlying assets).

To establish a basis for a haircut of less than 15% for commercial paper, nonconvertible debt, or preferred stock, a broker-dealer would have to establish, maintain, and enforce written policies and procedures for determining the creditworthiness of a security acquired by the firm. The range and type of specific factors considered would vary depending on the particular securities that are reviewed. A broker-dealer that applies a haircut below 15%, as described above, would have a greater burden to support its application of that haircut when a creditworthiness finding under one factor is contradicted by a finding under another factor. Further, any broker-dealer that determines that application of the factors specified above do not support a finding of a minimal amount of credit risk would apply the 15% haircut with respect to the subject security, or, if that security does not have a ready market, a 100% haircut.²⁹

²⁹ A financial instrument that possesses the necessary credit ratings under Rule 15c3-1 is nevertheless subject to the 100% deduction required by the rule if the financial instrument does not have a ready market. For example, commercial paper rated in the third highest credit rating category may not have a ready market and, therefore, would be subject to the 100% deduction. See, *e.g.*, Nandkumar Nayar and Michael S. Rozeff, *Ratings, Commercial Paper, and Equity Returns*, XLIX J. of Finance 1431, 1433, n.5 (1994) (noting

Each broker-dealer would be required to preserve for a period of not less than three years, the first two years in an easily accessible place, the written policies and procedures that the broker-dealer establishes, maintains, and enforces for assessing credit risk for commercial paper, nonconvertible debt, and preferred stock. Broker-dealers would be subject to this requirement in the Commission's broker-dealer record retention rule, Exchange Act Rule 17a-4, which the Commission is proposing to amend in conjunction with this rulemaking.³⁰

A broker-dealer's process for establishing creditworthiness and its written policies and procedures documenting that process would be subject to review in regulatory examinations by the Commission and self-regulatory organizations. A broker-dealer that applies a haircut of less than 15% for commercial paper, nonconvertible debt, and preferred stock without establishing, maintaining, and enforcing written policies and procedures reasonably designed to assess creditworthiness would be subject to disciplinary action for non-compliance with the rule and could be required to recalculate its net capital.

The Commission preliminarily believes that these new standards would enable broker-dealers to make the net capital computations required under the Net Capital Rule reflect the market and credit risk inherent in particular commercial paper, nonconvertible debt, and preferred stock.³¹ The Commission also recognizes that credit ratings may provide useful information to institutional and retail investors as part of the process of making an investment decision. The requirements of the current rule are based on the practice of many NRSROs to have at least eight categories of ratings for debt securities, with the top four ratings commonly referred to in the industry as "investment grade." Although the proposed amendments do not use the term "investment grade," they are meant to capture securities that should

that "issuers with the lowest ratings find that they cannot issue commercial paper in quantity"). The Commission notes that treatment of commercial paper rated in the third highest credit rating as discussed in this release is limited to Rule 15c3-1 only.

³⁰ Specifically, the Commission is proposing to adopt a new paragraph (b)(13) of Rule 17a-4, which would require broker-dealers to preserve the written policies and procedures the broker-dealer establishes, maintains, and enforces to assess creditworthiness of nonconvertible debt, preferred stock, and commercial paper under the Net Capital Rule.

³¹ See *Uniform Net Capital Rule*, Exchange Act Release No. 13635 (Jun. 16, 1977), 42 FR 31778 (Jun. 23, 1977).

generally qualify for that designation, without placing undue reliance on third-party credit ratings.

Currently, the Net Capital Rule distinguishes between those securities that are rated in one of the three highest categories by an NRSRO (*i.e.*, for commercial paper) and those securities that are rated in one of the four highest ratings by an NRSRO (*i.e.*, for nonconvertible debt and preferred stock). The proposed amendments would eliminate the distinction among types of securities. Instead, each of the three classes of securities would be subject to the same requirements under the proposed amendments.

According to data collected by the Commission, of the approximately 5,060 broker-dealers registered with the Commission as of year-end 2009, approximately 480 broker-dealers maintained proprietary positions in debt securities at that time.³² Thus, it appears that only a small percentage of active broker-dealers registered with the Commission would be impacted by the proposed amendments. The Commission preliminarily believes, based on its oversight activities, that many of the broker-dealers with substantial proprietary positions in debt securities already make independent assessments of creditworthiness based on the types of factors identified in the proposed amendments.

As noted above, the Commission does not intend through the proposed amendments to narrow or broaden the range of securities that generally qualify for reduced haircuts under the Net Capital Rule as currently written. The Commission recognizes that broker-dealers, when purchasing for their proprietary accounts, provide a substantial source of capital for issuers of commercial paper, nonconvertible debt, and preferred stock. Accordingly, any significant change in practice by broker-dealers, whether because of potential compliance costs, difficulties in applying the proposed criteria or minimal credit risk standard, or other factors, that results in a change in the

³² This number was obtained by reviewing broker-dealer Financial and Operational Combined Single (or "FOCUS") Reports for 2009 year-end and then calculating how many firms reported holding proprietary debt positions. For FOCUS Part II filers, the balances examined were "Bankers Acceptances" and "Corporate Debt." For FOCUS CSE filers, the balances examined were: "Money Market Instruments," "Private Label Mortgage Backed Securities," "Other Asset Backed Securities," and "Corporate Debt." For Part IIA filers, the balance examined was "Debt Securities." Broker-dealers that hold preferred stock also may hold positions in debt securities. However, because preferred stock is not a separate line item on the FOCUS Report, broker-dealers that hold only preferred stock and not other debt securities are not included in this estimate.

general allocation of such securities in proprietary accounts could have unintended consequences. Accordingly, the Commission is interested in receiving comment on the potential impact of the proposed amendments on the capital markets generally, and on capital raising efforts by issuers of the affected types of securities specifically, and on how any potential effect could be mitigated or eliminated.

The Commission requests comment on all aspects of these proposed amendments. In addition, the Commission requests comment on the following specific questions:

- Do broker-dealers that would be subject to the proposed amendments either already have processes in place for determining creditworthiness of commercial paper, nonconvertible debt, and preferred stock or have the financial sophistication and the resources necessary to adopt such processes without undue effort or expense? Are there particular types of broker-dealers that would not be capable of meeting this new standard without undue hardship? In what ways and to what extent, if any, would establishing and implementing procedures for determining creditworthiness in lieu of using a credit rating disproportionately impact medium-sized and smaller broker-dealers? Commenters who believe that medium-sized and smaller broker-dealers would be disproportionately affected by these amendments, should describe the firms that would be adversely impacted, as well as provide suggestions as to how the proposal could be amended to accommodate them.

- With respect to the factors a broker-dealer could consider, would the use of these factors in lieu of credit ratings reduce undue reliance on a third party's assessment of credit risk? To what extent, if any, is there a risk that undue reliance will shift from relying on a credit rating to relying on some other third party assessment of creditworthiness?

- What is the potential impact of moving from an objective standard to a more flexible standard? Is there the potential that a broker-dealer's evaluations of creditworthiness may be second-guessed? If so, how might the prospect of being second-guessed impact a broker-dealer's evaluation of minimal credit risk and the appropriate haircuts to take for purposes of the broker-dealer's net capital calculation?

- If broker-dealers establish and implement procedures for determining creditworthiness, some broker-dealers may determine that a security qualifies for a reduced haircut when it would not

have qualified for a reduced haircut under the current NRSRO standard. Alternatively, some broker-dealers may determine that a security does not qualify for a reduced haircut when the security would have qualified for a reduced haircut under the current standard. Describe the potential impact on capitalization and the efficient allocation of capital under these two scenarios and the likelihood of each occurring. In addition, with respect to the first scenario, describe the potential impact on the objective of Rule 15c3-1, which, among other things, is to protect investors by enabling a broker-dealer, if the firm experiences financial difficulty, to be in a position to meet all obligations to customers and counterparties and generate resources to wind-down its operations in an orderly manner without the need of a formal proceeding.

- What are the risks of using internal processes to make credit determinations and how could these risks be addressed? For example, would broker-dealers be likely to adopt procedures that minimize the credit risk associated with a particular security in order to minimize capital charges? How could this risk be addressed?

- Are there other factors a broker-dealer should use when determining creditworthiness? Should the Commission mandate that broker-dealers consider each factor in this release when assessing a security's credit risk? Should the list of factors be included in the text of Rule 15c3-1?

- Should the Commission place conditions on the ability of a broker-dealer to outsource factors related to the determination of creditworthiness to a third party? If the determination of factors related to creditworthiness is outsourced, how can the Commission determine that the outsourced determination meets the proposed standard?

- How often should a broker-dealer be required to update its assessment of a specific security to ensure the broker-dealer's determination of creditworthiness remains current? Should the rule contain a requirement that the assessment be updated after a specific period of time? Should the Commission limit the ability of a broker-dealer to outsource the monitoring of its determination of creditworthiness?

- Should the Commission require that the persons responsible for developing a broker-dealer's internal processes and applying them to possible positions in individual securities for purposes of the Net Capital Rule be separate from employees who make proprietary

investment decisions for the broker-dealer?

- What would be the appropriate level of regulatory oversight of a broker-dealer's credit determination processes? Should the Commission describe in more detail how examiners will examine these processes? How should a broker-dealer be able to demonstrate to regulators the adequacy of the processes that it adopts and that it is following them?

- Should the Commission require the securities industry self-regulatory organizations to set appropriate standards for broker-dealers to use in evaluating creditworthiness and evaluating individual positions in commercial paper, nonconvertible debt, and preferred stock for net capital purposes?

- Should the Commission require broker-dealers to create and maintain records of creditworthiness determinations? If so, what records should be required to be maintained and how should they be described in a rule? Are there standard records that are used when making creditworthiness determinations that the Commission could require broker-dealers to keep? Are there other measures the Commission could consider to reduce the risk that broker-dealers will adopt inadequate processes or fail to adhere to them?

- Rather than referencing a list of factors that broker-dealers could consider, should the rule reference a single or limited set of factors (e.g., credit spreads)? Could a simpler approach adequately capture the risks of holding the full range of securities covered by the rule?

- Are there alternate and more reliable means of establishing creditworthiness for purposes of the Net Capital Rule? Please include detailed descriptions.

- Should the Commission define "minimal amount of credit risk"? Commenters who believe the Commission should define this term should include a detailed description of what should be included in the definition.

2. Proposed Amendments to Appendix A to Rule 15c3-1

Appendix A to Rule 15c3-1 allows broker-dealers to employ theoretical option pricing models in determining net capital requirements for listed options and related positions.³³ Broker-dealers may also elect a strategy-based methodology.³⁴ The purpose of

³³ 17 CFR 240.15c3-1a.

³⁴ *Id.*

Appendix A is to simplify the net capital treatment of options in order to reflect the risk inherent in options and related positions.³⁵

Under Appendix A, broker-dealers' proprietary positions in "major market foreign currency" options receive more favorable treatment than options for all other currencies when using theoretical option pricing models to compute net capital deductions. The term "major market foreign currency" is currently defined to mean "the currency of a sovereign nation whose short-term debt is rated in one of the two highest categories by at least two nationally recognized statistical rating organizations and for which there is a substantial inter-bank forward currency market."³⁶

With respect to the definition of the term "major market foreign currency," the Commission proposes to remove from that definition the phrase "whose short-term debt is rated in one of the two highest categories by at least two nationally recognized statistical rating organizations." The change would modify the definition of that term to include foreign currencies only "for which there is a substantial inter-bank forward currency market." The Commission also is proposing to eliminate the specific reference in the rule to the European Currency Unit (ECU), which is identified by the rule as the only major market foreign currency under Appendix A.³⁷ However, because of the establishment of the euro as the official currency of the euro-zone, a specific reference to the ECU is no longer needed. The Commission preliminarily believes that specific reference to the euro also is not necessary, as it is a foreign currency with a substantial inter-bank forward currency market.

The Commission requests comment on all aspects of the proposed amendments to Appendix A to the Net Capital Rule. In addition, the Commission requests comment on the following specific questions:

- Is the proposed definition of "major market foreign currency" sufficiently clear to allow broker-dealers to determine which currencies qualify as major market foreign currencies?
- It is not the intention of the Commission to change the currencies that meet the definition of "major market foreign currency" under this rule. Does the new definition of "major market foreign currency" achieve this

goal? Does the Commission need to keep an example of a "major market foreign currency" in the definition?

- How should the Commission distinguish between major market foreign currencies and all other currencies? Should the rule provide that broker-dealers can apply for a Commission determination (e.g., in the form of an Order or other Commission action) that a currency be considered a major market foreign currency under Appendix A to Rule 15c3-1? Should a list be created and published on the Commission's Web site? Should the Commission rely on other lists, such as the list of member countries of the Organization for Economic Co-Operation and Development?³⁸ Should the determination be made by one of the self-regulatory organizations?

- Should the Commission replace the language in Appendix A to Rule 15c3-1 with a new standard? If so, what should that standard be? Should the Commission use the same standard of creditworthiness and require the same type of process that it has proposed above for Rule 15c3-1?

3. Proposed Amendments to Appendix E to Rule 15c3-1

Pursuant to Appendix E to Rule 15c3-1, a broker-dealer may apply to the Commission for authorization to use an alternative method for computing capital (i.e., the alternative net capital, or "ANC," computation).³⁹ Specifically, broker-dealers with internal risk management practices that utilize certain mathematical modeling methods to manage their own business risk, including value-at-risk ("VaR") models and scenario analysis, may apply to use these methods to compute net capital requirements for market risk and derivatives-related credit risk.

Under Appendix E, broker-dealers subject to the ANC computation are required to deduct from their net capital credit risk charges that take counterparty risk into consideration. This counterparty risk determination is currently based on either NRSRO ratings or a dealer's internal counterparty credit rating. To comply with Section 939A of the Dodd-Frank Act, the Commission is proposing to remove paragraphs (c)(4)(vi)(A) through (c)(4)(vi)(D) of Appendix E, which base credit risk charges for counterparty risk on NRSRO

ratings, and in place of these ratings, require a broker-dealer using the ANC computation to apply a credit risk weight of either 20%, 50%, or 150% with respect to an exposure to a given counterparty based on the internal credit rating the broker-dealer determines for the counterparty.

As a result, a broker-dealer that applies to use the approach set forth in Appendix E to determine counterparty risk would be required, as part of its initial application or in an amendment to the application, to request Commission approval to determine credit risk weights of either 20%, 50%, or 150% based on internal calculations and credit ratings. The Commission notes that all of the firms approved to use models to calculate market and credit risk charges under Appendix E to Rule 15c3-1 have been approved to determine credit ratings using internal ratings rather than ratings issued by NRSROs.⁴⁰ Under the proposal, firms that are already approved to use the ANC computation in Appendix E would not need to seek new approval from the Commission. Other broker-dealers applying for ANC computation in Appendix E would be required to seek approval of their methodology for determining internal ratings. A broker-dealer that is applying to use Appendix E and intends to use internal ratings to determine the applicable credit risk weights should so state in its application to the Commission.

As stated above, all of the broker-dealers approved to use Appendix E to Rule 15c3-1 have already developed models approved for use in performing the ANC computation, as well as internal risk management control systems. As such, each firm already employs an internal credit rating method (i.e., a non-NRSRO credit rating method) that would, under the proposed amendments, become the only option for determining the applicable credit risk weight.

The Commission generally requests comment on all aspects of the proposed amendments to Appendix E to Rule 15c3-1. In addition, the Commission requests comment on the following specific questions:

- Should the Commission replace provisions in Appendix E to Rule 15c3-1 with a new standard? If so, what should that standard be? For example, should the Commission use the same standard of creditworthiness that it has proposed above for commercial paper,

³⁵ See *Net Capital Rule*, Exchange Act Release No. 38248 (Feb. 6, 1997), 62 FR 6474 (Feb. 12, 1997).

³⁶ 17 CFR 240.15c3-1a(b)(1)(i)(C).

³⁷ *Id.*

³⁸ See http://www.oecd.org/pages/0,3417,en_36734052_36761800_1_1_1_1,00.html.

³⁹ As a condition of approval, applicants must maintain an "early warning" level of at least \$5 billion in tentative net capital, minimum levels of at least \$1 billion in tentative net capital, and \$500 million in net capital. See 17 CFR 240.15c3-1(a)(7) and (c)(15).

⁴⁰ Currently six broker-dealers are approved to use the ANC computation in Appendix E to Rule 15c3-1.

nonconvertible debt, and preferred stock?

- Should the Commission continue to use credit risk weights of 20%, 50%, or 150%? If not, what risk weights should the Commission require be applied?

- Should broker-dealers that are already approved to use Appendix E be required to seek a new determination by the Commission of the credit risk weights assigned to their internal ratings scale?

4. Proposed Amendments to Appendix F to Rule 15c3-1 and the General Instructions to Form X-17A-5, Part IIB

Appendix F to the Net Capital Rule sets forth a program for OTC derivatives dealers that allow them to use an alternative approach to computing net capital deductions, subject to certain conditions.⁴¹ Under Appendix F, OTC derivatives dealers with strong internal risk management practices may utilize the mathematical modeling methods used to manage their own business risk, including VaR models and scenario analysis, to compute deductions from net capital for market and credit risks arising from OTC derivatives transactions.⁴²

Under Appendix F to the Net Capital Rule, OTC derivatives dealers are required to deduct from their net capital credit risk charges that take counterparty risk into consideration. As part of this deduction, the OTC derivatives dealer must apply a counterparty factor of either 20%, 50%, or 100%.⁴³ In addition, the OTC derivatives dealer must take a concentration charge where the net replacement value in the account of any one counterparty exceeds 25% of the OTC derivatives dealer's tentative net capital.⁴⁴ The counterparty factor (*i.e.*, 20%, 50%, or 100%) to apply currently is based on either NRSRO ratings or the

firm's internal credit ratings.⁴⁵ The concentration charges also are based on either NRSRO ratings or the firm's internal credit ratings. All of the firms approved to use models to calculate market and credit risk charges under Appendix F to Rule 15c3-1 have been approved to determine credit risk charges using internal credit ratings.⁴⁶ To comply with Section 939A of the Dodd-Frank Act, the Commission is proposing to amend Appendix F to Rule 15c3-1 and to make conforming changes to Form X-17A-5, Part IIB.

Specifically, the Commission is proposing to revise paragraphs (d)(2), (d)(3)(i), (d)(3)(ii), (d)(3)(iii), and (d)(4) of Appendix F to the Net Capital Rule, which permit the use of NRSRO ratings when determining counterparty risk. As a result of these revisions, an OTC derivatives dealer that applies to use the approach set forth in Appendix F to determine counterparty credit risk charges would be required, as part of its initial application or in an amendment to the application, to request Commission approval to determine credit ratings using internal ratings rather than ratings issued by NRSROs. Under the proposal, firms that are already approved to use internal ratings pursuant to Appendix F would not need to seek new approval from the Commission. An OTC derivatives dealer that is applying to use Appendix F and intends to use internal ratings to determine the applicable credit risk weights should so state in its application to the Commission.

As stated above, all of the approved firms have already developed models to calculate market and credit risk under the alternative net capital calculation methods set forth in Appendix F. As such, each firm already employs a non-NRSRO ratings-based method that would, under the proposed amendments, become the only option for calculating credit risk charges.

Based on these proposed amendments to Appendix F to Rule 15c3-1, the Commission is proposing conforming changes to the General Instructions to Form X-17A-5, Part IIB. This form constitutes the basic financial and operational report required of OTC derivatives dealers to be filed with the Commission. Under the heading "Computation of Net Capital and Required Net Capital" and before the section "Aggregate Securities and OTC Derivatives Positions," the Commission is proposing conforming changes to the section "Credit risk exposure." This

section explains the counterparty charges for OTC derivatives dealers based on the language in Appendix F to Rule 15c3-1. Therefore, the Commission is proposing that all changes made to Appendix F to Rule 15c3-1 also be made to the section "Credit risk exposure" under the heading "Computation of Net Capital and Required Net Capital" in the General Instructions to Form X-17A-5, Part IIB.

The Commission generally requests comment on all aspects of the proposed amendments to Appendix F to Rule 15c3-1 and the conforming changes to the General Instructions to Form X-17A-5, Part IIB. In addition, the Commission requests comment on the following specific questions:

- Should the Commission replace the provisions in Appendix F to Rule 15c3-1 with a new standard? If so, what should that standard be? Should the Commission use the same standard of creditworthiness that it has proposed above for commercial paper, nonconvertible debt, and preferred stock?

- Should the Commission continue to use counterparty factors of 20%, 50%, or 100%? If not, what counterparty factors should the Commission require be applied?

- Should the OTC derivatives dealers that have been approved to use Appendix F be required to submit an amendment to their applications to use internal credit ratings?

5. Proposed Amendment to Appendix G to Rule 15c3-1

The Commission is also proposing a conforming amendment to Appendix G to Rule 15c3-1. Under Appendix G, a broker-dealer that uses the ANC computation can only do so if its ultimate holding company agrees to provide the Commission with additional information about the financial condition of the ultimate holding company and its affiliates. Appendix G applies to an ultimate holding company that has a principal regulator and is intended to ensure that the Commission can obtain certain information designed to help the Commission assess the financial and operational health of the ultimate holding company and its potential impact on the risk exposure of the broker-dealer.⁴⁷

The proposed amendment to Appendix G would delete references in that appendix to the provisions of

⁴¹ OTC derivatives dealers are a special class of broker-dealers that are exempt from certain broker-dealer requirements, including membership in a self-regulatory organization (17 CFR 240.15b9-2), regular broker-dealer margin rules (17 CFR 240.36a1-1), and application of the Securities Investor Protection Act of 1970 (17 CFR 240.36a1-2). OTC derivative dealers are subject to special requirements, including limitations on the scope of their securities activities (17 CFR 240.15a-1), specified internal risk management control systems (17 CFR 240.15c3-4), recordkeeping obligations (17 CFR 240.17a-3(a)(10)), and reporting responsibilities (17 CFR 240.17a-12). They are also subject to alternative net capital treatment (17 CFR 240.15c3-1(a)(5)). See 17 CFR 240.15a-1, Preliminary Note.

⁴² The minimum net capital requirements for an OTC derivatives dealer are tentative net capital of at least \$100 million and net capital of at least \$20 million. See 17 CFR 240.15c3-1(a)(5) and (c)(15).

⁴³ 17 CFR 240.15c3-1f(d)(2).

⁴⁴ 17 CFR 240.15c3-1f(d)(3).

⁴⁵ See 17 CFR 240.15c3-1f(d)(2) and (4).

⁴⁶ Currently four firms are using Appendix F to the Net Capital Rule.

⁴⁷ Currently, each broker-dealer that uses the ANC computation has an ultimate holding company that has a principal regulator. As a result of both changes to the Commission's regulatory programs and the Dodd-Frank Act, the Commission is no longer regulating ultimate holding companies.

Appendix E that the Commission is proposing to delete as described above. These references are found in paragraph (a)(3)(i)(F) to Appendix G. Because of the proposed amendments to Appendix E described above, the references to Appendix E in Appendix G would no longer be accurate.

The Commission generally requests comment on all aspects of the proposed amendment to Appendix G to Rule 15c3-1.

B. Proposed Amendment to Exhibit A to Rule 15c3-3

Exchange Act Rule 15c3-3 (the "Customer Protection Rule") protects customer funds and securities held by broker-dealers. In general, the Customer Protection Rule has two parts. The first part requires a broker-dealer to have possession or control of all fully paid and excess margin securities of its customers. In this regard, a broker-dealer must make a daily determination in order to comply with this aspect of the rule.

The second part covers customer funds and requires broker-dealers subject to the rule to make a periodic computation to determine how much money it is holding that is either customer money or money obtained from the use of customer securities ("credits"). From that figure, the broker-dealer subtracts the amount of money which it is owed by customers or by other broker-dealers relating to customer transactions ("debits"). If the credits exceed debits after this "reserve formula" computation, the broker-dealer must deposit the excess in a "Special Reserve Bank Account for the Exclusive Benefit of Customers" (a "Reserve Account"). If the debits exceed credits, no deposit is necessary. Funds deposited in a Reserve Account cannot be withdrawn until the broker-dealer completes another computation that shows that the broker-dealer has on deposit more funds than the reserve formula requires.

The Customer Protection Rule is designed to prevent broker-dealers from using customer money to finance their business, except as related to customer transactions, since customer funds (the credits) can be offset only by customer-related transactions (the debits). As a result, broker-dealers must provide the capital to finance their trades and firm activities and may not use customers' funds for such purposes.

Exhibit A to Rule 15c3-3 contains the formula that a broker-dealer must use to determine its reserve requirement. Under Note G to Exhibit A, a broker-dealer may include required customer margin for transactions in security

futures products as a debit in its reserve formula computation if that margin is required and on deposit at a clearing agency or derivatives clearing organization that:

1. Maintains the highest investment-grade rating from an NRSRO;
2. Maintains security deposits from clearing members in connection with regulated options or futures transactions and assessment power over member firms that equal a combined total of at least \$2 billion, at least \$500 million of which must be in the form of security deposits;
3. Maintains at least \$3 billion in margin deposits; or
4. Obtains an exemption from the Commission.⁴⁸

Requiring a clearing agency or a derivatives clearing organization to meet certain minimum criteria before margin deposits with that entity may be included as a debit in a broker-dealer's customer reserve formula is consistent with the customer protection function of Rule 15c3-3, because margin that is posted for customer positions in security futures products constitutes an unsecured receivable from the clearing agency or organization. Accordingly, this requirement is intended to provide reasonable assurance that customer margin deposits related to security futures products are adequately protected.

The Commission is proposing to remove the first criterion described above (*i.e.*, the highest investment-grade rating from an NRSRO). The Commission notes that the criteria are disjunctive and, therefore, a clearing agency or derivatives clearing organization needs to satisfy only one criterion to permit a broker-dealer to treat customer margin as a reserve formula debit. Consequently, the Commission preliminarily believes that the proposed amendment would not lessen the protections for customer funds and securities. Furthermore, while one potential criterion would be removed, there is only one clearing agency for security futures products (namely, the Options Clearing Corporation) and that clearing agency would continue to qualify under each of the other applicable criteria. Moreover, if a new registered clearing agency or derivatives clearing organization could not meet one of the remaining criteria, a broker-dealer may request an exemption for the clearing agency or organization under the rule.⁴⁹

⁴⁸ 17 CFR 240.15c3-3a, Note G.

⁴⁹ The Commission may, in its sole discretion, grant such an exemption subject to such conditions as are appropriate under the circumstances if the

The Commission preliminarily believes that eliminating the reference to NRSRO ratings in Note G to Exhibit A to Rule 15c3-3 will continue to advance the goals of the Customer Protection Rule by ensuring the long-term financial strength of clearing agencies and derivatives clearing organizations holding customer margin for positions in security futures products.⁵⁰ The Commission preliminarily believes that requiring a registered clearing agency or derivatives clearing organization to comply with one of the three remaining criteria will adequately serve the customer protection purpose of Rule 15c3-3.

The Commission generally requests comment on all aspects of the removal of paragraph (b)(1)(i) of Note G to Rule 15c3-3a. In addition, the Commission requests specific comment on the following questions:

- Should the Commission replace the language in paragraph (b)(1)(i) of Note G with a new standard? If so, what should that standard be? Should the Commission use the same standard of creditworthiness that it has proposed above for commercial paper, nonconvertible debt, and preferred stock?
- What factors should the Commission take into account when considering the potential regulatory compliance costs of removing references to NRSROs from paragraph (b)(1) of Note G? Commenters should include detailed descriptions of any potential costs.
- Do the guidelines offered by current paragraphs (b)(1)(ii)–(iv) of Note G provide sufficient means by which a registered clearing agency or derivatives clearing organization could be judged to meet the requirements of paragraph (b)(1) of Note G? If not, what additional information should be added to meet the requirements of paragraph (b)(1) of Note G?
- Are there clearing agencies or derivatives clearing organizations that would not meet the remaining standards contained in paragraph (b)(1) of Note G?

C. Exceptions for Investment Grade Nonconvertible and Asset-Backed Securities in Rules 101 and 102 of Regulation M

As a prophylactic anti-manipulation set of rules, Regulation M is designed to

Commission determines that such conditional or unconditional exemption is necessary or appropriate in the public interest and is consistent with the protection of investors. See paragraph (b)(iv) of Rule 15c3-3a, Note G.

⁵⁰ See Rule 15c3-3 Reserve Requirements for Margin Related to Security Futures Products, Exchange Act Release No. 50295 (Aug. 31, 2004), 69 FR 54182 (Sep. 7, 2004).

preserve the integrity of the securities trading market as an independent pricing mechanism by prohibiting activities that could artificially influence the market for an offered security. Rules 101 and 102 of Regulation M specifically prohibit issuers, selling security holders, distribution participants, and any of their affiliated purchasers, from directly or indirectly bidding for, purchasing, or attempting to induce another person to bid for or purchase a “covered security” until the applicable restricted period has ended.⁵¹

Rules 101(c)(2) and 102(d)(2) currently except “investment grade nonconvertible and asset-backed securities.”⁵² These exceptions apply to nonconvertible debt securities, nonconvertible preferred securities, and asset-backed securities that are rated by at least one NRSRO in one of its generic rating categories that signifies investment grade. In accordance with Section 939A(b) of the Dodd-Frank Act, the Commission is proposing to remove the references to credit ratings in Rules 101(c)(2) and 102(d)(2) and replace them with new standards relating to the trading characteristics of covered securities.

1. Background

Historically, the Rule 101(c)(2) and 102(d)(2) exceptions trace back to a no-action position taken by the staff in 1975 regarding Exchange Act Rule 10b-6, the predecessor to Rules 101 and 102.⁵³ The lead underwriter of an offering of debentures had written the staff seeking interpretive guidance because Rule 10b-6 prohibited it from making markets in the debt securities of the same issuer other than the security being distributed, as these other securities could be considered “of the same class and series” under Rule 10b-6(a) as the security being distributed.⁵⁴ The staff, with the Commission’s concurrence, provided no-action relief

permitting dealers participating in a distribution of debt securities of an issuer to bid for or purchase other outstanding debt securities of such issuer, but required that the new issue and outstanding issues be subject to certain investment grade ratings.⁵⁵ In granting relief, the staff emphasized representations from the underwriter that (1) “because the non-convertible bonds of particular issuers are not considered unique and because of the concept of relative value, it is simply not possible to manipulate the price of a corporate bond that has broad investor interest” and (2) purchasing activities in such securities generally are “unlikely to materially affect the price of [a nonconvertible debt security being offered] because of the availability of large amounts of securities of other issuers which have comparable quality yield [spreads].”⁵⁶

In 1983, the Commission amended the rule to fully except all investment grade nonconvertible debt securities from Rule 10b-6.⁵⁷ At that time, the Commission also added an exception for investment grade nonconvertible preferred securities. In proposing the rule changes, the Commission stated that “it is very difficult, if not impossible, to manipulate the price of investment grade debt. Investment grade debt securities are generally thought to trade in accordance with the concept of relative value, *i.e.*, such securities are to a large degree fungible,⁵⁸ so that

⁵⁵ Letter from Robert C. Lewis, Associate Director, the Division of Market Regulation, the Commission, to Donald M. Feuerstein, General Partner and Counsel, Salomon Brothers (Mar. 4, 1975).

⁵⁶ *Id.*

⁵⁷ *Prohibitions Against Trading by Persons Interested in a Distribution*, Exchange Act Release No. 19565 (Mar. 4, 1983), 48 FR 10628 (Mar. 14, 1983). See also *Prohibitions Against Trading by Persons Interested in a Distribution*, Exchange Act Release No. 18528 (Mar. 3, 1982), 47 FR 11482 (Mar. 16, 1982). The 1975 letter included a number of other requirements that were not codified. Letter from Robert C. Lewis, Associate Director, the Division of Market Regulation, the Commission, to Donald M. Feuerstein, General Partner and Counsel, Salomon Brothers (Mar. 4, 1975).

⁵⁸ With regard to whether investment grade nonconvertible preferred securities are largely fungible with investment grade nonconvertible preferred securities of other issuers, the Commission noted that “[n]onconvertible preferred securities possess some of the attributes of debt securities and, when rated investment grade, generally trade on the basis of their value in relation to comparably-rated offerings of other issuers.” *Prohibitions Against Trading by Persons Interested in a Distribution*, Exchange Act Release No. 19565 (Mar. 4, 1983), 48 FR 10628 (Mar. 14, 1983). The Commission further noted that the exceptions are based on the concept “that investment grade debt and preferred securities are traded on the basis of their yields and financial ratings and therefore are largely fungible.” *Id.* The Commission solicits comment below as to whether this understanding with respect to the fungibility of nonconvertible preferred securities remains accurate.

investors generally evaluate new offerings by looking at comparably rated securities of other issuers.”⁵⁹

When Rules 101 and 102 of Regulation M were adopted, the Commission substituted the concept of “same class and series” in Rule 10b-6 with the concept of “covered securities.” The Commission clarified that as a result of this change, “bids for and purchases of outstanding nonconvertible debt securities are not restricted unless the security being purchased is identical in all of its terms to the security being distributed.”⁶⁰ The effect of this change in application was that “as a practical matter, Rule 101 and Rule 102 will have very limited impact on debt securities, except for the rare situations where selling efforts continue over a period of time.”⁶¹ In contrast, under Rule 10b-6, bids for or purchases of debt securities of the issuer other than those being distributed could be prohibited if they were similar to the distributed securities in coupon interest rate and maturity date.

Investment grade asset-backed securities were also added to the exception with the adoption of Regulation M.⁶² The application of the exception to these securities was based on the premise that asset-backed securities also trade primarily on the basis of yield spread and credit rating and that asset-backed securities investors are concerned with “the structure of the class of securities and the nature of the assets pooled to serve as collateral for those securities.”⁶³

2. 2008 Proposal

In 2008, the Commission proposed to eliminate NRSRO references to address concerns that such references contributed to undue reliance on NRSRO ratings by market participants. Specifically, the Commission proposed to remove references to NRSRO ratings from the determination of whether investment grade nonconvertible debt, investment grade nonconvertible preferred, and investment grade asset-backed securities would be eligible for

⁵¹ “Covered security” is defined as “any security that is the subject of a distribution or any reference security,” and “reference security” is defined as “a security into which a security that is the subject of a distribution (‘subject security’) may be converted, exchanged, or exercised or which, under the terms of the subject security, may in whole or in significant part determine the value of the subject security.” 17 CFR 242.100.

⁵² 17 CFR 242.101(c)(2) and 242.102(d)(2).

⁵³ Letter from Robert C. Lewis, Associate Director, the Division of Market Regulation, the Commission to Donald M. Feuerstein, General Partner and Counsel, Salomon Brothers (Mar. 4, 1975).

⁵⁴ As explained below, the activity for which relief was sought in this letter would be permissible under Rules 101 and 102 today even without the investment grade securities exceptions or no action relief because of a change in the securities covered under Rules 101 and 102 as compared to the securities covered under Rule 10b-6.

⁵⁹ *Prohibitions Against Trading by Persons Interested in a Distribution*, Exchange Act Release No. 18528 (Mar. 3, 1982), 47 FR 11482 (Mar. 16, 1982).

⁶⁰ *Anti-manipulation Rules Concerning Securities Offerings*, Exchange Act Release No. 38067 (Dec. 20, 1996), 62 FR 520 (Jan. 3, 1997). The Commission noted that “Rule 101 does not apply to a security if there is a single basis point difference in coupon rates or a single day’s difference in maturity dates, as compared to the security in distribution.” *Id.*

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Anti-manipulation Rules Concerning Securities Offerings*, Exchange Act Release No. 38067 (Dec. 20, 1996), 62 FR 520 (Jan. 3, 1997).

the Rule 101(c)(2) and 102(d)(2) exceptions, and instead except nonconvertible debt securities and nonconvertible preferred securities based on the “well-known seasoned issuer” (“WKSI”) concept of Securities Act Rule 405 and except asset-backed securities that are registered on Form S-3 (“2008 Regulation M Proposals”).⁶⁴

Those commenters that addressed the proposed Regulation M changes expressed uniform opposition to the proposed amendments.⁶⁵ Many of these commenters stated their view that the proposal is not necessary to address concerns about investors’ undue reliance on NRSRO ratings.⁶⁶ Commenters also stated that, because the 2008 Regulation M Proposals would have altered the scope of the exceptions for investment grade nonconvertible debt securities, investment grade nonconvertible preferred securities, and asset-backed securities, they would have placed new burdens on issuers and underwriters by imposing the restrictions of Regulation M on currently excepted investment grade securities.⁶⁷ Additionally, commenters expressed the view that certain high yield securities that are currently subject to Regulation M, but are arguably more vulnerable to manipulation than securities currently excepted from Regulation M, would have been excepted from Rules 101 and

102 of Regulation M under the 2008 Regulation M Proposals.⁶⁸ These commenters did not suggest any substitute to the proposed rule changes.⁶⁹

3. 2009 Comment Period Re-Opening

In 2009, the Commission deferred consideration of the 2008 Regulation M Proposals and, in light of the uniform opposition by commenters and continuing concern regarding the undue influence of NRSRO ratings, the Commission reopened the comment period for the 2008 Regulation M Proposals.⁷⁰ The Commission received three additional comment letters.⁷¹ Of these, two reiterated earlier objections,⁷² and the third argued that the 2008 Regulation M Proposals would have adverse effects on foreign sovereign issuers of debt securities.⁷³ Although the Commission invited commenters to suggest alternative proposals, no new alternatives were suggested.

4. Current Proposal

In accordance with Section 939A(b) of the Dodd-Frank Act, and in light of the opposition to the 2008 Regulation M Proposals, the Commission is proposing new standards to replace the reference to NRSRO credit ratings in the Regulation M exceptions. Specifically, the Commission proposes to except nonconvertible debt securities, nonconvertible preferred securities, and asset-backed securities from Rules 101 and 102 if they: (1) Are liquid relative to the market for that asset class; (2) trade in relation to general market interest rates and yield spreads; and (3) are relatively fungible with securities of similar characteristics and interest rate yield spreads.

The proposed standards are an attempt to codify the subset of trading

characteristics of investment grade nonconvertible debt securities, nonconvertible preferred securities, and asset-backed securities, that make them less prone to the type of manipulation that Regulation M seeks to prevent. The standards are not intended as measures of or proxies for assessments of credit risk, or to provide substitute criteria for whether or not a security would be considered investment grade.

The application of Rules 101 and 102 of Regulation M to debt securities is very limited, as compared to Rule 10b-6. The Commission is interested in comment as to whether and in what circumstances issuers, selling shareholders, distribution participants, and their affiliated purchasers rely on the current exception for investment grade securities (including with respect to specific activities) and, in particular, whether this exception serves a continuing purpose with regard to nonconvertible debt and asset-backed securities. The Commission further solicits comment as to whether, if the application of Rules 101 and 102 of Regulation M to debt securities is in fact quite limited as a practical matter, the current investment grade exception should be eliminated or, alternatively, whether it should be expanded to except from Rules 101 and 102 all nonconvertible debt securities, nonconvertible preferred securities, and asset-backed securities (or some subset thereof).

a. Standards

i. Liquid Relative to the Market for the Asset Class

In order to qualify for the proposed exception, a nonconvertible debt, nonconvertible preferred, or asset-backed security would need to be liquid relative to the market for that asset class. The Commission believes that a high degree of liquidity is an important consideration in determining which securities should be eligible for the proposed exception from Rules 101 and 102. In general, the existence of substantial liquidity is indicative of an established, efficient market with a large number of participants, which is less likely to be subject to the type of manipulation with which Regulation M is concerned. Since this exception would apply primarily to a security for which the distribution continues after the security begins to trade, the Commission preliminarily believes that persons seeking to rely on this exception would be able to adequately identify securities that meet this standard.

⁶⁴ *Proposed Rule: References to Ratings of Nationally Recognized Statistical Rating Organizations*, Exchange Act Release No. 58070 (Jul. 1, 2008), 73 FR 40088 (Jul. 11, 2008).

⁶⁵ We received five comment letters that specifically addressed the Regulation M proposals and each opposed the proposals. See Letters from Keith F. Higgins, Chair, Committee on Federal Regulation of Securities, American Bar Association (“ABA”), to Florence E. Harmon, Acting Secretary, dated Oct. 10, 2008 (“ABA Letter”); Robert Dobilas, CEO and President, Realpoint LLC, to Secretary, dated Sep. 8, 2008; Letter from Jeremy Reifsnyder and Richard Johns, Co-chairs, American Securitization Forum (“ASF”) Credit Rating Agency Task Force, to Florence E. Harmon, Acting Secretary, dated Sep. 5, 2008 (“ASF Letter”); Deborah A. Cunningham and Boyce I. Greer, Co-chairs, Securities Industry and Financial Markets Association (“SIFMA”) Credit Rating Agency Task Force, to Florence E. Harmon, Acting Secretary, dated Sep. 4, 2008 (“SIFMA Letter 1”); and Mayer Brown LLP to Florence E. Harmon, Acting Secretary, dated Sep. 4, 2008 (“Mayer Brown Letter”). There were comment letters supportive of the Commission’s effort to minimize undue reliance on NRSRO ratings by market participants, however, these commenters did not discuss Regulation M. See, e.g., Letter from Suzanne C. Hutchinson, Executive Vice President, Mortgage Insurance Companies of America, to Florence E. Harmon, Acting Secretary, dated Sep. 5, 2008.

⁶⁶ See, e.g., SIFMA Letter 1 (“Regulation M is primarily directed at the actions of the issuers of securities and the investment banks who underwrite them; in contrast, the investors that the Commission is concerned with are not users of Regulation M”).

⁶⁷ ABA Letter, SIFMA Letter 1.

⁶⁸ *Id.*

⁶⁹ The ABA did, however, suggest that should the Commission insist on using the WKSI standard for investment grade nonconvertible debt and investment grade nonconvertible preferred securities, it do so only as an alternative to the current exceptions at Rules 101(c)(2) and 102(d)(2). ABA Letter. However, the ABA expressed its “strong[] belie[f] that the Commission should retain the current exceptions.” *Id.*

⁷⁰ *References to Ratings of Nationally Recognized Statistical Rating Organizations*, Exchange Act Release No. 60790 (Oct. 5, 2009); 74 FR 52374 (Oct. 9, 2009).

⁷¹ Letter from Mary Keogh, Managing Director, Regulatory Affairs and Daniel Curry, President, DBRS, Inc., to Elizabeth M. Murphy, Secretary, dated Nov. 13, 2009 (“DBRS Letter”); Letter from Steven G. Tepper, Arnold & Porter LLP, to the Honorable Mary L. Schapiro, Chairman, dated Dec. 8, 2009 (“Arnold & Porter Letter”); and Letter from Sean C. Davy, Managing Director, Corporate Credit Markets Division, SIFMA, to Elizabeth M. Murphy, Secretary, dated Dec. 8, 2009 (“SIFMA Letter 2”).

⁷² DBRS Letter and SIFMA Letter 2.

⁷³ Arnold & Porter Letter.

The Commission seeks comment on the standards that may be indicative of relative liquidity, such as the size of the issuance, the percentage of the average daily trading volume by persons other than the persons seeking to rely on the exception, and the number of market makers in the security being distributed other than those seeking to rely on the exception.⁷⁴ Other factors that could be considered include the overall trading volume of the security, the number of liquidity providers who participate in the market for the security, trading volume in similar securities or other securities from the same issuer, overall liquidity of all outstanding debt issued by the same issuer, how quickly an investor could be expected to be able to sell the security after purchase, and, in the case of asset-backed securities, the liquidity and nature of the underlying assets.⁷⁵

ii. Trade in Relation to General Market Interest Rates and Yield Spreads

A nonconvertible debt security, nonconvertible preferred security, or asset-backed security also would need to trade at prices that are primarily driven by general market interest rates and spreads applicable to a broad range of similar securities. This standard would limit the exception's availability to those securities that trade in relation to changes in broader interest rates (*i.e.*, based on their comparable yield spreads), as opposed to securities that trade in relation to issuer-specific information or credit quality.⁷⁶ This characteristic affords market participants the ability to use general market rates to make their own estimates of the value of such a security and whether such security is trading at prices outside of expected ranges. It would be more difficult for market participants to make such an independent judgment if the security traded in an idiosyncratic fashion based primarily on its specific characteristics, such that the traded price of the security could not readily be compared to similar issues. As noted above,

investment grade nonconvertible debt, investment grade nonconvertible preferred, and investment grade asset-backed securities were originally excepted in part because they trade in relation to general market interest rates and yield spreads.

iii. Relatively Fungible With Securities of Similar Characteristics and Interest Rate Yield Spreads

Finally, a nonconvertible debt, nonconvertible preferred, or asset-backed security would need to be relatively fungible (in terms of trading characteristics) with similar securities, *i.e.*, securities with similar interest rate yield spreads, in order to qualify for the proposed exception. This standard, along with the requirement that the security trade in relation to general market interest rates and yield spreads explained above, is an attempt to codify a further trading characteristic of the investment grade securities that are currently excepted from Rules 101 and 102. Together with the standard regarding trading in relation to general market interest rates and yield spreads, the Commission preliminarily believes that the fungibility requirement would limit the proposed exception to those securities that pose little risk of manipulation.

Being "relatively fungible" for these purposes would not require that the security, for example, be deliverable for a purchase order for a different security, but rather that a portfolio manager would be willing to purchase the security in lieu of another security that has similar characteristics (*i.e.*, yield spreads, credit risk, etc.). Securities with these characteristics would be less prone to market squeezes or other forms of manipulation. Note that in order to satisfy this requirement, a security need not be completely fungible for all purposes with another security that has similar characteristics.

The Commission preliminarily believes that persons seeking to rely on the exception would be able to objectively demonstrate these three standards were met.

b. Evaluation of the Security

The proposal would require the person seeking to rely on the exception to make the determination that the security in question is liquid relative to the market for the asset class, trades in relation to general market interest rates and yield spreads, and is relatively fungible with securities of similar characteristics and interest rate yield spreads. The determination must be made utilizing reasonable factors of

evaluation and must be subsequently verified by an independent third party.

Each person seeking to rely on the exception would be required to assess the standards laid out in the proposal with regard to the specific nonconvertible debt, nonconvertible preferred, or asset-backed security being distributed. Persons would be required to exercise reasonable judgment in conducting this analysis. Sole reliance on a third party's determination without any further analysis would not be considered to be based on reasonable judgment. Persons seeking to rely on the exception would need to demonstrate compliance with the requirements of this provision.

c. Third Party Verification

In addition to making a determination that the nonconvertible debt, nonconvertible preferred, or asset-backed security reasonably meets the standards of the proposed exception, a person seeking to rely upon the exception also would be required to obtain a verification of this determination by an independent third party. Each person seeking to rely on the exception would be required to make a reasonable determination of the independence and qualifications of a third party for this purpose, based on the third party's relevant professional background, experience, knowledge, and skills. Counsel to, or other affiliates of, the underwriter or issuer, would not meet the independence requirement.⁷⁷ Persons seeking to rely on the exception may be best positioned in the first instance to evaluate all of the factors that would be relevant to the determination, but they also would have an inherent conflict of interest. The third party verification requirement is intended to provide a reliable check on the reasonableness of that determination.

The Commission intends by this proposal generally to except the same types and amounts of securities that are currently excepted in Rules 101(c)(2) and 102(d)(2) without referencing credit ratings. To that end, the Commission is interested in comments on any added costs or other effects that the requirement of independent third party verification in particular may have in distributions of nonconvertible debt, nonconvertible preferred, and asset-backed securities that would result in making the exception less available than it is today. To the extent that the need to obtain a third party verification increases the costs that a person must

⁷⁴ See, e.g., Letter from Larry E. Bergmann, Senior Associate Director, Division of Market Regulation, the Commission, to Alan J. Sinsheimer, Sullivan & Cromwell (Jan. 12, 2000).

⁷⁵ This list is merely illustrative and should not be considered a necessary or exhaustive list of the factors that could reasonably be considered in evaluating liquidity.

⁷⁶ This was an important distinction for the Commission when adopting the current exceptions. "Investors are therefore more likely to compare yields of new non-investment grade debt offerings with those of outstanding debt securities of the same issuer." *Prohibitions Against Trading by Persons Interested in a Distribution*, Exchange Act Release No. 18528 (Mar. 3, 1982), 47 FR 11482 (Mar. 16, 1982).

⁷⁷ This is not an exhaustive list of persons who would not be considered to be independent.

incur in order to benefit from the exception for these securities from Rules 101 and 102 of Regulation M, the Commission seeks comment as to what those costs are and whether such costs in at least some cases would result in persons who currently rely on the exception determining not to do so. This in turn may effectively expand the circumstances in which Rules 101 and 102 of Regulation M apply, as compared to the status quo. Thus, an increase in costs resulting from the third party verification that is sufficient to alter the behavior of market participants may reduce the practical benefit of the exception.

The Commission also specifically solicits comment regarding the type of entity that would be considered an acceptable independent third party for purposes of this exception. For example, the Commission seeks comment as to whether to limit the acceptable independent third parties to those who could meet the definition of "qualified independent underwriter" for purposes of the SRO rules,⁷⁸ which could provide a familiar bright line standard. The Commission also seeks comment as to whether to limit the acceptable independent third parties to only entities that are registered with the Commission, which would ensure that the Commission has examination authority over those persons acting as independent third party verifiers. The Commission further seeks comment as to whether the proposal should limit the number of times a person seeking to rely on the exception could rely on the same independent third party.

5. Request for Comment

We solicit comments on all aspects of this proposal. We ask that commenters provide specific reasons and information to support alternative recommendations. Please provide empirical data, when possible, and cite to economic studies, if any, to support alternative approaches.

⁷⁸ See Financial Industry Regulatory Authority ("FINRA") Rule 5121(f)(12). This rule generally requires that a qualified independent underwriter be a FINRA member, have no conflict of interest in the offering, not be an affiliate of a FINRA member that does have a conflict of interest, not beneficially own more than 5% of the class of securities that would give rise to a conflict of interest, have agreed in writing to be a qualified independent underwriter and undertake the legal responsibilities and liabilities of an underwriter under the Securities Act, have specific offering experience, and not have any supervisory associated persons who are responsible for organizing, structuring, or performing due diligence with respect to corporate public offerings of securities that have certain disciplinary histories.

- How often are these exceptions utilized where no other exception from Rules 101 or 102 of Regulation M exists?

- Should the Commission remove the exception from Rules 101 and 102 of Regulation M for nonconvertible debt securities, nonconvertible preferred securities, and/or asset-backed securities completely? Why or why not? What specific trading activities that currently occur pursuant to the exception would then be prohibited during the restricted period because no other exception is available? What are the advantages and disadvantages of such trading activities? Should the Commission explicitly except any such specific activities in lieu of providing a generic exception for investment grade nonconvertible debt securities, nonconvertible preferred securities, and/or asset-backed securities? What benefits or challenges would this approach create?

- Should the Commission expand the exception to cover all nonconvertible debt securities, nonconvertible preferred securities, and asset-backed securities? What activities would then be allowed that were previously prohibited under Rules 101 and 102 of Regulation M? Would these new activities have any manipulative risk? Why or why not?

- Would the nonconvertible debt, nonconvertible preferred, and asset-backed securities excepted in the proposal be more vulnerable to manipulation than securities that meet the existing investment grade standard? Why or why not?

- Are the proposed standards an appropriate substitute for credit ratings in this context? Would the proposal capture the same type and quantity of securities that fall within the current Rule 101(c)(2) and Rule 102(d)(2) exceptions? What effect(s), if any, would the proposed modifications to the current exception have on the markets for nonconvertible debt, nonconvertible preferred and asset-backed securities?

- How difficult and costly in practice would the requirements of the proposed exception be to apply? If the requirements are more difficult or costly to apply, how might this impact the scope of securities subject to the restrictions of Regulation M? For example, to what extent, if any, might a narrower range of securities meet the exceptions as a result of the proposal, if adopted? If fewer securities are excepted from the restrictions of Regulation M, in what ways and to what extent, if any, would this impact the market for those securities that would no longer qualify for the exception?

- Will fewer nonconvertible debt securities, nonconvertible preferred

securities, and asset-backed securities issues meet the requirements for these exceptions? If so, what impact would this proposal have on the market for new issues of these securities?

- Please discuss whether and to what extent investors rely upon the current Rule 101(c)(2) and 102(d)(2) exceptions for investment grade nonconvertible and asset-backed securities when making a decision to invest in such securities. Please also discuss whether, given that Rules 101 and 102 of Regulation M are directed at distribution participants, issuers, and selling securities holders, Rules 101 and 102 of Regulation M pose any danger of undue reliance on NRSRO ratings.

- Are there factors other than those identified in the proposed standards that influence the trading of such securities? Are there additional standards that the Commission should consider? Are there any that the Commission should remove from the proposal?

- Should the proposed standards apply equally to nonconvertible debt, nonconvertible preferred, and asset-backed securities, or are there other standards that would be relevant to consider based on the type of security involved?

- Would persons needing to use the proposed exception have access to adequate information to determine whether a particular security meets the exception? Why or why not?

- Is the Commission's position (expressed at the time the exception was initially adopted)⁷⁹ that preferred securities are generally fungible with similar quality preferred securities still valid? Has the market for preferred securities changed to the extent that these securities are no longer generally fungible with similar quality preferred securities? If so, to what extent has the market changed? Rules 101(c)(2) and 102(d)(2) of Regulation M currently except investment grade nonconvertible preferred securities. Is this exception still relevant in the current marketplace for preferred securities? What would be the potential adverse consequences if preferred securities were no longer excepted from Rules 101 and 102?

- With regard to asset-backed securities, should the determination on behalf of the issuer that the security meets the proposed factors be made by the sponsor or depositor of the asset-backed security, or some other person? Please explain. What kinds of conflicts

⁷⁹ *Prohibitions Against Trading by Persons Interested in a Distribution*, Exchange Act Release No. 19565 (Mar. 4, 1983), 48 FR 10628 (Mar. 14, 1983).

of interest may arise in this situation relating to sponsors or depositors? For instance, the Commission could propose the following rule text: "With respect to an asset-backed security, the term issuer includes a sponsor, as defined in § 229.1011 of this chapter, or depositor, as defined in § 229.1011 of this chapter, that participates in the issuance of an asset-backed security." Does this further the goal of Regulation M and the reasons for the exception? What benefits or costs would be associated with this change?

- What impact, if any, will the potential costs of obtaining an independent third party verification have on the market for new issues of nonconvertible debt securities, nonconvertible preferred securities, and asset-backed securities? If these costs will have an impact, please explain how.

- Other than NRSROs, are there entities such as independent research firms or investment banks not involved in the distribution that would be willing and able to serve as independent third parties for these purposes?

- What additional costs, if any, will the requirement to use an independent third party for purposes of the third party verification proposal add to a distribution as compared to the current requirements of Rules 101(c)(2) and 102(d)(2)?

- Would the independent third party verification, if adopted, alter the amount or types of securities that can rely on the exception?

- What factors should be considered in qualifying an independent third party for purposes of the third party verification proposal?

- Does the independent third party verification requirement adequately address potential issuer, selling shareholder, distribution participant, and affiliated purchaser conflicts of interest?

- Would it be appropriate to utilize the definition, in whole or in part, of "qualified independent underwriter" from the SRO rules in establishing who may be an independent third party for purposes of the third party verification proposal? What are the benefits or drawbacks to utilizing this standard? What other alternatives should the Commission consider?

- The Commission would expect, if such an interpretation would be adopted, that the definition of "qualified independent underwriter" for these purposes would be similar to the requirements of FINRA Rule 5121(f)(12) and generally require that such persons (1) be registered with an SRO; (2) have no conflict of interest in the offering; (3) not be an affiliate of a person that does

have a conflict of interest; (4) not beneficially own more than 5% of the class of securities that would give rise to a conflict of interest; (5) have agreed in writing to be a qualified independent underwriter and undertake the legal responsibilities and liabilities of an underwriter under the Securities Act; (6) have specific offering experience; and (7) not have any supervisory associated persons who are responsible for organizing, structuring, or performing due diligence with respect to corporate public offerings of securities that have certain disciplinary histories. Would all of these requirements be appropriate? Are any of these requirements unnecessary?

- Should the Commission limit the eligibility to be an independent third party for purposes of the third party verification proposal to those registered with the Commission in some capacity? What are the benefits or drawbacks to utilizing this standard? What other alternatives should the Commission consider?

- In order to protect an independent third party verifier's independence, should the Commission limit the frequency with which a person could rely on the same independent third party for purposes of the third party verification proposal?

- Should the Commission instead require only that persons seeking to rely on the exception make a reasonable determination that the proposed factors are present in the security being offered, without any independent third party verification? If so, should the concern about conflicts of interest be addressed and how? What benefits would this approach provide? What other concerns could this approach raise?

- What are the risks of allowing parties to use internal processes to make determinations of reasonableness? For example, would parties be likely to adopt procedures that maximize the opportunity to take advantage of the exception? Would increased cost efficiencies arising from internal processes outweigh the conflicts of interest presented? How likely are there to be instances where a determination under the proposed amendments would result in a party qualifying for the exception when it would not have qualified under the current standard? How might the Commission attempt to mitigate such risks?

- Should the Commission, in lieu of the third party verification requirement, require that any person seeking to rely on the exception disclose in the offering documents relating to the distribution: (1) That the person is relying on the relevant exception; (2) that the person

has undertaken diligent review and, utilizing the factors identified in this proposal, reasonably concluded that the security meets the proposed factors; (3) the factors identified in the proposal and used by the person to make its conclusions; and (4) that the person or affiliated purchasers will be purchasing or bidding during the restricted period (if that is in fact the case)? Would this approach also address concerns about the cost and effectiveness of independent third party verification and have the added benefit of full disclosure to investors? Would this approach present costs that do not arise under the current exceptions? What other representations should be included in the offering documents if this approach is taken? What benefits would this approach provide? What other concerns could this approach raise?

- Should the Commission permit the third party verification requirement to be deemed satisfied if one of the purchasers of the security is an unaffiliated regulated entity, such as a money market fund⁸⁰ or a broker-dealer that determines that the lesser haircut would apply to the security under the Net Capital Rule proposal above?⁸¹ Such entities might be required to make their own determination regarding the creditworthiness of the security. Could this creditworthiness determination provide the benefits of an independent third party verifier (*i.e.*, an independent assessment of the security) without the cost of retaining such a verifier? What benefits would this approach provide? What other concerns could this approach raise? Would the timing of a distribution allow for this determination to be made prior to the beginning of the restricted period? Are there other entities that should be included under this alternative, and if so, which entities and why?

- Should persons subject to Rules 101 or 102 be able to rely on the determination of another person in the underwriting syndicate who is seeking to rely on the exception in connection with the same distribution or should all distribution participants, issuers, selling security holders, or affiliated purchasers be required to make their own determinations?

- The proposed criteria that, if satisfied, would except a specific security from Rules 101 and 102 of Regulation M, are designed to identify those characteristics of a security that

⁸⁰ See *References to Credit Ratings in Certain Investment Company Act Rules and Forms*, Investment Company Act Release No. 29592 (Mar. 3, 2011), 76 FR 12896 (Mar. 9, 2011).

⁸¹ See Section II.A.1, *supra*.

would correlate with whether or not such a security was susceptible to manipulation during a time when it was distributed. Previously these criteria were considered to be met if the security had an investment grade rating. In proposing the criteria above, the Commission has focused on those trading-oriented characteristics of securities that the Commission believes (a) may be typical of securities with an investment grade rating, and (b) that are relevant to the question about manipulation. However, the Commission also notes that another common characteristic of securities with an investment grade rating is credit quality, and hence price or yield spread. Is credit quality alone a good determinant of whether or not a security is susceptible to manipulation under the conditions in which Rules 101 and 102 of Regulation M is concerned? Why or why not? If so, given the required removal of any reference to a security's rating, how would credit quality be measured for the purposes of this rule? Would the price or yield of a security be a good proxy for credit quality? If so, should the Commission except nonconvertible debt securities, nonconvertible preferred securities, and asset-backed securities based on a specific premium to the London Interbank Offered Rate ("LIBOR") at pricing? Would the defined yield spread be difficult to determine for securities that are difficult to price? Would this approach lead to market participants adjusting the price of securities at issuance, delaying issuance, or engaging in other activities solely to obtain the exception? Is LIBOR an appropriate rate on which to base this test or would other rates be more appropriate? If such an approach was utilized, is at pricing the appropriate time at which to compare the rates? How should the spreads be calculated? Would nonconvertible preferred securities and asset-backed securities be able to continue to rely on the exception under this proposal? Would persons seeking to rely on the exception be able to determine this information before the beginning of the restricted period? What benefits would this approach provide? What other concerns could this approach raise? How difficult will it be to predict, ahead of issuance, what the new issue's yield spread to the reference rate will be at the time the issue is priced? What is the expected economic effect of difficulty in predicting the yield spread at the time of pricing? Would the number of issues brought to market be impacted?

- With regard to asset-backed securities, should the Commission, in place of or in addition to the proposed amendment, except asset-backed securities that would meet the requirements for shelf eligibility for such securities as recently proposed by the Commission?⁸² This would provide a bright line test for these securities but may alter the universe of asset-backed securities that could rely on the exceptions. What benefits would this approach provide? What other concerns could this approach raise? How would this approach address potential conflicts of interest involving the issuer, selling shareholder, distribution participant, or affiliated purchaser?

- Should the Commission except nonconvertible debt securities and nonconvertible preferred securities based on trading volume and outstanding relevant securities of the issuer? For example, the Commission could except nonconvertible debt securities where the issuer has at least \$1 billion in outstanding debt and the trading volume of the outstanding debt securities of that issuer equaled or exceeded 100% turnover over a six month period, excluding trading by persons claiming the exception. This would have the benefit of establishing a bright line standard and is similar to the actively-traded securities exception found in Rule 101,⁸³ but may except a different universe of securities, be difficult to determine for securities that are hard to value, and would not be available to securities of new issuers. What benefits would this approach provide? What other concerns could this approach raise? Would such an exception tailored for nonconvertible

⁸² *Asset-Backed Securities*, Exchange Act Release No. 61858 (Apr. 7, 2010), 75 FR 23328 (May 3, 2010). This proposal would extend shelf eligibility to asset-backed securities where (1) a certification is filed at the time of each offering of a shelf registration statement by the chief executive officer of the depositor that the assets in the pool have characteristics that provide a reasonable basis to believe that they will produce, taking into account internal credit enhancements, cash flows to service any payments due and payable on the securities as described in the prospectus; (2) the sponsor retains a specified amount of each tranche of the securitization, net of the sponsor's hedging; (3) a provision in the pooling and servicing agreement requires the party obligated to repurchase the assets for breach of representations and warranties to periodically furnish an opinion of an independent third party regarding whether the obligated party acted consistently with the terms of the pooling and servicing agreement with respect to any loans that the trustee put back to the obligated party for violation of representations and warranties and which were not repurchased; and (4) the issuer makes an undertaking to file Exchange Act reports so long as non-affiliates of the depositor hold any securities that were sold in registered transactions backed by the same pool of assets.

⁸³ 17 CFR 242.101(c)(1).

preferred (referencing \$1 billion outstanding equity and trading volume of the issuer's nonconvertible preferred securities) be appropriate? What other changes would need to be made in order to make the exception available to preferred securities generally? Are there different numerical thresholds that are better able to replicate the universe of currently excepted nonconvertible debt securities and preferred securities? If the Commission replaced the current criteria with a volume test, how much effort on the part of intermediaries would be required to demonstrate that a volume threshold was met? How difficult would it be for financial intermediaries to gather volume statistics? What would the range of associated costs be? If it was necessary under the volume test to exclude trading by persons subject to Rules 101 or 102, would that information be available to financial intermediaries? Are there other numerical tests of this type that would be more appropriate? How would this approach address potential conflicts of interest involving the issuer, selling shareholder, distribution participant, or affiliated purchaser?

- Should underwriters be required to keep records demonstrating their eligibility for the exception as modified by the proposal? Should underwriters be required to obtain records from the issuer or selling shareholder demonstrating eligibility for the exception as modified by the proposal and keep them? What records should be kept?

- Please comment generally on any relevant changes to the debt markets since Regulation M was adopted in 1996 and how these developments should affect the Commission's evaluation of the proposed amendments.

D. Proposed Amendments to Rule 10b-10

Exchange Act Rule 10b-10,⁸⁴ the Commission's customer confirmation rule, generally requires broker-dealers effecting transactions for customers in securities, other than U.S. savings bonds or municipal securities,⁸⁵ to provide those customers with a written notification, at or before completion of the securities transaction, disclosing certain information about the terms of the transaction. Specifically, Rule 10b-10 requires the disclosure of the date, time, identity, and number of securities bought or sold; the capacity in which the broker-dealer acted (*e.g.*, as agent or

⁸⁴ 17 CFR 240.10b-10.

⁸⁵ Municipal securities are covered by Municipal Securities Rulemaking Board rule G-15, which applies to all municipal securities brokers and dealers.

principal); yields on debt securities; and under specified circumstances, the amount of compensation the broker-dealer will receive from the customer and any other parties. By requiring these disclosures, the rule serves a basic customer protection function by conveying information that: (1) Allows customers to verify the terms of their transactions; (2) alerts customers to potential conflicts of interest; (3) acts as a safeguard against fraud; and (4) allows customers a means of evaluating the costs of their transactions and the quality of the broker-dealer's execution.

Paragraph (a)(8) of Rule 10b-10, which the Commission adopted in 1994, requires a broker-dealer to inform the customer in the confirmation if a debt security, other than a government security, is unrated by an NRSRO.⁸⁶ As explained in the 1994 Adopting Release, paragraph (a)(8) was intended to alert customers to the potential need to obtain more information about a security from a broker-dealer;⁸⁷ it was not intended to suggest that an unrated security is inherently riskier than a rated security. Rule 10b-10 does not require broker-dealers to disclose in customer confirmations the NRSRO rating for securities that are rated, although the Commission understands that some broker-dealers may do so voluntarily. The Commission has previously proposed, and re-proposed, the deletion of paragraph (a)(8) from Rule 10b-10.⁸⁸ The Commission's previous proposals to delete paragraph (a)(8) were prompted by concerns regarding the undue reliance on NRSRO ratings and confusion about the significance of those ratings. Section 939A of the Dodd-Frank Act requires the Commission to replace references to NRSRO ratings in its rules, where these act as a proxy for creditworthiness, with a different standard of creditworthiness. Because paragraph (a)(8) of Rule 10b-10 does not refer to NRSRO ratings as a means of determining creditworthiness, this provision does not come strictly within Section 939A's requirements. Nevertheless, the Commission

preliminarily believes that to the extent that the provision is intended to focus investor attention on ratings issued by NRSROs, as distinct from other items of information, deleting it is consistent with the intent of the Dodd-Frank Act. Accordingly, the Commission is now re-proposing to delete paragraph (a)(8) from Rule 10b-10.⁸⁹

However, the Commission wishes to consider the relative benefits of retaining this information in the customer confirmation against the benefits of removing it. The Commission notes that the current requirement to disclose the unrated status of a debt security provides investors with an item of factual information that is conveyed together with additional factual information about the terms of the transaction. The Commission also notes that if this provision were deleted from Rule 10b-10, broker-dealers would not be prohibited from continuing to provide this disclosure on a voluntary basis.⁹⁰ The Commission requests comment on the following:

- Would the investor protection function of Rule 10b-10 be, in any way, diminished by deleting paragraph (a)(8) from the rule? Are there any alternative means of providing this information to customers?
- What types of securities would typically be unrated by an NRSRO? What types of issuers would typically not have their securities rated by an NRSRO?
- Could the disclosure that a security is unrated be removed from a customer confirmation without causing customer confusion? If so, given the historical use and investor expectations related to this disclosure, could it be removed without implying that a security is in fact rated? Should broker-dealers be required to alert customers that the unrated status of a security is no longer being disclosed? If so, for how long?

• The preliminary note to Rule 10b-10 provides: "This section requires broker-dealers to disclose specified information in writing to customers at or before completion of a transaction. The requirements under this section that particular information be disclosed is not determinative of a broker-dealer's obligation under the general antifraud provisions of the federal securities laws

to disclose additional information to a customer at the time of the customer's investment decision." If paragraph (a)(8) were deleted, would the preliminary note to Rule 10b-10 affect a broker-dealer's decision to nonetheless continue to voluntarily disclose whether a security is unrated?

• If paragraph (a)(8) were deleted, is there a disclosure that should be required in the confirmation on a transitional or permanent basis that would help prevent customer confusion? For example, should the Commission require broker-dealers, either permanently or temporarily for a transition period, to disclose that broker-dealers are no longer required to include on the confirmation the fact that a security is unrated? Should such a disclosure be made on the confirmation, the account statement, or in a separate document accompanying the confirmation or account statement? What are the costs associated with providing this disclosure on the confirmation, the account statement or in a separate document?

• If the requirement to disclose that a security is unrated were deleted from Rule 10b-10, would broker-dealers nevertheless feel compelled to include the disclosure in order to satisfy their sales practice obligations?

• Should the requirement to disclose that a security is unrated be replaced by a requirement to provide a general statement regarding the importance of considering an issuer's creditworthiness?

• If the requirement to disclose that a security is unrated were deleted from the rule, are there alternative external or objective measures of credit risk that could be substituted for ratings by an NRSRO? Is it practicable to replace it with a requirement to disclose specific information regarding an issuer's creditworthiness? If so, what specific information should the Commission consider including?

III. Requests for Comment on Section 939(e) of Dodd-Frank

Section 939(e) of the Dodd-Frank Act⁹¹ deleted Exchange Act references to credit ratings by NRSROs in Exchange Act Section 3(a)(41),⁹² which defines the term "mortgage related security," and in Exchange Act Section 3(a)(53),⁹³ which defines the term "small business related security." The credit rating references in Sections 3(a)(41) and 3(a)(53) effectively exclude from the respective definitions

⁸⁶ See *Confirmation of Transactions*, Exchange Act Release No. 34962 (Nov. 10, 1994), 59 FR 59612 (Nov. 17, 1994) ("1994 Adopting Release").

⁸⁷ *Id.* The Commission stated that "[i]n most cases, this disclosure should verify information that was disclosed to the investor prior to the transaction. If the customer was not previously informed on the security's unrated status, the confirmation may prompt a dialogue between the customer and the broker-dealer."

⁸⁸ See, e.g., *References to Ratings of Nationally Recognized Statistical Rating Organizations*, Exchange Act Release No. 60790 (Oct. 5, 2009), 74 FR 52374 (Oct. 9, 2009); *Proposed Rule: References to Ratings of Nationally Recognized Statistical Rating Organizations*, Exchange Act Release No. 58070 (Jul. 1, 2008), 73 FR 40088 (Jul. 11, 2008).

⁸⁹ Consistent with that change, the Commission is also proposing to redesignate paragraph (a)(9) of the rule, related to broker-dealers that are not members of the Securities Investor Protection Corporation ("SIPC"), as paragraph (a)(8).

⁹⁰ Indeed, based on a limited review of customer confirmations, the Commission understands that in addition to disclosing the unrated status of a security, some broker-dealers may also voluntarily include the NRSRO ratings for rated securities.

⁹¹ See Public Law 111-203 § 939(e).

⁹² 15 U.S.C. 78a(3)(a)(41).

⁹³ 15 U.S.C. 78a(3)(a)(53).

securities that otherwise meet the definitions but are not rated by at least one NRSRO in the top two credit rating categories in the case of mortgage related securities or in the top four credit rating categories in the case of small business related securities. In place of the credit rating references, Congress added language stating that a mortgage related security and a small business related security will need to satisfy “standards of credit-worthiness as established by the Commission.”⁹⁴ This replacement language will go into effect on July 21, 2012 (*i.e.*, two years after the Dodd-Frank Act was signed into law).⁹⁵ Thus, before that time, the Commission will need to establish a new standard of creditworthiness for each Exchange Act definition. As is discussed below, the Commission is requesting comment on potential “standards of credit-worthiness” for purposes of Sections 3(a)(41) and 3(a)(53) as the Commission considers how to implement Section 939(e) of the Dodd-Frank Act.

A. Exchange Act Section 3(a)(41)

Congress defined the term “mortgage related security” in Section 3(a)(41) as part of the Secondary Mortgage Market Enhancement Act of 1984 (“SMMEA”).⁹⁶ SMMEA was intended to encourage private sector participation in the secondary mortgage market by, among other things, relaxing certain regulatory burdens that affected the ability of private-label issuers⁹⁷ to sell their mortgage-backed securities.⁹⁸ For example, SMMEA removed obstacles for privately sponsored mortgage-backed

securities by, among other things, preempting certain state investment laws so that state regulated institutions might purchase privately sponsored mortgage-backed securities to the same extent as agency securities, granting authority for certain depository institutions to invest in these securities, and requiring states to exempt privately sponsored mortgage-backed securities from state registration to the same extent as agency securities, unless the state specifically deemed otherwise.⁹⁹ A security that qualifies as a mortgage related security, as defined in Section 3(a)(41), receives the benefits intended by SMMEA.¹⁰⁰

Generally, Section 3(a)(41) defines the term “mortgage related security” as a “security that is rated in one of the two highest rating categories by at least one [NRSRO],” which (1) represents ownership of one or more promissory notes, or interests therein, which notes (a) are directly secured by a first lien on a single parcel of real estate upon which is located a dwelling or mixed residential and commercial structure, or on a residential manufactured home or one or more parcels of real estate upon which is located one or more commercial structures and (b) were originated by a savings or banking institution approved for insurance by the Secretary of the U.S. Department of Housing and Urban Development; or (2) is secured by one or more promissory notes, or interests therein, and provides for payments of principal in relation to payments, or reasonable projections of payments, on notes, or interests therein, meeting the requirements specified above.

When Congress adopted SMMEA, it used NRSRO ratings to specify mortgage related securities that qualify for benefits under the legislation. As reflected in Section 939(e) of the Dodd-Frank Act, Congress has chosen to no longer rely on credit ratings by NRSROs to make this distinction, and instead has instructed the Commission to establish a new standard of creditworthiness that does not rely on credit ratings by NRSROs. Before acting on this authority, the Commission invites interested persons to submit written comments on potential alternatives the Commission should consider for purposes of implementing Section 939(e) of the Dodd-Frank Act.

One potential alternative the Commission is considering is a new rule under the Exchange Act that would apply the “minimal amount of credit

risk” standard the Commission is proposing with respect to the Net Capital Rule, as described above, to persons assessing whether a security is a mortgage related security within the meaning of Section 3(a)(41). The Commission preliminarily believes that the proposed minimal amount of credit risk standard for mortgage related securities would be consistent with the intended objective in Section 3(a)(41) of excluding from the definition mortgage related securities of lesser credit quality. The Commission further believes that the factors set forth above for facilitating determinations by broker-dealers as to whether a security satisfies the minimal amount of credit risk standard under the Net Capital Rule could facilitate determinations by others as to when mortgage related securities are subject to a minimal amount of credit risk under Section 3(a)(41). The Commission notes, however, that nonconvertible debt and preferred stock are currently required to be rated in one of the four highest credit rating categories by two NRSROs to qualify for reduced haircuts under the Net Capital Rule, and that a mortgage related security that qualifies as such under the current definition of that term in Section 3(a)(41) is required to satisfy a slightly more stringent level of credit quality (*i.e.*, to be rated in one of the two highest rating categories of one NRSRO).

B. Exchange Act Section 3(a)(53)

Congress defined the term “small business related security” in Section 3(a)(53) as part of the Riegle Community Development and Regulatory Improvement Act of 1994 (the “CDRI”).¹⁰¹ Among other things, the CDRI removed limitations on purchases by national banks of certain small business-related securities. The stated intent of Congress in the CDRI was to increase small business access to capital by removing impediments in existing law to the securitizations of small business loans.¹⁰² The CDRI built on the framework for securitizations established by SMMEA to create a similar framework for these securities with the goal of stimulating the flow of funds to small businesses.

Generally, Section 3(a)(53) defines the term “small business related security” as “a security that is rated in one of the four highest rating categories by at least

⁹⁴ See Public Law 111–203 § 939(e)(1) and (e)(2).

⁹⁵ See Public Law 111–203 § 939(g).

⁹⁶ Public Law 98–440, § 101, 98 Stat. 1689 (1984).

⁹⁷ Most mortgage-backed securities are issued by the Government National Mortgage Association (“Ginnie Mae”), a U.S. government agency, or the Federal National Mortgage Association (“Fannie Mae”) and the Federal Home Loan Mortgage Corporation (“Freddie Mac”), U.S. government-sponsored enterprises. Ginnie Mae, backed by the full faith and credit of the U.S. government, guarantees that investors receive timely payments. Fannie Mae and Freddie Mac also provide certain guarantees and, while not backed by the full faith and credit of the U.S. government, have special authority to borrow from the U.S. Treasury. Some private institutions, such as brokerage firms, banks, and homebuilders, also securitize mortgages, known as “private-label” mortgage securities.

⁹⁸ The legislation was aimed at encouraging participation in the secondary mortgage market by investment banks, investment entities, mortgage bankers, private mortgage insurance companies, pension funds and other investors, depository institutions and federal credit unions. See Kenneth G. Lore & Cameron L. Cowan, *Mortgage-Backed Securities: Developments and Trends in the Secondary Market* 2–39 (2001), at 1–14. See also Edward L. Pittman, *Economic and Regulatory Developments Affecting Mortgage Related Securities*, 64 Notre Dame L. Rev. 497, 499 (1989).

⁹⁹ See *Protecting Investors: A Half Century of Investment Company Regulation*, Division of Investment Management (May 1992).

¹⁰⁰ See Pittman *supra* note 98, at 514.

¹⁰¹ Public Law 103–325, § 202, 108 Stat. 2198 (1994).

¹⁰² See Conference Report on the CDRI, Vol. 140 Cong. Record, pp. H6685, H6690 (Aug. 2, 1994). See also Remarks of Sen. Domenici, Vol. 140 Cong. Record, p. S11039, S11043–43 (Aug. 2, 1994) (discussing national banks’ authority to purchase commercial mortgage related securities under conditions established by the Office of the Comptroller of the Currency).

one [NRSRO]" and either (i) represents an interest in promissory notes or leases of personal property evidencing the obligation of a small business concern and originated by an insured depository institution supervised and examined by federal or state authority or certain other regulated types of issuers, or (ii) is secured by promissory notes or leases of personal property (with or without recourse to the issuer or lessee) and provides for payments of principal in relation to payments, or reasonable projections of payments, on notes or leases of the type described in the preceding clause.

When Congress adopted the term "small business related security" in the CDRI, it used NRSRO ratings to specify small business related securities that would qualify for benefits under the legislation. As reflected in Section 939(e) of the Dodd-Frank Act, Congress has chosen to no longer rely on credit ratings by NRSROs to make this distinction, and instead has instructed the Commission to establish a new standard of creditworthiness that does not rely on credit ratings of NRSROs. Before acting on this authority, the Commission invites interested persons to submit written comments on potential alternatives the Commission should consider for purposes of implementing Section 939(e) of the Dodd-Frank Act.

One potential alternative the Commission is considering is a new rule under the Exchange Act that would apply the "minimal amount of credit risk" standard the Commission is proposing with respect to the Net Capital Rule, as described above, to persons assessing whether a security is a small business related security within the meaning of Section 3(a)(53). The level of credit quality Congress intended for a small business related security to satisfy in Section 3(a)(53) to qualify for benefits under the CDRI is the same level of credit quality that nonconvertible debt and preferred stock must currently satisfy to qualify for reduced haircuts under the Net Capital Rule (*i.e.*, NRSRO credit ratings in one of the four highest rating categories). The Commission preliminarily believes that the minimal amount of credit risk standard for small business related securities would be consistent with the intended objective of Congress in Section 3(a)(53) by excluding from the definition small business related securities of lesser credit quality. The Commission further preliminarily believes that the proposed factors set forth above for facilitating determinations by broker-dealers as to whether a security satisfies the minimal

amount of credit risk standard under the Net Capital Rule could facilitate determinations by others as to when a small business related security is subject to a minimal amount of credit risk under Section 3(a)(53).

C. Requests for Comment

The Commission requests comment on all aspects of how to implement Section 939(e) with respect to the definitions of mortgage related security and small business related security. In addition, the Commission requests comment on the following specific questions. In responding, commenters should distinguish between the two definitions to the extent that they believe that the two definitions should be treated differently for purposes of new rules.

- Is the minimal credit risk standard a practical and workable alternative for purposes of Section 3(a)(41) and Section 3(a)(53)? If not, what creditworthiness standard would be more appropriate?
- Who should be responsible for determining whether a security is creditworthy for these purposes? For example, is the sponsor, which is often involved in most, if not all, aspects of the securitization process, the most appropriate person to make this determination? Is the trustee a more appropriate person to make this determination based on the fiduciary relationship between the trustee and investors in the trust? Would an underwriter be an acceptable person to make the determination? Who else would be appropriate to make this determination?
- If the sponsor or another person makes the creditworthiness determination, could imposing disclosure obligations on that person with respect to its creditworthiness determination mitigate potential conflicts of interest?
- Should two or more persons be able to make the creditworthiness determination for the same security? If so, how could potential inconsistencies in that determination be resolved?
- If a sponsor or other person makes the creditworthiness determination, should that person be potentially liable to persons who relied on the determination? If so, what standard of liability should be applied?
- How often should creditworthiness determinations be made under Section 3(a)(41) or Section 3(a)(53) in order to determine if a security qualifies as a mortgage related security or small business related security?
- What objective measures could be used to determine whether securities qualify as mortgage related securities or

small business related securities? Please explain what measures or creditworthiness standards the Commission should consider.

- Should the Commission adopt rules that are designed to allow regulators or other persons to examine or verify that creditworthiness determinations are consistent with the requirements of the rules? Should creditworthiness determinations be subject to regulatory review? Should the Commission require a person making the determination to create, maintain, and make available for examination certain records related to the determination?

- Should the Commission impose a more stringent creditworthiness standard than the minimal credit risk standard that is being proposed for purposes of the Net Capital Rule? If so, what standard should apply, and how could it be distinguished from the minimal credit risk standard?

- Would application of the minimal credit risk standard proposed for purposes of the Net Capital Rule result in securities of lesser credit quality qualifying as mortgage related securities or small business related securities as compared to securities that currently qualify as such under Section 3(a)(41) or Section 3(a)(53)? If so, please explain why this would be the case and provide examples.

- An alternative to credit ratings, if too rigid, could narrow the types of financial instruments that qualify under Section 3(a)(41) or Section 3(a)(53) and, if too flexible, could broaden the types of financial instruments that qualify under Section 3(a)(41) or Section 3(a)(53). In discussing potential alternatives to credit ratings, please analyze their potential impacts on competition and capital formation.

IV. Paperwork Reduction Act

Certain provisions of the proposed amendments to the rules and form contain "collection of information requirements" within the meaning of the Paperwork Reduction Act of 1995 ("PRA").¹⁰³ The hours and costs associated with preparing and filing the disclosure, filing the form and schedules and retaining records required by these regulations constitute reporting and cost burdens imposed by each collection of information. 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 control number. The titles of the affected information forms are Rule 15c3-1 (OMB Control Number 3235-0200),

¹⁰³ 44 U.S.C. 3501 *et seq.*

Rule 15c3-3 (OMB Control Number 3235-0078), Rule 17a-4 (OMB Control Number 3235-0279) and Form X-17A-5, Financial and Operational Combined Uniform Single Report, Part IIB, OTC Derivatives Dealer (OMB Control Number 3235-0498); Rule 101 (OMB Control Number 3235-0464) and Rule 102 (OMB Control Number 3235-0467) of Regulation M; and Rule 10b-10 Confirmation of Transactions,” (OMB Control Number 3235-0444). For the reasons discussed below, the Commission does not believe the proposed amendments, if adopted, would result in a material or substantive revision to these collections of information.¹⁰⁴ The cost estimates contained in this section do not include any other possible costs or economic effects beyond the costs required to be calculated for PRA purposes.¹⁰⁵

A. Summary of Collection of Information

As discussed above, the Commission is proposing amendments to Rule 15c3-1, Appendices A, E, F, and G to Rule 15c3-1, Exhibit A to Rule 15c3-3, Rule 17a-4, the General Instructions to Form X-17A-5, Part IIB, Rules 101 and 102 of Regulation M, and Rule 10b-10. These amendments, in part, are proposed to comply with Section 939A of the Dodd-Frank Act, which requires the Commission to replace references to credit ratings in all of its regulations with a standard of creditworthiness that the Commission deems appropriate.

The proposed amendments to the Net Capital Rule and Rule 17a-4 create a new standard of creditworthiness that will allow broker-dealers to establish their own policies and procedures to determine whether a security has only a minimal amount of credit risk. If a broker-dealer chooses to establish these policies and procedures it would create a new “collection of information” burden for those broker-dealers, as explained below. In addition, the proposed amendments to the Customer Protection Rule remove one method for verifying the status of a registered clearing agency or derivatives clearing organization under Note G to Exhibit A. Broker-dealers who may have to use a new method for verifying the status of a registered clearing agency or derivatives clearing organization may have a new “collection of information” within the meaning of the PRA.

The proposed changes to Rules 101 and 102 of Regulation M would amend the exceptions for nonconvertible debt, nonconvertible preferred, and asset-

backed securities in those rules. Under the proposed amendments, distribution participants, issuers, selling shareholders, and affiliated purchasers of such persons would need to assess nonconvertible debt, nonconvertible preferred, and asset-backed securities to determine whether that security is liquid relative to the market for that asset class, trades in relation to general market interest rates and yield spreads, and is relatively fungible with securities of similar characteristics and interest rate yield spreads in order to rely on the exception. Further, distribution participants, issuers, selling shareholders, and affiliated purchasers of such persons would need to obtain an independent third-party to verify their analysis under the proposal. Persons seeking to rely on these proposed revised exceptions would need to demonstrate compliance with the proposed revised exceptions. These requirements would impose a new “collection of information” within the meaning of the PRA.

The proposed amendment to Rule 10b-10 would eliminate a requirement for transaction confirmations for debt securities (other than government securities) to inform customers if a security is unrated by an NRSRO. Although Section 939A of the Dodd-Frank Act requires the Commission to replace references to NRSRO ratings in its rules with a different standard of creditworthiness, the reference to NRSROs in Rule 10b-10 does not come strictly within Section 939A’s requirements. The Commission believes, however, that deleting paragraph (a)(8) would make Rule 10b-10 consistent with how references to NRSROs and their ratings are being dealt with in other Commission rules pursuant to the requirements of the Dodd-Frank Act.

B. Proposed Use of Information

The purpose of written policies and procedures, and the retention of these policies and procedures, is to ensure that examination staff, from either the Commission or an SRO, could review the policies and procedures to determine if the broker-dealer has an acceptable process for determining if a security has only a minimal amount of credit risk. In addition, written policies and procedures would give the staff consistent guidance on how to determine a minimal amount of credit risk.

As discussed above, the proposed changes to Rules 101 and 102 of Regulation M would amend the exceptions for nonconvertible debt, nonconvertible preferred, and asset-backed securities in those rules. Under

the proposed amendments, distribution participants, issuers, selling shareholders, and affiliated purchasers of such persons would need to assess nonconvertible debt, nonconvertible preferred, and asset-backed securities to determine whether that security is liquid relative to the market for that asset class, trades in relation to general market interest rates and yield spreads, and is relatively fungible with securities of similar characteristics and interest rate yield spreads in order to rely on the exception. Further, distribution participants, issuers, selling shareholders, and affiliated purchasers of such persons would need to obtain an independent third-party to verify their analysis under the proposal. Persons seeking to rely on these proposed revised exceptions would need to demonstrate compliance with the proposed revised exceptions. The information collected under the proposal would be used to ensure that the nonconvertible debt, nonconvertible preferred, and asset-backed securities less likely to be subject to manipulation are excepted from Rules 101 and 102 of Regulation M, at the same time meeting the mandates of Section 939A of the Dodd-Frank Act.

The proposed amendment to Rule 10b-10 would eliminate a requirement for transaction confirmations for debt securities (other than government securities) to inform customers if a security is unrated by an NRSRO. This proposed amendment would alter neither the general requirement that broker-dealers generate transaction confirmations and send those confirmations to customers, nor the potential use of information contained in confirmations by the Commission, self-regulatory organizations, and other securities regulatory authorities in the course of examinations, investigations and enforcement proceedings. Moreover, the proposed amendment is not expected to change the cost of generating and sending confirmations, and, the Commission believes that broker-dealers may not need to incur significant costs if they choose not to input information that a debt security is unrated into their existing confirmation systems. Accordingly, the Commission does not believe the proposed amendment would result in a material or substantive revision to these collections of information if adopted.

C. Respondents

The Commission estimates that the proposed collections of information would apply to the following number of respondents:

¹⁰⁴ 5 CFR 1320.5(g).

¹⁰⁵ See discussion below in Section V.C.2.

- Proposed amendments to Rule 15c3–1 and Rule 17a–4: 480 broker-dealers.
- Proposed amendments to Appendices A, E, F, and G to Rule 15c3–1: 172 broker-dealers.
- Proposed amendments to Exhibit A to Rule 15c3–3: 90 broker-dealers.
- Proposed amendments to Form X–17A–5: 4 broker-dealers.
- Proposed amendments to Regulation M: 2533 respondents. The Commission bases this estimate on the total number of respondents to Rules 101 (1588) and 102 (945).
- Proposed amendments to Rule 10b–10: 530 broker-dealers.

The Commission generally requests comment on all aspects of these estimates for the number of broker-dealers. Commenters should provide specific data and analysis to support any comments they submit with respect to these estimates with respect to the number of respondents.

D. Total Initial and Annual Reporting and Recordkeeping Burden

1. Rule 15c3–1 and Rule 17a–4

The proposed amendments to Rule 15c3–1 and Rule 17a–4 would modify broker-dealers' existing practices to impose additional recordkeeping burdens. The proposed amendments would replace NRSRO ratings-based criteria for evaluating creditworthiness with an option for a broker-dealer to apply new standards based on the broker-dealer's own evaluation of creditworthiness. A broker-dealer that did not want to make such an evaluation could instead take the higher haircuts. A broker-dealer that chooses to evaluate the creditworthiness of securities would have to explain how the haircuts used for net capital purposes meet the standards set forth in the proposed amendments. As such, the Commission believes that firms would be required to develop (if they have not already) criteria for assessing creditworthiness and apply those criteria to the securities included in the net capital calculation. The Commission preliminarily believes, however, that most firms that deduct haircuts for purposes of the Net Capital Rule when evaluating debt securities already have such an assessment process in place. The Commission preliminarily believes that broker-dealers that do not have such a system in place do not normally hold debt securities or, if they do, would choose to take the higher haircuts rather than create such a process. In addition, the expectation that the broker-dealer be able to explain how its haircuts meet the standards set forth in

the proposed amendments would result in the creation and maintenance of records of those assessments.

The Commission preliminarily believes that all broker-dealers already have policies and procedures in place for evaluating the overall risk and liquidity levels of the securities they use for the purposes of the Net Capital Rule and that they retain these policies and procedures; however, the proposed amendments, which specifically address credit risk, could result in additional burdens for those broker-dealers that choose to use them. The proposed amendments would apply to the approximately 480 broker-dealers¹⁰⁶ that hold debt securities and take haircuts on these securities pursuant to paragraphs (c)(2)(vi)(E), (c)(2)(vi)(F)(1), (c)(2)(vi)(F)(2) and (c)(2)(vi)(H) of Rule 15c3–1. The Commission estimates that, on average, broker-dealers will spend 25 hours developing policies and procedures or revising their current policies and procedures for evaluating creditworthiness for the purposes of the Net Capital Rule, resulting in an aggregate initial burden of 12,000 hours.¹⁰⁷ This estimate is based on the Commission's belief that many of these broker-dealers already have their own criteria in place for evaluating creditworthiness and, therefore, most broker-dealers will only be revising their current policies and procedures for evaluating creditworthiness.

The Commission further estimates that, on average, each broker-dealer will spend an additional 10 hours a year reviewing and adjusting its own standards for evaluating creditworthiness, for a total of 4,800 annual hours across the industry.¹⁰⁸ This estimate does not reflect the time it will take for each broker-dealer to apply and implement its own standards for evaluating creditworthiness. This estimate reflects the Commission's belief that these broker-dealers already have their own criteria in place. The Commission also estimates that firms would use a controller to review these standards, both initially and on an annual basis. The Commission estimates the per-firm costs of the controller to be \$10,825 initially and \$4,330 on an annual basis, for an aggregate industry cost of \$5,196,000 initially and \$2,078,400 on an annual basis.¹⁰⁹ The

Commission preliminarily believes that the proposed requirement to retain the policies and procedures for three years pursuant to Rule 17a–4 would result in de minimis costs. The three year preservation requirement in Rule 17a–4 will only be applicable once a broker-dealer changes its policies and procedures. In addition, all broker-dealers are currently required to comply with the three year preservation period in Rule 17a–4 for other records and should have procedures to satisfy such preservation requirements in place.

The proposed amendments to the appendices to Rule 15c3–1 include amendments to certain recordkeeping and disclosure requirements that are subject to the PRA. The proposed amendment to Appendix A to Rule 15c3–1 removes the NRSRO reference from the definition of "major market foreign currency." The Commission preliminarily believes that 158 broker-dealers trade in foreign currency and, therefore, would be affected by the proposed amendment.¹¹⁰ However, it is not the intention of the Commission that the currencies meeting the definition of "major market foreign currency" should change. If, however, a broker-dealer wanted to request that a new currency meet the definition of "major market foreign currency" it would have to submit such a request to the Commission. The Commission preliminarily believes that submitting such a request to the Commission would take approximately ten hours for a total burden of 1,580 hours.¹¹¹ Additionally, the Commission believes that a broker-dealer would use an attorney to prepare this request, for a cost of \$3,540 per firm

("SIFMA") Report on Management and Professional Earnings in the Securities Industry 2010, which provides base salary and bonus information for middle management and professional positions within the securities industry, as modified by Commission staff to account for an 1800-hour work-year and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead. Hereinafter, references to data derived from the report as modified in the manner described above will be cited as *SIFMA Report on Management and Professional Earnings in the Securities Industry 2010*. The Commission believes that the reviews required by the proposed amendments would be performed by the controller at an average rate \$433 per hour. Furthermore, the Commission believes that the review process will entail twenty-five hours initially and ten hours on an annual basis. $\$433 \times 25 = \$10,825 \times 480 = \$5,196,000$; $\$433 \times 10 = \$4,330 \times 480 = \$2,078,400$.

¹¹⁰ To arrive at this number, the Commission requested from the Options Clearing Corporation ("OCC") the number of broker-dealers that are authorized to clear foreign currency options. The Commission was given the number of 158. Although 158 broker-dealers are authorized to clear foreign currency options, the Commission does not know if all of these broker-dealers are actually clearing foreign currency options.

¹¹¹ $158 \text{ broker-dealers} \times 10 \text{ hours} = 1,580$.

¹⁰⁶ This number was obtained by reviewing all FOCUS 2009 year-end submissions and then calculating how many firms report holding proprietary debt positions. See *supra* note 32.

¹⁰⁷ $480 \text{ broker-dealers} \times 25 \text{ hours} = 12,000 \text{ hours}$.

¹⁰⁸ $480 \text{ broker-dealers} \times 10 \text{ hours} = 4,800 \text{ hours}$.

¹⁰⁹ For the purposes of this analysis, the Commission is using salary data from the Securities Industry and Financial Markets Association

and an aggregate industry cost of \$559,320.¹¹²

The proposed amendments to Appendices E and F to Rule 15c3–1 and conforming amendments to Appendix G would remove the provisions permitting reliance on NRSRO ratings for the purposes of determining counterparty risk. As a result of these deletions, an entity that wished to use the approach set forth in these appendices to determine counterparty risks would be required, as part of its initial application to use the alternative approach or in an amendment, to request Commission approval to determine credit risk weights based on internal calculations and make and keep current a record of the basis for the credit risk weight of each counterparty.

The Commission does not believe that the removal of the option permitting reliance on NRSRO ratings would affect the small number of entities that currently elect to compute their net capital deductions pursuant to the alternative methods set forth in Appendix E or F. Although the collection of information obligations imposed by the proposed amendments are mandatory, applying for approval to use the alternative capital calculation is voluntary. To date, a total of six entities are using the methods set forth in Appendix E, while four are using the methods set forth in Appendix F. All of the approved firms already have developed models to calculate market and credit risk under the alternative net capital calculation methods set forth in the appendices as well as internal risk management control systems.¹¹³ As such, each firm already employs the non-NRSRO ratings-based method that would, under the proposed amendments, become the only option for determining counterparty credit risk under Appendices E and F. Since each entity already employs its own models to calculate market and credit risk and keeps current a record of the basis for the credit risk weight of each counterparty, the proposed amendments would not alter the paperwork burden

currently imposed by Appendices E and F.

The Commission currently anticipates that three additional firms may apply for permission to use Appendix E and one additional firm may apply to use Appendix F. However, the Commission preliminarily believes that there should be no additional paperwork burden on these firms based on the proposed amendments. Any firm that applies to use Appendices E or F to Rule 15c3–1 must submit its internal models to the Commission for approval as part of that process. These models will calculate market risk and credit risk, as well as counterparty risk, which is not a change from the previous approval process for a firm that is applying to use Appendix E or Appendix F. In fact, the Commission believes that the only change to this process will be that the Commission will assign ratings scales to these models that can be used to determine counterparty risk when approving the models. Thus, the Commission does not believe the proposed amendments to Appendices E and F will alter the paperwork burden for such firms.

The instructions to Form X–17A–5 Part IIB currently include a summary of the credit risk calculation in paragraph (d) of Rule 15c3–1f. Paragraph (d) of Rule 15c3–1f is proposed to be amended to remove that part of the credit risk calculation that is summarized in Form X–17A–5 Part IIB. Accordingly, the Commission has proposed a conforming amendment to the form that would remove the summary of the credit risk calculation. The summary in the instructions provides additional information for the benefit of the filer and is not related to the information reported on the forms. Accordingly, the Commission does not believe the proposed amendment would result in a substantive revision to these collections of information if adopted.

The Commission requests comment on all aspects of these proposed estimates. In addition, the Commission requests specific comment on the following items related to these estimates:

- Is the Commission correct in its hours estimates and belief that many broker-dealers already have their own policies and procedures in place for evaluating creditworthiness?
- Is the Commission correct in its belief that broker-dealers would engage outside counsel to review their internally generated standards for creditworthiness? If not, how would firms review such standards and what would be the effect of such differing approaches on our burden estimates?

- Is the Commission correct in its belief that new firms that apply to use the standards in Appendices E and F to Rule 15c3–1 will not have an extra burden as a result of the proposed amendments?

- Is the Commission correct in its estimation of the number of broker-dealers that trade foreign currency options?
- Is the Commission correct in its estimation on the number of hours it would take for a firm to make a submission to the Commission requesting that a currency be designated as a major market foreign currency?
- Is the Commission correct in its belief that a firm would engage outside counsel to make this submission? Or would a firm handle this internally?

2. Exhibit A to Rule 15c3–3

The proposed amendment to Note G to Exhibit A to Rule 15c3–3 would potentially modify broker-dealers' existing practices to impose additional recordkeeping burdens. Currently, Note G to Exhibit A to Rule 15c3–3 allows a broker-dealer to include, as a debit in the formula for determining its reserve requirements, the amount of customer margin related to customers' positions in security futures products posted to a registered clearing or derivatives organization that meets one of four standards, including maintaining the highest investment grade rating from an NRSRO.¹¹⁴ The proposed amendment would remove the standard of a registered clearing or derivatives organization that has the highest investment grade rating from an NRSRO as one of the four options a broker-dealer can look at prior to keeping customers' positions in security future products with such a firm. As such, the Commission believes that firms that previously relied on NRSRO ratings for the purposes of Note G would be required to use another method for assessing the creditworthiness of registered clearing or derivatives organizations. In addition, the expectation that the broker-dealer be able to explain that any such clearing or derivatives organizations it uses meet

¹¹² The Commission believes that the reviews required by the proposed amendments would be performed by an attorney at an average rate of \$354 per hour. Furthermore, the Commission believes that the review process will entail ten hours of initial work. 10 hours × \$354 = \$3,540 per firm. 158 broker-dealers × \$3,540 = \$599,320 aggregate industry cost. *SIFMA Report on Management and Professional Earnings in the Securities Industry 2010*.

¹¹³ See, e.g., *Alternative Net Capital Requirements for Broker-Dealers That Are Part of Consolidated Supervised Entities*, Exchange Act Release No. 49830 (Jun. 8, 2004), 69 FR 34428 at 34456 (Jun. 21, 2004).

¹¹⁴ A broker-dealer may also include customer margin related to customers' positions in security futures products posted to a registered clearing or derivatives organization (1) that maintains security deposits from clearing members in connection with regulated options or futures transactions and assessment power over member firms that equal a combined total of at least \$2 billion, at least \$500 million of which must be in the form of security deposits; (2) that maintains at least \$3 billion in margin deposits; or (3) which does not meet any of the other criteria but which the Commission has agreed, upon a written request from the broker-dealer, that the broker-dealer may utilize. 17 CFR 240.15c3–3a, Note G, (b)(1)(ii)–(iv).

the standard set forth in the proposed amendment would result in the creation and maintenance of records of those assessments. The Commission estimates that approximately 90 firms would be required to comply with the provisions of Note G.¹¹⁵ In the final release adding Note G to Exhibit A to Rule 15c3-3,¹¹⁶ the Commission estimated that under subparagraph (c) to Note G, each broker-dealer would spend approximately 0.25 hours to verify that the clearing organizations they used met the conditions of Note G. Using that same hours estimate, the Commission estimates an aggregate one-time total of 22.5 hours¹¹⁷ for broker-dealers to verify the status of a registered clearing or derivatives organization under the proposed amendment. The Commission believes that the proposed amendment would impose an additional one-time burden for broker-dealers that need to change how they evaluate the creditworthiness of a registered clearing or derivatives organization. Given the additional options set forth in Note G, the Commission estimates this would result in the broker-dealer spending, on average, one hour determining whether a clearing organization meets the remaining requirements of Note G,¹¹⁸ resulting in an aggregate initial burden of 90 hours.¹¹⁹ The Commission also estimates that firms would use a senior operations manager to review these standards. The Commission estimates the one-time costs of senior operations manager to be \$331 per-firm, resulting in an aggregate industry cost of \$29,790.¹²⁰

¹¹⁵ The number 90 comes from reviewing the members of the OCC listed in the member directory on the OCC's Web site (<http://www.optionsclearing.com/membership/member-information/>). Of the list of 231 members, the Commission looked only at those who trade in single stock futures. Of the list of members that trade in single stock futures, the Commission deleted any members who had the exact same firm name but different firm numbers.

¹¹⁶ See *Reserve Requirements for Margin Related to Security Futures Products*, Exchange Act Release No. 34-50295 (Aug. 31, 2004), 69 FR 54182 at 54188 (Sept. 7, 2004).

¹¹⁷ $0.25 \times 90 = 22.5$.

¹¹⁸ Currently the OCC is the only clearing agency registered with the Commission. The OCC maintains far more than \$3 billion in margin deposits, which is another way for a broker-dealer to verify a registered clearing agency or derivatives clearing organization under Note G. Thus, the Commission believes that any broker-dealer who is currently using NRSRO ratings to verify a registered clearing agency or derivatives clearing organization will be able to quickly verify the registered clearing agency or derivatives clearing organization using a different method.

¹¹⁹ $90 \text{ broker-dealers} \times 1 \text{ hour} = 90 \text{ hours}$.

¹²⁰ The Commission believes that the reviews required by the proposed amendments would be performed by a senior operations manager at an average rate of \$331 per hour. Furthermore, the

The Commission generally requests comment on all aspects of these proposed estimates. In addition, the Commission requests specific comment on the following items related to these estimates:

- Is the Commission correct in its estimate of the number of broker-dealers that would be affected by the proposed amendment to Note G?
- Is the Commission correct in its belief that broker-dealers would engage a senior operations manager to review their standards for verifying the status of a registered clearing agency or derivatives clearing organization? If not, how would firms review such standards and what would be the effect of such differing approaches on its burden estimates?

3. Regulation M

As discussed above, the proposed changes to Rules 101 and 102 of Regulation M would amend the exceptions for nonconvertible debt securities, nonconvertible preferred securities, and asset-backed securities in those rules. Under the proposed amendments, distribution participants, issuers, selling shareholders, and affiliated purchasers of such persons would need to assess nonconvertible debt, nonconvertible preferred, and asset-backed securities to determine whether that security reasonably is liquid relative to the market for that asset class, trade based on yield, and fungible with securities with similar yields in order to rely on the exception. Further, distribution participants, issuers, selling shareholders, and affiliated purchasers of such persons would need to obtain an independent third-party to verify their analysis under the proposal. Persons seeking to rely on these proposed revised exceptions would need to demonstrate compliance with the proposed revised exceptions.

The Commission initially estimates that there are approximately 863 distributions of nonconvertible debt, nonconvertible preferred, and asset-backed securities, on average, annually that would be subject to the proposed revised exceptions. The Commission bases this estimate on the average number of offerings of investment grade nonconvertible debt, investment grade nonconvertible preferred, and investment grade asset-backed securities over the last three years.¹²¹ The

Commission believes that the review process will entail one hour of initial work. $\$331 \times 1 = \$331 \times 90 = \$29,790$. *SIFMA Report on Management and Professional Earnings in the Securities Industry 2010*.

¹²¹ Rules 101 and 102 only apply to distributions, not all offerings of securities. As a result, the

Commission believes that this is a reasonable estimate since it expects that the number of distributions eligible for the proposed revised exceptions should be similar to the number of distributions currently excepted under Rules 101(c)(2) and 102(d)(2).

The Commission initially estimates that the proposed revised exceptions would impose an average annual burden of 1 hour per distribution.¹²² This accounts for the internal time to obtain the information necessary to comply with the proposed revised exceptions and conduct analysis based on this information. Further, the Commission initially estimates that the proposed revised exceptions would impose an outside cost burden to retain an independent third party to verify the analysis by the person seeking to rely on the proposed revised exceptions, resulting in an estimated average annual burden of \$4,800¹²³ per distribution. Based on the total number of distributions estimated to be subject to the proposed revised exceptions (863), the Commission estimates that the total average annual burden is approximately 863 hours and \$4.1 million.

The collection of information would be necessary to obtain the benefit of the proposed revised exceptions. The proposed revised exceptions do not prescribe retention periods. All registered broker-dealers engaged in underwriting that would be subject to the proposed revised exceptions are currently required to retain records in accordance with Rules 17a-2 through 17a-4. The collection of information under the proposed revised exceptions would be provided to Commission and SRO examiners but would not be subject to public availability.

We specifically request comment on all aspects of these proposed estimates.

4. Rule 10b-10

The proposed amendment to Rule 10b-10 is not expected to change the

Commission discounted the actual average number of offerings of nonconvertible debt, investment grade nonconvertible preferred, and investment grade asset-backed securities over the last three years (1,151) by 25%.

¹²² We anticipate that the 1 hour would be spent by business analysts of the person seeking to rely on the proposed revised exceptions.

¹²³ We estimate that an outside management consultant would spend 8 hours and charge \$600 per hour to verify the analysis. The \$600 per hour figure is from the 75th percentile figure for a management consultant from <http://www.payscale.com>, adjusted for an 1800-hour work-year and multiplied by a 5.35 factor which is normally used to include benefits but here is used as an approximation to offset the fact that New York salaries are typically higher than the rest of the country. The result is \$596 per hour, which can be rounded to \$600 per hour. We request comment on this estimate.

cost of generating and sending confirmations, and, the Commission believes that broker-dealers may not need to incur significant costs if they choose not to input information that a debt security is unrated into their existing confirmation systems. Accordingly, the Commission does not believe the proposed amendment would result in any substantive change in a broker-dealer's record-keeping or reporting burdens.

5. Request for Comment

Pursuant to 44 U.S.C. 3306(c)(2)(B), the Commission requests comment on the proposed collections of information in order to: (1) Evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the Commission, including whether the information would have practical utility; (2) evaluate the accuracy of the Commission's estimates of the burden of the proposed collections of information; (3) determine whether there are ways to enhance the quality, utility, and clarity of the information to be collected; (4) evaluate whether there are ways to minimize the burden of the collection of information on those who respond, including through the use of automated collection techniques or other forms of information technology; and (5) evaluate whether the proposed rule amendments would have any effects on any other collection of information not previously identified in this section.

Persons who desire to submit comments on the collection of information requirements should direct their comments to the OMB, *Attention: Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs*, Washington, DC 20503, and should also send a copy of their comments to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090, and refer to File No. S7–15–11. OMB is required to make a decision concerning the collections of information between 30 and 60 days after publication of this document in the **Federal Register**; therefore, comments to OMB are best assured of having full effect if OMB receives them within 30 days of this publication. Requests for the materials submitted to OMB by the Commission with regard to these collections of information should be in writing, refer to File No. S7–15–11, and be submitted to the Securities and Exchange Commission, Office of Investor Education and Advocacy, 100 F Street, NE., Washington, DC 20549–0213.

V. Economic Analysis

As discussed above, the Dodd-Frank Act requires that the Commission and other federal agencies replace references to credit ratings in all of its regulations with a standard of creditworthiness that the Commission deems appropriate. The proposed amendments to Rule 15c3–1, Appendices A, E, F, and G to Rule 15c3–1, Exhibit A to Rule 15c3–3, Rule 17a–4, the General Instructions to Form X–17A–5, Part IIB, Rules 101 and 102 of Regulation M, and Rule 10b–10 would accomplish this task by eliminating the reference to and requirement for the use of NRSRO ratings in these rules. The Commission recognizes that there are additional external costs associated with the adoption of the proposed amendments that are separate from the hour burdens discussed in the Paperwork Reduction Act. Thus, the Commission has identified certain costs and benefits of the proposed rule amendments and requests comment on all aspects of this cost-benefit analysis, including identification and assessment of any costs and benefits not discussed in the analysis.¹²⁴

The Commission seeks comment and data on the value of the benefits identified. The Commission also seeks comments on the accuracy of its cost estimates in each section of this cost-benefit analysis, and requests those commenters to provide data, including identification of statistics relied on by commenters to reach conclusions on cost estimates. Finally, the Commission seeks estimates and views regarding these costs and benefits for particular types of market participants, as well as any other costs or benefits that may result from these proposed rule amendments.

Under Section 3(f) of the Exchange Act,¹²⁵ the Commission shall, when engaging in rulemaking that requires the Commission to consider or determine whether an action is necessary or appropriate in the public interest, consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation. Section 23(a)(2) of the Exchange Act¹²⁶ requires the Commission to consider the competitive effects of any rules the Commission adopts under the Exchange Act. Section 23(a)(2) prohibits the Commission from adopting any rule that would impose a burden on competition not necessary or appropriate in furtherance of the

purposes of the Exchange Act. The Commission's preliminary view, as discussed in greater detail with respect to each proposed amendment below, is that any potential burden on efficiency, competition, and capital formation resulting from the proposed rules would be consistent with the intent of Congress as expressed by the Dodd-Frank Act.

A. Rule 15c3–1 and Rule 17a–4

1. Benefits

The Commission anticipates that one of the primary benefits of the proposed amendments, if adopted, would be the benefit to broker-dealers of reducing their possible undue reliance on NRSRO ratings that could be caused by references to NRSROs in its rules. The rule amendments could encourage broker-dealers to examine more than a single source of information, such as a rating, when analyzing the creditworthiness of a financial instrument. Significantly, the Commission believes that eliminating the reliance on NRSRO ratings in its rules would remove any appearance that the Commission has placed its imprimatur on such ratings. The Commission, however, also recognizes that credit ratings may provide useful information to institutional and retail investors as part of the process of making an investment decision.

The Commission preliminarily believes that the proposed amendments to the Net Capital Rule and its appendices, as well as the conforming amendment to Rule 17a–4, could result in a better overall assessment of the risks associated with securities held by broker-dealers for the purposes of net capital calculations as well as of the long-term financial strength and general creditworthiness of clearing organizations to which customers' positions in security futures products are posted. As the NRSROs themselves have stressed, the ratings they generate focus solely on credit risk, that is, the likelihood that an obligor or financial obligation will repay investors in accordance with the terms on which they made their investment.¹²⁷ Many broker-dealers already conduct their own risk evaluation. However, for those broker-dealers that do not, developing

¹²⁴ SIFMA Report on Management and Professional Earnings in the Securities Industry 2010.

¹²⁵ 15 U.S.C. 78c(f).

¹²⁶ 15 U.S.C. 78w(a)(2).

¹²⁷ See, e.g., *Inside the Ratings: What Credit Ratings Mean*, Fitch, Aug. 2007 ("Inside the Ratings"), p. 1; Testimony of Michael Kanef, Group Managing Director, Moody's Investors Service, Before the United States Senate Committee on Banking, Housing, and Urban Affairs (Sep. 26, 2007), p. 2; Testimony of Vickie A. Tillman, Executive Vice President, Standard & Poor's Credit Market Services, Before the United States Senate Committee on Banking, Housing, and Urban Affairs (Sep. 26, 2007), p. 3.

their own means of evaluating risk—including, as would be required by the proposed amendments to the Net Capital Rule, an evaluation of the degree of liquidity—should allow them to better incorporate the overall levels of various categories of risk associated with the securities they hold for their net capital calculations and lead to a better understanding of the risks associated with those securities. The Commission believes that for those broker-dealers that do not currently have their own means of evaluating risk for purposes of the Net Capital Rule, the approach outlined in this release is the best option, outside of using NRSRO ratings, for a broker-dealer to evaluate the risks associated with those securities.

2. Costs

The Commission anticipates that broker-dealers could incur additional costs if the proposed amendments are adopted because of the costs associated with performing a more detailed and comprehensive analysis of the debt securities. These costs could include establishing, reviewing, and adjusting the various policies and procedures needed for a comprehensive analysis of the debt securities. There also could be costs associated with applying and implementing these adjusted procedures.

The Commission believes that the costs of compliance with the proposed amendments to the Net Capital Rule and its appendices, as well as the conforming amendment to Rule 17a-4, would be minimal for those entities that already employ their own criteria in determining credit risk for net capital purposes. Of the approximately 480 broker-dealers that hold proprietary debt positions, the Commission recognizes that the level of sophistication varies widely. The institutions with less sophisticated internal procedures for analyzing credit risk may incur costs to establish and develop procedures that would be used to assess financial instruments for the purposes of determining whether the lower haircuts could appropriately be applied.

In the event the broker-dealer inaccurately evaluates the creditworthiness and liquidity of its positions, a potential cost could be that the broker-dealer is required to take a larger haircut on its proprietary positions, and, therefore, reserve additional capital. This could affect its ability to hold its positions or to add to its positions. In addition, the proposed rule could potentially affect the ability of issuers of commercial paper,

nonconvertible debt, and preferred stock to raise capital if broker-dealers change their investment decisions for their proprietary accounts as a result of potential costs or other aspects of the proposed amendments.

Some broker-dealers may determine a security qualifies for a reduced haircut when it would not have qualified under the current NRSRO standard. This could have a potential impact on the firm's ability, if it experiences financial difficulties, to be in a position to meet all obligations to customers, investors, and other counterparties and generate resources to wind-down its operations in an orderly manner without the need of a formal proceeding, with attendant costs.

In addition, those broker-dealers whose internal evaluations differ from the ratings may have extra costs during examinations to prove to the regulators the accuracy of their internal evaluations. Those broker-dealers that do not have their own criteria for determining credit risk for net capital purposes will have larger start up costs than other broker-dealers. However, the Commission believes that firms that hold a small number of securities for net capital purposes may do an internal cost benefit analysis and decide to take the 15% haircut instead of creating an internal credit risk evaluation process if the costs of creating such an evaluation process are too high. To the extent that broker-dealers decide to take the 15% haircut instead of creating an internal credit risk evaluation process, it is possible that those broker-dealers may maintain more net capital than would be required by the Net Capital Rule.

For firms that use Appendix A to Rule 15c3-1, the Commission preliminarily believes there will be minimal costs associated with the proposed amendments. The proposed amendments to the definition of "major market foreign currency" will not change what foreign currencies meet the definition; it will only change the wording of the definition. Therefore, the Commission does not believe there will be any additional costs associated with the proposed amendments.

As for the firms that use Appendix E and F to Rule 15c3-1, these firms are already using internal ratings scales to determine credit risks for each counterparty. Any new firms that apply to use either Appendix E or Appendix F will not incur any additional costs as a result of the proposed amendments. Currently, firms that apply to use these appendices must have their internal models approved by the Commission prior to using their selected appendix. Although the Commission will have to

assign a ratings scale to the output of the internal models during the approval process, the Commission does not believe this step will cause broker-dealers or OTC derivatives dealers who are applying to use these appendices to incur any additional costs. Furthermore, because these firms have traditionally used models, as opposed to NRSRO ratings, to compute capital charges, the Commission does not believe these firms will incur any additional costs by complying with the proposed amendments.

B. Exhibit A to Rule 15c3-3

1. Benefits

The Commission believes that eliminating the reliance on NRSRO ratings in its rules would remove any appearance that the Commission has placed its imprimatur on such ratings. The Commission preliminarily believes that the proposed amendments to Note G to Exhibit A to Rule 15c3-3 would serve to promote efficiency and capital formation. As noted above, the Commission believes that broker-dealers will develop their own means of evaluating the long-term financial strength and general creditworthiness of clearing organizations to which customers' positions in security futures products are posted for purposes of Note G to Exhibit A to Rule 15c3-3. These broker-dealers would be better positioned to incorporate the overall levels of various categories of risk associated with those organizations into their assessments, creating a more efficient means of evaluating those organizations for the sake of the Customer Protection Rule, rather than simply relying on NRSRO credit ratings alone. As the NRSROs themselves have stressed, the ratings they generate focus solely on credit risk, that is, the likelihood that an obligor or financial obligation will repay investors in accordance with the terms on which they made their investment.¹²⁸ The Commission does not anticipate that the proposed amendments to Note G to Exhibit A to Rule 15c3-3 would have any impact on competition.

¹²⁸ See, e.g., *Inside the Ratings: What Credit Ratings Mean*, Fitch, Aug. 2007 ("Inside the Ratings"), p. 1; Testimony of Michael Kanef, Group Managing Director, Moody's Investors Service, Before the United States Senate Committee on Banking, Housing, and Urban Affairs (Sep. 26, 2007), p. 2; Testimony of Vickie A. Tillman, Executive Vice President, Standard & Poor's Credit Market Services, Before the United States Senate Committee on Banking, Housing, and Urban Affairs (Sep. 26, 2007), p. 3.

2. Costs

The Commission believes that the costs of compliance with Note G to Exhibit A to Rule 15c3–3 would be minimal because the amendment would simply eliminate one factor a broker-dealer can use to evaluate a clearing organization. The Commission believes that the removal of one of these four means of complying with section (b)(1) of Note G will not adversely affect the purpose of this section; namely to ensure that a broker or dealer has the margin related to security futures products on deposit only with qualified registered clearing agencies or derivatives clearing organizations. As stated in the Paperwork Reduction Act section, the Commission anticipates that a broker-dealer will incur a one-time cost and an annual cost to verify that a clearing organization or derivatives clearing organization meets the requirements of Note G. If a broker-dealer is currently using a verification process other than the use of NRSRO ratings, that broker-dealer will not incur any one-time costs.

C. Rules 101 and 102 of Regulation M

The purpose of the proposed revised exceptions from Rules 101 and 102 of Regulation M for nonconvertible debt, nonconvertible preferred, and asset-backed securities is to address Section 939A of the Dodd-Frank Act as well as place the emphasis of the exception on the trading aspects of the securities by those bringing it to market, ensuring that the exception is utilized in reference to securities that are less likely to be subject to manipulation.

The Commission preliminarily believes that the proposed amendments to Rules 101 and 102 of Regulation M are intended to promote capital formation. The proposed amendments should promote continued investor trust in the offering process by proposing an exception from Regulation M's Rule 101 and 102 prohibitions limited to those securities which are less vulnerable to manipulation. Such investor trust in our markets should promote continued capital formation. The Commission believes that the proposals should foster continued market integrity which should also translate into capital formation by only allowing for non-manipulative buying activity during distributions. Issuers of nonconvertible debt, nonconvertible preferred securities and asset-backed securities who fall within the proposed exceptions may be encouraged to engage in capital formation knowing that the proposed exceptions are available for their buying activity as well as the buying activity of

distribution participants. For these reasons, the Commission preliminarily believes that the proposed exceptions will promote efficient capital formation and competition.

The Commission has considered the proposed amendments to Rules 101 and 102 of Regulation M in light of the standards cited in Section 23(a)(2) and believes preliminarily that, if adopted, they would not likely impose any significant burden on competition not necessary or appropriate in furtherance of the Exchange Act. The proposals would apply equally to all distribution participants, issuers, selling shareholders, and affiliated purchasers. Thus, no person covered by Regulation M should be put at a competitive disadvantage and the proposal would not impose a significant burden on competition not necessary or appropriate in furtherance of the Act.

1. Benefits

The proposed revised exceptions should continue to promote investor trust in the offering process and the market as a whole by excepting only those nonconvertible debt, nonconvertible preferred, and asset-backed securities that are less vulnerable to manipulation. Market integrity would also continue to be promoted, which benefits the market and all participants.

2. Costs

The Commission expects the costs of the proposal to modify Rules 101 and 102 of Regulation M to be minimal to most persons subject to those rules. The Commission expects the number of instances in which the proposed revised exceptions would be triggered to be limited. The proposed revised exceptions would only be triggered when there is an offering of nonconvertible debt, nonconvertible preferred, or asset-backed securities that qualifies as a distribution under Regulation M where a distribution participant, issuer, selling shareholder, or affiliated purchaser bids for, purchases, or attempts to induce another person to bid for or purchase the covered security during the applicable restricted period. As there may be offerings of nonconvertible debt, nonconvertible preferred, and asset-backed securities that do not constitute a distribution for purposes of Regulation M, the prohibitions of Rules 101 and 102 of Regulation M would not be triggered and, thus, the need for reliance upon either the current or proposed revised exceptions would not be necessary. Additionally, even if a distribution of the nonconvertible debt,

nonconvertible preferred, or asset-backed securities exists, a person subject to the prohibitions of Rules 101 or 102 of Regulation M could structure buying activity before or after the applicable restricted period so as not to incur any costs, even if minimal, associated with relying on the proposed revised exceptions.

When the proposed revised exceptions would be used, however, the Commission believes that there would be increased costs for distribution participants, issuers, selling shareholders, and affiliated purchasers under the proposed revised exceptions compared to the expected costs under the current exceptions in Rules 101(c)(2) and 102(d)(2). Distribution participants, issuers, selling shareholders, and affiliated purchasers would need to reasonably determine whether a security is liquid relative to the market for that asset class, trades in relation to general market interest rates and yield spreads, and is relatively fungible with securities of similar characteristics and interest rate yield spreads in order to rely on the exception. This determination would require the distribution participant, issuer, selling shareholder, or affiliated purchaser to train staff and devote manpower and other resources towards making this assessment when relying on the proposed revised exceptions. As detailed in the PRA section above, the Commission preliminarily estimates total annual ongoing internal costs of approximately \$167,422 for distribution participants, issuers, selling shareholders, and affiliated purchasers seeking to rely on the exception.¹²⁹

Further, distribution participants, issuers, selling shareholders, and affiliated purchasers would need to obtain an independent third party to verify this initial assessment. This process would create new costs to be borne by distribution participants, issuers, selling shareholders, and affiliated purchasers when relying on the proposed revised exceptions to hire such a party and review this verification. Distribution participants, issuers, selling shareholders, and affiliated purchasers seeking an independent third party verification that the issue meets the criteria required to obtain the proposed exceptions may find that the price of the independent

¹²⁹ This figure was calculated as follows (1 business analyst hours × \$194) = \$194 per response × 863 responses = \$167,422 total cost for all respondents. The Commission estimates that the average hourly rate for an intermediate business analyst in the securities industry is approximately \$194 per hour. *SIFMA Report on Management and Professional Earnings in the Securities Industry 2010*.

third party verification could potentially lead to other economic effects. These effects could include, for instance, the potential for the verifier to be liable for claims if the exception is disputed after it has been relied upon. While difficult to quantify, the Commission preliminarily estimates that it is possible for the verifier's potential liability to be a significant multiple of the compliance-hours-cost-estimate provided for PRA purposes, and will depend upon the perceived risk in asserting that the security is liquid relative to the market for that asset class, trades in relation to general market interest rates and yield spreads, and is relatively fungible with securities of similar characteristics and interest rate yield spreads. These are new costs not currently borne by distribution participants, issuers, selling shareholders, or their affiliated purchasers. If potential liability leads to increased costs in obtaining an independent third party, some persons who currently rely on the exception may determine that it is no longer cost effective to qualify for the exception. This may have the effect of limiting the instances in which the exception is utilized, which in turn may expand the scope of the restrictions of Rules 101 and 102 of Regulation M. Thus, the increase in costs resulting from the third party verification may, in effect, narrow the exceptions for those who currently rely on them.

The Commission also expects that there could be a small number of securities taken out of this exception as a result of the proposed change. Costs for issuers, selling shareholders, underwriters, brokers, dealers, any other distribution participants, or affiliated purchasers of any of these persons affected by this change would be more significant in that these persons may now be required to comply with Rule 101 or 102 of Regulation M where they did not have to before. As a result of this change, these affected parties and their affiliated purchasers would be prohibited from bidding for, purchasing, or attempting to induce any person to bid for or purchase the covered security during the restricted period. However, the Commission does not expect there to be a significant number of these persons. Further, these persons may be able to rely on a different exception from Rule 101 or 102 depending on the circumstances.

D. Rule 10b-10

1. Benefits

The proposed amendments to Rule 10b-10 eliminate a requirement for

transaction confirmations for debt securities (other than government securities) to inform customers if a security is unrated by an NRSRO. The other requirements of Rule 10b-10 would remain unchanged. Eliminating this requirement would avoid giving credit ratings an imprimatur that may inadvertently suggest to investors that an unrated security is inherently riskier than a rated security. Accordingly, the Commission anticipates that investors and the marketplace would benefit from the elimination of this requirement, in light of concerns about promoting overreliance on securities ratings or creating confusion about the significance of those ratings. More generally, eliminating this requirement is consistent with the goal of promoting a dialogue between broker-dealers and their customers—prior to purchase—regarding the creditworthiness of issuers, and should help avoid promoting the use of credit ratings as an oversimplified shorthand that replaces a more complete discussion of credit quality issues.

2. Costs

The Commission does not expect the proposed amendment to result in any significant changes in the costs associated with Rule 10b-10. Broker-dealers will continue to generate transaction confirmations and send those confirmations to customers, and the proposed amendment, if adopted, would not be expected to change the cost of generating and sending confirmations. Moreover, the Commission believes that broker-dealers may not need to incur significant costs if they choose not to input information that a debt security is unrated into their existing confirmation systems.

E. Request for Comment on Economic Analysis

The Commission requests data to quantify the costs and the benefits above. The Commission seeks estimates of these costs and benefits, as well as any costs and benefits not already described, which could result from the adoption of the proposed amendments.

- The Commission seeks specific comments on the economic analysis outlined above with respect to Rule 15c3-1, its Appendices and Rule 17a-4. Are there any additional costs associated with these proposed amendments that were not factored into the above analysis? Commenters should provide specific examples of cost estimates.

- The Commission seeks specific comments on the economic analysis outlined above with regard to Exhibit A

to Rule 15c3-3. Are there any additional costs associated with the proposed amendment that were not factored into the above analysis? Commenters should provide specific examples of cost estimates.

- The Commission seeks specific comments on the economic analysis outlined above with regard to the proposed revised exceptions to Rules 101 and 102 of Regulation M. What new costs would the proposed revised exceptions create for those seeking to rely on them? Are there any costs not already accounted for in this proposal created by the proposed revised exceptions?

- The Commission seeks specific comments on the economic analysis outlined above with regard to the Rule 10b-10. Are there any additional costs associated with this proposal that were not factored into the above analysis? Commenters should provide specific examples of cost estimates.

VI. Consideration of Impact on the Economy

For purposes of the Small Business Regulatory Enforcement Fairness Act of 1996 ("SBREFA"), the Commission must advise OMB as to whether the proposed regulation constitutes a "major" rule. Under SBREFA, a rule is considered "major" where, if adopted, it results or is likely to result in: (1) An annual effect on the economy of \$100 million or more (either in the form of an increase or decrease); (2) a major increase in costs or prices for consumers or individual industries; or (3) significant adverse effect on competition, investment or innovation. If a rule is "major," its effectiveness will generally be delayed for 60 days pending Congressional review.

The Commission requests comment on the potential impact of the proposed rules and form on the economy on an annual basis, on the costs or prices for consumers or individual industries, and on competition, investment, or innovation. Commenters are requested to provide empirical data and other factual support for their view to the extent possible.

VII. Initial Regulatory Flexibility Analysis

Section 3(a) of the Regulatory Flexibility Act of 1980¹³⁰ requires the Commission to undertake an initial regulatory flexibility analysis of the proposed rule on small entities unless the Commission certifies that the rule, if adopted, would not have a significant economic impact on a substantial

¹³⁰ 5 U.S.C. 603(a).

number of small entities.¹³¹ Pursuant to Section 605(b) of the Regulatory Flexibility Act (“RFA”), the Commission hereby certifies that the proposed amendments to the rule, would not, if adopted, have a significant economic impact on a substantial number of small entities.

For purposes of Commission rulemaking in connection with the RFA, small entities include broker-dealers with total capital (net worth plus subordinated liabilities) of less than \$500,000 on the date in the prior fiscal year as of which its audited financial statements were prepared pursuant to Rule 17a-5(d) under the Exchange Act,¹³² or, if not required to file such statements, a broker or dealer that had total capital (net worth plus subordinated liabilities) of less than \$500,000 on the last day of the preceding fiscal year (or in the time that it has been in business, if shorter); and is not affiliated with any person (other than a natural person) that is not a small business or small organization.¹³³

The proposed amendments to the securities haircut provisions in paragraphs (E), (F), and (H) of Rules 15c3-1(c)(2)(vi) and the conforming amendment to Rule 17a-4, if adopted, would not have a significant economic impact on a small number of entities. The Commission preliminarily believes that a broker-dealer with less than \$500,000 in total capital holds very few positions and, in particular, a small number of debt securities. Thus, the Commission preliminarily believes that there are few small entities that will be subject to these new rules. In addition, if there are small broker-dealers that hold these debt positions, they are already required to examine the risk associated with their debt securities when taking haircuts on these securities. The proposed amendments could alter this process but it would not be a new process that the small broker-dealer would have to comply with. Accordingly, the rule would not have any significant economic impact on small entities because even if they have to change their current process, they are still required to examine the risk associated with their debt securities.

The proposed amendment to Appendix A to Rule 15c3-1 will not be a burden to small entities. Although the definition of major market foreign currency will change, the currencies that meet the definition will not change.

The proposed amendments to the Appendices E and F to Rule 15c3-1

(which include conforming amendments to Appendix G to Rule 15c3-1 and the General Instructions to Form X-17A-5, Part IIB), if adopted, would not apply to small entities. Appendices E and G apply to broker-dealers that are part of a consolidated supervised entity and Appendix F and Form X-17A-5, Part IIB apply to OTC Derivatives Dealers that have applied to the Commission for authorization to compute capital charges as set forth in Appendix F in lieu of computing securities haircuts pursuant to Rule 15c3-1(c)(2)(vi). All of these brokers or dealers would be larger than the definition of a small broker dealer in Rule 0-10.

The proposed amendments to Exhibit A to Rule 15c3-3, if adopted, would not have a significant economic impact on a substantial number of small entities. The proposed amendments to Exhibit A to Rule 15c3-3 would apply only to broker-dealers that clear and carry positions in security futures products in securities accounts for the benefit of customers. None of those broker-dealers affected by the rule is a small entity as defined in Rule 0-10.¹³⁴

With respect to the amendments to Rules 101 and 102 of Regulation M, it is unlikely that any broker-dealer that is defined as a “small business” or “small organization” as defined in Rule 0-10 could be an underwriter or other distribution participant as they would not have sufficient capital to participate in underwriting activities. Small business or small organization for purposes of “issuers” or “person” other than an investment company is defined as a person who, on the last day of its most recent fiscal year, had total assets of \$5 million or less. The Commission believes that none of the various persons that would be affected by this proposal would qualify as a small entity under this definition as it is unlikely that any issuer of that size had investment grade securities that could rely on the existing exception. Therefore, the Commission believes that these amendments would not impose a significant economic impact on a substantial number of small entities.

The Commission believes that the proposed amendment to Rule 10b-10 will not have a significant economic impact on a substantial number of small entities. While some broker-dealers that effect transactions in the debt securities currently subject to paragraph (a)(8) of that rule may be small entities, the

proposed amendment should not result in any significant change to the cost of providing confirmations to customers in connection with those transactions.

The Commission encourages written comments regarding this certification. The Commission solicits comment as to whether the proposed amendments to Rule 15c3-1, Appendices A, E, F, and G to Rule 15c3-1, Exhibit A to Rule 15c3-3, Rule 17a-4, the General Instructions to Form X-17A-5, Part IIB, Rules 101 and 102 of Regulation M, and Rule 10b-10, could have an effect on small entities that has not been considered. The Commission requests that commenters describe the nature of any impact on small entities and provide empirical data to support the extent of such impact.

VIII. Statutory Basis and Text of the Proposed Amendments

Pursuant to the Exchange Act, 15 U.S.C. 78a *et seq.*, and particularly, Sections 3(b), 15, 23(a), and 36 (15 U.S.C. 78c(b), 78o, 78w(a), and 78mm), thereof, and Sections 939 and 939A of the Dodd-Frank Act, the Commission is proposing to amend §§ 240.10b-10, 240.15c3-1, 240.15c3-1a, 240.15c3-1e, 240.15c3-1f, 240.15c3-1g, 240.15c3-3a, 240.17a-4, 242.101, 242.102, and Form X-17A-5 Part IIB General Instructions under the Exchange Act.

List of Subjects in 17 CFR Parts 240, 242, and 249

Brokers, Fraud, Reporting and recordkeeping requirements, Securities.

Text of Amendment

In accordance with the foregoing, Title 17, Chapter II of the Code of Federal Regulations is proposed to be amended as follows:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The authority citation for part 240 is amended by adding sectional authorities for §§ 240.15c3-1a, 240.15c3-1e, 240.15c3-1f, 240.15c3-1g and for § 240.15c3-3a in numerical order, and by revising the sectional authorities for §§ 240.10b-10, 240.15c3-1, and 240.17a-4.

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z-2, 77z-3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78e, 78f, 78g, 78i, 78j, 78j-1, 78k, 78k-1, 78l, 78m, 78n, 78n-1, 78o, 78o-4, 78p, 78q, 78s, 78u-5, 78w, 78x, 78ll, 78mm, 80a-20, 80a-23, 80a-29, 80a-37, 80b-3, 80b-4, 80b-11, and 7201 *et seq.*; 18 U.S.C. 1350 and 12 U.S.C. 5221(e)(3), unless otherwise noted.

* * * * *

¹³¹ 5 U.S.C. 605(b).

¹³² See 17 CFR 240.17a-5(d).

¹³³ See 17 CFR 240.0-10(c).

¹³⁴ The main clearing organization, the OCC, requires its members to have total capital of \$2.5 million, far above the \$500,000 total capital threshold for a small business in Rule 0-10.

Section 240.10b-10 is also issued under secs. 2, 3, 9, 10, 11, 11A, 15, 17, 23, 48 Stat. 891, 89 Stat. 97, 121, 137, 156, (15 U.S.C. 78b, 78c, 78i, 78j, 78k, 78k-1, 78o, 78q) and Pub. L. No. 111-203, secs. 939, 939A, 124. Stat. 1376 (2010) (15 U.S.C. 78c, 15 U.S.C. 78o-7 note).

* * * * *

Section 240.15c3-1 is also issued under secs. 15(c)(3), 15 U.S.C. 78o(c)(3) and Pub. L. No. 111-203, secs. 939, 939A, 124. Stat. 1376 (2010) (15 U.S.C. 78c, 15 U.S.C. 78o-7 note).

Sections 240.15c3-1a, 240.15c3-1e, 240.15c3-1f, 240.15c3-1g are also issued under Pub. L. No. 111-203, §§ 939, 939A, 124. Stat. 1376 (2010) (15 U.S.C. 78c, 15 U.S.C. 78o-7 note).

* * * * *

Section 240.15c3-3a is also issued under Pub. L. No. 111-203, §§ 939, 939A, 124. Stat. 1376 (2010) (15 U.S.C. 78c, 15 U.S.C. 78o-7 note).

* * * * *

Section 240.17a-4 also issued under secs. 2, 17, 23(a), 48 Stat. 897, as amended; 15 U.S.C. 78a, 78d-1, 78d-2; sec. 14, Pub. L. 94-29, 89 Stat. 137 (15 U.S.C. 78a); sec. 18, Pub. L. 94-29, 89 Stat. 155 (15 U.S.C. 78w); and Pub. L. No. 111-203, secs. 939, 939A, 124. Stat. 1376 (2010) (15 U.S.C. 78c, 15 U.S.C. 78o-7 note)

§ 240.10b-10 [Amended]

2. Section 240.10b-10 is amended by removing paragraph (a)(8) and redesignating paragraph (a)(9) as paragraph (a)(8).

3. Section 240.15c3-1 is amended by revising paragraphs (c)(2)(vi)(E) introductory text, (c)(2)(vi)(F)(1) introductory text, (c)(2)(vi)(F)(2) introductory text, and (c)(2)(vi)(H).

The revisions read as follows:

§ 240.15c3-1 Net capital requirements for brokers or dealers.

* * * * *

(c) * * *

(2) * * *

(vi) * * *

(E) *Commercial paper, bankers acceptances and certificates of deposit.* In the case of any short term promissory note or evidence of indebtedness which has a fixed rate of interest or is sold at a discount, which has a maturity date at date of issuance not exceeding nine months exclusive of days of grace, or any renewal thereof, the maturity of which is likewise limited, and has only a minimal amount of credit risk as determined by the broker or dealer pursuant to written policies and procedures the broker or dealer establishes, maintains, and enforces to assess creditworthiness, or in the case of any negotiable certificates of deposit or bankers acceptance or similar type of instrument issued or guaranteed by any bank as defined in section 3(a)(6) of the Securities Exchange Act of 1934, the

applicable percentage of the market value of the greater of the long or short position in each of the categories specified below are:

* * * * *

(F)(1) *Nonconvertible debt securities.* In the case of nonconvertible debt securities having a fixed interest rate and a fixed maturity date, which are not traded flat or in default as to principal or interest and which have only a minimal amount of credit risk as determined by the broker or dealer pursuant to written policies and procedures the broker or dealer establishes, maintains, and enforces to assess creditworthiness, the applicable percentages of the market value of the greater of the long or short position in each of the categories specified below are:

* * * * *

(2) A broker or dealer may elect to exclude from the above categories long or short positions that are hedged with short or long positions in securities issued by the United States or any agency thereof or nonconvertible debt securities having a fixed interest rate and a fixed maturity date and which are not traded flat or in default as to principal or interest, and which have only a minimal amount of credit risk as determined by the broker or dealer pursuant to written policies and procedures the broker or dealer establishes, maintains, and enforces to assess creditworthiness, if such securities have maturity dates:

* * * * *

(H) In the case of cumulative, non-convertible preferred stock ranking prior to all other classes of stock of the same issuer, which has only a minimal amount of credit risk as determined by the broker or dealer pursuant to written policies and procedures the broker or dealer establishes, maintains, and enforces to assess creditworthiness, and which are not in arrears as to dividends, the deduction shall be 10% of the market value of the greater of the long or short position.

* * * * *

§ 240.15c3-1a [Amended]

4. Section 240.15c3-1a is amended by removing the phrase “whose short term debt is rated in one of the two highest categories by at least two nationally recognized statistical rating organizations and” and removing the sentence “For purposes of this section, the European Currency Unit (ECU) shall be deemed a major market foreign currency.” from paragraph (b)(1)(i)(C).

5. Section 240.15c3-1e is amended by:

a. Revising the introductory text in paragraph (c)(4)(vi);

b. Removing paragraphs (c)(4)(vi)(A) through (c)(4)(iv)(D);

c. Redesignating paragraphs (c)(4)(vi)(E), (F), and (G) as paragraphs (c)(4)(vi)(A), (B), and (C), respectively; and

d. Revising newly redesignated paragraph (c)(4)(vi)(A).

The revisions read as follows:

§ 240.15c3-1e Deductions for market and credit risk for certain brokers or dealers (Appendix E to 17 CFR 240.15c3-1).

* * * * *

(c) * * *

(4) * * *

(vi) *Credit risk weights of counterparties.* A broker or dealer that computes its deductions for credit risk pursuant to this Appendix E shall apply a credit risk weight for transactions with a counterparty of either 20%, 50%, or 150% based on an internal credit rating the broker or dealer determines for the counterparty.

(A) As part of its initial application or in an amendment, the broker or dealer may request Commission approval to apply a credit risk weight of either 20%, 50%, or 150% based on internal calculations of credit ratings, including internal estimates of the maturity adjustment. Based on the strength of the broker's or dealer's internal credit risk management system, the Commission may approve the application. The broker or dealer must make and keep current a record of the basis for the credit rating of each counterparty;

* * * * *

6. Section 240.15c3-1f is amended by:

a. Removing the phrase from paragraph (d)(2), “the counterparty factor. The counter party factors are:” and adding in its place “a counterparty factor of 20%, 50%, or 100% based on an internal credit rating the OTC derivatives dealer determines for the counterparty.”; and

b. Revising paragraphs (d)(3)(i), (d)(3)(ii), (d)(3)(iii), and (d)(4).

The revisions read as follows:

§ 240.15c3-1f Optional market and credit risk requirements for OTC derivatives dealers (Appendix F to 17 CFR 240.15c3-1).

* * * * *

(d) * * *

(3) * * *

(i) For counterparties for which an OTC derivatives dealer assigns an internal rating for senior unsecured long-term debt or commercial paper that would apply a 20% counterparty factor under (d)(2)(i) of this section, 5% of the amount of the net replacement value in excess of 25% of the OTC derivatives dealer's tentative net capital;

(ii) For counterparties for which an OTC derivatives dealer assigns an internal rating for senior unsecured long-term debt that would apply a 50% counterparty factor under (d)(2)(ii) of this section, 20% of the amount of the net replacement value in excess of 25% of the OTC derivatives dealer's tentative net capital;

(iii) For counterparties for which an OTC derivatives dealer assigns an internal rating for senior unsecured long-term debt that would apply a 100% counterparty factor under (d)(2)(iii) of this section, 50% of the amount of the net replacement value in excess of 25% of the OTC derivatives dealer's tentative net capital.

(4) Counterparties may be rated by the OTC derivatives dealer, or by an affiliated bank or affiliated broker-dealer of the OTC derivatives dealer, upon approval by the Commission on application by the OTC derivatives dealer. Based on the strength of the OTC derivatives dealer's internal credit risk management system, the Commission may approve the application. The OTC derivatives dealer must make and keep current a record of the basis for the credit rating for each counterparty.

* * * * *

§ Section 240.15c3-1g [Amended]

7. Section 240.15c3-1g(a)(3)(i)(F) is amended by removing the phrase "paragraphs (c)(4)(vi)(D) and (c)(4)(vi)(E)" and adding in its place "paragraph (c)(4)(vi)(A) and paragraph (c)(4)(vi)(B)".

§ 240.15c3-3a [Amended]

8. Section 240.15c3-3a is amended by removing paragraph (b)(1)(i) of Note G and redesignating paragraphs (b)(1)(ii), (iii), and (iv) as paragraphs (b)(1)(i), (ii), and (iii), respectively.

9. Section 240.17a-4 is amended by:

a. Removing the phrase from paragraph (b)(12), "§ 240.15c3-1e(c)(4)(vi)(D) and (E)" and adding in its place "§ 240.15c3-1e(c)(4)(vi)"; and

b. Adding paragraph (b)(13).

The addition reads as follows:

§ 240.17a-4 Records to be preserved by certain exchange members, brokers and dealers.

* * * * *

(b) * * *

(13) The written policies and procedures the broker-dealer establishes, maintains, and enforces to assess creditworthiness for the purpose of § 240.15c3-1(c)(2)(vi)(E), (F)(1), (F)(2), and (H).

* * * * *

PART 242—REGULATIONS M, SHO, ATS, AC, AND NMS AND CUSTOMER MARGIN REQUIREMENTS FOR SECURITY FUTURES

10. The general authority citation for Part 242 is revised and the following citations are added in numerical order to read as follows:

Authority: 15 U.S.C. 77g, 77q(a), 77s(a), 78b, 78c, 78g(c)(2), 78i(a), 78j, 78k-1(c), 78l, 78m, 78n, 78o(b), 78o(c), 78o(g), 78q(a), 78q(b), 78q(h), 78w(a), 78dd-1, 78mm, 80a-23, 80a-29, 80a-37, unless otherwise noted.

* * * * *

Sections 242.101 and 242.102 are also issued under Pub. L. No. 111-203, §§ 939, 939A, 124. Stat. 1376 (2010) (15 U.S.C. 78c, 15 U.S.C. 78o-7 note).

* * * * *

11. Section 242.101 is amended by revising paragraph (c)(2) to read as follows:

§ 242.101 Activities by distribution participants.

* * * * *

(c) * * *

(2) *Certain nonconvertible and asset-backed securities.* Nonconvertible debt securities, nonconvertible preferred securities, and asset-backed securities, that are determined and demonstrated by the distribution participant or affiliated purchaser, and verified by an independent third party, utilizing reasonable factors of evaluation to:

(i) Be liquid relative to the market for that asset class;

(ii) Trade in relation to general market interest rates and yield spreads; and

(iii) Be relatively fungible with securities of similar characteristics and interest rate yield spreads; or

* * * * *

12. Section 242.102 is amended by revising paragraph (d)(2) to read as follows:

§ 242.102 Activities by issuers and selling security holders during a distribution.

* * * * *

(d) * * *

(2) *Certain nonconvertible and asset-backed securities.* Nonconvertible debt securities, nonconvertible preferred securities, and asset-backed securities, that are determined and demonstrated by the issuer, selling security holder, or affiliated purchaser, and verified by an independent third party, utilizing reasonable factors of evaluation to:

(i) Be liquid relative to the market for that asset class;

(ii) Trade in relation to general market interest rates and yield spreads; and

(iii) Be relatively fungible with securities of similar characteristics and interest rate yield spreads; or

* * * * *

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

13. The authority citation for Part 249 is amended by adding the following citation in numerical order to read as follows:

Authority: 15 U.S.C. 78a *et seq.*, 7201 *et seq.*, 18 U.S.C. 1350, unless otherwise noted.

Section 249.617 is also issued under Pub. L. 111-203, §§ 939, 939A, 124. Stat. 1376 (2010) (15 U.S.C. 78c, 15 U.S.C. 78o-7 note).

* * * * *

14. Amend Form X-17A-5 Part IIB General Instructions (referenced in § 249.617) by:

a. Removing Schedule IV: Internal Credit Rating Conversion; and

b. Removing all but the first sentence in the section "Credit risk exposure" under the heading "Computation of Net Capital and Required Net Capital," and adding a second sentence that reads "The counterparty charge is computed using the credit risk weights assigned to the OTC derivatives dealer's internal calculations by the Commission under paragraph (d)(2) of Appendix F."

Note: The text of Form X-17A-5 Part IIB does not, and this amendment will not, appear in the Code of Federal Regulations

* * * * *

Dated: April 27, 2011.

By the Commission.

Elizabeth M. Murphy,
Secretary.

[FR Doc. 2011-10619 Filed 5-5-11; 8:45 am]

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S. 307/P.L. 112-11

To designate the Federal building and United States courthouse located at 217 West King Street, Martinsburg, West Virginia, as the "W. Craig Broadwater Federal Building and United States

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S.J. Res. 8/P.L. 112-12

Providing for the appointment of Stephen M. Case as a citizen regent of the Board of Regents of the Smithsonian Institution. (Apr. 25, 2011; 125 Stat. 214)

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